

105 CMR 130.000: HOSPITAL LICENSURE

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130.001: Purpose

105 CMR 130.000 sets forth standards for the maintenance and operation of hospitals.

130.010: Scope

105 CMR 130.000 applies to every hospital subject to licensure under M.G.L. c. 111, §§ 51 through 56, except as stated in 105 CMR 130.000.

130.020: Definitions

Accreditation. Process of evaluation and approval of hospitals conducted by the Joint Commission, the American Osteopathic Association (AOA), or conducted by another accrediting body approved by the federal Centers for Medicare and Medicaid Services (CMS) and the Commissioner.

Ambulatory Care Service. Health care services that do not require overnight hospital stay.

Autopsy. A post mortem examination performed by a physician, including the removal and examination of organs, to determine a medical disease, medical condition, or the cause and manner of death, or for other diagnostic, education, quality improvement, or research purposes.

Beds Out of Service. Beds not occupied and not qualified for patient occupancy pursuant to the applicable requirements of 105 CMR 130.000.

Birth Center. A home-like facility where low risks births are planned to occur following normal, uncomplicated pregnancy.

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Birth Center Services. Professional midwifery services provided to low risk childbearing women during pregnancy, birth, and puerperium and to the infant during the immediate newborn period by nurse-midwives or by obstetricians or family practitioners. Birth center services are provided in a free standing facility.

Burn Unit. An intensive care unit for burned inpatients needing care of a more intensive nature than is provided in medical/surgical beds. Burn units are staffed with specially trained physicians, nurses, and support personnel and contain specialized monitoring and therapeutic equipment needed to provide care for severely burned patients.

Campus. One of several premises on the license of a hospital that provides health care services.

Cardiac Catheterization Services. Diagnostic and interventional services, other than cardiac surgery, that involve the introduction of physical objects (such as catheters) into the heart, its chambers, the pericardium, or the great vessels proximal to the heart.

Cardiac Surgery. Surgery on the heart and the thoracic great vessels. Most cardiac surgery requires the use of a heart-lung machine. Those procedures previously requiring the heart-lung machine but now sometimes performed “off-pump” (*e.g.* coronary artery bypass) are still considered as cardiac surgery. Examples of cardiac surgery include coronary artery bypass grafts, heart valve repair or replacement, heart transplantation, surgery of the thoracic aorta, repair of congenital heart defects and minimally invasive heart surgery.

Center for Health Information and Analysis or CHIA. The entity established pursuant to M.G.L. c. 12C.

Chronic Care Service. A service, other than a rehabilitation, psychiatric, substance use disorder, intermediate care facility, or skilled nursing facility service, that has an average length of inpatient stay greater than 25 days and that meets the long-term care hospital patient level criteria issued by the Federal Centers for Medicare and Medicaid Services.

Commissioner. The Commissioner of the Massachusetts Department of Public Health or his or her designee.

Coronary Care Unit. An intensive care unit staffed with specially trained nursing and supportive personnel and equipped with necessary diagnostic, monitoring, and therapeutic equipment needed to provide specialized medical and nursing care to inpatients who, because of heart seizure, open heart surgery, or conditions threatening to the heart, require intensified, comprehensive observation and care.

Critical Care Beds. Beds licensed as intensive care, coronary care, pediatric intensive care, neonatal intensive care and (intensive) burn unit service beds.

Data Analysis Center (DAC). The organization contracted by the Department to receive, process, analyze and report on the patient-specific cardiac surgery and Percutaneous Coronary Interventions (PCI) outcome data submitted by the acute care hospital.

Decedent. A deceased individual or fetus, including a stillborn infant.

Deemed Status. That standing granted to an accredited hospital by the Commissioner under 105 CMR 130.000, which exempts the hospital from inspection for compliance with most Medicare Conditions of Participation.

Department. The Massachusetts Department of Public Health.

Designated Trauma Center. A hospital that has been verified by the American College of Surgeons as a level 1, 2 or 3 adult trauma center, or a level 1 or 2 pediatric trauma center and meets applicable Department standards for designation, or a hospital that has applied for and is in the process of verification as specified in 105 CMR 130.851 and meets applicable Department standards for designation.

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Dialysis Service. Chronic or acute service, provided in a discrete unit or facility, for treatment of patients with kidney failure. This service includes hemodialysis, peritoneal dialysis or both and related specialized staff and support services.

Emergency Service. A service maintained primarily to provide care to outpatients who are in need of immediate medical care to prevent loss of life or aggravation of physiological or psychological illness or injury.

Electrophysiology Service. The study of the electrical conduction activity of the heart and characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization procedure.

Essential Health Service. A campus, or any of the services enumerated in the definition of service in 105 CMR 130.020 that is not included in the Excluded Services list. Essential Health Service also includes outpatient dental services, outpatient psychiatric and mental health services, and outpatient reproductive health services:

Excluded Services List:

- (1) Skilled nursing facility service;
- (2) Intermediate care facility service;
- (3) Cardiac catheterization service (diagnostic, pediatric, diagnostic and interventional);
- (4) Chronic care service;
- (5) Electrophysiology;
- (6) Hematopoietic Progenitor/Stem Cell Collection, Processing, and Transplant Service;
- (7) Hematopoietic Progenitor/Stem Cell Transplantation Program or Clinical Transplantation Program;
- (8) Trauma service as a designated trauma center as defined in 105 CMR 130.851;
- (9) Primary Stroke Service;
- (10) Medical Control Service.

Hospice Service. A coordinated program of home care and inpatient care and services, provided by or arranged to be provided by an interdisciplinary team for persons who are determined to be terminally ill with a limited life expectancy. Inpatient hospital beds used to care for hospice patients shall be licensed as medical/surgical beds.

Hospital. Any institution in Massachusetts, however named, whether conducted for charity or for profit, that is advertised, announced, established or maintained for the purpose of caring for persons admitted thereto for diagnosis or medical, surgical or restorative treatment which is rendered within said institution. Hospital shall not include any hospital operated by the Commonwealth of Massachusetts or by the United States.

Intensive Care Unit. A unit physically and identifiably separate from general routine (and other) patient care areas, in which are concentrated special equipment and skilled personnel for the care of critically ill inpatients requiring immediate and concentrated continuous care and observation, and which meets the Medicare requirements in 42 CFR 413.53(d) for intensive care type inpatient hospital units.

Intermediate Care Facility Service. For services licensed prior to April 21, 1988, a long-term care service that provides routine nursing services and periodic availability of skilled nursing, restorative and other therapeutic services. Intermediate care patients are in a stable condition, needing only supportive nursing care, supervision and observation, and do not require the constant care provided in skilled nursing beds.

Medical/Surgical Service. A general, routine adult acute care service providing medical and/or surgical and nursing care to inpatients on the basis of physicians' orders and nursing care plans.

National Cardiovascular Data Registry (NCDR™). The CathPCI database developed and maintained by the American College of Cardiology.

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Non English Speaker. A person who cannot speak or understand, or has difficulty speaking or understanding English, because the speaker primarily or only uses a spoken language other than English.

Organ. Organs, tissues, and other parts of a human body, including but not limited to eyes, skin, bones, and arteries. Organ shall not mean tissue samples or fluids that are retained to determine the cause and manner of death.

Order of Priority. The ranking of an individual who is qualified to provide consent to an autopsy.

Pediatric Cardiac Catheterization Services. Providing cardiac catheterization services on an organized, regular basis to infants and children younger than 18 years old.

Percutaneous Coronary Interventions (PCI). The procedure for remodeling a blood vessel through the introduction of an expandable balloon catheter.

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.

Psychiatric Service. A service for inpatients in need of intensive, 24-hour, psychiatric and nursing care and supervision, not including persons hospitalized for substance use disorders. A staff of mental health specialists provides psychiatric, psychological and social evaluation, treatment and aftercare planning.

Rehabilitation Service. A service that provides physical restoration and emotional, mental, social and vocational restoration and adjustment for persons with disabilities and meets the inpatient rehabilitation hospital patient and facility criteria issued by the Federal Centers for Medicare and Medicaid Services. The service consists of evaluation, treatment, education, training and placement provided by qualified personnel. A rehabilitation service is directed by a physician experienced and qualified in the field of rehabilitation; and consists of a team effort of the various disciplines of rehabilitation services. The services that shall be provided include at a minimum intensive skilled rehabilitation nursing, physical therapy, occupational therapy, speech therapy, pathology, social services, prosthetic and/or orthotic fitting, and psychological services. Optional services include recreation therapy, dental services, special education, and vocational assessment and counseling.

Rural Hospital. An acute care hospital licensed under M.G.L. c. 111, § 51, which:

- (1) has 50 or fewer licensed beds and based on the published United States Census 2000 data of the US Census Bureau is in a city or town whose population is less than 20,000 and is located within a city, town, service area, or County whose population density is less than or equal to 500 people per square mile and which applies for such a designation; or
- (2) is a hospital designated as a Critical Access Hospital as of July 1, 2005 by the Federal Department of Health and Human Services in accordance with federal regulations and state requirements.

Satellite Emergency Facility (SEF). A health care facility off the premises of a hospital that is listed on the license of the hospital, at which the hospital is authorized pursuant to 105 CMR 130.820 through 130.836 to accept patients transported to the SEF by ambulance, and which operates on a seven day per week 24 hour per day basis. SEFs must comply with all requirements of the federal Emergency Medical Treatment and Active Labor Act (EMTALA).

Satellite Unit. An operation off the premises of the hospital at which the hospital provides outpatient health care services.

Service. Any of the following specific services, which the Department will list on a hospital's license if the Department licenses the hospital to deliver the service.

- Ambulatory Care Services
- Birth Center Services

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Burn Unit
 Cardiac Catheterization Services (diagnostic)
 Cardiac Catheterization Services (diagnostic and interventional)
 Cardiac Catheterization Services (pediatric)
 Cardiac Surgery
 Chronic Care Service
 Continuing Care Nursery Service
 Coronary Care Unit
 Designated Trauma Center
 Dialysis Service
 Electrophysiology Service
 Emergency Services
 Hematopoietic Progenitor/Stem Cell Collection, Processing and Transplantation Services
 Hematopoietic Progenitor/Stem Cell Transplantation Program or Clinical Transplantation Program
 Intensive Care Unit
 Intermediate Care Facility Service
 Maternal and Newborn Service
 Medical Control Service
 Medical/Surgical Service
 Neonatal Intensive Care Unit
 Pediatric Intensive Care Unit
 Pediatric Service
 Primary Stroke Service
 Psychiatric Service
 Rehabilitation Service
 Satellite Emergency Facility
 Skilled Nursing Facility Service
 Special Care Nursery Service
 Substance Use Disorder Service

Skilled Nursing Facility Service. For services licensed prior to April 21, 1988, a long-term care service that provides continuous skilled nursing care, and restorative and other therapeutic services where beneficial, for patients who have a deteriorating condition requiring skilled care or who show potential for improvement or restoration to a stabilized condition. Patients in skilled nursing care require more intense and continuous skilled nursing care than the supportive nursing care provided in intermediate care beds.

Society of Thoracic Surgeons (STS) National Database. The cardiac surgery database developed and maintained by the Society of Thoracic Surgeons (STS).

Substance Use Disorder Service. A detoxification and/or rehabilitative treatment service for individuals and their families experiencing the dysfunctional effects of the use of alcohol and/or drugs.

Support Service means any of the following:

- (1) Blood Bank means a facility or support service equipped and staffed to procure, draw, process and/or store and dispense to transfusion services human whole blood and/or its components and/or derivatives.
- (2) Clinical Laboratory means a facility or place, however named, the purpose of which is to make biological, serological, chemical, immunohematological, cytological, pathological, or other examinations of materials derived from a human body.
- (3) Transfusion Support Service means a facility or place designed, equipped and staffed to administer human whole blood and/or its components and/or derivatives in transfusion.

Trauma. Tissue injury due to the direct effects of externally applied mechanical, thermal, electrical, electromagnetic or nuclear energy, as further defined in the Statewide Treatment Protocols established under 105 CMR 170.000: *Emergency Medical Services System*. Trauma shall not mean toxic ingestion, poisoning or foreign body ingestion.

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Transfer of Ownership shall include but not be limited to the following transfers:

- (1) a transfer of a majority interest in the ownership of a hospital;
- (2) in the case of a privately-held for-profit corporation, transfer of a majority of any class of the stock thereof;
- (3) in the case of a partnership, transfer of a majority of the partnership interest;
- (4) in the case of a trust, change of the trustee or a majority of trustees; or
- (5) in the case of a non-profit corporation, such changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control of the hospital.

A transfer of ownership shall also be deemed to have occurred where foreclosure proceedings have been instituted by a mortgagee in possession.

Transfer of Ownership also means any change in the ownership interest or structure of the hospital or the hospital's organization or parent organization(s) that the commissioner determines to effect a change in control of the operation of the hospital.

The commissioner may, in his or her discretion, determine that a proposed transaction does not rise to the level of a transfer of ownership.

130.050: Waiver of Requirements Imposed on Hospitals

The Commissioner may waive the applicability to a particular hospital of one or more of the requirements imposed by 105 CMR 130.000 upon finding that:

- (A) Compliance would cause undue hardship to the hospital;
- (B) The hospital's non-compliance does not jeopardize the health or safety of its patients and does not limit the hospital's capacity to give adequate care;
- (C) The hospital has instituted compensating features that are acceptable to the Commissioner; and
- (D) The hospital provides to the Commissioner written documentation supporting its request for a waiver.

130.051: Special Projects

The Department will consider proposals for special projects for the innovative delivery of hospital services. No such proposal shall be implemented without prior written approval of the Department. The Department may impose conditions on special projects as necessary.

130.100: Requirement of License

Every hospital shall obtain a hospital license from the Department for all premises under its control at which clinical services are provided.

130.101: Application for License

- (A) Applicants must submit license applications or for renewal of such license on a form provided by the Department and accompanied by all supporting documents required by 105 CMR 130.000. Applications for initial licensure shall be submitted at least 60 days prior to the anticipated provision of clinical services.
- (B) In addition to the above requirement hospitals seeking deemed status under 105 CMR 130.000 shall file a consent form provided by the Department concerning release of information under 105 CMR 130.202.
- (C) The applicant must include the hospital license fee.
- (D) If the application is for an acute-care hospital resulting from a transfer of ownership, the applicant must submit:
 - (1) information on all financial transactions related to the transfer, including remuneration of all officers of hospitals affected by the transaction; and

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- (2) if the transferor is a non-profit entity, an attestation that the hospital's governing board publicly presented and evaluated all proposals for the merger or acquisition that resulted in the proposed transfer.

130.102: Local Approvals

The applicant shall furnish an inspection certificate issued by the Department of Public Safety, Division of Inspection and a certificate of inspection issued by the head of the local fire department in support of each application for licensure.

130.103: Incidents of Ownership

(A) Each hospital shall be designated by a permanent and distinctive name, which shall appear on the application for a license and which shall not be changed without prior notification to the Department. The name of the hospital shall not tend in any way to mislead the public as to the type or extent of care provided by the facility.

(B) The Department may request a hospital to submit in support of its application for an original license, or upon any change of ownership such additional information concerning ownership and control as the Department may require.

130.104: Evidence of Responsibility and Suitability

(A) In determining whether an applicant for a license for an acute-care hospital is responsible and suitable to be granted a hospital license, the Department shall consider all relevant information including, but not limited to, the following:

- (1) The applicant's history in providing acute care, including in states other than Massachusetts, if any, measured by compliance with the applicable statutes and regulations governing the operation of hospitals in such states. Assessment of this factor shall include the ability and willingness of the applicant to take corrective action when notified by the Department of regulatory violations and any proceedings in which the applicant was involved that proposed or led to a limitation upon or a suspension, revocation, or refusal to grant or renew a health care facility license or certification for Medicaid or Medicare to the applicant;
- (2) The applicant's financial capacity to provide acute care in compliance with state law and 105 CMR 130.000 as evidenced by sufficiency of present resources and assessment of past history, including financial involvement with health care facilities that have filed petitions for bankruptcy;
- (3) The history of criminal conduct of the applicant, and of the chief executive officer and chief financial officer of the applicant, as evidenced by criminal proceedings against those individuals or against health care facilities in which those individuals either owned shares of stock or served as corporate officers, and which resulted in convictions, or guilty pleas, or pleas of *nolo contendere*, or admissions of sufficient facts;
- (4) The participation of persons residing in the hospital's primary service area in oversight of the resulting hospital if the applicant is a non-profit entity; and
- (5) Whether the transaction will create a significant effect on the availability or accessibility of health care services to the communities served by the hospital.

(B) In determining whether an applicant for a license for hospital that does not provide acute care is responsible and suitable to be granted a hospital license, the Department shall consider all relevant information including, but not limited to, the following:

- (1) The applicant's history of prior compliance with Massachusetts state laws and regulations governing health facility operation. Assessment of this factor shall include the ability and willingness of the applicant to take corrective action when notified by the Department of regulatory violations;
- (2) The applicant's financial capacity to provide hospital care in compliance with state law and 105 CMR 130.000 as evidenced by sufficiency of present resources and assessment of past history, including financial involvement with health care facilities that have filed petitions for bankruptcy;

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(3) The history of criminal conduct of the applicant, and of the chief executive officer and chief financial officer of the applicant, as evidenced by criminal proceedings against those individuals or against health care facilities in which those individuals either owned shares of stock or served as corporate officers, and which resulted in convictions, or guilty pleas, or pleas of *nolo contendere*, or admissions of sufficient facts; and

(4) The applicant's history of statutory and regulatory compliance for health care facilities in other jurisdictions, including proceedings in which the applicant was involved that proposed or led to a limitation upon or a suspension, revocation, or refusal to grant or renew a health care facility license or certification for Medicaid or Medicare to the applicant.

130.105: Updating of Information

All information required by the Department under 105 CMR 130.101 and 130.103 shall be kept current by each hospital. Changes in this information shall be reported to the Commissioner within 30 calendar days of occurrence.

130.107: Submission and Approval of Architectural Plans and Specifications

In the case of new construction of a hospital, or alterations or additions to an existing hospital, the hospital must submit preliminary architectural plans and final architectural plans and specifications for written approval prior to commencing said new construction or alterations or additions. The Department shall establish standards for review and approval of plans as administrative guidelines, based on the Facility Guidelines Institute's Guidelines applicable to design and construction of hospitals and outpatient health care facilities.

130.108: Condition of Licensure

(A) Each hospital shall participate in risk management programs as required under M.G.L. c. 111, § 203(d).

(B) Applicants for a license for an acute-care hospital must submit a plan, to be approved by the Department, for the provision of community benefits, including the identification and provision of essential health services. In approving the plan, the Department may take into account the applicant's existing commitment to primary and preventive health care services and community contributions as well as the primary and preventive health care services and community contributions of any predecessor hospital. The Department may waive this requirement, in whole or in part, at the request of the applicant which has provided or at the time the application is filed, is providing substantial primary and preventive health care services and community contributions in its service area. The Department may consider a hospital's community benefits plan that is filed with the Attorney General's office or with the Department in compliance with the Determination of Need program and has been made public, to meet the requirements of 130 CMR 130.108.

(C) Each hospital shall comply with all applicable state and federal statutes and regulations pertaining to health care facilities.

130.109: Transfer of Ownership or Location

(A) To transfer ownership or location, a hospital must comply with any additional procedures set forth in 105 CMR 100.000: *Determination of Need*.

(B) A licensed hospital must notify the Department immediately in writing of any proposed change in name or location of a facility. A license shall not be transferred from one person or entity to another or from one location to another.

(C) The proposed licensee shall submit a Notice of Intent to acquire a hospital to the Department at least 90 calendar days in advance of any transfer of ownership.

(1) If the hospital is an acute-care hospital, the Department shall schedule a public hearing on the proposed transfer of ownership.

130.109: continued

(2) If the transfer of ownership will follow the merger or acquisition of the hospital, the board of trustees of the hospital must publicly present and evaluate all proposals for such a merger or acquisition.

(D) Any person applying for a license as a result of any transfer of ownership shall file an application for licensure within two business days of the transfer or such longer period in advance as the Commissioner shall prescribe.

(E) An application filed as a result of a transfer of ownership, if timely filed, shall have the effect of a license for a period of three months from the date of filing or until such time as the Department takes action on the application. If not timely filed, such an application shall not have such effect.

(F) Any notice of hearing, order or decision which that the Department or the Commissioner issues for a hospital prior to a transfer of ownership shall be effective against the former owner prior to such transfer and, where appropriate, the new owner, following such transfer unless said notice, order or decision is modified or dismissed by the Department or by the Commissioner.

(G) A transfer of ownership shall not be recognized and the new owner shall not be considered suitable for licensure when the transfer is proposed or made to circumvent the effect and purposes of 105 CMR 130.000. The Department shall consider the following factors in determining whether a transfer has been proposed or made to circumvent 105 CMR 130.000:

- (1) the transferor's record of compliance with Department licensure laws and 105 CMR 130.000;
- (2) the transferor's current licensure status;
- (3) the transferor's familial, business and/or financial relation to the transferee;
- (4) the terms of the transfer; and
- (5) the consequences of the transfer.

130.110: Issuance of License

(A) The Department shall issue a hospital license to any applicant that meets all of the applicable requirements of 105 CMR 130.000. Every license shall state the name and address of the hospital if either differs from that of the licensee; the period of licensure; the specific service(s) for which the hospital is licensed; and the name and address of any satellite unit for which the Department has authorized coverage by the hospital license.

(B) Except for units licensed prior to April 21, 1988 no hospital shall provide long-term care services under a license issued pursuant to M.G.L. c. 111, § 51 through 56 but shall seek licensure under M.G.L. c. 111, § 71.

130.111: Right to Visit and Inspect

The Department or its agents may visit a hospital subject to licensure under M.G.L. c. 111, § 51, and any satellite unit of the hospital, at any time without prior notice and inspect it, its staff, activities, and records to determine the hospital's compliance with state law and 105 CMR 130.000.

130.112: Deficiency Statements

After every Department inspection in which any violation of 105 CMR 130.000 is observed, the Commissioner or his or her designee shall prepare a deficiency statement citing every violation observed, a copy of which shall be sent to the hospital.

130.113: Plans of Correction

A hospital shall submit to the Department a written plan of correction of violations cited in a deficiency statement prepared pursuant to 105 CMR 130.111 within ten calendar days after the deficiency statement is sent. Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with 105 CMR 130.000 will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. A plan of correction that does not meet the requirements of 105 CMR 130.112 shall be considered unacceptable by the Department and returned to the hospital.

130.121: Licensed Bed Capacity

(A) Each license shall specify the total number of beds within the hospital and the number of beds in each specific service for which the hospital is licensed.

130.122: Beds Out of Service and Discontinuation of Service

(A) A hospital may remove beds from service temporarily, within the discretion of the licensee, except that any hospital that intends to remove beds from service for more than six months shall notify the Department in writing at least 30 days prior to such removal.

(B) Nothing in 105 CMR 130.122 shall be construed to authorize a licensee to discontinue any service, as defined in 105 CMR 130.020 to the public entirely or in substantial part except upon notice to the Department as described in 105 CMR 130.122. Notice to the Department shall be given at least 90 calendar days in advance of the planned closure of the service:

At least 30 days prior to notifying the Department of the proposed closure of an essential health service, the hospital shall inform either electronically or in writing the Department and the following parties of its intent to submit notice to close a service:

- (1) The hospital's patient and family council;
- (2) Each staff member of the hospital;
- (3) Every labor organization that represents the hospital's workforce during the period of the essential services closure;
- (4) The members of the General Court who represent the city or town in which the hospital is located; and
- (5) A representative of the local officials of the city or town in which the hospital is located.

With respect to the proposed closure of an essential health service, the 90 day notice to the Department shall at a minimum provide current utilization rates for service(s) being discontinued, describe the anticipated impact on individuals in the hospital's service area, provide the date set for discontinuation, include the names and addresses of any organized health care coalitions and community groups that are known to the hospital when the notice is issued to the Department, a detailed account of any community engagement and planning which has occurred prior to such filing, and such other information as the Commissioner may require. With respect to the proposed closure of an essential health service, the hospital shall also send a copy of the notice that it submits to the Department to the Health Policy Commission, Office of the Attorney General, Center for Health Information and Analysis, and Executive Office of Labor and Workforce Development as well as each of the health care coalitions and community groups identified by the hospital in its notice to the Department. The Commissioner or his or her designee may waive the 90-day time frame for notifying the Department of a planned discontinuation of a service only in extraordinary circumstances where the Commissioner has determined that such a waiver is necessary to protect the health and safety of patients served by the hospital.

(C) The Commissioner may, in exceptional circumstances, find that a health service not otherwise defined as an essential health service, is necessary for preserving access and health status of patients in the hospital's service area. If the Commissioner makes such a determination, the Department shall immediately notify the hospital of its decision and inform the hospital that the procedures and requirements contained in 105 CMR 130.122(C) through (I) are applicable to its proposal for discontinuation of the health service(s) in question.

130.122: continued

(D) Except in the circumstances noted in 105 CMR 130.122(E)(1) and (2); if the Department finds that a hospital proposes to discontinue an essential health service, discontinue an essential health service at a campus, or discontinue services entirely at a campus, the Department shall publish a notice of a public hearing in the legal notice section of local newspapers serving residents of the hospital's service area at least 21 calendar days prior to the date of the hearing. The notice shall set forth the name and address of the hospital, briefly describe the proposed modifications in existing services, and indicate the date, time and location of the hearing. The hearing shall take place in the hospital's service area no later than 60 calendar days prior to the proposed closure date set out in the hospital's notice submitted pursuant to 105 CMR 130.122(C). At the public hearing, the hospital shall describe the services to be closed, plans for alternate access to the service, and shall afford the opportunity for interested parties to present their comments on the hospital's proposal.

(1) The requirements at 105 CMR 130.122(D) through (I) for a public notice, hearing and subsequent determinations, planning and reporting by the Department and the hospital shall not be applicable when there is no interruption in services to patients because the Department expects to license another applicant that is simultaneously seeking licensure pursuant to M.G.L. c. 111, §§ 51 through 56, or, in the case of hospice services, licensure pursuant to M.G.L. c. 111, § 57D to continue providing the same services to the same patients as are currently served by the hospital that is providing a notice of discontinuation pursuant to 105 CMR 130.122(C). To qualify for this exception, the hospital and the applicant who is seeking the Department's licensure approval, must ensure that there is no interruption in the service(s) that are provided to the patients currently served by the hospital at this same site.

(2) The requirements at 105 CMR 130.122(D) through (I) for a public notice, hearing and subsequent determinations, planning and reporting by the Department and the hospital shall not be applicable when a hospital proposes to discontinue services at an existing campus or site in order to continue providing the same service(s), without interruption, to the same patient population at a new site that is located within the same zip code area, or within a five-mile or equivalent driving distance radius of the location where service(s) are being discontinued. The new site must have sufficient physical capacity and resources to serve the same patient volume as was previously served by the hospital at the site where service(s) are to be discontinued.

(E) Within 15 calendar days of the hearing held pursuant to 105 CMR 130.122(E), the Department shall make a determination as to whether the discontinued service is necessary for preserving access and health status in the hospital's service area. In making its determination, the Department shall consider the evidence presented at the public hearing, the current utilization of the service, the capacity of alternative delivery sites to provide the service, travel times to alternative service delivery sites, the clinical importance of local access to the service, and any other relevant information available to the Department.

(F) If the Department finds that the discontinued service is necessary for preserving access and health status in the hospital's service area, the hospital shall, within 15 calendar days of such finding, submit a plan for assuring access to such necessary service(s) following the hospital's closure of the service(s). The plan must include the following elements:

- (1) Information on utilization of the service prior to proposed closure.
- (2) Information on the location and service capacity of alternative delivery sites.
- (3) Travel times to alternative service delivery sites.
- (4) An assessment of transportation needs post closure and a plan for meeting those needs.
- (5) A protocol that details mechanisms to maintain continuity of care for current patients of the discontinued service.
- (6) A protocol that describes how patients in the hospital's service area will obtain the services at alternative delivery sites.

(G) The Department shall review the plan submitted by the hospital pursuant to 105 CMR 130.122(G) to determine if the plan ensures access to the essential service(s) in question following the hospital's closure of the service(s). The Department shall complete its review of the plan and send the hospital written approval or written comments within ten calendar days of receiving the plan from the hospital. In the event that the essential service is a psychiatric or mental health service, the Department shall consult with the Department of Mental Health. The hospital shall submit a response within ten calendar days to any comments issued by the Department.

130.122: continued

(H) The Department shall monitor implementation of the hospital's plan for preserving access to necessary health care services following closure of the service(s).

130.124: Period of License

(A) The Department shall issue a hospital license for a period of two years.

(B) Provided a licensed hospital submits a timely application for a renewal license, its previous license shall be valid until the Department acts on its renewal application.

130.125: Coverage of License

A license is valid only for the premises and specific services authorized by the Department.

130.126: Posting of License and DPS Certificate

(A) The hospital shall conspicuously post the license on the hospital's premises and shall conspicuously post a copy of its license in each satellite unit of the hospital.

(B) The hospital shall conspicuously post its current inspection certificate issued by the Department of Public Safety.

130.127: Emergency Department Wayfinding, Signage, Lighting and Security Requirements

On and after January 1, 2024, hospitals with emergency departments must adhere to the wayfinding, signage, and security requirements in 105 CMR 130.127 and in guidelines of the Department.

(A) Signage and Wayfinding.

(1) Public entrances to the emergency department shall be clearly marked from external approaches and shall be identified by exterior signage and visible from public thoroughfares. Signs identifying the emergency department shall read "EMERGENCY" in all caps in red on a white background or white on a red background and public entrances to emergency departments when applicable, shall be distinguishable from the emergency department ambulance entrance.

(2) Emergency department patient drop off and entry areas and hospital perimeter doors, which include, but may not be limited to, doors that are locked at night, main entrance doors, emergency department entrance doors, ambulance entrances and any door a patient may typically use to enter the hospital, shall be well lit and include directions to the emergency department. Emergency patient vehicle drop off and external and internal entry areas shall be lit to be distinguishable from other entrances.

(3) Exterior hospital entry points shall be clearly identified from all major exterior routes including roadways, public transportation stops, and vehicular parking.

(4) Exterior hospital emergency department identification and directional signs shall be sufficiently lit to allow drivers and pedestrians to see signage after dark and during inclement weather. Hospitals must place directional signs leading to the emergency department in such a manner as to ensure visual continuity in accordance with guidance from the Department.

(5) Exterior wayfinding shall clearly define the access pathways from public thoroughfares to the hospital main entrance and emergency department entrance.

(B) Security and Communications.

(1) Hospitals with an emergency department shall maintain lighted communications technology, such as two-way live audio-visual communication technology, with duress alarm features across the grounds of the hospital facility, which shall at a minimum contain communication devices at the hospital main entrances, emergency department entrance, ambulance entrances, and any exterior door a patient may typically use, and in strategic locations around hospital grounds to communicate with on-duty personnel. Such technology shall be accessible to people with low vision, hearing loss, difficulties with speech and cognitive processing. The system shall include emergency duress button stations that are well marked and lit, and not dependent solely on audio communication.

130.127: continued

- (2) Hospital security desks and emergency department front desks shall be staffed 24 hours per day, seven days per week, or the hospital shall have a phone number posted at these locations that can connect patients with hospital personnel who can provide immediate assistance.
- (3) Hospitals shall have written policies and procedures for the video/audio monitoring 24 hours per day, of exterior entrances and emergency department patient drop off and entry areas with security technology that includes the ability to record and play back recordings, and the ability to store recording footage for up to 14 days.
- (4) Hospitals shall have written policies and procedures to ensure that patients on hospital grounds seeking emergency medical care who cannot physically access the emergency department are quickly located and are immediately given appropriate care.
- (5) Hospitals shall ensure that all staff and security have appropriate staff training, including on disability and disability access at the emergency department and how to communicate with, accommodate, and provide support for such individuals, as well as staff responsibilities when patients or companions have difficulty locating and entering an emergency department.
- (6) Hospital emergency departments shall have a unique street address for navigational purposes unless the emergency department shares the address with the currently used patient access point and the address for the emergency department shall be listed on the hospital homepage.

130.128: Annual Review

Hospitals with emergency departments shall conduct an annual review of security, wayfinding, signage and lighting policies and procedures, technologies and features. At minimum, the review shall take place during the daytime and nighttime, and shall include plans to maintain and keep lighting, footpaths and signs clear of debris, vegetation, or snow; include a review of surveillance monitoring and patrols by hospital security; include a review of the effectiveness of hospital signs and symbols for patients for whom English is not their first language; and any additional requirements included in guidelines of the Department. Hospital personnel from multiple departments, including security, facilities maintenance, risk management and the emergency department, or their equivalent positions, shall participate in the annual review. Policies and procedures should be reviewed annually and made available to DPH upon request.

130.130: Grounds for Refusal to Renew and Revocation of a License

The Department may refuse to renew, or revoke a license, either wholly or with respect to a specific service or specific services, or a part or parts thereof, for cause. Cause shall include, but shall not be limited to, the following:

- (A) Lack of legal capacity to provide the service(s) to be covered by a license;
- (B) Lack of responsibility and suitability to operate a hospital;
- (C) Failure to submit the required license fee;
- (D) Violation of any relevant state or federal statute or regulation pertaining to operation of the hospital;
- (E) Violation of any applicable provision of 105 CMR 130.000 and failure to submit an acceptable plan of correction pursuant to 105 CMR 130.112; or failure to remedy or correct a cited violation by the date specified in the plan;
- (F) Willful misrepresentation of information or data submitted to the Department or any other agency of the Commonwealth; or
- (G) Failure to participate in risk management programs as required under M.G.L. c. 111, § 203(d).

130.131: Refusal to Renew or Revocation of a License or Part of a License: Right to Prior Adjudicatory Proceeding

Whenever the Commissioner decides to revoke or refuse to renew a license or part of a license, he or she shall initiate an adjudicatory hearing in accordance with the requirements of M.G.L. c. 30A. All such adjudicatory proceedings shall be conducted in accordance with 801 CMR 1.00: *Adjudicatory Rules of Practice and Procedure*.

130.132: Grounds for Suspension: Right to Subsequent Adjudicatory Proceeding

(A) The Commissioner may suspend a hospital's license or a part of its license covering a specific service or specific services or a part or parts thereof, or suspend admissions to the hospital or further functioning of its emergency department or operating room(s), if he or she decides that any violation of state law or 105 CMR 130.000 poses an imminent risk to the safety or proper medical care of the hospital's patients. The Commissioner shall give the licensee written notice thereof, stating the reason(s) for the suspension. The suspension or other sanction shall take effect immediately upon issuance of the notice. The Department shall commence an adjudicatory hearing within 21 calendar days of the notice of suspension as set forth in 105 CMR 130.131. The subject of such a hearing shall be limited to the facts relating to the suspension.

(B) In the event the Commissioner determines that the violation of state law or of 105 CMR 130.000 that posed an imminent risk to the safety or proper medical care of the hospital's patients is corrected prior to the decision of the hearing officer, the Commissioner may lift the suspension by giving written notice to the hospital.

130.133: Final Agency Decision and Judicial Review

The decision of a hearing officer in any adjudicatory proceeding conducted pursuant to 105 CMR 130.131 or 130.132 shall be reviewed by the Commissioner. The Commissioner's decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

130.200: Incorporation of Medicare Conditions of Participation in Hospitals

Each hospital shall meet all of the requirements of the Medicare Conditions of Participation for Hospitals, 42 CFR 482.11 through 482.62 (Conditions of Participation), except the requirement for institutional plan and budget specified in 42 CFR 482.12(d), for utilization review specified in 42 CFR 482.30, the requirement for compliance with the Life Safety Code specified in 42 CFR 482.41(b), and any requirement that conflicts with the Supplementary Standards in 105 CMR 130.000.

130.202: Accreditation as Equivalent: Deemed Status

(A) If a hospital is currently accredited by the Joint Commission, AOA, or another accrediting body approved by CMS and the Commissioner, the Commissioner may deem the hospital to meet all the requirements of the Conditions of Participation except any requirement promulgated by regulation by the Secretary of Health and Human Services pursuant to 42 U.S.C. § 1395x(e)(9) which the Secretary, after consulting with the Joint Commission, AOA or another accrediting body approved by CMS and the Commissioner, identifies as being more stringent or more precise than the requirements for accreditation; and except the requirements for utilization review specified in 105 CMR 130.200; and with respect to psychiatric hospitals subject to licensure.

(B) Each accredited hospital which desires to obtain deemed status shall release to the Commissioner a copy of the hospital's current accreditation letter and the accrediting agency's explanation of its survey findings. The hospital shall also sign a Department consent form indicating it:

- (1) Agrees to permit Department observers at the summation conferences scheduled at the completion of an accreditation; and
- (2) Agrees upon request to release to the Commissioner any other accreditation information requested.

130.203: Validation Survey

The Commissioner may require a survey of an accredited hospital to verify the hospital has implemented the accrediting agency's recommendations for correction of deficiencies. The Department may identify hospitals for such surveys on a selective sample basis, or on the basis of the severity of deficiencies cited by the accrediting agency, or on the basis of the hospital's history of noncompliance with 105 CMR 130.000.

130.204: Loss of Deemed Status

- (A) The Commissioner may revoke the deemed status of an accredited hospital if:
- (1) The hospital fails to cooperate in the conduct of a Department validation survey or complaint investigation;
 - (2) The hospital fails to comply with any of the provisions of 105 CMR 130.202(A) and (B); or
 - (3) The Commissioner finds the hospital is out of compliance with one or more Conditions of Participation and a significant deficiency is determined to exist.
- (B) An accredited hospital which is dissatisfied with the denial or revocation of its deemed status by the Commissioner shall be entitled to an informal administrative review. The hospital must request informal review in writing within 15 days of the date it receives notice of the denial or revocation of its deemed status by the Commissioner. The request shall state the reasons why the hospital considers the denial or revocation incorrect and be accompanied by any supporting evidence and arguments.
- (C) The Commissioner shall notify the hospital, in writing, of the results of the informal administrative review within 20 days of receipt of request for informal review. Failure of the Commissioner to respond within that time shall be considered confirmation of the denial or revocation.
- (D) Following denial or revocation under 105 CMR 130.204(A), the Commissioner may, upon application of the hospital, grant deemed status to an accredited hospital if he or she finds the hospital meets the requirements of 105 CMR 130.202.

130.205: Requirements for Non-accredited Hospitals

If a hospital is not accredited by the Joint Commission, AOA, or another accrediting body approved by CMS and the Commissioner, or chooses not to participate in the deemed status licensure program as set forth in 105 CMR 130.202 through 130.204, it shall be subject to a full survey for licensure by the Department.

130.206: Prohibition Against Discrimination

- (A) No hospital shall discriminate in the provision of service against any person on the basis of race, creed, color, sex, handicap, or national origin.
- (B) No hospital which participates in the Medicaid program under Title XIX of the Social Security Act shall discriminate in the provision of service against any Medicaid recipient.

130.310: Director of Nursing Service

Each hospital shall establish a nursing service under the direction of a registered nurse, currently registered by the Board of Registration in Nursing under M.G.L. c. 112, § 74, who holds a baccalaureate degree in nursing and who has had at least four years experience in nursing practice, at least two of which were in an administrative or supervisory capacity.

130.311: Registered Nurse Coverage

There shall be a sufficient number of registered nurses on duty at all times to plan, supervise and evaluate nursing care, as well as to give patients the nursing care that requires the judgment and specialized skills of a registered nurse.

- (A) Supervisory Coverage. Registered nurses shall be assigned to supervise nursing care and nursing personnel according to a written staffing plan that provides for adequate coverage for all nursing units during each shift.
- (B) Unit Coverage. At least one registered nurse shall be assigned to work in each nursing unit at all times. The only exceptions to 105 CMR 130.311(B) shall be the following:

130.311: continued

(1) If a registered nurse is on duty in one nursing unit of a skilled nursing unit or of a chronic disease hospital, an adjoining nursing unit (on the same floor or floor above or below, if readily accessible) may be staffed by licensed practical nurses, provided that the registered nurse on duty shall be readily available to go from one nursing unit to another when skilled nursing services are needed.

(2) If a registered nurse is available to provide supervision and skilled nursing services when needed, an outpatient ambulatory care unit (not an emergency service unit) in which skilled nursing care is not routinely needed, may be staffed by licensed practical nurses.

(C) Intensive Care Units. The ratio of qualified registered nurses to patients in the unit must comply with M.G.L. c. 111, § 231 and 958 CMR 8.00: *Patient Assignment Limits for Registered Nurses in Intensive Care Units in Acute Hospitals.*

130.312: Registered Nurses, Licensed Practical Nurses, and Ancillary Staff Coverage

The number of registered nurses, licensed practical nurses and unlicensed nursing personnel assigned to each nursing unit shall be consistent with the types of nursing care needed by the patients and the capabilities of the staff.

130.320: Satellite Units

A satellite unit shall comply with all relevant requirements in 105 CMR 130.000.

130.325: Requirement That Personnel Be Vaccinated against Influenza Virus

(A) Definitions.

(1) For purposes of 105 CMR 130.325, personnel means an individual or individuals employed by or affiliated with the hospital, whether directly, by contract with another entity, or as an independent contractor, paid or unpaid including, but not limited to, employees, members of the medical staff, contract employees or staff, students, and volunteers who either work at or come to the licensed hospital site, whether or not such individual(s) provide direct patient care.

(2) For purposes of 105 CMR 130.325, the requirement for influenza vaccine or vaccination means immunization by either influenza vaccine, inactivated or live; attenuated influenza vaccine, including seasonal influenza vaccine pursuant to 105 CMR 130.325(B); and/or other influenza vaccine pursuant to 105 CMR 130.325(C).

(B) Each hospital shall ensure that all personnel are vaccinated with seasonal influenza vaccine unless an individual declines vaccination in accordance with 105 CMR 130.325(F). When feasible, and consistent with any guidelines of the Commissioner, each hospital shall ensure that all personnel are vaccinated with seasonal influenza vaccine annually.

(C) Each hospital also shall ensure that all personnel are vaccinated against other pandemic or novel influenza virus(es) as specified in guidelines of the Commissioner, unless an individual declines vaccination in accordance with 105 CMR 130.325(F). Such guidelines may specify:

- (1) the categories of personnel that shall be vaccinated and the order of priority of vaccination of personnel, with priority for personnel with responsibility for direct patient care;
- (2) the influenza vaccine(s) to be administered;
- (3) the dates by which personnel must be vaccinated; and
- (4) any required reporting and data collection relating to the personnel vaccination requirement of 105 CMR 130.325(C).

(D) Each hospital shall provide all personnel with information about the risks and benefits of influenza vaccine.

130.325: continued

(E) Each hospital shall notify all personnel of the influenza vaccination requirements of 105 CMR 130.325 and shall, at no cost to any personnel, provide or arrange for vaccination of all personnel who cannot provide proof of current immunization against influenza, as required pursuant to 105 CMR 130.325(B) and (C), unless an individual declines vaccination in accordance with 105 CMR 130.325(F).

(F) Exceptions.

(1) A hospital shall not require an individual to receive an influenza vaccine pursuant to 105 CMR 130.325(B) or (C) if:

- (a) the vaccine is medically contraindicated, which means that administration of influenza vaccine to that individual would likely be detrimental to the individual's health;
- (b) vaccination is against the individual's religious beliefs; or
- (c) the individual declines the vaccine.

(2) An individual who declines vaccination for any reason shall sign a statement declining vaccination and certifying that he or she received information about the risks and benefits of influenza vaccine.

(G) Unavailability of Vaccine. A hospital shall not be required to provide or arrange for influenza vaccination during such times that the vaccine is unavailable for purchase, shipment, or administration by a third party, or when complying with an order of the Commissioner that restricts the use of the vaccine. A hospital shall obtain and administer influenza vaccine in accordance with 105 CMR 130.325 as soon as vaccine becomes available.

(H) Documentation.

(1) A hospital shall require and maintain for each individual proof of current vaccination against influenza virus pursuant to 105 CMR 130.325(B) and (C) or the individual's declination statement pursuant to 105 CMR 130.325(F).

(2) Each hospital shall maintain a central system to track the vaccination status of all personnel.

(3) If a hospital is unable to provide or arrange for influenza vaccination for any individual, it shall document the reasons such vaccination could not be provided or arranged for.

(I) Reporting and Data Collection. Each hospital shall report information to the Department documenting the hospital's compliance with the personnel vaccination requirements of 105 CMR 130.325, in accordance with reporting and data collection guidelines of the Commissioner.

130.330: Serious Complaint Procedure

Each hospital shall develop a written procedure that assures prompt and complete investigations of all serious complaints filed against the hospital, employees of the hospital or members of its medical or professional staff. The procedure shall include, at a minimum, the following provisions:

(A) Designation of a senior member of the hospital administration as the person responsible for overseeing the investigation of serious complaints lodged against the hospital, an employee or member of the medical staff;

(B) Establishment of a reporting procedure that ensures the designated administrator will receive within one day from hospital staff, in writing, reports of serious complaints;

(C) Development by the designated administrator of a written process of investigation, which shall include the following:

- (1) A process of fact-gathering that he or she will utilize, including provision for interviewing of the complainant, patient, and relevant witnesses;
- (2) Creation of a complaint file that includes the original report of complaint, progress reports as investigation is carried out and outcome of investigation including action taken, if any;
- (3) Notification of the complainant of the outcome of the investigation.

(D) The complaint files shall be available for inspection by agents of the Department.

130.331: Serious Incident and Accident Reports

(A) Each hospital shall immediately report to the Department, pursuant to Department guidelines, any of the following occurring on premises covered by its license:

- (1) Death that is unanticipated, not related to the natural course of the patient's illness or underlying condition, or that is the result of an error or other incident as specified in guidelines of the Department;
- (2) Full or partial evacuation of the facility for any reason;
- (3) Fire;
- (4) Suicide;
- (5) Serious criminal acts;
- (6) Pending or actual strike action by its employees, and contingency plans for operation of the hospital;
- (7) Other serious incidents or accidents as specified in guidelines of the Department.

(B) Each hospital shall immediately report to the Department, for any patient treated at the hospital, any suspected instance(s) of abuse, neglect, mistreatment of that patient or misappropriation of that patient's property at or by a nursing home, rest home, home health, home maker or hospice.

(C) Each hospital shall report to the Department any other serious incident or accident occurring on premises covered by the hospital's license that seriously affects the health and safety of a patient(s) or that causes serious physical injury to a patient(s) within seven calendar days of the date of occurrence of the event.

(D) If a hospital makes a report of any incident pursuant to 105 CMR 130.331(A), (B) or (C), and the incident meets the definition of Serious Reportable Event or a Serious Adverse Drug Event in 105 CMR 130.332, the hospital also shall comply with the requirements of 105 CMR 130.332.

(E) The Department shall establish guidelines for the reporting of serious incidents and accidents pursuant to 105 CMR 130.331, including the means of reporting (for example, telephonic report or written report provided to the Department by facsimile, electronic means, delivery, or other means).

130.332: Serious Reportable Events (SREs) and Serious Adverse Drug Events (SADE)

(A) Definitions Applicable to 105 CMR 130.332.

National Quality Forum (NQF). The not-for-profit membership organization created to lead national collaboration to improve health and measurement and reporting.

Preventable. An event that could have been anticipated and prepared for, but that occurs because of an error or other system failure, including, but not limited to lack of adherence to best practices, patient safety guidelines or established policies and procedures.

Serious Adverse Drug Event (SADE). Any untoward, preventable medical occurrence associated with the use of a controlled substance, as defined in M.G.L. c. 94C, § 1, in humans that results in any of the following outcomes:

- (1) death;
- (2) a life-threatening outcome;
- (c) inpatient hospitalization or prolongation of existing hospitalization;
- (d) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or
- (e) a congenital anomaly or birth defect;

provided, however, that adverse medical occurrences directly associated with the use of a controlled substance in humans that may not immediately result in one of the outcomes listed in 105 CMR 130.332: Serious Adverse Drug Event (SADE)(a) through (e) may be considered a serious adverse drug event when they develop into or result in any of the outcomes listed in 105 CMR 130.332: Serious Adverse Drug Event (SADE)(a) through (e).

130.332: continued

Serious Reportable Event (SRE). An event that occurs on premises covered by a hospital's license that results in an adverse patient outcome, is clearly identifiable and measurable, has been identified to be in a class of events that are largely preventable and harmful, and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the hospital. The Department will issue a list of SREs based on those events included on the NQF table of reportable events to which 105 CMR 130.332 applies.

Unambiguously the Result of a System Failure. Events determined by the hospital to result from:

- (1) a failure to follow the hospital's policies and procedures;
- (2) inadequate or non-existent hospital policies and procedures; or
- (3) inadequate system design.

(B) Reporting of SREs.

- (1) Within seven calendar days of the date of discovery of an SRE, a hospital shall:
 - (a) file a written report with the Department of an SRE (SRE report) as specified in guidelines of the Department;
 - (b) inform the patient or the patient's representative orally or in writing or both about:
 1. the occurrence of the SRE including unanticipated outcomes of care, treatment and services provided as the result of an SRE;
 2. the hospital's policies and procedures and documented review process for making a preventability determination as required by 105 CMR 130.332(C); and
 3. the option to receive a copy of the SRE report filed with the Department; and
 - (c) affirm on the SRE report that the hospital has complied with the patient notification requirements of 105 CMR 130.332(B)(1)(b).
- (2) A hospital that provides services resulting from an SRE that did not occur on its premises shall file a written report with the Department within seven calendar days of the date of discovery of the SRE. The reporting hospital shall comply with the requirements of 105 CMR 130.332(B)(1), but need not make a preventability determination for the SRE.
- (3) If a SRE is also a SADE, the hospital shall also comply with the requirements of 130.332(E).

(C) Preventability Determination.

- (1) A hospital shall establish policies and procedures for a documented review process to determine whether an SRE was:
 - (a) preventable; and
 - (b) unambiguously the result of a system failure. A hospital shall make a preventability determination for all SREs occurring on premises covered by its license.
- (2) No later than 30 days after the date of reporting of the SRE to the Department the hospital shall:
 - (a) make the preventability determination required by 105 CMR 130.332(C)(1);
 - (b) file an updated SRE report with the Department describing the hospital's preventability determination including, at a minimum, the following:
 1. narrative description of the SRE;
 2. analysis and identification of the root cause of the SRE;
 3. analysis of the preventability criteria required by 105 CMR 130.332(C)(1);
 4. description of the corrective actions developed, implemented and to be monitored by the hospital following discovery of the SRE; and
 5. whether the hospital intends to charge or seek reimbursement for services provided by the hospital as a result of the SRE; and
 - (c) provide a copy of the updated SRE report to the Department, the patient and any responsible third-party payer.

(D) Reimbursement for SREs.

- (1) A hospital may not charge or seek reimbursement from a patient or responsible third-party payer for services provided as a result of an SRE occurring on premises covered by the hospital's license if the hospital determines that the SRE was:
 - (a) preventable; and
 - (b) unambiguously the result of a system failure, as required by 105 CMR 130.332(B) and (C).

130.332: continued

(2) A hospital shall immediately suspend or rescind any claims to any patient or responsible third-party payer pending the preventability determination and notification requirements of 105 CMR 130.332(C).

(3) A hospital may charge or seek reimbursement for services it provides that result from an SRE that did not occur on its premises; however a hospital that provides services (treating facility) resulting from an SRE occurring on premises of a separately licensed hospital or an ambulatory surgery center licensed pursuant to 105 CMR 140.000: *Licensure of Clinics* (responsible facility), may not charge or seek reimbursement for those services, if the treating facility and the responsible facility have common ownership or a common corporate parent.

(4) Any dispute(s) arising between the hospital and any responsible third-party payer resulting from a charge or claim for reimbursement for services provided by the hospital as a result of an SRE shall be addressed through the third-party payer's provider claims appeals process.

(5) The provisions of 105 CMR 130.332(D) shall not be construed to prohibit a Medicare provider from submitting a claim for reimbursement to the Medicare program.

(6) For services to MassHealth members, the hospital shall perform the documented review process solely for purposes of reporting, not for purposes of determining reimbursement.

(E) Serious Adverse Drug Events.

(1) Within seven days of the date of discovery of a medication error that occurs or occurred on the premises of the hospital and that meets the definition of a SADE, a hospital shall report the SADE to the Department as specified in guidelines of the Department.

(2) If a SADE also is an SRE, the hospital shall also comply with the requirements of 105 CMR 130.332(B), (C) and (D).

(3) Upon first discovering, through diagnostic evaluation and assessment of an individual patient, that a SADE has resulted from a patient's use, consumption or interaction with any pharmaceutical or drug preparation, a hospital must report the event to the federal MedWatch Program, as well as the pharmacy from which the drug was produced or compounded in addition to all other reporting requirements.

(4) Any facility failing to comply with 105 CMR 130.332(E) may:

(a) be fined up to \$1,000 per day per violation;

(b) have its license revoked or suspended by the Department; or

(c) be fined up to \$1,000 per day per violation and have its license revoked or suspended by the Department.

130.340: Discharge Planning Service Required

(A) Each acute-care hospital shall organize a multi-disciplinary discharge planning service to aid the attending physician and the patient and/or as appropriate the patient's family/patient representative in planning for the continuing care needs of the patient upon discharge from the hospital. The discharge planning service shall be responsible for coordinating the transfer of the patient from the hospital setting to an appropriate independent living arrangement or to another institution.

For the purposes of 105 CMR 130.000, a patient representative may be a court-appointed guardian; a person with written authorization to act on the patient's behalf; or if neither of the above is available, a person who has been known to the patient and determined by the discharge planning service to be acting responsibly on the patient's behalf.

(B) Each patient receiving discharge planning services in a hospital licensed under 105 CMR 130.000 shall have the following rights as set forth in 105 CMR 130.000:

(1) To participate in the discharge planning process to the maximum extent possible, with the assistance of family members or other representatives where the patient does not object to such assistance.

(2) To review any information which the hospital has about out-of-hospital resources including community based services capable of meeting the patient's discharge needs.

(3) To receive a written discharge plan, in non-technical language, along with sufficient oral explanations to assist the patient in understanding the plan.

(4) To acknowledge participation in and receipt of the discharge plan by signing it and, where the patient is unable or refuses to sign the plan, to have the reasons for such inability or refusal noted in the patient's medical records.

130.340: continued

- (5) To meet with the discharge planning coordinator and physician to attempt to resolve questions or disagreements about the discharge plan.

130.341: Discharge Planning Coordinator and Staff

- (A) The hospital administrator in conjunction with the nursing and Case Management department and other hospital departments as appropriate shall designate a specific individual or unit to be responsible for coordination of discharge planning.
- (B) If an individual, the coordinator for discharge planning shall be a licensed professional approved by the hospital. The individual shall have competence to carry out discharge planning responsibilities based on education, experience, and knowledge of community resources.
- (C) Whenever a specific discharge planning unit is designated, there shall be at least a licensed professional approved by the hospital assigned to the unit to assess patient needs and to plan together for continuity of patient care. Accountability for all aspects of the service of the unit shall be clearly delineated in the hospital's organizational and administrative documents.
- (D) The hospital shall retain sufficient staff to provide discharge planning services to all patients requiring such services.
- (E) A discharge planning coordinator shall be a member of the Utilization Review Committee.
- (F) There shall be an effective mechanism in place that establishes timely communication between discharge planning staff and the utilization review coordinator.

130.342: Discharge Planning

- (A) There shall be written policies and procedures concerning the implementation of discharge planning services, which reflect acceptable standards of practice and compliance with applicable regulations.
- (B) The coordinator of discharge planning or discharge planning unit shall be responsible for the coordination of patients' plans for continuing care in cooperation with the patient's physician, nurse practitioner or physician's assistant and in cooperation with the patient, and/or the family/representative as appropriate and other members of the professional staff.
- (C) The coordinator of discharge planning or the discharge planning unit shall establish effective systems for identifying patients in need of the hospital's discharge planning service. The goal of these systems shall be the early, as well as ongoing, identification of patients in need of discharge planning assistance.
- (1) These systems shall include but not be limited to:
- (a) requests for discharge planning consultation from the professional staff, the patient, or his or her family/patient representative;
 - (b) regular multidisciplinary meetings to review an individual patient's need for continuing care; and
 - (c) implementation of a high risk screening system to identify patients who may require discharge planning services.
- (2) The coordinator of discharge planning or the discharge planning unit shall be responsible for developing a written procedure describing the systems employed by the hospital to identify patients in need of discharge planning assistance.
- (D) Early Screening.
- (1) High risk case finding screening criteria shall be in writing and reflect the hospital's experience with patients requiring post-hospital care. Criteria shall be reviewed and revised as needed but at least annually.
 - (2) At a minimum high risk screening criteria shall include the lack of a readily available informal personal support network, *e.g.*, family support.

130.342: continued

(3) The hospital's high-risk screening and assessment system shall include the following provisions:

- (a) all patients shall be screened against the hospital's high-risk criteria within 24 hours of admission; and
- (b) an initial discharge planning assessment of all patients determined to be high-risk shall take place as soon as possible, but at least within two working days of the identification of such patients.

(E) Policies regarding Outpatient Discharge Planning Services.

(1) The coordinator of discharge planning or discharge planning unit shall develop policies and procedures and written criteria for use in the hospital emergency service and day surgical services indicating the circumstances under which discharge planning services shall be provided for a person who is in need of post-emergency or post-ambulatory surgical planning services but not in need of in-patient hospital care.

(2) Policies shall as appropriate reflect compliance with the requirements of 105 CMR 130.343(A) and (B), (D) through (H) and 130.345(B) relative to Medicare patients receiving services in emergency departments of acute hospitals.

(F) Discharge planning staff shall maintain in writing a description of out-of-hospital resources, which shall be readily available to the attending physician, nurse practitioner, physician's assistant, other members of the professional staff, the patients and their families/patient representatives.

(1) Resource information available shall cover the range of services in the hospital's primary service area that have the capability of assisting the patient and/or the patient's family/representative in meeting the patient's discharge needs. Where possible, information shall include admission and discharge policies and payment criteria.

(2) The hospital shall employ reasonable efforts to identify and arrange for necessary post-discharge services for patients from outside of the hospital's primary service area.

(3) The hospital shall make reasonable efforts to keep resource information current.

(G) In instances where the professional services of the discharge planning coordinator or unit are not required, professional staff of the appropriate professional departments shall plan for and coordinate the patient's discharge in accordance with departmental policy outlining their responsibility.

130.343: Discharge Plan

(A) Each patient determined to need assistance with arrangements for post-hospital care shall have a comprehensive, individualized discharge plan, which is in writing and is consistent with medical discharge orders and identified patient needs. A discharge plan for patients treated in the emergency department of an acute hospital shall mean a plan that addresses the specific problem for which the patient is seen in the emergency department.

Except for the requirements of 105 CMR 130.343(B) and (D) through (F), the requirements of 105 CMR 130.342 do not apply to Medicare patients who are transferred from the emergency department of one acute hospital to another acute hospital and to a Medicare patient residing in a nursing home who, after treatment in an emergency department, is returned back to that nursing home provided appropriate transfer/referral forms are properly completed to include information to assure continuity of care.

The plan shall include at least the following information:

- (1) identification of the post hospital services needed by the patient including home health and homemaker service, and of the post-hospital social needs of the patient, as determined in accordance with procedures set forth in 105 CMR 130.342;
- (2) the services arranged for the patient;
- (3) the names, addresses and telephone numbers of service providers;
- (4) the service schedule as requested by the hospital;
- (5) medications prescribed and instructions for their use or verification that such information was provided separately; and
- (6) scheduled follow-up medical appointments or verification that such information was provided separately.

130.343: continued

(B) The discharge plan shall be developed with the participation of appropriate health professionals, the patient and as appropriate the patient's family/patient representative. In instances of Medicare patients treated in emergency departments of acute hospitals, participation in the plan means that the patient receives an oral explanation of the treatment that was provided and written follow-up care instructions regarding care and other services necessary after discharge. Such instructions and information about necessary services shall be signed by the patient. If the patient is unable to sign, a notation shall be included in the patient's record that indicates the reason the patient is unable to sign.

(C) The patient shall receive the discharge plan in accordance with the following:

(1) As soon as the plan is completed and to the extent possible, at least before the end of the working day on the day before discharge, the patient and/or as appropriate the patient's family shall receive an oral and written discharge plan in understandable language that includes the post-hospital services that are required and the arrangements made for the provision of these services.

(2) In addition, for all Medicare patients, the hospital shall comply with all Medicare discharge requirements as set out in 42 CFR 482.43.

(D) The patient's medical record shall document that the plan was communicated orally to the patient and/or as appropriate the family/patient representative.

(E) For non-English speaking patients, the hospital shall provide translation assistance to assist the patient and/or as appropriate the family/patient representative in understanding the discharge plan.

(F) If a patient, and/or the patient's family/patient representative, as appropriate, notifies any professional staff member involved in the patient's care that the patient and/or the patient's family/patient representative does not agree with the discharge plan, the discharge planning coordinator and patient's physician shall arrange and conduct a meeting with the patient and/or family in an effort to develop a plan that is acceptable. For the purposes of 105 CMR 130.343, the nurse, social worker or other responsible emergency department health care professional may be considered the discharge coordinator and the emergency room physician may be considered the patient's physician.

(G) The discharge planning unit shall notify the patient's physician, nurse practitioner or physician's assistant of any difficulties that are impeding the patient's discharge, such as unavailability of necessary services and/or the patient/family representative's objection to the discharge plan.

(H) No patient shall be discharged or transferred without an order by a physician, nurse practitioner or physician's assistant, except where such patient leaves against medical advice.

130.344: Patient Signature Requirement

(A) The discharge plan provided to the patient or as appropriate the patient's family/patient representative shall include a signature line for the patient and/or as appropriate the patient's family/patient representative to acknowledge their participation in the development of the discharge plan and their receipt of the written plan.

(B) A copy of the signed discharge plan shall be retained in the patient's record.

(C) If the patient or as appropriate the patient's family/patient representative does not sign the plan, the reason for not signing, including any objection to the plan, shall be noted on the written plan and a copy shall be retained in the patient's medical record.

130.346: Timely Transfer of Information and Notice of Discharge

(A) The discharge planning service shall be responsible for the coordination of the timely transfer of appropriate information from the hospital to the post-hospital institution or agency caring for the patient in order to ensure continuity of patient care. The discharge planning coordinator or discharge planning unit shall carry out this function in conjunction with other health care professional(s) responsible for the completion of referral information required by 105 CMR 130.000 and in accordance with hospital policy.

(1) When a patient is transferred to another institution, a patient assessment form with pertinent patient care information to assure continuity of care shall be completed and shall accompany the patient.

(2) When a patient is discharged and referred to a community agency for continuing care, a patient care referral form with pertinent patient care information to assure continuity of care shall be completed and sent to the agency prior to or at the time of patient discharge.

(3) The medical discharge summary shall be sent by the hospital to the receiving inpatient institution at the time of the patient's discharge or to the appropriate community agency no later than 72 hours following discharge of the patient.

(B) The hospital shall give notice of the anticipated or impending transfer of the patient to the community agency or institution as soon as the discharge plan is complete, but not less than 24 hours prior to discharge, except in the case of a medically necessary emergency transfer. The hospital shall assist in making arrangements for safe transportation of the patient during transfer.

130.347: Discharge Planning Records

The discharge planning service shall maintain records that enable appropriate hospital personnel to prepare periodic reports about discharge planning services, including the number and types of placement and referrals.

130.348: Monitoring Quality of Service

The discharge planning service shall develop and implement a system to monitor the quality of the discharge planning services provided by the hospital.

130.349: Follow-up Monitoring

There shall be a program for the routine follow-up monitoring of selected discharged patients for whom post-hospital services were arranged.

(1) The program shall at least include follow-up monitoring of patients discharged with multiple services or otherwise complex post-hospital needs and lack of an informal personal support network.

(2) There shall be a written plan for follow-up monitoring that at a minimum describes which patients will be monitored, the time frame for the follow-up monitoring, including which patients require a follow-up contact within 24 hours of the planned initiation of service.

130.365: Substance Use Disorder Services

No hospital may offer a substance use disorder treatment program unless issued an approval for such program by the Department's Bureau of Substance Abuse Services.

130.370: Retention of Records

(A) A hospital shall maintain records of the diagnosis and treatment of patients under its care for the retention period specified in M.G.L. c. 111, § 70 after the discharge or the final treatment of the patient to whom the record relates. Medical records may be handwritten, printed, typed or in electronic digital format, or converted to electronic digital format or an alternative archival method. Handwritten, printed or typed medical records that have been converted to electronic digital format or an alternative archival format may be destroyed before the expiration of the retention period specified in M.G.L. c. 111, § 70. The manner of destruction must ensure the confidentiality of patient information. For purposes of 105 CMR 130.370, medical records in electronic digital format shall have the same force and effect as the original records from which they were made. A hospital shall include with the patient's medical record all trip records submitted by Emergency Medical Technicians on each ambulance run in accordance with 105 CMR 170.345(C). A hospital shall maintain the unprotected exposure forms in compliance with the requirements of 105 CMR 172.002(C).

(B) For the purpose of 105 CMR 130.370, a hospital shall not be required to consider the following as part of the medical record subject to the retention requirements in M.G.L. c. 111, § 70: radiological films, scans, other image records, raw psychological testing data, electronic fetal monitoring tracings, electroencephalograph, electrocardiography tracings and the like, provided that any signed narrative reports, interpretations or, sample tracings that are generated to report the results of such tests and procedures shall be maintained as part of the record. Such records as described in 105 CMR 130.370(B) shall be retained for a period of at least five years following the date of service.

(C) Medical records retained by the hospital in accordance with 105 CMR 130.370(A) or (B) shall be made available for inspection and copying upon written request of the patient or his or her authorized representative. The hospital may charge a reasonable fee for copying, not to exceed the rate of copying expenses as specified in M.G.L. c. 111, § 70.

(D) A hospital shall maintain and use patient records in a manner that protects the confidentiality of the information contained therein. Printed copies of electronically stored records shall be destroyed in a manner that ensures the confidentiality of patient information.

(E) A hospital shall make all patient records available promptly to any agent of the Department.

(F) At the expiration of the retention period specified in M.G.L. c. 111, § 70, which begins after the discharge or the final treatment of the patient to whom a retained medical record relates, a hospital may destroy the medical record. The manner of destruction must ensure the confidentiality of patient information. At least 30 days prior to the proposed date of destruction of a medical record(s), a hospital shall provide written notification to the Department, generally indicating the type of records to be destroyed and the dates of service which exceed the applicable retention period, in a manner specified by the Department, of the hospital's intent to destroy medical record(s) that exceed the 20 year retention period. A hospital may, but is not required to, notify a patient before destroying the patient's medical record pursuant to 105 CMR 130.370.

(G) A hospital shall provide written notice to a patient of the patient's right to inspect and to receive a copy of the patient's medical records and the hospital's medical record retention policy, as specified in M.G.L. c. 111, § 70.

(H) The purpose of 105 CMR 130.370 is to establish a minimum retention period and does not preclude hospitals from maintaining records for a longer period of time.

130.371: Posting of Notice of Patients' Rights

A hospital shall have visibly posted a notice that has the heading "NOTICE OF PATIENTS' RIGHTS" in block letters at least one inch high that contains all the rights provided by M.G.L. c. 111, § 70E. The notice shall be posted in at least one central area where all patients are likely to see it. In addition, each patient, upon admittance to the hospital, shall be given a written document containing all the rights provided by M.G.L. c. 111, § 70E.

130.375: Electronic Health Records

(A) Definitions applicable to 105 CMR 130.375

Acute Hospital. A hospital with a majority of medical-surgical, pediatric, obstetric, and maternity beds, as defined by the Department.

Centers for Medicare & Medicaid Services (CMS). The agency within the federal Department of Health and Human Services responsible for administering Medicare, Medicaid, and the Children's Health Insurance Program.

Certification Commission for Healthcare Information Technology (CCHIT). The nonprofit organization authorized by the Office of the National Coordinator for Health Information Technology to test and certify EHR technology to the certification criteria specified in 45 CFR Part 170.

Certified Electronic Health Record (Certified EHR) Technology. EHR technology that has been tested and certified by CCHIT or another agency or organization approved by ONC-HIT to test and certify EHR technology.

CMS Stage 1 Meaningful Use Criteria. The Stage 1 meaningful use objectives and measures specified in 42 CFR Part 495.

CMS Stage 2 Meaningful Use Criteria. The Stage 2 meaningful use objectives and measures specified in 42 CFR Part 495.

Computerized Provider Order Entry (CPOE). A system that enables the provider to directly enter medication orders, laboratory orders, and radiology orders from a computer or other electronic device. The order is then documented or captured in a digital, structured, and computable format for use in improving the safety and efficiency of the ordering process.

Electronic Health Record (EHR) Technology. Computer technology that records patient health-related information and:

- (1) includes patient demographic and clinical health information, such as medical history and problem lists;
- (2) has the capacity to:
 - (a) provide clinical decision support;
 - (b) support provider order entry;
 - (c) capture and query information relevant to health care quality;
 - (d) exchange electronic health information with, and integrate such information from other sources;
 - (e) protect the confidentiality, integrity and availability of health information stored and exchanged.

Eligible Professional (EP). An eligible professional as defined in 42 CFR 495.100 or a Medicaid eligible professional as defined in 42 CFR 495.304.

Non-acute Hospital. A hospital licensed under 105 CMR 130.000 that is not an acute hospital.

Office of the National Coordinator for Health Information Technology (ONC-HIT). The agency within the federal Department of Health and Human Services responsible for authorizing organizations to test and certify EHR technology to the certification criteria specified in 45 CFR Part 170.

Satellite Community Health Center (SCHC). A satellite unit of a hospital that also is a federally-qualified health center operating in conformance with federal rules for community health centers at 42 U.S.C. 254b and currently participating in the Massachusetts Medicaid program, or a community health center with an active provider agreement with MassHealth under 130 CMR 405.000: *Community Health Center Services*.

2014 Edition EHR Certification Criteria. The 2014 EHR certification criteria specified in 45 CFR Part 170.

130.375: continued

(B) Implementation of Certified Electronic Health Record Technology in Hospitals.

- (1) A hospital shall provide documentation to the Department demonstrating that it has implemented Certified Electronic Health Record Technology and that it utilizes CPOE, as specified in 105 CMR 130.375 and in guidelines of the Department.
- (2) A hospital shall submit data regarding its implementation and use of Certified EHR Technology, as specified in guidelines of the Department.
- (3) An acute care hospital shall:
 - (a) register and attest to compliance with CMS Meaningful Use Criteria, as specified in guidelines of the Department; and
 - (b) utilize CPOE as specified in 42 CFR Part 495 and guidelines of the Department.
- (4) Non-acute hospitals. A non-acute hospital shall:
 - (a) implement Certified EHR Technology, as specified in 45 CFR Part 170 and in guidelines of the Department; and
 - (b) utilize CPOE, as specified in guidelines of the Department.
- (5) Documentation of Meaningful Use.
 - (a) A hospital shall, upon request of the Department, submit documentation to the Department pertaining to the hospital's use of Certified EHR Technology, Medicare payment adjustments, and CMS registration and attestation, as specified in guidelines of the Department.
 - (b) A hospital shall keep documentation supporting its demonstration of meaningful use for six years following the EHR reporting period, as defined in 42 CFR 495.4.

(C) Implementation of Certified EHR Technology in Satellite Community Health Centers.

- (1) A hospital licensed to operate a Satellite Community Health Center shall provide documentation to the Department demonstrating that the SCHC has implemented Certified EHR Technology, that its eligible professionals have registered with CMS and attested to compliance with CMS EHR Meaningful Use Criteria, and that it utilizes CPOE, as specified in 105 CMR 130.375 and in guidelines of the Department.
- (2) No later than October 1, 2016, an SCHC shall:
 - (a) implement Certified EHR Technology, as specified in 45 CFR Part 170 and in guidelines of the Department;
 - (b) attest that at least 70% of eligible professionals employed by the SCHC have registered with CMS and attested to compliance with CMS Stage 1 meaningful use criteria, as specified in guidelines of the Department; and
 - (c) utilize CPOE, as specified in guidelines of the Department.
- (3) After October 1, 2016 the Department may require that a higher percentage of eligible professionals employed by the SCHC register with CMS, attest to compliance with CMS EHR meaningful use criteria, and utilize CPOE as specified in guidelines of the Department.
- (4) Review of Meaningful Use.
 - (a) A SCHC shall, upon request of the Department, submit documentation to the Department pertaining to its use of Certified EHR Technology and meaningful use by eligible professionals, as specified in guidelines of the Department.
 - (b) A SCHC shall keep documentation supporting its eligible professionals' demonstration of meaningful use for six years following the EHR reporting period, as defined in 42 CFR 495.4.

130.380: Anatomical Donations

In accordance with M.G.L. c. 113A and the terms defined therein, each hospital shall enter into agreements or affiliations with organ procurement organizations for coordination of procurement and use of anatomical gifts. Each hospital shall make a reasonable search of an individual whom the hospital reasonably believes to be dead or near death for a document of gift or other information identifying the individual as a donor or as an individual who has made a refusal. For the purposes of 105 CMR 130.380, an individual who has sustained either:

- (1) irreversible cessation of circulatory and respiratory functions; or
- (2) irreversible cessation of all functions including the entire brain, including the brain stem, is dead. Determination of death shall be made in accordance with accepted medical standards.

130.382: Autopsy Consent Procedures

(A) No hospital shall permit the autopsy of a decedent without the consent of the authorized person named in 105 CMR 130.386. Any such consent shall meet the requirements set forth in 105 CMR 130.384.

(B) No hospital that performs an autopsy shall use organs removed from the body for any purpose other than to determine a medical disease or condition, or the cause or manner of death unless the person authorizing the autopsy consents to such other use, or unless otherwise required by law. Any such consent shall meet the requirements set forth in 105 CMR 130.384(A)(6).

130.383: Autopsies Performed Pursuant to M.G.L. c. 38, § 4

The requirements of 105 CMR 130.382 through 130.387 shall not apply to autopsies performed by a hospital pursuant to M.G.L. c. 38, § 4; provided, however, that when the chief medical examiner or his or her designee releases the body of a decedent, the hospital shall not retain or otherwise dispose of any organs released with the body without consent that meets the requirements of 105 CMR 130.384(A)(6).

130.384: Autopsy Consent Requirements

(A) The hospital shall use a standardized written autopsy consent form that includes at a minimum:

- (1) the name of the decedent and date and time of death;
- (2) the name of the hospital where the autopsy is to be conducted;
- (3) the general purpose for which the autopsy is to be conducted;
- (4) opportunity for the person authorizing the autopsy to state any specific requests or concerns regarding the autopsy. If the hospital is unable to comply with any such request or address any such concern, the hospital shall not perform an autopsy on the decedent.
- (5) opportunity for the person authorizing the autopsy to specify any limitations on the autopsy;
- (6) a separate section regarding disposition of the organs following the autopsy, including:
 - (a) notification that the person authorizing the autopsy has the right to control the final disposition of the organs;
 - (b) a statement that the hospital will return all organs with the body of the decedent at the time the body is released, except for those organs for which prolonged fixation or complete detailed examination is required to complete the autopsy, unless the person authorizing the autopsy affirmatively designates an alternate disposition. The hospital shall specify those particular organ(s) for which prolonged fixation or detailed examination is required to complete the autopsy and inform the person authorizing the autopsy that he or she has the right to control the final disposition of the organ(s) being retained. If at the time consent is requested the hospital cannot specify with certainty the organs for which prolonged fixation or detailed examination is required, it shall so state and shall specify the time and manner in which it will provide the information about such organs to the person authorizing consent.
 - (c) opportunity to designate the disposition of the organs, including but not limited to for research purposes. The hospital may limit such disposition to those methods that conform to all applicable requirements for safe handling and disposal of organs.
- (7) the signature and printed name of the person who obtained the consent, including his or her title and relationship to the hospital;
- (8) the signature and printed name of a witness to the consent;
- (9) the date and time of the signing of the consent form;
- (10) the printed name of the person who is authorized to consent to the autopsy pursuant to 105 CMR 130.386, including his or her relationship to the decedent; and
- (11) the signature of the person authorizing the autopsy.

(B) The hospital shall provide a copy of the signed consent form to the person authorizing the autopsy.

130.385: Telephonic Consent

A hospital may obtain consent to autopsy by telephone. Such consent shall be valid without the signature of the person authorizing consent if it meets all of the following requirements:

- (A) The consent shall follow a conversation that meets the following requirements:
 - (1) The person requesting the consent shall read in its entirety the consent form specified in 105 CMR 130.384 to the person authorizing consent and shall mark answers to all items in the presence of the witness;
 - (2) The person authorizing consent shall have the opportunity to ask questions regarding the scope and purpose of the autopsy; and
 - (3) The witness shall listen to the conversation in its entirety, with the permission of all parties to the conversation.
- (B) The hospital shall provide a copy of the consent form to the person authorizing the autopsy.
- (C) The consent form shall state that the authorization was received by telephone.

130.386: Classes of Persons Authorized to Consent

- (A) The following order of priority is set forth for persons authorized to give consent for an autopsy:
 - (1) an agent of the decedent including, but not limited to, a health care agent appointed under a health care proxy pursuant to M.G.L. c. 201D, unless the power of attorney for health care or other record prohibits the agent from consenting to an autopsy;
 - (2) the spouse of the decedent;
 - (3) an adult child of the decedent;
 - (4) a parent of the decedent;
 - (5) an adult sibling of the decedent;
 - (6) an adult grandchild of the decedent;
 - (7) a grandparent of the decedent;
 - (8) an adult who exhibited special care and concern for the decedent;
 - (9) a person who was acting as a guardian of the decedent at the time of death; or
 - (10) any other person having the authority to dispose of the decedent's body.
- (B) If a member of the highest priority class available to give consent opposes the autopsy and makes such opposition known to the hospital prior to the autopsy, the hospital shall not perform an autopsy on the decedent.
- (C) If the class that is authorized to give consent to an autopsy contains more than one member, the hospital is required to obtain consent from only one member of that class. If a member of the same class as the person who is authorized to give consent to an autopsy opposes the autopsy and makes such opposition known to the hospital prior to the autopsy, the hospital shall not perform an autopsy on the decedent.
- (D) A separated spouse, if available after diligent search, shall explicitly waive consent in writing or by a witnessed telephonic communication before a member of a lower priority class is authorized to give consent.
- (E) A person of the highest priority class available to give consent who is younger than 18 years old, is not emancipated, or has been adjudicated mentally incompetent may not be the consenting party of record.
- (F) A woman who is younger than 18 years old may consent to the autopsy of her deceased child or fetus.

130.387: Responsibilities of Hospital Regarding Consent to Autopsy

The hospital shall establish written policies and procedures consistent with 105 CMR 130.382 through 105 CMR 130.387, including procedures for obtaining and documenting consent that meets the requirements in 105 CMR 130.384 and 130.385.

130.390: Mammography Facility - Licensure

Each hospital operating a mammography facility, as defined in M.G.L. c. 111, § 5Q and 105 CMR 127.000: *Licensing of Mammography Facilities*, shall obtain and maintain a license issued pursuant to 105 CMR 127.000.

130.395: Disposition of Remains Following the Death of a Fetus

(A) Hospitals shall have a written policy concerning disposition of remains of a fetus following the death of a fetus (other than by abortion) irrespective of the duration of the pregnancy.

(B) Hospitals shall have a written protocol that provides that following the death of a fetus (other than by abortion), and irrespective of the duration of the pregnancy, the parent is informed:

- (1) of the availability of counseling, and how to access these services;
- (2) of the parent's right to direct either burial, entombment, or cremation or disposal of the remains by the hospital;
- (3) in writing, that disposal of the remains by the hospital will be in conformance with state law and (105 CMR 480.000: *Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter VIII)*); and
- (4) of the availability of a written description of the hospital's policy with respect to the disposition of the remains.

(C) For the purposes of 105 CMR 130.395, fetus shall mean fetus or an embryo.

130.510: Hospital-based Hematopoietic Progenitor/Stem Cell Transplantation Program

105 CMR 130.510 through 130.580 set forth the licensure standards for a hospital-based Hematopoietic Progenitor/Stem Cell Transplantation Program.

130.520: Definitions Applicable to 105 CMR 130.520 Through 130.580

The following definitions apply in 105 CMR 130.520 through 130.580 when used in regard to hematopoietic progenitor/stem cell transplantation services and programs.

Cell Processing Facility. A clinical laboratory that processes and stores hematopoietic progenitor/stem cell components for clinical transplantation programs.

Collection. Any procedure for harvesting hematopoietic progenitor/stem cells regardless of technique or source.

Collection Facility or Service. A facility or service that collects or harvests hematopoietic progenitor/stem cells for clinical transplantation programs.

FACT Standards. Department guidelines based upon the FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration

Foundation for the Accreditation of Cell Therapy (FACT). The national accrediting body for hematopoietic progenitor/stem cell collection, processing and transplantation services.

Hematopoietic Progenitor/Stem Cell Collection, Processing and Transplantation Services (HPCCPTS). A service performing blood and marrow transplantation in the treatment of human disease. The service includes all phases of the collection, processing and administration of hematopoietic progenitor/stem cells. This includes but is not limited to cells isolated from bone marrow, peripheral blood, or placental/umbilical cord blood, and any of a variety of manipulations including removal or enrichment of various cell populations, expansion of hematopoietic cell populations, cryopreservation, infusion, expansion or activation of mononuclear cell populations for immunological therapy, and genetic modification of lymphoid or hematopoietic cells, when the cells are intended to permanently or transiently engraft in the recipient, and/or be used in the treatment of disease. HPCCPTS does not include the collection, processing or administration of erythrocytes, mature granulocytes, platelets, plasma or plasma-derived components intended for transfusion support.

130.520: continued

Hematopoietic Progenitor/Stem Cell Transplantation Program or Clinical Transplantation Program. Consists of an integrated medical team housed in geographically contiguous or proximate space with a single Program Director, common staff, training programs, protocols and quality assessment systems licensed pursuant to 105 CMR 130.520 through 130.580.

Hematopoietic Progenitor/Stem Cells. Primitive pluripotent hematopoietic cells capable of self-renewal as well as maturation into any of the hematopoietic lineages, including committed and lineage-restricted progenitor cells, unless otherwise specified in the (FACT) Standards, regardless of tissue source.

Labeling. Steps taken to identify the original hematopoietic progenitor/stem cell collection, any components, and any component modifications; to complete the required reviews; and to attach the appropriate labels.

Manipulation. An *ex vivo* procedure(s) that selectively removes, enriches, expands or functionally alters hematopoietic progenitor/stem cells.

Processing. All aspects of manipulation, labeling, and infusion of harvested material, regardless of source.

Stem Cell Transplant Program Director (Program Director). A physician who is board certified by a nationally recognized accrediting body in hematology or hematology/oncology and has expertise in bone and marrow transplantation for the treatment of disease and has operational oversight of the hematopoietic progenitor/stem cell transplantation program.

Transplantation. The infusion of autologous, syngeneic or allogeneic hematopoietic progenitor/stem cells with the intent of providing transient or permanent engraftment in support of therapy of disease.

130.527: Program Requirements

(A) The Program shall be part of a comprehensive hematopoietic progenitor/stem cell collection, processing and transplantation service.

(B) A clinical program that includes non-contiguous institutions in the same metropolitan area shall have a single Program Director, common protocols, staff training, quality assessment systems, review of clinical results and evidence of frequent, regular interaction by all members of the multidisciplinary team.

(C) A hospital licensed to provide a hematopoietic progenitor/stem cell transplantation program shall provide or arrange for collection and processing of hematopoietic progenitor/stem cells through collection facilities or services and cell processing laboratories that meet (FACT) accreditation standards. Collection facilities and/or processing laboratories serving one or more clinical transplantation programs are acceptable.

(1) If the collection facility or service used by the hospital transplantation program is located outside the United States, the collection facility must be affiliated with the National Marrow Donor Program (NMDP) or the World Marrow Donor Association (WMDA).

(2) The cell processing facility shall be:

(a) for facilities located within Massachusetts, a licensed, federally certified clinical laboratory, as defined under 42 USC 263A (the Clinical Laboratory Improvement Amendments);

(b) for laboratories located outside Massachusetts but within the United States, a federally certified clinical laboratory, as defined under 42 USC 263A (the Clinical Laboratory Improvement Amendments); or

(c) for laboratories located outside of the United States, a laboratory that is affiliated with the National Marrow Donor Program (NMDP) or the World Marrow Donor Association (WMDA).

(D) Autologous hematopoietic progenitor/stem cell transplantation may be performed in a separately licensed freestanding clinic if:

130.527: continued

- (1) the clinic transplantation services are a formal part of a hospital-based transplantation program; and
- (2) the hospital-based transplantation program has a current, written collaboration agreement with the freestanding separately licensed clinic that describes the services and responsibilities of each entity and complies with the requirements of 105 CMR 130.536.

130.535: Prerequisites for Pediatric Transplantation Program

A hospital that provides or intends to provide a hematopoietic progenitor/stem cell transplantation program for pediatric patients shall have a licensed Level III pediatric service.

130.536: Prerequisites for Autologous Hematopoietic Progenitor/Stem Cell Transplantation Services Provided in a Freestanding Clinic

If, as part of a hospital-based hematopoietic progenitor/stem cell transplantation program, the hospital intends to provide autologous hematopoietic progenitor/stem cell transplantation services in a separately licensed freestanding clinic, the hospital must have a written, current collaboration agreement with that clinic that describes the responsibilities of each entity. The collaboration agreement shall at a minimum:

- (1) Describe the services to be provided at the clinic site;
- (2) Describe the support services available at the hospital site, with particular attention to availability for patient care consultation by all members of the multidisciplinary team, including but not limited to physicians, nurse practitioners, physician's assistants, nurses, nutritionists, social workers, physical therapists and psychologists;
- (3) Describe the oversight responsibilities of the hospital;
- (4) Identify a physician, nurse practitioner, physician's assistant or nurse coordinator on site at the clinic;
- (5) Describe the quality assessment and assurance programs for transplantation at the clinic site, with particular attention to how the assessment data is used to improve services and how the data is integrated in the both the clinic's and the hospital's quality assurance programs; and
- (6) Be signed and dated by the Hospital Administrator, Hospital Vice President of Nursing or Clinical Services, Hospital Hematopoietic Progenitor/Stem Cell Transplantation Program Director, Clinic Medical Director and Clinic Physician or Nurse Coordinator.

130.540: Application to Provide Hematopoietic Progenitor/Stem Cell Transplantation Program

(A) A hospital licensed or operated by the Commonwealth pursuant to M.G.L. c. 111, § 51, that provides or is seeking to provide an hematopoietic progenitor/stem cell transplantation program shall provide documentation to the Department that it has received and maintains accreditation by (FACT). A copy of (FACT) accreditation documentation shall be submitted to the Department upon receipt from (FACT).

- (1) Hospitals seeking to initiate an hematopoietic progenitor/stem cell transplantation program and hospitals providing autologous or allogenic hematopoietic progenitor/stem cell transplantation services that intend to expand the transplantation program to also provide allogeneic or autologous transplantation services shall submit to the Department at least 90 days prior to performing the first transplant, a written statement signed under pains and penalties of perjury by a person authorized to act on behalf of the applicant that attests that the applicant's transplantation service meets the (FACT) accreditation standards, except for the transplant volume requirement, that the hospital will file an application for accreditation by (FACT) once the program has completed, within a 12 month period, ten of each type of transplant (allogeneic or autologous) for which it seeks accreditation, and the hospital will provide written confirmation of the filing of the accreditation application.
- (2) Subsequent to receipt of the information required by 105 CMR 130.540(A)(4), the Department shall grant a provisional license for the service that identifies the type of transplant to be performed.
 - (a) Within 30 months from the date of the issuance of the provisional license, the hospital shall file the (FACT) accreditation application(s) and provide the Department with written confirmation of the filing.

130.540: continued

(b) If the hospital fails to file the (FACT) application within the specified time period, the Department shall notify the applicant that the Department has not received satisfactory written documentation of filing for accreditation by (FACT) and offer the applicant the opportunity to submit the documentation within two weeks or such other time period as the Department shall define.

(c) If the applicant fails to submit the documentation required by 105 CMR 130.540(A)(5)(a) or (b), the Department shall revoke the provisional license and, without further hearing, refuse to issue a license for the transplantation program.

(d) If satisfactory written documentation of accreditation by (FACT) by type of transplant performed is not received by the Department within one year from the application date for accreditation, the Department shall notify the applicant that the Department has not received documentation of accreditation by (FACT) and offer the applicant the opportunity to submit the documentation within two weeks or such other time period as the Department shall define.

(e) If the applicant does not submit the documentation required by 105 CMR 130.540(A)(5)(d), the Department shall revoke the provisional license and, without further hearing, refuse to issue a license for the transplantation program.

(B) In its letter of application, a hospital shall describe its hematopoietic progenitor/stem cell transplantation program including, but not limited to, identification of the Transplant Program Director, the patient population, type of service, location and size of the service and any portions of the service that are outside of the licensed applicant facility.

130.560: Renewal of Hematopoietic Progenitor/Stem Cell Transplantation Program Licensure

The hospital shall apply for renewal of its approval to perform allogenic and/or autologous hematopoietic progenitor/stem cell transplantation at the time of renewal of the hospital's license.

130.570: Reporting to the Department of Public Health

As a condition of maintenance and renewal of licensure of the program, the hospital shall submit information as requested by the Department regarding the transplantation service.

130.580: Denial, Revocation or Refusal to Renew Licensure of the Transplantation Program Based on Lack of Accreditation by FACT

Loss or denial of accreditation shall be reported in writing to the Department within 48 hours of receipt of such notice to the hospital from FACT. Failure to receive or maintain accreditation by FACT shall result in the denial, revocation or refusal to renew the licensure of the transplantation program without further hearing.

130.601: Definitions Applicable to 105 CMR 130.601 through 130.650

The following definitions apply in 105 CMR 130.000 when used with regard to maternal and newborn services:

Antepartum Patient. Any pregnant woman who is characterized as having a high-risk obstetric complication or a pregnant patient with a medical or surgical condition.

Audiologist. An audiologist licensed by the Commonwealth of Massachusetts pursuant to the Board of Registration of Speech-language Pathology and Audiology regulations at 260 CMR 1.00: *Standards, Complaint and Grievance Procedure*, who meets such requirements for additional experience as defined by the Department in the Universal Newborn Hearing Screening Guidelines.

130.601: continued

Birth Hospital. For the purposes of 105 CMR 130.000 and 142.000: *Operation and Maintenance of Birth Centers*, a hospital with a maternal and newborn service, as designated by the Department pursuant to 105 CMR 130.000, or a hospital without a maternal and newborn service but with a pediatric service, as designated by the Department pursuant to 105 CMR 130.700, from which an infant may be initially discharged to home.

Birthing Room. A room designed to provide family-centered care in a "homelike" environment for low-risk mothers throughout the labor, delivery and immediate recovery periods.

Certified Nurse Midwife. An individual authorized by the Board of Registration in Nursing under M.G.L. c. 112, § 80C and authorized to practice as a nurse-midwife pursuant to 244 CMR 4.00: *Advanced Practice Registered Nursing*.

Cesarean/Delivery Room. A room staffed and equipped to handle low-risk to high-risk deliveries, including cesarean births, and have capabilities of administering all forms of anesthesia, including inhalation agents.

Clinical Nurse Specialist. A registered nurse with a current license from the Massachusetts Board of Registration in Nursing. For the purpose of 105 CMR 130.601 through 130.650, the clinical nurse specialist must be master's prepared with clinical expertise in advance nursing practice in the specialty area of maternal or neonatal health.

Continuing Care Nursery. A nursery that is specially equipped and staffed to offer a variety of specialized services as specified in 105 CMR 130.630(E) to mild or moderately ill infants born at the level IB hospital or to retrotransferred stable - growing or recovery infants who do not require intensive or special care.

Critical Care Obstetrics Team. A team including representatives from the following available 24 hours a day, seven days a week: Maternal-fetal medicine consultant; in-house obstetrician; in-house nursing staff with demonstrated competency in critical care; in-house anesthesia; in-house neonatologist and other medical specialties available, as needed, including at a minimum infectious disease, pulmonary, surgery, and cardiology.

Critical Congenital Heart Disease. A group of defects that cause severe and life-threatening symptoms and require intervention within the first days or first year of life.

Designated Service Levels. Levels of care based on services provided by the hospital as approved by the Department of Public Health.

Family-centered Care. A method of providing services that fosters the establishment and maintenance of parent-newborn-family relationships. The family may consist of the parent(s) and child and may include other identified support persons (biologically or nonbiologically related) for the mother and infant.

Family Practitioner. A physician licensed by the Massachusetts Board of Registration in Medicine who has completed a residency in family medicine, which includes training in internal medicine, pediatrics and obstetrics and is certified or board eligible for certification by the American Board of Family Practice.

Freestanding Pediatric Hospital with Neonatal Subspecialty Services. A service that has the capabilities to provide care to moderately to severely ill newborns who require neonatal intensive care services and to newborns with medical problems.

Hearing Screening. A test to detect hearing thresholds of 30 decibels or greater in either ear in the speech frequency range. The methodology shall be one defined as acceptable by the American Academy of Pediatrics and the American Speech and Hearing Association for the purposes of newborn infant hearing screening. The hospital's or birth center's screening outcomes shall meet referral rates established by the Department in the *Universal Newborn Hearing Screening Guidelines*.

130.601: continued

Labor Room. An area in which the mother experiences the first stage of labor.

Labor-delivery Suite. That part of a maternal and newborn service used to care for patients during labor, delivery and recovery. It shall include physically contiguous labor room(s), cesarean/delivery room(s) and ancillary facilities.

Labor-delivery-recovery-postpartum Room (LDRP or Single-Room Maternity Care). A room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery, recovery and postpartum periods.

Labor-delivery-recovery Room (LDR). A room designed, staffed and equipped to care for mothers, newborns and their families throughout the labor, delivery and recovery periods.

Lactation Consultant. An individual certified as an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience.

Level I - Community-based Maternal and Newborn Service. A community-based maternal and newborn service including Level IA and Level IB services that meets the requirements in 105 CMR 130.630.

Level IA Service. A community-based maternal and newborn service with a well newborn nursery that provides for the care and management of maternal conditions consistent with American College of Obstetricians and Gynecologists (ACOG) guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.

Level IB Service. A Level I community-based maternal and newborn service with a continuing care nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 35 weeks gestation.

Level II Service. A community-based maternal and newborn service with a Special Care Nursery including Level IIA and Level IIB services that meets the requirements in 105 CMR 130.640.

Level IIA Service. A community-based Level II maternal and newborn service with a Special Care Nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 34 weeks gestation.

Level IIB Service. A community-based maternal and newborn service with a Special Care Nursery that provides for the care and management of maternal conditions consistent with ACOG guidelines, including management of pregnancies judged unlikely to deliver before 32 weeks gestation.

Level III Maternal and Newborn Service. A maternal and newborn service that provides for the care and management of maternal conditions consistent with ACOG guidelines, including pregnancies at all gestational ages and that meets the requirements in 105 CMR 130.650.

Maternal and Newborn Service. That part of the hospital in which care is routinely delivered to mothers and newborns.

Maternal-fetal Medicine Specialist. An obstetrician/gynecologist who is licensed by the Massachusetts Board of Registration in Medicine and is certified or board eligible for certification in the subspecialty of maternal-fetal medicine by the American Board of Obstetrics and Gynecology.

Neonatal Fellow. A physician licensed by the Massachusetts Board of Registration in Medicine who is enrolled in a fellowship in neonatology.

130.601: continued

Neonatal Intensive Care Unit. A unit located either in a hospital with a Level III maternal and newborn service or a freestanding pediatric hospital with neonatology specialty services that provides a comprehensive range of specialty and subspecialty services to severely ill infants.

Neonatal Nurse Practitioner. An individual authorized by the Massachusetts Board of Registration in Nursing under M.G.L. c. 112, § 80B and authorized to practice as a nurse practitioner pursuant to 244 CMR 4.00: *Advanced Practice Registered Nursing* who holds certification as a neonatal nurse practitioner from a nationally recognized accrediting body acceptable to the Board.

Neonatal Resuscitation Program (NRP). The American Academy of Pediatrics' course designed to teach resuscitation of the newborn.

Neonatologist. A physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or board eligible for certification in neonatology by the American Board of Pediatrics.

Newborn Infant. For the purposes of 105 CMR 130.000 and 142.000: *Operation and Maintenance of Birth Centers*, an infant younger than three months old.

Obstetrician. A physician licensed by the Massachusetts Board of Registration in Medicine and who is certified or board eligible for certification by the American Board of Obstetrics and Gynecology.

Pediatrician. A physician licensed by the Massachusetts Board of Registration in Medicine who is certified or board eligible for certification in pediatrics by the American Board of Pediatrics.

Postpartum Unit. That part of a maternal and newborn service that is used exclusively for postpartum care. Postpartum beds include beds located in labor-delivery-recovery- postpartum rooms.

Recovery Area. A specifically designated area within the labor-delivery suite used to care for patients recovering immediately after delivery.

Retro-transfer or Retrotransferred Infant. An infant who required transfer to a more acute level facility for diagnosis or treatment not available in the birth hospital, who no longer requires these services, and is transferred back to the birth hospital or to another hospital with the level of service meeting his or her needs.

Risk Assessment of the Infant. The process of evaluating the newborn to determine whether he or she has special risks or combination of risks for adjustment to extrauterine life, health or survival in order to determine the need for specialized services, which includes a review of social, economic, genetic, and medical history findings prior to delivery or within the newborn period.

Risk Assessment of the Maternal Patient. The process of medically evaluating the mother to determine whether she has special risks or combination of risks to her own health and well-being or to that of the fetus in order to determine the need for specialized services and which includes a review of social, economic, genetic and/or medical conditions during the antepartal, intrapartal and/or postpartal periods.

Special Care Nursery. A nursery that is specially equipped and staffed to offer a variety of specialized services to moderately ill infants who do not require intensive care.

Transfer Infant. Any infant who is transferred from the birth hospital because he or she requires acute services for diagnosis and treatment not available at the birth hospital.

Well Newborn Nursery. A room housing newborns who do not need continuing care, special care of intensive care newborn services.

130.605: Department Designation of Level of Maternal and Newborn Care in a Hospital

- (A) Each hospital shall file an application as directed by the Department identifying the level of maternal and/or newborn services which the hospital requests approval to provide.
- (B) The Department shall base approval of such applications upon documentation submitted by each hospital demonstrating compliance with the requirements of the requested level.
- (C) After initial designation, the hospital shall re-apply for designation of its maternal and/or newborn services each time that it applies for renewal of its hospital license.

130.610: Establishment of the Statewide Perinatal Advisory Committee

The Department may from time to time convene a state Perinatal Advisory Committee to advise the Department on issues related to 105 CMR 130.615 through 130.628 (Maternal and Newborn Services). The Advisory Committee shall serve solely in an advisory capacity and shall not have authority to make binding decisions. The Committee may include representatives of the following groups: physicians, nurses, including nurse practitioners and nurse midwives, hospital administrators, and consumers.

130.615: Patient/Family Services

- (A) Each hospital with a maternal and newborn service shall provide culturally and linguistically appropriate prenatal, postnatal and family-planning services either directly or through referral to an outside agency.
- (B) The hospital shall make health education materials and activities available in the major languages identified through the acute hospital's language needs assessment pursuant to 105 CMR 130.1103(A) and plain language.
- (C) The hospital shall have visitation policies for all service levels that promote parent-infant contact and maintenance of the family unit, while providing safety and privacy. These written policies shall be made available to families.
- (D) The hospital shall develop policies and procedures to provide information and referrals, where appropriate, to parents of babies with special health needs about resources such as early intervention, self-help groups, and other community contacts as soon as possible after delivery.
- (E) The hospital shall develop and implement policies and procedures regarding providing support and referral for the family experiencing the death of a newborn, and providing families the opportunity to see, hold and participate in the care of their infant during and after the dying process.
- (F) The hospital shall provide information about the Women, Infants and Children (WIC) program's benefits and services. As appropriate, staff shall refer patients to the WIC program closest to their residence.

130.616: Administration and Staffing

- (A) Perinatal Committee. Each maternal and newborn service shall establish a multidisciplinary perinatal committee or its equivalent responsible for developing a coordinated approach to maternal and newborn care
- (2) Written Collaboration and Transfer Agreements.
 - (1) Each hospital with a maternal and newborn service that is not designated as a Level III service shall develop a written collaboration/transfer agreement with at least one primary Level III maternal and newborn service. The agreement shall include provisions for consultation; guidelines for maternal and newborn transfer, including provision of relevant medical information and ongoing patient-centered communications before, during and after transport or retro-transfer; provision for professional educational offerings; and take into consideration unusual circumstances, such as lack of available bed or patient request.

130.616: continued

(2) Collaboration/transfer agreements between hospitals that regularly transfer patients shall include provisions for monitoring the quality of care provided to transfers with a focus on outcomes.

(3) A maternal and newborn center located close to a level III service in another state may develop an agreement with that center, provided the center meets the applicable regulations for that state.

(C) Administrative Policies. Each maternal and newborn service shall develop and implement written administrative policies that include, but are not limited to, previously discharged or retro-transferred infants and antenatal patients, and include the following:

(1) on-site availability 24 hours a day, of at least one professional, licensed staff member who is a provider of neonatal resuscitation and trained by a recognized program, such as the American Academy of Pediatrics' Neonatal Resuscitation Program (NRP).

(2) The maternal and newborn service shall be self-contained and discrete from other hospital services and be situated so as to accommodate patient flow without passing through other functional areas of the hospital. There shall be limited access to the service.

(D) Patient Care Policies. Each maternal and newborn service shall develop and implement written patient care policies and procedures, supported by evidence based resources, which include, but are not limited to:

(1) Pain Management;

(2) Care of the Newborn. Each maternal and newborn service shall develop and implement written patient care policies and procedures, supported by evidence based resources, which include, but are not limited to:

(a) Apgar scoring.

(b) Thermoregulation, including skin-to-skin contact when appropriate.

(c) Eye prophylaxis for ophthalmia neonatorum.

(d) Collection of cord blood sample.

(e) Vitamin K administration.

(f) Infant security policies and procedures developed in conjunction with the hospital's security and pediatric departments. At a minimum, the policy shall address:

1. a process for identifying the newborn at the time of delivery;

2. use of an acceptable identification system;

3. procedure for rebanding an infant;

4. identification of individuals who can remove a newborn from the nursery;

5. visitation policies outlining who is allowed to visit and when; and

6. a plan for educating parents regarding the security procedures.

(g) Promotion of parent-newborn contact.

(h) Infant feeding (including flexible schedule per parent's request), output measurement and skin-to-skin care.

(i) Comfort measures and reduction of pain and trauma during invasive procedures.

(j) Complete physical examination by a physician or neonatal nurse practitioner within 24 hours of birth or upon admission, including infants who are retrotransferred.

(k) Stabilization and management of the infant requiring transfer including the opportunity for the family to see and touch the infant before transfer.

(l) Hearing screening through the Universal Newborn Screening Program.

1. Prior to the hearing screening of a newborn infant, the hospital or birth center shall include information explaining the importance of newborn hearing screening and follow up in materials distributed to parents or guardians in accordance with the hospital's established culturally and linguistically appropriate policies and procedures.

2. Each birth hospital and birth center shall ensure a hearing screening is performed on all newborn infants before the newborn infant is initially discharged to home in accordance with the hospital's established policies and procedures.

a. If a newborn infant is transferred directly from the birth hospital or birth center to another hospital, the responsibility for screening lies with the hospital from which the infant is initially discharged to home.

130.616: continued

- b. By three months of age, an infant shall receive hearing screening. If an infant cannot be screened by the age of three months due to delayed physiological development or physiological instability as a result of illness or premature birth, the infant shall be screened prior to discharge and as early as physiological development or stability will permit reliable screening.
- 3. Such screening shall not be performed if the parent or guardian of the newborn infant objects to the screening based upon sincerely held religious beliefs.
- 4. If an infant is not successfully screened or missed a screening prior to discharge, the birth hospital or birth center shall contact a Department approved screening center to make an appointment for a screening.
- 5. The birth hospital or birth center shall inform, orally and in writing, a parent or guardian of the newborn infant if the infant was not successfully screened or missed a screening. This information shall also be provided in writing to the newborn infant's primary care physician and the Department through its electronic birth certificate system or such mechanism as specified by the Department, and in accordance with the hospital's established policies and procedures.
 - a. Such notice shall occur prior to discharge whenever possible, but in any case no later than ten days following discharge.
 - b. The birth hospital or birth center so informing the parent or guardian and physician shall provide written information to the parent or guardian and physician regarding appropriate follow-up for an infant who missed a screening or was not successfully screened in accordance with the hospital's established policies and procedures.
- 6. If an infant did not pass the hearing screening, the birth hospital or birth center shall contact a Department approved diagnostic test center to make an appointment for a diagnostic test.
- 7. The birth hospital or birth center shall inform, orally and in writing, a parent or guardian of the newborn infant if the infant did not pass the screening. This information shall also be provided in writing to the newborn infant's primary care physician as well as to the Department through its electronic birth certificate system or such mechanism as specified by the Department and in accordance with the hospital's established policies and procedures.
 - a. Such notice shall occur prior to discharge whenever possible, but in any case no later than ten days following discharge.
 - b. The birth hospital or birth center so informing the parent or guardian and physician shall provide written information to the parent or guardian and physician regarding appropriate follow-up for an infant who did not pass the screening.
- 8. Screening Protocols.
 - a. The birth hospital or birth center shall designate a program director who is responsible for the provision of newborn infant hearing screening services. The program director shall be an audiologist, neonatologist, pediatric otolaryngologist, neonatal or perinatal nurse, or pediatrician. The program director may delegate duties related to the oversight of the hearing screening service to appropriately trained staff.
 - b. A licensed audiologist shall oversee the provision of screening services and shall train the persons performing the screening.
 - c. Each birth hospital and birth center shall develop and update accordingly a protocol for newborn hearing screening. The protocol shall identify, at minimum, the necessary training and supervision of staff, maintenance of appropriate equipment, screening methods, infection control procedures, documentation and communication procedures, methods for ensuring appropriate follow-up for newborns that did not pass the test or were not screened, quality review and data reporting as required by the Department.
- (m) Newborn blood screening required by statute.
- (n) Appropriate administration of hepatitis B vaccine and hepatitis B immune globulin to all infants according to the recommendation of the Centers for Disease Control Advisory Committee on Immunization Practices and the Massachusetts Immunization Program.

130.616: continued

- (o) Screening for critical congenital heart disease with pulse oximetry or other test approved by the Department as set forth in guidelines, unless the parent or guardian of the infant has objected to the screening based on sincerely held religious beliefs.
 - (3) Admission and/or treatment of patients who have delivered outside of the maternal and newborn service or hospital, including home births.
 - (4) Use of the maternity service for gynecology patients. Gynecology patients shall not be routinely cared for on a maternity unit. However, the hospital shall develop and implement appropriate policies and procedures in the event that it is necessary for gynecology patients to be placed on the unit.
 - (5) Protocols to ensure that the care of obstetrical patients hospitalized for medical/surgical conditions is coordinated, including consultation with obstetrical services medical and nursing staff.
 - (6) Policies for the safe and secure storage and handling of infant feedings, formula and breast milk, including policies to ensure the correct labeling and identification of all infant feeding.
- (E) Quality Assurance and Education Program.
- (1) Each maternal and newborn service shall have an ongoing documented, evidence-based, quality assurance program including problem identification, action plans, evaluation and follow-up. A multi-disciplinary approach shall be required.
 - (2) The quality assurance program shall include an annual Hearing Screening Program Evaluation of critical performance data, including but not limited to, number of live births, number of infants screened, number of infants who passed the screening, number of infants who did not pass the screening in the right ear, number of infants who did not pass the screening in the left ear, number of infants who did not pass the screening in both ears, number of infants who missed screening or were unsuccessfully screened, the number of infants referred for diagnostic testing, and the number of parents or guardians who refused screening.
- (F) Nurse Staffing. The Maternal and Newborn service shall meet the following requirements:
- (1) A registered nurse who has successfully completed a recognized program in neonatal resuscitation, such as the Neonatal Resuscitation Program (NRP), shall be present during the delivery. A second registered nurse shall be immediately available as additional support until the mother and infant are stabilized.
 - (2) A registered nurse shall be on duty in each patient care unit on every shift. The hospital shall ensure that all licensed nursing staff caring for maternal and newborn patients have demonstrated current competency in providing care in the specialty area. All licensed nursing staff shall receive orientation and periodic in-service education related to the current best practices for maternal and newborn care including training or documented skill in at least the following areas:
 - (a) Evaluation of the condition of the mother, fetus and newborn.
 - (b) Assessment of risk during the labor, delivery, recovery and postpartum periods.
 - (c) Fetal assessment modalities including use of electronic fetal monitor, auscultation tools, interpretation of fetal heart-rate patterns and initiation of appropriate nursing interventions for non-reassuring patterns (for nurses caring for pregnant women).
 - (d) Nursing management of emergency situations that specifies communication and decision-making responsibilities and chain of command.
 - (e) Adult and newborn resuscitation.
 - (f) Immediate care and assessment of the newborn.
 - (g) Family-centered care that is culturally and linguistically appropriate.
 - (h) Support of the normal processes of labor and birth.
 - (i) Mother and infant security.
 - (j) Initiation and support of lactation.
 - (3) The licensed nursing staff shall receive documented retraining in adult and neonatal cardio-pulmonary resuscitation every two years and mock code drills every year. Each maternal and newborn service shall provide licensed nursing staff with continuing education in specialty areas of the service.

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(4) The hospital shall plan, develop and budget its nurse staffing pattern for the maternal and newborn service using data from a patient classification system acceptable to the Department. If a classification system is not used, the hospital shall apply nationally recognized staffing standards acceptable to the Department based upon the facility's case-mix and volume.

(G) Lactation Care and Services. Each hospital shall deliver culturally and linguistically appropriate lactation care and services by staff members with knowledge and experience in lactation management. At a minimum, each hospital shall provide every mother and infant requiring advanced lactation support with ongoing consultation during the hospital stay from an International Board Certified Lactation Consultant (IBCLC) or an individual with equivalent training and experience. An educational program of lactation support for maternal and newborn staff shall be offered by qualified staff.

130.619: Labor-delivery Suite

(A) Labor Room.

(1) A labor room shall meet the Labor Room requirements set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines as referenced in 105 CMR 130.107, and additionally must provide emergency medications, appropriate clinical equipment to monitor, stabilize and resuscitate the mother and newborn(s), and assistive equipment to facilitate patient involvement in the delivery process.

(2) Construction of new units or alterations or additions to existing maternal and newborn units shall provide a minimum of 120 square feet per bed in labor rooms.

(B) Cesarean/Delivery Room.

(1) A cesarean/delivery room shall meet the Cesarean/Delivery Room requirements set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines as referenced in 105 CMR 130.107, and additionally must provide emergency medications, appropriate clinical equipment to monitor, stabilize and resuscitate the mother and newborn(s), and assistive equipment to facilitate patient involvement in the delivery process.

(2) The cesarean/delivery room shall meet the infection control standards of the hospital's operating rooms.

(3) Additional surgical procedures limited to pregnancy related conditions only, such as dilatation and curettage and postpartum tubal ligations, may be performed within the cesarean/delivery room.

(4) Construction of new units or alterations or additions to existing maternal and newborn units shall provide at least 400 square feet of space in each cesarean/delivery room, except that such rooms that are not used for cesarean births shall contain at least 300 square feet.

(C) Recovery Area. A recovery area shall meet the Recovery Area requirements set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines as referenced in 105 CMR 130.107, and additionally must provide emergency medications, appropriate clinical equipment to monitor, stabilize and resuscitate the mother and newborn(s), and assistive equipment to facilitate patient involvement in the delivery process. Hospital policy shall state the types of patient conditions requiring admission to the recovery area.

130.620: Birthing Room

If the services include birthing room(s), the birthing room(s) shall meet all the requirements of a labor, delivery, recovery room (LDR) in 105 CMR 130.621.

130.621: Labor-delivery - Recovery Room

(A) A labor-delivery - recovery room shall meet the Labor-delivery - Recovery Room requirements set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines as referenced in 105 CMR 130.107, and additionally must provide emergency medications, appropriate clinical equipment to monitor, stabilize and resuscitate the mother and newborn(s), and assistive equipment to facilitate patient involvement in the delivery process.

(B) There shall be written policies and procedures for the labor-delivery-recovery room that shall include, at a minimum, provisions for the following:

- (1) Admission criteria.
- (2) Criteria for transfer to the cesarean/delivery birth room.
- (3) Restriction of anesthesia to local or regional modes.
- (4) Care of the normal newborn including the minimum length of time the infant remains in the labor-delivery-recovery room.

(C) Construction of new units or alterations or additions to existing maternal and newborn units shall provide a minimum of 250 square feet of floor space for each labor-delivery-recovery room.

(D) The labor-delivery-recovery room shall have single patient occupancy.

130.622: Labor-delivery - Recovery-postpartum Room (Single Room Maternity Care)

(A) A labor-delivery - recovery-postpartum room shall meet the Labor-delivery - Recovery-postpartum Room requirements set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines as referenced in 105 CMR 130.107, and additionally must provide emergency medications, appropriate clinical equipment to monitor, stabilize and resuscitate the mother and newborn(s), and assistive equipment to facilitate patient involvement in the delivery process.

(B) There shall be written policies and procedures for the labor-delivery-recovery- postpartum room that shall include, at a minimum, provisions for the following:

- (1) Admission criteria.
- (2) Criteria for transfer to the cesarean/delivery room.
- (3) Restriction of anesthesia to local or regional modes.

(C) Construction of new units or alterations or additions to existing maternal and newborn units shall provide a minimum of 250 square feet of floor space for each labor-delivery-recovery-postpartum room.

130.623: Postpartum Unit

(A) A postpartum unit shall meet the postpartum room requirements set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines as referenced in 105 CMR 130.107, and must also provide emergency medications, appropriate clinical equipment to monitor, stabilize and resuscitate the mother and newborn(s) and assistive equipment to facilitate patient involvement.

(B) Provisions shall be made to accommodate the mother and infant in the same room 24 hours a day as requested by the mother.

(C) Equipment for each room in the postpartum unit shall include at least the following:

- (1) Suction and oxygen capabilities.
- (2) Staff emergency call system.

(D) Construction of new units or alterations or additions to existing maternal and newborn units shall provide a minimum 124 square feet per bed in multiple bedrooms and 150 square feet in single bedrooms.

130.624: Nursery

- (A) A nursery shall meet the Nursery requirements set forth in administrative guidelines of the Department based on the Facility Guidelines Institute's Guidelines as referenced in 105 CMR 130.107, and additionally must provide appropriate clinical equipment to monitor, stabilize and resuscitate the mother and newborn(s), and assistive equipment to facilitate patient and family involvement.
- (B) Each service must maintain a well-newborn nursery to accommodate its patients in accordance with the hospital's established policies and procedures.
- (C) All newborns in the nursery shall at all times be in direct view of personnel accountable for them.
- (D) Well-newborn nurseries shall ensure restricted, secure access. Special care nurseries shall be arranged so that entrance is gained solely through a well-lighted anteroom with provision for a handwashing and gowning area.
- (E) The following shall be readily available to the nursery:
- (1) Separate and secure refrigerator and freezer for storage of breast milk.
 - (2) Electric breast pump and collection kits.
 - (3) Appropriate facilities and necessary equipment for circumcision.
 - (4) Hearing screening equipment.
 - (5) Washable infant scales.

130.626: Infection Control

Each maternal and newborn unit shall develop and implement policies incorporating universal precautions as defined in guidelines issued by the Centers for Disease Control and Prevention, and addressing, at a minimum, the ability for mothers and infants to be placed in isolation together and vaccination of health care professionals.

130.627: Records

(A) Maternal Record. The obstetrics service shall establish and maintain a system for obtaining prenatal records or summaries of records of patients at 24 weeks of pregnancy (with updates as warranted in accordance with hospital policy) and for making them available to the staff of the labor and delivery unit when the patient is admitted for delivery. Such records shall be maintained as part of the mother's permanent record.

In addition to the requirements for all hospital patient records, the mother's record shall include:

- (1) Mother's medical and obstetric history including prenatal course.
- (2) Antenatal blood serology, Rh factor, blood type, HBsAg test, rubella antibody and Group B streptococcal culture results. In addition, results of maternal HIV testing, if applicable.
- (3) Admission obstetrical examination including the condition of both mother and fetus.
- (4) Complete description of progress of labor and delivery, signed by the attending physician, or certified nurse midwife, including reasons for induction and operative procedures.
- (5) Type of medications, analgesia and anesthesia administered to the patient during labor and delivery.
- (6) Signed report of qualified obstetric or other consultant when such service has been obtained.
- (7) Names and credentials of all those present during delivery.
- (8) Description of postpartal course, including complications and treatments, signed by the attending physician or certified nurse midwife.
- (9) Medications, including contraceptives, prescribed at discharge.
- (10) Infant's condition at birth including gestational age, weight, Apgar score, blood type, and results of initial physical assessment.
- (11) Nursing assessment, diagnosis, interventions and teaching.
- (12) Method of infant feeding and infant feeding plan of care and progress and documentation of lactation care and services provided.

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(13) If neonatal death occurs, cause of death, assessment of the family's coping mechanisms and plans for follow-up and/or referral of the family.

(B) Newborn Record. In addition to the requirements for all patient records, the newborn record shall include:

- (1) Significant maternal diseases.
- (2) Mother's obstetric history including estimated date of confinement and prenatal care course.
- (3) Maternal antenatal blood serology, typing, Rh factors, rubella antibody titer, coombs test for maternal antibodies if indicated, and prenatal HBsAg test results.
- (4) Results of any significant prenatal diagnostic procedures including genetic testing and/or chromosomal analysis.
- (5) Complications of pregnancy or delivery.
- (6) Duration of ruptured membranes.
- (7) Medications, analgesic and/or anesthesia administered to the mother.
- (8) Complete description of progress of labor including diagnostic tests, treatment rendered and reasons for induction or operative procedures.
- (9) Date and time of birth.
- (10) Cause of death if it occurs.
- (11) Condition of the infant at birth including Apgar score, resuscitation, time of sustained respirations, description of congenital anomalies, gestational age, head circumference, length, weight, pathological conditions and treatments.
- (12) Number of cord vessels and description of any placental anomalies.
- (13) Written verification of eye prophylaxis, vitamin K and mandated screening tests, including time and date.
- (14) Infant Feeding.
 - (a) Method of feeding including feeding plan of care.
 - (b) Documentation of at least two successful feedings, for both breastfeeding and formula fed infants.
- (15) Report of infant's initial medical examination within 24 hours of birth, signed by the infant's attending physician or his or her physician designee or neonatal nurse practitioner.
- (16) Informed consent for circumcision or any other surgical procedures.
- (17) Physician progress notes written in accordance with hospital policy.
- (18) A report of discharge examination signed by attending physician, certified nurse midwife pediatric nurse practitioner or neonatal nurse practitioner within 24 hours of discharge.
- (19) Nursing assessment, diagnosis, interventions and teaching.
- (20) Documentation that hearing screening has been performed, screening results and referral, if any. If a referral is made, the medical record shall document the date, time and location of the follow-up appointment.
- (21) Discharge instruction sheet including feeding plan, referrals and follow-up care signed by the infant's practitioner.

130.628: Data Collection and Reporting Systems

(A) Each maternal and newborn service shall comply with reporting requirements in accordance with Department guidelines.

(B) The hospital shall report the death of a pregnant woman during any stage of gestation, labor or delivery or the death of a woman within 90 days of delivery or termination of pregnancy to the Department in accordance with Department guidelines.

130.630: Level I - Community-based Maternal and Newborn Service

The Level I capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IB, IIA, IIB or Level III services. The Level 1 service provides for the care and management of well newborns, stable infants born at 35 weeks gestation, including stable retro-transferred infants not needing Level IB, IIA, IIB or III services.

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The Level I Service shall meet all of the General Requirements for Maternal and Newborn Services contained in 105 CMR 130.601 through 130.628 and, in addition, the following:

(A) Administration and Staffing.

- (1) An obstetrician certified by the American Board of Obstetrics and Gynecology shall be designated as medical director of the maternal service. The medical director or his or her designee shall be available on-call 24 hours a day.
- (2) A physician certified by the American Board of Pediatrics and experienced in the care of newborns shall be designated as medical director of the newborn service. The medical director or his or her designee shall be available on-call 24 hours a day.
- (3) The medical directors of the maternal service and the newborn service shall collaborate in the overall medical management of the maternal and newborn service.
- (4) An obstetrician with full privileges shall be available on-call 24 hours a day.
- (5) A pediatrician, family practitioner or a neonatal nurse practitioner with full privileges shall be available on-call 24 hours a day.
- (6) A registered nurse designated by the hospital shall be accountable for the 24 hour nursing management of the Level I service. At a minimum, this nurse shall be baccalaureate prepared (master's preferred) and have at least two years experience in the care of stable newborns.
- (7) A registered nurse educator, prepared at the baccalaureate level, shall have dedicated responsibility for coordinating and providing educational and training activities to enhance staff knowledge of relevant procedures and technological advances for staff of the maternal and newborn service.
- (8) Anesthesiologists shall be available in-house or on-call such that emergency cesarean deliveries can be started within 30 minutes of the recognition of the need for the procedure.

(B) Services. The Level I Maternal and Newborn Service shall provide the following services:

- (1) Social risk assessment and social work services provided by a licensed social worker(s) with experience in social assessment of and planning for perinatal patients (mother/infant dyad), as determined appropriate by the patient(s) health care team. These services may be provided by the hospital social service department or through contracted services with public or private social service agencies.
- (2) Nutritional consultation by a dietician registered by the Commission on Dietetic Registration and experienced in maternal and newborn nutritional needs available seven days a week, as determined appropriate by the patient(s) health care team.
- (3) Medical risk assessment and early identification of high-risk maternal, fetal and newborn patients, including access to or consultation with subspecialty services 24 hours a day.
- (4) Continuous internal and external electronic fetal monitoring and auscultation.
- (5) Blood for transfusions including O negative and fresh frozen plasma 24 hours a day.
- (6) Respiratory therapists shall be available on call 24 hours a day.
- (7) Radiology services, including portable x-ray and ultrasound on-call 24 hours a day.
- (8) Clinical laboratory services, including microchemistry, on-call 24 hours a day.
- (9) Ongoing care, monitoring, stabilization, and resuscitation, available 24 hours a day for infants born in-house and for retrotransfers.
- (10) Registered pharmacist services, available at a minimum by telephone consultation, with access to, at minimum, neonatal, pediatric and maternal pharmacological resources, and 24-hour access to emergency drugs.
- (11) Emergency cesarean surgical birth within 30 minutes of the decision to perform the procedure.

(B) Policies and Procedures. The Level I Maternal and Newborn Service shall develop those policies and procedures listed in 105 CMR 130.601 through 130.628 and other policies and procedures as deemed appropriate by the hospital perinatal committee. Such policies shall be submitted to the Department upon request.

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(C) Level IB Service Designation. The services capabilities include the management of uncomplicated pregnancies and the management of pregnancy complications not requiring the facilities and resources of Level IIA, IIB or Level III services. Provides for the care and management of well newborns, stable infants born at ; 35 weeks gestation, including stable retro-transferred infants not needing Level IIA, IIB or III services. A Level I service may be designated as a Level IB service with a continuing care nursery service if the requirements of 105 CMR 130.630(E)(1) through (4) are met 24 hours a day, seven days a week:

(1) Administration and Staffing.

(a) A physician certified by the American Board of Pediatrics with experience in the care of special care newborns shall be designated as the medical director of the Level IB Continuing Care Nursery Service. The medical director or his or her designee shall be available on-call 24 hours a day.

(b) A pediatrician with Continuing Care Nursery privileges shall be available on-call 24 hours a day.

(c) Nursing.

1. The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the Continuing Care Nursery service. At a minimum, such nurse shall be baccalaureate prepared (master's preferred) and have additional education in the 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. The hospital shall provide a baccalaureate prepared nurse educator with dedicated responsibility for coordinating and providing education activities to enhance staff knowledge or relevant procedures and technological advances for staff of the maternal and newborn service.

(d) A respiratory therapist with pediatric experience trained in neonatal transition and disease pathology (*e.g.* NRP) shall be present in-house to provide consultation on oxygen therapy and equipment maintenance.

(e) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written hospital policy.

(2) Services. For designation as a Level IB Continuing Care Nursery Service, the hospital shall provide Level I care and services as well as the following Level IB care and services 24 hours a day, seven days a week:

(a) Continuous oxygen administration and short term oxygen therapy *via* nasal cannula and/or oxyhood.

(b) Umbilical artery and vein line insertion and maintenance, and maintenance of peripheral inserted central catheter (PICC).

(c) Long term antibiotic therapy *via* PICC.

(d) Gavage feedings.

(e) Management of mild apnea of prematurity.

(f) Positive infant stimulation, as appropriate, including but not limited to tactile, kinesthetic, auditory and visual measures such as rocking, touching, and vocalization to support positive and reciprocal interaction between infant and parents.

(g) Radiology, including portable x-ray 24 hours a day. Access to radiologist on staff, available daily to interpret neonatal studies, such as chest and abdominal radiographs and cranial ultrasounds.

(h) Clinical laboratory services including microchemistry, in-house 24 hours a day.

(i) Respiratory therapy services, in-house, 24 hours a day.

(j) Access to an ophthalmologist with experience diagnosing conditions such as retinopathy of prematurity.

(k) Access to the services of a developmental specialist.

(3) Policies and Procedures. The Level IB Continuing Care Nursery shall have written policies and procedures for the following:

(a) Consultation with and/or transfer to a Level II or III service. All infants requiring mechanical ventilation shall be transferred to a Level III unit.

(b) The circumstances when the presence of a pediatrician designated to be responsible for newborn resuscitation and stabilization is required. A pediatrician with sole responsibility for resuscitation shall be present during the delivery of an infant anticipated to require stabilization and during the period awaiting actual transfer of the infant to a Level II or III service.

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- (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) An 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.

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(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, neurosurgery, 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.

130.650: continued

- (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.

130.720: continued

- (5) Pediatric-sized emergency resuscitation equipment is available in the ICU.
- (6) Emergency laboratory services utilizing microtechniques shall be available in-hospital 24 hours a day.
- (7) A radiology technician shall be available in-hospital 24 hours a day.

(K) A pediatric service shall provide education on chronic and other related conditions to families of pediatric patients with such conditions, and services to such families.

(L) A pediatric service admitting a newborn infant, as defined under 105 CMR 130.601, from either another hospital, birth center, or home, shall verify that the newborn hearing screening has been conducted by the hospital or birth center from which the newborn infant has been transferred or where the newborn infant was born and, in the event it has not been conducted, shall ensure that the screening is performed prior to discharge of the newborn infant, in a manner consistent with standards established by the Department under 105 CMR 130.616(D)(2)(I).

130.730: Requirements for Uncomplicated Pediatric Services (Level I)

Uncomplicated pediatric services (Level I) must meet the following requirements in addition to those listed in 105 CMR 130.720:

(A) A physician with pediatric experience shall be designated as the Chief of Pediatrics. The Chief of Pediatrics or the Chief's designee shall be on call at all times for the care of pediatric patients.

(B) A registered nurse with clinical pediatric experience must be on duty 24 hours a day for the direct supervision of pediatric nursing care.

(C) There must be specific beds within an adult care unit designated for pediatric patients. These beds and other equipment must be adaptable for pediatric patients younger than 15 years old. The area must be equipped with bathroom facilities for the exclusive use of pediatric patients.

(D) Social services for pediatric patients shall be available in-hospital or through consultant arrangements and families of pediatric patients must be made aware of social services offered.

(E) At a minimum, consultant arrangements shall be made for the provision of physical and occupational therapy for pediatric patients.

130.740: Requirements for General Pediatric Services (Level II)

General pediatric services (Level II) must meet the following requirements in addition to those listed in 105 CMR 130.720:

(A) Environment. The hospital must have either:

- (1) a discrete unit designated for pediatric patients; or
- (2) a discrete sub-unit within an adult care unit containing beds permanently designated as pediatric beds, provided this sub-unit meets the following requirements:
 - (a) Such pediatric beds are located in a specific room, or contiguous specific rooms, and such beds and other support equipment are appropriate for pediatric patients younger than 15 years old.
 - (b) The nursing station or sub-station serving pediatric patients is adjacent to the room(s) containing beds designated for pediatric patients. Observation of these rooms is possible from the nursing station or sub-station.
 - (c) The pediatric service has written policies specifying the ages and types of diagnoses of patients who may be admitted to the sub-unit for elective and emergency purposes, and the types of procedures that may be performed on them.
 - (d) The pediatric sub-unit is situated in such a way that the flow of adult patients through it is discouraged.

130.740: continued

(3) The service must have an area or areas that are used primarily for recreation or play, and equipped with items appropriate for the pediatric patients of the age using the areas.

(B) Administration and Staffing.

(1) The hospital must have a designated Chief of Pediatrics who is a board certified pediatrician. The Chief of Pediatrics or one or more physicians designated by the Chief shall be on call at all times for the care of pediatric patients.

(2) There must be a physician trained in pediatric resuscitation available in-hospital 24 hours a day.

(3) Any pediatric residents and interns assigned to a Level II service shall be supervised by a pediatrician with full privileges at the hospital.

(4) A registered nurse designated by the hospital shall be accountable for the 24 hour nursing management of the Level II service. At a minimum, this nurse shall have at least five years of documented nursing experience of which at least two years is pediatric nursing experience and be bachelor's prepared.

(5) At least one registered nurse with pediatric nursing experience shall be assigned to work in each pediatric unit or sub-unit at all times.

(C) Services.

(1) Social services for pediatric patients must be available in-hospital or through consultant arrangements, and their existence must be made known to the families of pediatric patients.

(2) Physical and occupational therapy services shall be available in-hospital or through consultant arrangements.

(3) A technician to perform laboratory tests shall be available on a 24-hour basis, in-hospital or on call within 15 minutes.

(4) A radiology technician shall be available on a 24-hour basis, in-hospital or ready to obtain images within 30 minutes.

(5) When necessary, a registered dietitian shall be available to Level II service staff and the families of pediatric patients for consultation concerning pediatric nutrition.

(6) Pharmacy services including 24-hour availability of medications and intravenous solutions must be available in-hospital. Pharmacy consultations with pharmacists experienced in pediatrics must be available on call 24 hours a day.

130.750: Requirements for Tertiary Pediatric Services (Level III)

Tertiary pediatric services (Level III) must meet the requirements listed in 105 CMR 130.720 and 130.740. In addition, Level III services must meet the following requirements (in case of conflict between these requirements and those listed in 105 CMR 130.740, Level III services must meet the requirements listed in 105 CMR 130.750):

(A) At least one social worker with an M.S.W. and experience working with pediatric patients and their families must be assigned to the pediatric service.

(B) Occupational therapy services must be available in-hospital and provided or supervised by an occupational therapist with documented experience as a pediatric occupational therapist.

(C) Physical therapy services must be available in-hospital and provided or supervised by a physical therapist with documented experience as a pediatric physical therapist.

(D) There must be a board certified or board eligible radiologist or a radiology resident in-hospital at all times.

(E) At least one radiologist and one radiology technician in the hospital at all times must have training and experience in pediatric radiology and radiologic technology respectively beyond that required for board certification in radiology and certification in radiologic technology.

(F) There must be a pediatric patient recreation program supervised by at least one trained activity therapist, whose education and experience is in one or more of the following fields: child development, early childhood education, or early childhood counseling.

130.750: continued

(G) Each Level III service must have a pediatric intensive care unit (PICU), discrete from the adult ICU, that is designed and staffed to provide for critically ill or potentially critically ill pediatric patients who need highly specialized intervention and advanced life-support technology. The PICU shall meet the following requirements:

- (1) The PICU shall be directed by a board-certified pediatrician, or a pediatric anesthesiologist board-certified in anesthesiology, who has documented special training and experience in the care and management of critically-ill pediatric patients.
- (2) The PICU Director shall be assisted by at least one Associate Director who is a board-certified pediatrician or anesthesiologist with special training and experience in the care and management of critically ill pediatric patients.
- (3) A physician who is responsible for the PICU patients shall be in-hospital 24 hours a day.
- (4) A person capable of intubating and resuscitating pediatric patients shall be available within or immediately adjacent to the PICU 24 hours a day.
- (5) Consultant board-certified physicians with training and experience in the following: pediatric surgery, cardio-thoracic surgery, neurosurgery, and neurology shall be available to the PICU 24 hours a day. Consultants from other subspecialties shall be available as necessary.
- (6) The hospital shall designate a registered nurse who has responsibility and accountability for the 24 hour nursing management of the PICU service. She or he shall have at least five years of nursing experience, of which at least two years is pediatric nursing experience, be bachelor's prepared and meet the qualifications for the management position as defined by hospital policy.
- (7) Registered nurses in the PICU shall have had documented experience in either clinical pediatric nursing or adult medical/surgical nursing and shall have received specialized orientation in the care and management of critically-ill pediatric patients prior to assuming PICU staff nurse positions.
- (8) The registered nurse/patient ratio in the PICU shall be between 1:1 and 1:2, depending upon the number of nursing care hours required by each patient in accordance with M.G.L. c. 111, § 231 and 958 CMR 8.00: *Patient Assignment Limits for Registered Nurses in Intensive Care Units in Acute Hospitals*.
- (9) Support personnel Respiratory therapy services necessary to operate, maintain, regulate, or repair monitoring and ventilatory equipment shall be available to the PICU 24 hours a day.

130.760: Requirements for Pediatric Specialty Services

Pediatric specialty services must apply to the Department, as set forth in guidance by the Department, for designation of the level of their pediatric service as so defined in 105 CMR 130.700. Absent a waiver from the Department, each such service shall comply with all the requirements for the level of care at which it is designated.

130.761: Emergency Service - Pediatric Patients

(A) All hospitals providing emergency care for pediatric patients, as defined by 105 CMR 130.700, shall meet the following requirements:

- (1) At least one physician with training in pediatric resuscitation shall be on duty in the emergency room at all times.
- (2) A pediatrician or a general or family practitioner who regularly sees pediatric patients of all ages shall be on call 24 hours a day and available for consultation in the emergency room within 30 minutes.
- (3) The hospital shall develop and implement a policy providing for consultation and/or referral from the emergency room to an appropriate pediatric inpatient service.
- (4) Equipment and medication necessary for pediatric emergency resuscitation shall be readily available in the emergency room.
- (5) Radiology and laboratory services, including appropriately board-certified physicians and technicians, shall be available on call 24 hours a day.
- (6) The emergency service shall develop and implement written policies and procedures for the management of pediatric problems.

130.761: continued

(B) Emergency services in hospitals having a tertiary pediatric service (Level III) as defined by 105 CMR 130.705, shall meet the requirements of 105 CMR 130.761(A) and in addition the following requirements:

- (1) At least one physician experienced in pediatric emergency care shall be on duty in the emergency care area at all times.
- (2) There shall be board certified or board eligible physician coverage on call to provide care for any critically injured or ill pediatric patient at all times. This coverage shall include but not necessarily be limited to pediatrics, surgery, and anesthesiology.
- (3) Social services and psychiatric services shall be available on call 24 hours a day.

130.800: Hospice Services

A hospital that provides a hospice service must be licensed pursuant to 105 CMR 141.000: *The Licensure of Hospice Programs*.

130.810: Birth Center Services

An applicant to add a birth center to its license shall develop, through an interdisciplinary team, written policies and procedures to ensure the safe operation of the birth center prior to submitting an application for approval. A birth center shall implement, and review and revise through an interdisciplinary team as needed but not less than once a year, its written policies and procedures. A birth center shall ensure that all staff, including any temporary staff and volunteers, are trained and determined to be competent as needed for their duties on the policies and procedures developed by the facility. A birth center's policies shall include at a minimum, but not be limited to:

- (A) Patient admission criteria including specific information by which a woman's risk status will be established.
- (B) Off-hour coverage.
- (C) Consultation and referral for obstetric and pediatric care.
- (D) Specific patient transfer criteria.
- (E) Emergency procedures, including adult and neonatal intubation and resuscitation.
- (F) Standards for medication procurement, storage and administration.
- (G) Protocols for screening newborns for critical congenital heart disease with pulse oximetry or another test approved by the Department in accordance with Department guidelines.

130.811: Staffing

A birth center shall have adequate, trained staff who are licensed as required are available at all times to meet the needs of its patients, including but not limited to:

- (A) Director of the Birth Center.
 - (1) A birth center shall have a director who shall be responsible to the facility administrator for the operation and maintenance of the center.
 - (2) The director must be a certified nurse-midwife, or an obstetrician or family practitioner with obstetrical privileges in a nearby hospital licensed in Massachusetts or operated by the Commonwealth.
- (B) Director of Medical Affairs.
 - (1) A birth center shall have a Director of Medical Affairs who shall be an obstetrician or gynecologist with full obstetrical privileges at a nearby hospital.

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)(I). 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 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 for further opportunities for improvement.

(C) The program shall include, but not be limited to, assessments of the following:

- (1) Appropriate patient selection (according to preestablished 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's 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 per day, seven days per 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.