

105 CMR 130.000: HOSPITAL LICENSURE

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

130.1800: Patient and Family Advisory Council

130.1801: Policies and Procedures for Patient and Family Advisory Council

130.001: Purpose

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

130.002: Authority

105 CMR 130.000 is adopted under the authority of M.G.L. c. 111, §§ 3 and 51 through 56.

130.003: Citation

105 CMR 130.000 shall be known and may be cited as 105 CMR 130.000: *Hospital Licensure*.

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 means that 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.

NON-TEXT PAGE

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

Campus One of several premises on the license of a hospital that provides an essential health service.

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

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

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

Department means the Massachusetts Department of Public Health.

Essential Health Service means 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 below. Essential Health Service also includes outpatient dental services, outpatient psychiatric and mental health services, and outpatient reproductive health services:

Excluded Services List:

- (A) Skilled nursing facility service;
- (B) Intermediate care facility service;
- (C) Cardiac catheterization service;
- (D) Chronic care service;
- (E) Hematopoietic Progenitor/Stem Cell Collection, Processing, and Transplant Service;
- (F) Hematopoietic Progenitor/Stem Cell Transplantation Program or Clinical Transplantation Program;
- (G) Trauma service as a designated trauma center as defined in 105 CMR 130.851;
- (H) Primary Stroke Service.
- (I) Medical Control Service.

Hospital means any institution in the Commonwealth of Massachusetts, however named, whether conducted for charity or for profit, which 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. This definition shall not include any hospital operated by the Commonwealth of Massachusetts or by the United States.

Hospital Service Area means the geographic area calculated based upon the Determination of Need standards developed pursuant to 105 CMR 100.540 for purposes of calculating the Acute Care Bed Need for Medical/Surgical Services.

Non English Speaker means 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.

Relationship of Mutual Support shall mean for the purposes of 105 CMR 130.207 and 130.208 a relationship between two individuals, each unmarried and competent to contract, characterized by mutual caring and emotional support; an agreement to share basic living expenses; a sharing of living quarters and an intent to do so indefinitely; a mutual assumption of responsibility for each other's welfare; and a mutual expectation that the relationship is exclusive and will endure over time.

Rural Hospital means 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 Unit means an operation off the premises of the hospital, such as a clinic or clinical laboratory at which the hospital provides health care services.

Service means 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. The services listed herein for licensure purposes may be different from those specified in the definition of "major service" in 105 CMR 100.040: Determination of Need. The Department does not intend by this difference to limit its authority to determine what constitutes a major service or a substantial change in services for determination of need purposes.

(A) 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.

(B) 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.

(C) 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.

(D) Burn Unit. A special treatment 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.

(E) Pediatric Service. A pediatric service as defined in 105 CMR 130.703, or a pediatric specialty service, as defined in 105 CMR 130.707, which is Level I, II or III, as defined in 105 CMR 130.704 through 130.706, for pediatric patients, as defined in 105 CMR 130.701.

(F) Pediatric Intensive Care Unit. A pediatric intensive care unit as defined in 105 CMR 130.750(J), for pediatric patients, as defined in 105 CMR 130.701.

(G) (1) Maternal and Newborn Service. A service providing care to maternal and newborn patients as defined in 105 CMR 130.601.

(2) Neonatal Intensive Care Unit. Neonatal intensive care unit, as defined in 105 CMR 130.601.

(H) Special Care Nursery Service. A special care nursery as defined in 105 CMR 130.601.

(I) Continuing Care Nursery Service. A continuing care nursery as defined in 105 CMR 130.601.

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

(K) Substance Abuse 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.

(L) Chronic Dialysis Service. A service for treatment of patients with end-stage renal disease who do not require 24 hour hospitalization. This service includes dialysis facilities for providing hemodialysis, peritoneal dialysis or both and related specialized staff and support services.

(M) Chronic Care Service. A chronic care service is a service, other than a rehabilitation, psychiatric, substance abuse, intermediate care facility, or skilled nursing facility service, which has an average length of inpatient stay greater than 25 days. Any hospital licensed for a medical/surgical service, which otherwise meets the definition set out in 105 CMR 130.026(M) and which has had approved or has filed a complete application pursuant to 105 CMR 100.600 prior to the effective date of 105 CMR 130.026(M), shall continue to be licensed as a medical/surgical service.



(N) Rehabilitation Service. A rehabilitation service provides physical restoration and emotional, mental, social and vocational restoration and adjustment for handicapped and disabled persons. 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.

(O) Skilled Nursing Facility Service. For services licensed prior to the enactment of St. 1988, c. 23 on April 21, 1988, a long-term care service which 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.

(P) Intermediate Care Facility Service. For services licensed prior to the enactment of St. 1988 c. 23 on April 21, 1988, a long-term care service which 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.

(Q) Ambulatory Care Services. Health care services for patients who do not use overnight facilities.

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

(S) 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. The birth center must be nearby but not be physically attached in any manner, including connection by corridors, to any other hospital services including the obstetrics service. A birth center is not a birth room or birthing suite or other short stay inpatient service.

(T) 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 as defined in 105 CMR 130.026(A).

(U) Cardiac Catheterization Services. Diagnostic and therapeutic services, other than cardiac surgery, which are not usually performed at the patient's bedside and which involve the introduction of physical objects (such as catheters) into the heart, its chambers, the pericardium, or the great vessels proximal to the heart. Examples of cardiac catheterization services are right heart and left heart cardiac catheterization, coronary angiography, ventriculography, and percutaneous coronary interventions. Excluded from this definition are: bedside cardiac and pulmonary artery catheterization using floating and/or indwelling catheters; the implantation, repair, and replacement of cardiac pacemaker devices; and cardiac radionuclide scanning procedures that do not require the use of the cardiac catheterization laboratory.

(V) Hematopoietic Progenitor/Stem Cell Collection, Processing and Transplantation Services (HPCCPTS) means 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.

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(W) 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 130.510 through 130.580.

(X) Cardiac Surgery means 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.

(Y) Angioplasty means the procedure for remodeling a blood vessel through the introduction of an expandable balloon catheter, and includes percutaneous intervention (PCI) on the heart. Examples of PCI include angioplasty, stents, atherectomy, brachytherapy, and/or local drug delivery.

(Z) 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, as defined in the document 'Resources for Optimal Care of the Injured Patient: 1999' by the Trauma Subcommittee of the American College of Surgeons (ACS) and its successors; 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.

(AA) 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.

(BB) Medical Control Service means the organized provision of medical control as defined in 105 CMR 130.1501.

Support Service means any of the following:

(A) 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.

(B) 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.

(C) 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. Trauma shall not mean toxic ingestion, poisoning or foreign body ingestion.

#### 130.050: Waiver of Requirements Imposed on Hospitals

The Commissioner or his designee may waive the applicability to a particular hospital of one of 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 Department; and

(D) The hospital provides to the Commissioner or his designee written documentation supporting its request for a waiver.

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130.051: Special Projects

The Department will consider proposals for special projects for the innovative delivery of hospital services. No such plan shall be implemented without prior written approval of the Department. Such plans shall be implemented only on an experimental basis and subject to renewal of the approval by the Department at such periods as the Department shall fix.

130.100: Requirement of License

Every hospital shall obtain a hospital license from the Department hereinafter referred to as a "license".

130.101: Application for License

(A) Application for a license to establish or maintain a hospital or for renewal of such license shall be filed on a form provided by the Department and accompanied by all supporting documents required by 105 CMR 130.000.

(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 hospital license fee shall accompany every application submitted.

130.102: Local Approvals

The applicant shall furnish the following evidence of approvals from local authorities in support of each application for licensure:

(A) An inspection certificate issued by the Department of Public Safety, Division of Inspection; and

(B) A certificate of inspection issued by the head of the local fire department. (M.G.L. c. 111, § 51.)

An application without these approvals shall be deemed incomplete and returned to the applicant.



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 the following information in support of its application for an original license, or upon any change of ownership:

(1) A copy of its by-laws and articles of incorporation, partnership agreement, or other charter, and if ownership of the hospital has been transferred, a copy of documentary evidence (such as a contract or a deed) showing the transfer of ownership, so that the Commissioner or his designee may satisfy himself that the applicant or hospital is legally empowered to provide services.

(2) The information on ownership and control required by U.S. Department of Health and Human Services Medicare and Medicaid provider disclosure regulations, 42 C.F.R. 420.206 and 455.104.

130.104: Evidence of Responsibility and Suitability

(A) In determining whether an applicant 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 governing health facility operation, and 105 CMR. 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

(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; and

(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 which 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.

(B) The Commissioner or his/her designee will consider the evidence produced and make licensure recommendations accordingly.

130.105: Updating of Information

All information required by the Department under 105 CMR 130.103(B) and 130.104 shall be kept current by each hospital. Changes in this information shall be reported to the Commissioner or his designee within 30 days of occurrence.

130.106: Construction Requirements

No original license shall be issued to establish a hospital, except a college and school infirmary, unless it complies with the construction standards of the state building code and is of at least type 1-B fireproof construction.

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130.107: Submission and Approval of Architectural Plans and Specifications

In the case of new construction of a hospital, or in the case of alterations or additions to an existing hospital, preliminary architectural plans and final architectural plans and specifications shall be submitted to the Commissioner or his designee. Written approval of the Commissioner or his designee shall be obtained prior to said new construction or alterations or additions. (M.G.L. c. 111, § 51.) Standards for review and approval of plans shall be established as administrative guidelines by the Department, based on the American Institute of Architects' Guidelines for Design and Construction of Hospitals and Health Care Facilities.

130.108: Condition of Licensure

Each hospital shall participate in risk management programs as required under M.G.L. c. 111, § 203(d) and related regulations of the Board of Registration in Medicine at 243 CMR 3.00 et seq.

130.110: 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, whether or not the hospital or satellite unit has been granted deemed status, 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.

130.111: Deficiency Statements

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

130.112: 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 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 which does not meet the requirements of 105 CMR 130.112 shall be considered unacceptable by the Department and returned to the hospital.

130.120: Issuance of License

(A) A hospital which meets all of the applicable regulations and laws shall be recommended for licensure to the Public Health Council. Upon the approval of the application for a license by the Public Health Council, the Department shall issue a hospital license to the applicant. 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) which the hospital is licensed to deliver; 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 the enactment of St. 1988 c. 23 on April 21, 1988 a hospital shall not 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.

130.121: Licensed Bed Capacity

(A) Each license shall have as a term the total number of beds within the hospital's bed capacity and the number of beds in each specific service the hospital is licensed to deliver which the licensee has qualified for patient occupancy by meeting the applicable provisions of 105 CMR 130.000. The numbers so fixed shall be the hospital's licensed bed capacity, in toto and with respect to each service, provided that such licensed bed capacity shall be adjusted by the Commissioner or his or her designee as follows:

- (1) After receipt of a request by the licensee to increase the number of beds in a specific service in accordance with a Determination of Need (DON) granted pursuant to M.G.L. c. 111, §§ 25B-G or for which DON approval is not required under M.G.L. c. 111, § 25B through G; provided, however, that no such increase shall be allowed in a hospital's licensed medical/surgical beds in any fiscal year in which licensed medical/surgical beds were reduced under the provisions of 105 CMR 130.123(A)(2) except as provided in 105 CMR 130.121(A)(4)(c); or
- (2) Following the licensee's notice to the Commissioner that the hospital intends to reduce the beds in a specific service by a specific number; or
- (3) Upon an automatic reduction in bed capacity or discontinuation of a service pursuant to 105 CMR 130.122; or
- (4) With respect to medical/surgical beds:
  - (a) as provided in 105 CMR 130.121(A)(1), (2), or (3);
    - (b) where an adjustment in licensed medical/ surgical bed capacity is required following submission of the annual written statement pursuant to 105 CMR 130.123(A); or
    - (c) in the case of a hospital that has filed a request or an application to increase the number of medical/surgical beds during the same fiscal year that the hospital's licensed medical/surgical beds were reduced under the provisions of 105 CMR 130.123(A)(2), either after receipt of such a request to increase the number of medical/surgical beds in accordance with a determination of need granted pursuant to M.G.L. c. 111, §§ 25B through G, or following approval of such an application for an increase in beds pursuant to 105 CMR 130.123(b).

(B) In all instances noted in 105 CMR 130.121(A) the licensee shall notify the Department in writing of the requested licensure bed quota adjustment. Prior to any increase in total bed number or number of beds in each specific service as a result of circumstances set forth in 105 CMR 130.121(A)(1), the licensee shall submit and receive Department approval of architectural plans that demonstrate that the location of the additional beds meets licensure requirements related to physical plant, and building fire and safety. Any written notice filed by the licensee pursuant to 105 CMR 130.123(A) or (B) shall satisfy the written notice requirement of 105 CMR 130.131.

130.122: Beds out of Service and Discontinuation of Service

(A) Each licensee shall maintain its licensed bed capacity at all times in toto and with respect to each service in accordance with the applicable provisions of 105 CMR 130.000. A hospital shall obtain the approval of the Commissioner, or his or her designee, in writing, prior to removing chronic, or rehabilitation service beds from service for any period in excess of three months.

(B) A hospital may remove beds other than chronic or rehabilitation service beds from service temporarily within the discretion of the licensee, except that any hospital that intends to remove medical/surgical beds from service for more than six consecutive months in one fiscal year incident to a construction project shall request permission from the Commissioner or his or her designee by letter application made at least two weeks in advance of the commencement of the construction project. Such permission shall be granted by the Commissioner or his or her designee to facilitate renovation, remodeling or other construction authorized by a determination of need or for which a determination of need is not required. The Commissioner, or his or her designee, shall not grant approval for removal of beds incident to construction, unless he or she has determined that the construction project requires the beds to be out of service and the hospital has submitted, for approval by the Commissioner or his or her designee, plans for such construction project. Beds removed from service for which such approval by the Commissioner or his or her designee has not been granted shall not be used for offset purposes pursuant to 105 CMR 130.123(A)(3)(a)1..

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(C) 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 days in advance of the planned discontinuance of the service. With respect to the proposed closure of an essential health service, such notice shall at a minimum provide current utilization rates for service(s) being discontinued, describe the anticipated impact of discontinuance on individuals in the hospital's service area, provide the date set for discontinuation, and 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. 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 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 discontinuance of a service only in extraordinary circumstances where the Commissioner or his or her designee has determined that such a waiver is necessary to protect the health and safety of patients served by the hospital.

(D) The Commissioner or his or her designee may, in exceptional circumstances, find that a health service not otherwise included in the definition of Essential Health Service at 105 CMR 130.020, is necessary for preserving access and health status of patients in the hospital's service area. If the Commissioner or his or her designee makes such a determination, the Department shall immediately notify the hospital of its decision and inform the hospital that the regulatory 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

(E) Except in the circumstances noted in 105 CMR 130.122(E)(1) and (2), 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 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 days prior to the proposed discontinuance 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.

Exceptions: 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 the following circumstances exist:

(1) 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 array of 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) which are provided to the patients currently served by the hospital at this same site.

(2) 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 radius of the location or equivalent driving distance, 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.



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(F) 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, an any other relevant information available to the Department.

(G) 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 discontinuance and a plan for meeting those needs.
- (5) 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 access the services at alternative delivery sites.

(H) The plan submitted to the Department by the hospital pursuant to 105 CMR 130.122(G) shall be reviewed by the Department to determine if the plan assures 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 days of receiving the plan from the hospital. In the event that the essential service is a psychiatric or mental health service, the Department's review of the plan shall be performed in consultation with the Department of Mental Health. The hospital shall submit a timely response to any comments issued by the Department.

(I) The Department shall monitor implementation of the hospital's plan for preserving access to necessary health care services following closure of the service(s). In addition, within one year of closure of the service(s), the Department shall prepare a post-closure report that evaluates the extent to which access to necessary health care services has been preserved. Whenever possible, the hospital shall collaborate with the Department and assist in the development of the post-closure report by submitting utilization data and other relevant information that is requested by the Department to use in preparing the report.

130.123: Required Written Statements and Licensed Medical/Surgical Bed Quota Adjustment

(A) Annual Statement and Licensed Bed Quota Adjustment

(1) Each hospital shall file with the Commissioner, or his or her designee, an annual sworn, notarized written statement listing the number of beds it has qualified for patient occupancy, pursuant to 105 CMR 131.121(A) and 105 CMR 130.123(A)(2), as of the first day of its fiscal year, in each specific service the hospital is licensed to deliver and in toto. Such statement shall be filed simultaneously with the hospital's filing of Rate Setting Commission Form 403.

(2) In accordance with the provisions of St. 1988 c. 23, § 38, each such annual statement shall also contain a requested licensure adjustment in medical/surgical beds calculated pursuant to 105 CMR 130.123, as of the first day of such hospital's fiscal year. The hospital shall report the actual numbers used in the calculation and submit a copy of the schedule III of the Rate Setting Commission form 403 to the Department.

As of such date, each hospital's number of licensed medical/surgical beds, excluding all critical care beds, shall equal the lessor of:

- (a) the number of medical/surgical licensed beds as reported for the prior year on Rate Setting Commission form 403, schedule III, column 4, line 1 or

(b) a number equal to the average daily census for such prior year divided by 75/100. Such average daily census shall be calculated by dividing the number reported in Rate Setting Commission form 403, schedule III, column 6, line 1, by 365.

(3)(a) The Commissioner, or his or her designee, shall adjust the hospital's total licensed bed capacity according to the calculation set forth in 105 CMR 130.123(A)(2); provided, however, that any reduction in licensed medical/surgical bed capacity required by such calculation shall be offset by the following:

1. the number of medical/surgical beds, if any, that were out of service during the prior fiscal year pursuant to an approval granted by the Commissioner, or his or her designee, for removal of beds from service incident to a construction project only, provided that such beds were out of service for at least six months during that prior year, and

2. The number of medical/surgical beds, if any, that were added to the hospital's licensed medical/surgical bed capacity during the prior fiscal year, provided that such beds were licensed for less than six months during that prior year.

(b) In the event that the number of beds calculated for offset pursuant to 105 CMR 130.123(A)(3)(a) exceeds the number of beds reduced pursuant to the calculation set forth in 105 CMR 130.123(A)(2), then the hospital's total licensed medical/surgical bed capacity shall equal the number of medical/surgical licensed beds as reported for the prior year on Rate Setting Commission form 403, schedule III, column 4, line 1.

(4) In the event that a hospital fails to file, in a timely manner, an annual statement in conformance with 105 CMR 130.123, the Commissioner or his or her designee shall obtain, from the Rate Setting Commission, a copy of such hospital's Rate Setting Commission Form 403, Schedule III and shall adjust the hospital's medical/surgical beds as of the first day of such hospital's fiscal year according to the calculation set forth in 105 CMR 130.123(A)(2).

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(5) The Department may retrospectively or prospectively waive the imposition of any reduction in licensed bed capacity required by the calculation set forth in 105 CMR 130.123(A)(2) for financially troubled hospitals, which serve otherwise underserved populations, to assist such hospitals to maintain the provision of services within its service area, qualify for Medicare disproportionate share payments, or for any other reasonable purpose as determined by the Department.

(B) Report of Occupancy Rate and Licensed Bed Quota Adjustment Following Annual Adjustments

(1) If a hospital which has experienced a reduction in licensed medical/surgical bed capacity pursuant to 105 CMR 130.123(A) experiences 85% average occupancy for its adult medical/surgical beds excluding all critical care beds for three consecutive months during such hospital's fiscal year, it may, by letter application documenting such occupancy, request to increase its licensed number of such beds to a number equal to the average daily census of adult medical/surgical beds excluding all critical care beds, divided by 75/100, or to a number equal to its number of licensed beds for the preceding fiscal year, whichever is less.

(2) In support of a letter application for an increase in medical/surgical beds, the hospital shall submit confirming occupancy rate information to the Department and shall attest to the accuracy of the data by affidavit signed by the hospital's chief executive officer.

(3) The Commissioner shall approve or disapprove such application, within ten days after filing, of a letter application deemed to be complete by the Commissioner, or his or her designee, on the basis of a review limited to the sole issue of whether such hospital is in fact experiencing such occupancy.

(4) If such application has not been acted upon by the Commissioner within such time limit, the application shall be deemed approved.

(5) Each licensee shall maintain its licensed bed capacity at all times in accordance with the provisions of St. 1988, c, 23 and all applicable rules and regulations promulgated by the Department.

130.124: Period of License

(A) Ordinarily, a hospital license shall be issued by the Department for a period of two years.

(B) The Department may in the alternative issue a provisional license for a period of no more than one year to a hospital which is not in full compliance with applicable requirements but which, the Department finds, is in substantial compliance with such requirements and demonstrates potential for achieving full compliance within the provisional licensure period. Consecutive provisional licenses shall not be issued to a hospital.

(C) 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. Upon receipt of a renewal license, the hospital shall return the expired license to the Department by certified mail.

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's license shall be conspicuously posted on the hospital's premises. A duplicate license shall be posted conspicuously in each satellite unit of the hospital.

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(B) The hospital's current inspection certificate issued by the Department of Public Safety shall be posted conspicuously on the premises.

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, as determined pursuant to 105 CMR 130.103; or

(B) Lack of responsibility and suitability to operate a hospital, as determined pursuant to 105 CMR 130.104; or

(C) Failure to submit the required license fee; or

(D) Violation of any state statute pertaining to hospital licensure; or

(E) Violation of any applicable provision of 105 CMR 130.000; or

(F) Lack of financial capacity to provide hospital care; or

(G) Willful misrepresentation of information or data submitted to the Department or any other agency of the Commonwealth.

(H) Failure to participate in risk management programs as required under M.G.L. c. 111, § 203(d) and related regulations of the Board of Registration in Medicine at 243 CMR 3.00 et seq.

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

Whenever the Commissioner or his designee decides to revoke or refuse to renew a license or part of a license, he 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 or, in his absence, the person designated to carry out the Department's administrative and executive functions, 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 decides that any violation of state law or of any of 105 CMR 130.000 poses an imminent risk to the safety or proper medical care of the hospital's patients. Whenever the Commissioner decides to take any of these measures, he 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 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 which 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.

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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 C.F.R. 482.11 through 482.62 (hereinafter Conditions of Participation), except the requirement for institutional plan and budget specified in 42 C.F.R. 482.12(d), for utilization review specified in 42 C.F.R. 482.30, the requirement for compliance with the Life Safety Code specified in 42 C.F.R. 482.41(b), and any requirement that conflicts with the Supplementary Standards in 105 CMR 130.000 Subparts C and D.

130.201: Special Requirements for Psychiatric Services

In addition to the requirements of 105 CMR 130.200, each psychiatric hospital subject to licensure, or psychiatric service of a hospital, shall meet the additional special staffing and medical records requirements which are considered necessary for the provision of active treatment in psychiatric hospitals as defined in 42 U.S.C. 1395x(f) and 42 C.F.R. 482.60 through 482.62 except any such requirement that conflicts with the Supplementary Standards in 105 CMR 130.000 Subparts C and D.

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 or his designee 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, except the special requirements specified in 105 CMR 130.201.

(B) Each accredited hospital which desires to obtain deemed status shall release to the Commissioner or his or her designee 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 or his or her designee any other accreditation information requested.

130.203: Validation Survey

The Commissioner or his or her designee 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 non-compliance with 105 CMR 130.000.

130.204: Loss of Deemed Status

(A) The Commissioner or his or her designee may revoke the deemed status of an accredited hospital if:

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- (1) The hospital fails to cooperate in the conduct of a Department validation survey or complaint investigation; or
- (2) The hospital fails to comply with any of the provisions of 105 CMR 130.202(A) and (B); or
- (3) The Commissioner or his or her designee 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 or his or her designee 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 or his or her designee. 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 or his or her designee 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 or his or her designee 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 accredited 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.

130.207: County Hospitals - Assuring Visitation

All county hospitals shall ensure that visitation privileges for persons having a relationship of mutual support with patients are the same as visitation privileges established for spouses at each facility.

130.208: Visitation Privileges - Conditions

As a condition of visitation privileges being extended to a person having a relationship of mutual support with a patient, the patient must certify to the official in charge of the county hospital, where necessary, the existence of his or her relationship of mutual support.

130.300: Applicability of 105 CMR 130.000 Subpart C

The requirements of 105 CMR 130.000 Subpart C are applicable to all hospitals subject to Department licensure.

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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. The requirement of a baccalaureate degree may be waived for any person in a position of nursing service director on the effective date of 105 CMR 130.000, and for any person who has a baccalaureate or advanced degree in a related health care field. A request for waiver under 105 CMR 130.310 must be submitted in writing to the Department.

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 which 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 this requirement shall be the following:

- (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) Adult Intensive Care Unit/Coronary Care Unit Coverage. The ratio of qualified registered nurses to patients in the unit may be varied from time to time on the basis of such factors as patients' conditions and availability of other personnel. There shall be at all times, however, at least one qualified registered nurse for every four patients in the unit.

130.312: RN, LPN, 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 clinic shall comply with the requirements of 105 CMR 130.102, 130.107 and 130.124 with respect to its premises. A hospital clinical laboratory or clinic, whether a satellite or not, shall comply with requirements applicable to such facilities if licensed independently.

130.325: Requirement that Personnel be Vaccinated Against Vaccine

(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).

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(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 of Public Health or his/her designee, each hospital shall ensure that all personnel are vaccinated with seasonal influenza vaccine no later than December 15, 2009 and annually thereafter.

(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 or his/her designee, 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.

(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 which 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 or his/her designee.



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130.330: Serious Complaint Procedure

Each hospital shall develop a written procedure that assures prompt and complete investigations of all serious complaints which are filed against employees of the hospital or members of its medical 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 an employee or member of the medical staff;
- (B) Establishment of a reporting procedure which assures that 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 will utilize, including provision for interviewing of a patient complainant;
  - (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 any of the following which occurs 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 or misappropriation of that patient at a nursing home, rest home, home health, home maker or hospice facility.
- (C) Each hospital shall report to the Department any other serious incident, accident or serious reportable event pursuant to 105 CMR 130.332(A) (SRE) 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 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 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, accidents and SREs 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).

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130.332: Serious Reportable Events (SREs)

(A) Definitions applicable to 105 CMR 130.332.

Ambulatory Surgery Center (ASC) means an entity subject to licensure or licensed under M.G.L. c. 111, § 51 and 105 CMR 140.000 to provide surgical services.

National Quality Forum (NQF) means the not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting.

130.332: continued

Preventable means events that could have been avoided by proper adherence to applicable patient safety guidelines, best practices, and hospital policies and procedures.

Serious Reportable Event (SRE) means 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 usually or reasonably preventable, 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 Based on the Hospital's Policies and Procedures means events that have been determined by the hospital to result from:

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

**(B) Reporting of SREs.**

- (1) Within seven 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);
  - (b) provide a copy of the SRE report to any responsible third-party payer;
  - (c) inform the patient or the patient's representative verbally and in writing 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
  - (d) affirm on the SRE report that the hospital has complied with the patient notification requirements of 105 CMR 130.332(B)(1)(c).
- (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 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.

**(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) within the hospital's control; and
  - (c) 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 any corrective measures taken 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.

130.332: continued

(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) within the hospital's control; and
  - (c) unambiguously the result of a system failure, as required by 105 CMR 130.332(B) and (C).
- (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 resulting from an SRE (treating facility) occurring on premises of a separately licensed hospital or an ambulatory surgery center licensed pursuant to 105 CMR 140.000 (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.

Preamble: Discharge Planning Service

The Department of Public Health recognizes that proper discharge planning is critical to the health and safety of patients. Inadequate planning may result in such adverse results to patients as untimely discharges, the release of patients to inappropriate levels of care, re-admissions to the hospital and losses of gains made during initial hospitalizations. It is the purpose of 105 CMR 130.000, consistent with the principles of patient participation and sound medical practice, to require and promote efficient and effective communication among the patient, the patient's family members and other representatives, the physician, aftercare providers and the hospital in the discharge planning process. 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.
- (5) To meet with the discharge planning coordinator and physician to attempt to resolve questions or disagreements about the discharge plan.

130.340: Discharge Planning Service Required

Each 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.

## 130.340: continued

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.

For the purpose of 105 CMR 130.340 through 130.350, acute hospital shall mean a hospital subject to licensing pursuant to M.G.L. c. 111, §§ 51 through 53 but shall not include:

- (1) Psychiatric Hospitals as defined in 42 CFR 412.23(a);
- (2) Rehabilitation Hospitals as defined in 42 CFR 412.23(b);
- (3) Alcohol/Drug Hospitals as defined in 42 CFR 412.23(c);
- (4) Chronic Care Hospitals; and
- (5) School and college infirmaries.

130.341: Discharge Planning Coordinator and Staff

(A) The hospital administrator in conjunction with the Nursing and Social Service Departments 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 social worker or a registered nurse preferably a community health nurse. 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 registered nurse and social worker 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) 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 and in cooperation with the patient, and/or the family/representative as appropriate and other members of the professional staff.

(B) 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 family/patient representative;
- (b) regular multidisciplinary meetings to review 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.

130.342: continued

## (C) 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.
- (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
  - (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.

## (D) 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), (B), (D), (E), (F), (G) and (H) and 105 CMR 130.345(B) relative to Medicare patients receiving services in emergency departments of acute hospitals.

## (E) Discharge planning staff shall maintain in writing a description of out-of-hospital resources which shall be readily available to the attending physician, 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 which 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.

## (F) In instances where the professional services of the discharge planning coordinator or unit is 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. For purposes of 130 CMR 130.000, a discharge plan for Medicare 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;

130.343: continued

- (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;
- (6) scheduled follow-up medical appointments or verification that such information was provided separately.

(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) Medicare Inpatients in Acute Hospitals

(a) In the case of Medicare patients in acute hospitals, the Medicare patient and/or as appropriate the patient's family shall receive an oral and written discharge plan in understandable language that include the post hospital services that are required and the arrangements made for the provision of these services. The hospital shall present the discharge plan to the patient as soon as the plan is completed but at least 24 hours prior to discharge, except where not feasible due to a short length of stay. If a patient representative as defined in 105 CMR 130.340, is acting on behalf of the patient, the hospital shall provide the patient representative the discharge plan within the required time frame.

(b) If the plan is revised due to the medical needs of the patient or due to a space becoming available in an appropriate institutional setting, the 24 hour requirement shall not apply to the amended plan, except insofar as such timing relates to the filing of a request for review with the advocacy office as provided for in 105 CMR 130.345(A).

(2) All Other Patients. In all other cases, 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.

(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 of any difficulties which 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 a physician's order, except there 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.

130.345: Additional Requirements Relative to Medicare Patients in Acute Hospitals

(A) Requirements Applicable to Medicare Inpatients in Acute Hospitals

(1) Front Page. Each acute hospital shall have a clear, concise front page on the discharge plan which shall be used for each Medicare patient. The front page shall be written in large print and understandable language. (For the purpose of this requirement, large print shall mean 14 point or larger type.) The front page shall contain at least the following:

(a) the name and telephone number of the hospital discharge planning coordinator to be contacted in the event the patient has any problems with post-hospital services after the patient leaves the hospital;

(b) a notice that, in the event the patient or the patient's representative does not agree with the discharge plan, the discharge planning coordinator and the patient's physician shall meet with the patient or the patient's representative in an effort to develop a plan that is acceptable to the patient;

(c) a notice, including the advocacy office telephone number, that, if an acceptable resolution is not reached as a result of the meeting provided for in 105 CMR 130.345(A)(1)(b), the patient or the patient's representative may file a request for review of the discharge plan with the advocacy office as provided for in 105 CMR 131.000: The Operation of the Advocacy Office;

(d) a notice that signing the discharge plan does not necessarily indicate approval of the plan and does not preclude the right to request a meeting or a review pursuant to 105 CMR 130.345(A)(1)(b) and (c); and

(e) a signature line for the patient or the patient's representative acknowledging participation in the development of the discharge plan and receipt of a copy of the plan.

(2) Advocacy Office Review. Acute care hospitals shall comply with the requirements relating to requests for reviews of discharge plans as set out in 105 CMR 131.000: The Operation of the Advocacy Office.

(3) Prerequisites of Discharge

(a) No Medicare patient determined to need assistance with post-hospital care shall be discharged from an acute care hospital until the hospital has made all appropriate contacts to initiate the provisions for aftercare services.

(b) No acute hospital may discharge a Medicare patient determined to need assistance with post-hospital care without the patient or patient's representative having received, read and signed the front page of the discharge plan or upon decision of the Advocacy Office.

(B) Front Page Requirements Applicable to Medicare Patients Treated in Emergency Departments of Acute Hospitals. In order to meet the front page requirement in the case of Medicare patients treated in the emergency room of an acute hospital, the hospital shall provide each Medicare patient the notice required under 105 CMR 131.110 and the written instructions required in 105 CMR 130.343(B).

(1) The notice shall inform patients in need of post-emergency care of their right to receive a written discharge plan and their right to meet with the emergency doctor and nurse/discharge planner if the patient disagrees with the discharge plan. The notice shall include a signature line which shall be signed by the patient upon his receipt of the discharge instructions.

(2) The written instructions shall include the name and telephone number of the emergency department person to contact if the patient has any problem upon discharge and include a signature line for the patient or patient's representative.



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 insure continuity of patient care. The discharge planning coordinator or discharge planning unit shall carry out this function in conjunction with other health care professional responsible for the completion of referral information required herein 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 written records which contain sufficient information to enable the Coordinator or Unit to prepare periodic reports on the number of patients for whom coordination of discharge planning was provided and the types of placement and referrals made.

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.

130.349A: Policies and Procedures

There shall be written policies and procedures concerning the operation of the discharge planning service which reflect acceptable standards of practice and compliance with applicable regulations.

130.350: Clinical Laboratory Services

Licensing requirements applicable to clinical laboratories that are parts of or under the control of hospitals are those set out in 105 CMR 180.000: The Operation, Approval and Licensing of Clinical Laboratories, which are incorporated herein by reference.

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130.360: Medical Waste Disposal

Licensing regulations governing the disposal of infectious or physically dangerous medical or biological waste are set forth in 105 CMR 480.000 State Sanitary Code, Chapter VIII which are incorporated by reference in 105 CMR 130.360.

130.365: Substance Abuse Services

Each hospital that offers a separate, identifiable substance abuse treatment program for persons with substance use disorders whether as an inpatient or outpatient program shall comply with the applicable regulatory requirements set forth in 105 CMR 164.000, Licensure of Substance Abuse Treatment Programs, which are incorporated by reference in 105 CMR 130.365. No hospital may offer a substance abuse treatment program unless the Department's Bureau of Substance Abuse Services has issued an approval for such program.

130.370: Retention of Records

(A) In accordance with M.G.L. c. 111, § 70 a hospital shall maintain records of the diagnosis and treatment of patients under its care for a minimum of 20 years 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 20 year retention period. 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. 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.

(C) Medical records retained by the hospital in accordance with 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 20 years 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.

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(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.

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.

NON-TEXT PAGE

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130.380: Request for Consent to Anatomical Donations

Each acute hospital shall comply with 105 CMR 800.000 et seq.: *The Massachusetts Request for Consent to Anatomical Donations* which are incorporated herein by reference.

For the purpose of 105 CMR 130.380 an acute hospital shall mean any hospital licensed under M.G.L. c. 111, § 51 which contains a majority of medical, surgical, pediatric, obstetric and maternity beds.

130.381: Definitions

The following definitions apply in 105 CMR 130.382 through 130.387.

Autopsy means 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.

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

Organ means 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 means the ranking of an individual who is qualified to provide consent to an autopsy.

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 105 CMR 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 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;

130.384: continued

(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) the spouse of the decedent;
  - (2) an adult son or daughter of the decedent;
  - (3) either parent of the decedent;
  - (4) an adult brother or sister of the decedent;
  - (5) a guardian of the decedent at the time of death; or
  - (6) any person authorized or under obligation to dispose of a 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.

130.386: continued

(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 has not yet attained the age of 18, is not emancipated, or has been adjudicated mentally incompetent may not be the consenting party of record.

(F) A woman who is under the age of 18 years old may consent to the autopsy of her deceased child or fetus.

130.387: Responsibilities of Hospital

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 105 CMR 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, shall obtain and maintain a license issued pursuant to 105 CMR 127.000 et seq.

130.395: Disposition of Remains Following the Death of a Fetus

In conformance with M.G.L. c. 111, § 202:

(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 which 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 hospital licensure requirements (105 CMR 480.000); 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.

130.400: Applicability of 105 CMR 130.000 Subpart D

The requirements of 105 CMR 130.000 Subpart D are applicable to hospitals subject to Department licensure to the extent to which they provide the particular service(s) specified herein.

130.500: Blood Banks and Transfusion Services

Licensing requirements applicable to blood banks and transfusion services that are parts of hospitals are those set out in 105 CMR 135.000: *The Use of Blood, Blood Components and Derivatives for the Purpose of Transfusion*, which is incorporated herein by reference.

130.510: Purpose

105 CMR 130.510 through 130.580 set forth the licensure standards for a hospital-based Hematopoietic Progenitor/Stem Cell Transplantation Program. Any hospital wishing to provide hematopoietic progenitor/stem cell transplantation shall request prior approval from the Department.

130.520: Definitions

The following definitions apply in 105 CMR 130.000 when used in regard to hematopoietic progenitor/stem cell transplantation services and programs.

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

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

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

FAHCT Standards means the current North American edition of Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation published by FAHCT.

Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) is the national accrediting body for hematopoietic progenitor/stem cell collection, processing & transplantation services.

Hematopoietic Progenitor/Stem Cell Collection, Processing and Transplantation Services (HPCCPPTS) means 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. HPCCPPTS does not include the collection, processing or administration of erythrocytes, mature granulocytes, platelets, plasma or plasma-derived components intended for transfusion support.

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 130.510 through 130.580.

Hematopoietic Progenitor/Stem Cells means 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 FAHCT Standards, regardless of tissue source.

Labeling means 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 means an ex vivo procedure(s) that selectively removes, enriches, expands or functionally alters hematopoietic progenitor/stem cells.

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



130.520: continued

Transplantation means 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.

130.525: Department Approval to Provide Hematopoietic Progenitor/Stem Cell Transplantation Program

A hospital licensed or operated by the Commonwealth pursuant to M.G.L. c. 111, § 51, that provides or intends to provide an hematopoietic progenitor/stem cell transplantation program shall apply for and receive approval from the Department in order to provide the service. The Department shall grant its approval if the hospital meets the requirements in 105 CMR 130.510 through 130.580, complies with the standards of the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) and receives and maintains accreditation by FAHCT for the clinical transplantation program.

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 an 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 FAHCT 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), or

(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:

(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.

130.530: Incorporation of *Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation*

In addition to the requirements in 105 CMR 130.510 through 580, each hospital that provides or intends to provide hematopoietic progenitor/stem cell transplantation shall at a minimum meet the requirements of the current North American edition of *Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation* published by the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT).

105 CMR: DEPARTMENT OF PUBLIC HEALTH

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, nurses, nutritionists, social workers, physical therapists and psychologists;
- (3) Describe the oversight responsibilities of the hospital;
- (4) Identify a physician 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 FAHCT. A copy of FAHCT accreditation documentation shall be submitted to the Department upon receipt from FAHCT.

- (1) By no later than July 12, 1998, a hospital providing autologous and allogeneic hematopoietic progenitor/stem cell transplantation services on or before June 12, 1998 shall submit to the Department a 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 program meets the FAHCT accreditation standards for autologous and allogeneic transplantation services and that by no later than September 12, 1998, the hospital will apply for accreditation by FAHCT and provide the Department with written confirmation of the filing.
- (2) By no later than July 12, 1998, a hospital providing only autologous hematopoietic progenitor/stem cell transplantation services on or before June 12, 1998 that intends to expand the transplantation program to also provide allogeneic transplantation services, shall submit to the Department a 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 program meets the FAHCT accreditation standards for autologous transplantation services and that the transplantation program will apply for accreditation by FAHCT for autologous transplantation no later than September 12, 1998 and provide the Department with written confirmation of the filing. The hospital shall file a separate notice regarding allogeneic transplantation as required by 105 CMR 130.540(A)(4).
- (3) Subsequent to receipt of the documentation required by 105 CMR 130.540(A)(1) or (2), the Department shall grant a provisional license for the program that identifies the type of transplants performed (allogeneic and/or autologous).

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

(b) If the applicant does not submit the documentation required by 105 CMR 130.540(A)(3)(a), the Department shall revoke the provisional license and, without further hearing, refuse to issue a license for the transplantation program.

(4) Hospitals seeking to initiate an hematopoietic progenitor/stem cell transplantation program and hospitals providing autologous hematopoietic progenitor/stem cell transplantation services on or before June 12, 1998 that intend to expand the transplantation program to also provide allogeneic 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 FAHCT accreditation standards, except for the transplant volume requirement, that the hospital will file an application for accreditation by FAHCT 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.

(5) 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 FAHCT accreditation application(s) and provide the Department with written confirmation of the filing.

(b) If the hospital fails to file the FAHCT 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 FAHCT 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 FAHCT 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 FAHCT 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. At a minimum, the description shall:

- (1) identify the Transplantation Program Director and provide a current curriculum vitae;
- (2) describe the type(s) of hematopoietic progenitor/stem cell transplantation the service will perform (autologous, allogeneic and/or syngeneic);
- (3) state whether this program will provide transplantation services to adults or pediatric patients, and if providing transplantation services to pediatric patients, indicate that the facility operates a licensed Level III pediatric service;
- (4) include projected transplantation volume by type [adult, pediatric, autologous, allogeneic (matched and mismatched), and syngeneic] for the first three years of licensure and an explanation of the basis for the projected volume;
- (5) identify any portion of the transplantation service which will be performed in a setting that is other than part of the licensed applicant facility, i.e., a separately licensed freestanding clinic, and include a copy of a signed, current collaboration agreement with that clinic;
- (6) indicate how many beds will be designated for use in the transplantation program and where the beds are located (building, floor, and department);
- (7) list any special equipment needed to perform transplantation; and
- (8) identify the cell collection and processing facilities or services the transplant program will regularly use. The applicant must indicate all cell collection and processing facilities or services used will meet FAHCT accreditation standards.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

130.550: Issuance of an Amended Hospital License

Upon receipt of satisfactory written documentation of FAHCT accreditation by the type of transplants performed, the Department shall issue an amended hospital license which indicates that the hospital is authorized to perform hematopoietic progenitor/stem cell transplantation (allogeneic and/or autologous for adult and/or pediatric patients). For multiple hospitals that form one program, each hospital shall have the service added to its license. In such cases, the license will indicate that the hospital is part of a multiple hospital program.

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

The hospital shall apply for renewal of its license to perform 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 FAHCT

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 FAHCT. Failure to receive or maintain accreditation by FAHCT shall result in the denial, revocation or refusal to renew the licensure of the transplantation program without further hearing.

130.601: Definitions

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

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

Birthing Room shall mean 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 shall mean 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 et seq.

Cesarean/Delivery Room shall mean 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 shall mean 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.

Critical Care Obstetrics Team shall mean 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.

Continuing Care Nursery shall mean 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.

130.601: continued

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

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

Family Practitioner shall mean 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 an active candidate for certification by the American Board of Family Practice.

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

Gynecology Patient shall mean any woman with or suspected of having a health problem related to her reproductive organs.

Labor Room shall mean an area in which the mother experiences the first stage of labor.

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

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

Lactation Consultant shall mean 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 shall mean a community-based maternal and newborn service including Level IA and Level IB services that meets the requirements in 105 CMR 130.630.

Level I A service shall mean 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 shall mean 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 shall mean 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 II A Service shall mean 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.

130.601: continued

Level IIB Service shall mean 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 and that meets the requirements in 105 CMR 130.640.

Level III Maternal and Newborn Service shall mean 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-fetal Medicine Specialist shall mean an obstetrician/gynecologist who is licensed by the Massachusetts Board of Registration in Medicine and is certified or is an active candidate for certification in the subspecialty of maternal-fetal medicine by the American Board of Obstetrics and Gynecology.

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

Neonatal Fellow shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is completing a fellowship in neonatology.

Neonatal Intensive Care Unit shall mean 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 shall mean 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 et. seq who holds certification as a neonatal nurse practitioner from a nationally recognized accrediting body acceptable to the Board.

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

Neonatologist shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in neonatology by the American Board of Pediatrics.

Obstetrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine and who is either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology.

Pediatrician shall mean a physician licensed by the Massachusetts Board of Registration in Medicine who is either certified or an active candidate for certification in pediatrics by the American Board of Pediatrics.

Postpartum Unit shall mean 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 shall mean a specifically designated area within the labor-delivery suite used to care for patients recovering immediately after delivery.

Recovery Infant shall mean an infant who required acute care services for diagnosis and treatment, whose acute phase of illness has passed, and who now needs limited therapeutic intervention prior to discharge.

Retrotransferred Infant shall mean 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/her needs.

130.601: continued

Risk Assessment of the Infant shall mean the process of evaluating the newborn to determine whether he/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 shall mean 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 shall mean 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.

Stable-growing Infant shall mean the medically stable infant with a low birth weight who requires only a weight increase to be ready for discharge.

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

Well Newborn Nursery shall mean 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) The Department shall designate the level of maternal and newborn care of each hospital subject to Department licensure that provides maternal and/or newborn services as defined in 105 CMR 130.020.

(B) As directed by the Department, each hospital with maternal and/or newborn services shall file an application with the Department identifying the level of maternal and/or newborn services for which the hospital requests designation.

(C) The Department shall base such designation upon documentation submitted by each hospital regarding its maternal and/or newborn services and/or on-site evaluations by Department staff to determine compliance with the requirements of that level. The designation process is not intended to supersede the Department's authority to determine what constitutes a major service or a substantial change in service for determination of need purposes.

(D) After the 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 shall establish a state Perinatal Advisory Committee to advise the Department on issues related to 105 CMR 130.615 through 130.628 (Maternal and Newborn Services). This Committee's membership shall be multidisciplinary. It shall include but not necessarily be limited to one or more members of the following groups: physicians, nurses, including nurse practitioners and nurse midwives, hospital administrators, and consumers. It shall be representative of the various parts of the state and all levels of perinatal care.

The Committee may develop operating procedures agreed upon by the Department that includes the opportunity for the regular rotation of committee members.

130.615: Patient/Family Services

(A) The mother and infant shall receive care in the facility providing the level of service required for their unique medical needs.

130.615: continued

(B) Each hospital with a maternal and newborn service shall provide prenatal, postnatal and family-planning services either directly or through referral to an outside agency, including the following:

- (1) Preparation for the birthing experience for the mother, her family and/or significant other(s).
- (2) Organized family-education program with associated written and/or multimedia health instructional materials including, but not limited to:
  - (a) Normal maternal care such as nutrition, rest and other basic needs.
  - (b) Signs and symptoms of pre-term labor by 20 weeks, if applicable.
  - (c) Normal newborn care and well child care, including recommended immunization and developmental assessment schedules and infant safety, including information about shaken baby syndrome.
  - (d) State newborn blood screening information and materials provided at the time of admission prior to screening.
  - (e) Abnormal symptoms in mother and/or infant for which the family should seek medical attention, including infant jaundice.
  - (f) Anticipatory guidance and available resources for peripartum mental health issues and family adjustment issues.
  - (g) Family planning.
  - (h) Dangers of second-hand smoke.
- (3) Infant feeding instruction and support during hospitalization and provision of information on resources to assist the mother and family after discharge, including, for breast feeding mothers, community-based lactation consultant resources and availability of breast pumps.

(C) Health education materials and activities shall be available in the major languages identified through the acute hospital's language needs assessment required under 105 CMR 130.1103(A) and literacy levels of the population served by the maternal and newborn service.

(D) 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.

- (1) Hospitals shall provide educational information to all visitors indicating that the following persons should not visit: those who have been exposed to or have manifestation of communicable diseases for which the newborn is at particular risk, e.g., impetigo, active tuberculosis, acute respiratory disease as well as vaccine-preventable diseases, particularly measles, mumps, rubella, pertussis, varicella and influenza.
- (2) Siblings shall be permitted to visit the mother and newborn on a daily basis in accordance with written hospital visitation policy.
- (3) Policies for other visitors shall be formulated primarily for the support and comfort of mothers and infants.
- (4) The hospital shall have a policy to address the safety and security of mothers and infants.

(E) The hospital shall establish policies to ensure that the staff provide ongoing information to families about the condition and progress of mother and/or infant. The policies shall also include a process to assist families in obtaining ongoing information about the condition of the infant who has been transferred to another level of care. For the limited-English-proficient population, the hospital shall ensure that timely interpreter services are available. Services using nurse practitioners or pediatric residents shall inform families of the role and scope of clinical responsibilities of these health care providers.

(F) Culturally and linguistically appropriate nutritional consultation shall be available for mothers and infants.

(G) Culturally and linguistically appropriate social work services shall be available for mothers and infants.



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(H) Each maternal and newborn service shall have written protocols for the hospital management, support, and discharge planning of patients from identified groups in the population served by the facility who have special needs, e.g., adolescents, and mothers with known physical or cognitive impairments, substance abuse, psychiatric diagnoses or psychosocial concerns.

(I) Each service shall have a written policy that provides for discharge planning and referrals to community agencies and healthcare providers, including lactation consultants as needed.

(J) Mothers of babies with special health needs shall receive information about appropriate resources such as early intervention, self-help groups, and other community contacts as soon as possible after delivery.

(K) Each service shall provide support and referral for the family experiencing perinatal grief because of the death of a neonate. All families shall be given the opportunity to see, hold and participate in the care of their infant during and after the dying process.

(L) The maternal and newborn service shall provide information about the Women, Infants and Children (WIC) program's benefits and services to all mothers. As appropriate, staff shall refer a mother to the WIC program closest to her residence.

130.616: Administration and Staffing(A) Perinatal Committee.

(1) 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 including but not limited to the following:

- (a) Developing a statement of goals and objectives of family-centered care.
- (b) Long-range program planning.
- (c) Establishing, approving, reviewing and planning the implementation of policies and procedures.
- (d) Reviewing and evaluating process and outcome of maternal and newborn care delivered by the service, including appropriateness of multidisciplinary staffing patterns to ensure safe patient care.
- (e) Reviewing service data and statistics.
- (f) Providing a mechanism to encourage and obtain community input on the service.
- (g) Participating in the evaluation of staff education needs.

(2) The committee shall meet at least quarterly and include physician and nurse leaders from both the maternal and newborn services and representatives from other services as appropriate.

(B) 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; and provision for professional educational offerings.

(2) In its collaboration/transfer agreement with a level III service, a hospital that is designated by the Department as a level II maternal and newborn service and that retains neonatal nurse practitioners to provide on-site delivery room and special care nursery coverage shall include provisions for administrative and clinical collaboration specific to the neonatal nurse practitioners. At a minimum specific provisions shall include the planned schedule of rotation of the neonatal nurse practitioner to the level III service and the mechanism for the periodic evaluation of the neonatal nurse practitioner's performance as required under 105 CMR 130.640(E)(3)(b)(iii).

(3) 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.

- (4) Guidelines for maternal and newborn transfer shall reflect recommendations from the quality assurance activities. The guidelines shall address the following: initiation of transfer; acceptance of transfer; delineation of responsibilities of referring hospital, transport team and receiving hospital; patient consent; transfer procedures and retro-transfer policy and procedures.
- (5) The Level III hospital receiving a request for a transfer shall accept all medically appropriate obstetrical and neonatal patients for which it has the resources to provide the appropriate level of care. If a bed or appropriate resources are not available, upon the request of the referring hospital, the Level III hospital shall offer assistance and advice on possible alternative Level III hospitals for transfer.
- (6) The Level III hospital receiving transfers shall return maternal and neonatal patients to the transferring hospital when it is clinically appropriate to do so. The hospital shall inform the patient and/or patient's family that the patient may be transferred back when such a retro-transfer is medically appropriate.
- (7) 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.
- (8) Copies of current written collaboration/transfer agreements shall be submitted to the Department upon request.

(C) Administrative Policies. Each maternal and newborn service shall develop and implement written administrative policies that include provisions for the following:

- (1) Staff privileges granted to each physician, nurse midwife and each nurse practicing in an advanced practice role shall specify those areas in which his/her practice is limited and/or requires consultation before therapeutic intervention.
- (2) Documentation of informed consent for both maternal and newborn care.
- (3) On-site availability 24 hours a day, of at least one professional 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).
- (4) Management of high-risk mothers and newborns including identification of high risk patients and consultation with appropriate specialists for the purpose of determining treatment and/or the need to transfer to the hospital's specialized medical, surgical or critical care services or to another facility offering the level of care required by the patient. Such policies shall include use of appropriate alternative facilities, if beds in the usual affiliated transfer institution are not available. Such policies shall address maintaining family-centered care.
- (5) Placement of and care of:
  - (a) antenatal patients (hospitalized for pregnancy-related conditions) on the maternal and newborn service; and
  - (b) antenatal patients hospitalized for medical/surgical conditions that are not pregnancy-related.
- (6) Admission of the previously-discharged (to home), or retrotransferred recovery stable-growing infant under the following circumstances:
  - (a) The infant previously discharged to home may be readmitted to the newborn nursery provided that the infant is within two weeks of discharge from that nursery, has a noninfectious condition and is approved for readmission by the medical director of the newborn service and the maternal and newborn nursing administrator or their designee(s).
  - (b) The retrotransferred recovery infant may be admitted to the newborn nursery upon written order of the attending physician and approval of the medical director of the newborn service and the maternal and newborn nursing administrator or their designee(s).
  - (c) The newborn service may admit a retrotransferred recovery infant who was not born at that hospital, providing the hospital offers the level of service required by the infant and is geographically close to the parents.
  - (d) The retrotransferred infant who is transferred from a hospital unit with known multi-drug-organism colonization or infection, including methicillin-resistant staphylococcus aureus, shall be managed with contact precautions in accordance with the Centers for Disease Control and Prevention guidance until the presence of infection or colonization with an antibiotic-resistant organism has been ruled out.

(7) Provision for a written discharge summary to another maternal and newborn service at the time of the patient's transfer or to the primary care provider at the time of the patient's discharge. The summary shall include diagnosis and treatment provided.

(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 shall include provisions for the following:

- (1) Triage of patients presenting to the service to establish the diagnosis of labor, need for admission, transfer and/or other care management.
- (2) Communication and decision making responsibilities with specified chain of command.
- (3) Pain management, including the use of non pharmacological support techniques, analgesic medication and parenteral therapy. Routine standing orders shall not be permitted.
- (4) Fetal assessment modalities including the use of electronic fetal monitoring and auscultation with guidelines for interpretation.
- (5) Elective and emergency cesarean birth.
- (6) Criteria for induction and augmentation of labor.
- (7) Initiation and management of epidural analgesia and regional anesthesia.
- (8) Criteria for when the presence of a pediatrician and specialized personnel are required at birth.
- (9) Care of the mother in the immediate post partum period, including immediate post-surgical recovery care.
- (10) Immediate nursing assessment of the newborn by a registered nurse with specific clinical criteria for notifying a pediatric provider.
- (11) Support of lactation initiation and maintenance for mothers who choose breast feeding. Such policies shall provide for the following:

- (a) No standing orders for antilactation drugs.
- (b) Unless medically contraindicated, encouragement of breastfeeding as soon after birth as the baby is interested. A mother separated from her infant shall be assisted to initiate and maintain her milk production.
- (c) Frequent nursing periods, based on the infant's needs.
- (d) Supplemental bottle feeding for medical reasons or on request of the mother only.
- (e) Sample formula and/or formula equipment distributed to breast-feeding mothers only when an individual physician order is written or on the request of the mother.

(12) Care of the Newborn. Such policies shall provide for the following:

- (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:
  - (i) a process for identifying the newborn at the time of delivery;
  - (ii) use of an acceptable identification system;
  - (iii) procedure for rebanding an infant;
  - (iv) identification of individuals who can remove a newborn from the nursery;
  - (v) visitation policies outlining who is allowed to visit and when; and
  - (vi) 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 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.
- (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.

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- (13) Planning for discharge, including documentation of follow-up care arrangements and referral to appropriate community services and providers for both mother and infant.
- (14) Admission and/or treatment of patients who have delivered outside of the maternal and newborn service or hospital, including home births.
- (15) Use of the maternity service for gynecology patients. Gynecology patients shall not be routinely cared for on a maternity unit; however, in the event that they are placed on the unit, they shall be in rooms separate from maternity patients and the following shall be required:
  - (a) Provision for the availability of maternity beds to meet patient needs.
  - (b) Admission guidelines with exclusionary criteria for patients:
    - (i) requiring radioactive implants;
    - (ii) who have active infection or are colonized with a potentially virulent or drug resistant organism that would put others at risk, for which appropriate and consistent use of recommended infection control practices cannot be assured; or
    - (iii) requiring significant medical or surgical care in addition to gynecologic care;
    - (iv) visiting policies shall be consistent with those on the maternity service.
- (16) 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.
- (17) Offering and administering a dose of measles-mumps-rubella (MMR) vaccine to all mothers who are rubella antibody negative prior to discharge.
- (18) 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 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 at least an annual review of transfer cases, management of cases, and educational programs and protocols among facilities that transport maternal and neonatal patients to one another pursuant to collaboration/transfer agreements.
- (3) Outcome statistics including neonatal and perinatal mortality, as well as appropriateness of neonatal and maternal transfers, shall be compiled in a standardized manner and reviewed at a minimum on a quarterly basis by the hospital perinatal committee. Neonatal and maternal deaths after transfer or discharge from the facility (within first 28 days of birth) shall be included in the statistics.
- (4) 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 shall assess the needs, plan the care and evaluate the care delivery including the health education of each patient.
- (2) A registered nurse shall observe and care for the mother, fetus and newborn during the labor, delivery and recovery periods.
- (3) 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.
- (4) A registered nurse shall complete an initial newborn nursing assessment and shall be responsible for notifying the physician of any abnormalities or problems.
- (5) A registered nurse shall be on duty in each patient care unit on every shift.

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- (6) 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.
- (7) 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.
- (8) 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 to the facility's case-mix and volume.

(G) Lactation Care and Services.

- (1) 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.
- (2) Each maternal and newborn service shall develop written, evidence-based breastfeeding policies and procedures and include these in staff education and competency reviews.
- (3) An educational program of lactation support for maternal and newborn staff shall be offered by qualified staff and shall address the following areas:
- (a) The nutritional and physiological aspects of human lactation.
  - (b) Positioning of mother and infant to promote effective sucking, milk release and production.
  - (c) Practices to avoid, recognize and treat common breastfeeding complications.
  - (d) Nutritional needs of the mother during lactation and monitoring the nutritional needs of the infant.
  - (e) Safe techniques for milk expression and storage of milk.
  - (f) Information about community support services available to the family after discharge.
  - (g) Cultural values related to breastfeeding.

130.617: Ancillary Services

(A) Laboratory. The clinical laboratory services available for maternal and newborn patients shall be defined by the Chief of Laboratory Services in consultation with the Chief(s) of both Maternal and Newborn Services and the hospital administrator or his or her designee.

(B) Radiology.

(1) The diagnostic imaging and radiological procedures available for maternal and newborn patients shall be defined by the Chief of Radiology in consultation with the Chief(s) of both the Maternal and Newborn Services and the hospital administrator or his or her designee.

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- (2) The maternal and newborn service shall have written policies for diagnostic radiologic examination of pregnant patients aimed at preventing excessive radiation exposure to the fetus and mother.
- (3) A written request for a diagnostic radiologic examination of a pregnant patient shall clearly indicate to the person taking the x-ray that the patient is pregnant.
- (4) Each radiologic service shall have an orientation training program and protocols for personnel performing infant x-rays, which address at a minimum safe positioning of the newborn, measures to minimize x-ray exposure and prevention of x-ray exposure to the infant's gonads.

130.618: Environment: General Requirements

- (A) Unless otherwise specified, new construction or alterations/additions to existing services shall meet the requirements of 105 CMR 130.107.
- (B) 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.
- (C) All equipment, furnishings and decorations in the maternal and newborn service shall be made of washable materials.
- (D) The environment shall foster family-centered care including provisions for:
  - (1) Mothers and infants to room-in together 24 hours a day.
  - (2) Respect for the privacy of all mothers and families.
  - (3) Visitation for father or significant other(s) 24 hours a day.
  - (4) Accommodating visitors.
  - (5) Private area for mothers to nurse and/or use breast pump.
  - (6) Rapid reunion of mother and infant after medical/surgical procedures, including cesarean section and circumcision.
- (E) Maternal and newborn services shall have the capability to provide care during labor, delivery, recovery and postpartum periods. Maternal and newborn services may have any one or a combination of several functional configurations including labor-delivery suites, birthing rooms, combination labor-delivery-recovery rooms and labor-delivery-recovery-postpartum rooms. Sufficient equipment shall be available to accommodate rooms in the event of simultaneous use. Each facility shall have at least one delivery room equipped for cesarean births. Cesarean births shall be performed in this room.
- (F) The maternal and newborn service shall have appropriate resources and facilities to care for antepartum patients requiring stabilization, hospitalization, or transfer for obstetrical conditions.
- (G) Antepartum facilities shall be designed to ensure that outpatient areas are separate from inpatient service areas.

## 130.619: Labor-delivery Suite

(A) Labor Room.

- (1) At least two labor beds shall be provided for each delivery room. (Birthing room; labor, delivery, recovery room; and labor, delivery, recovery and post-partum room beds may be substituted for labor beds.)
- (2) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide a minimum of 120 square feet per bed in labor rooms.
- (3) Labor rooms shall not accommodate more than two mothers. Partitions or curtains shall be provided to insure privacy for multiple-occupancy rooms.
- (4) Labor rooms shall have the traditional hospital wall covering and furnishings or an attractive comfortable "homelike" family-centered decor.
- (5) The labor room shall contain or have access to toilet and shower facilities.
- (6) Each labor room shall contain the following:

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- (a) Nurse call system.
  - (b) Emergency call or intercommunication system.
  - (c) Oxygen outlet(s).
  - (d) Suction outlet(s).
  - (e) Sphygmomanometer with adult stethoscopes.
  - (f) Fetoscope or instrument for fetal auscultation.
  - (g) Clock with sweep second hand.
  - (h) Lighting for examinations.
  - (i) Bed for each patient.
  - (j) Seating for family members.
  - (k) Functional source of emergency electrical power.
- (7) Each labor room shall have readily available:
- (a) Handwashing units with hands-free controls.
  - (b) Emergency delivery kit.
  - (c) Resuscitation medications and equipment for both mother and infant.
  - (d) Electronic fetal monitoring equipment.
- (8) All facilities, furnishings and equipment shall be washable.
- (9) The labor room shall have access to a delivery room for emergency cesarean birth management.
- (10) The maternal and newborn service shall designate adequate and appropriate space for labor triage.

**(B) Cesarean/Delivery Room.**

- (1) The cesarean/delivery room shall meet the infection control standards of the hospital's operating rooms.
- (2) 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.
- (3) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 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.
- (4) Environmental requirements for the cesarean/delivery room shall include:
  - (a) Adequate lighting for vaginal and cesarean births.
  - (b) Temperature control to prevent chilling of mother and newborn.
  - (c) Functional source of emergency electrical power.
  - (d) Oxygen and suction outlets for both mother and newborn.
  - (e) Emergency call system.
  - (f) Scrub sinks with hands-free controls in or adjacent to the room.
  - (g) Wall clock with sweep second hand.
  - (h) Mirrors for mothers to observe births.
- (5) The cesarean/delivery room shall contain at least the following equipment:
  - (a) Delivery bed permitting variation in position for birth as well as anesthesia administration.
  - (b) Facilities for both regional and inhalation anesthesia.
  - (c) Immediate availability of adult and newborn resuscitation equipment including the following:
    - (i) Emergency medications.
    - (ii) Airway and intubation instruments.
    - (iii) Defibrillator.
    - (iv) Cardiac monitor.
    - (v) Oxygen administration equipment and oxygen saturation monitor.
    - (vi) Blood and intravenous administration sets.
  - (d) Heated, temperature controlled neonatal examination and resuscitation bed.
  - (e) Instruments for vaginal delivery, repair of lacerations, cesarean birth and management of obstetric emergencies.
  - (f) Infant identification materials.
  - (g) Equipment for clamping of the umbilical cord.
  - (h) Blanket warmer in or adjacent to the room.

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- (i) Fluid warmer.
- (j) Availability of continuous internal and external fetal monitoring and auscultation tool.

(C) Additional Equipment and Facilities. The labor/delivery suite shall contain:

- (1) Access to radiologic viewboxes or digital imaging.
- (2) Access to stretcher with siderails.
- (3) Adequate clean storage and preparation area.
- (4) Ready access to sterilization facilities.
- (5) At least one soiled workroom with adequate space and facilities for cleaning equipment.
- (6) Sleeping, shower, locker, lounge and toilet facilities for staff, separate from patients' area.
- (7) Documentation area for administrative functions.
- (8) Lounge accessible to patients and visitors.

(D) Recovery Area. Each maternal and newborn service that provides a separate recovery area shall meet the following requirements:

- (1) Hospital policy shall state the types of patient conditions requiring admission to the recovery area.
- (2) Each recovery area shall contain at least two beds and the following:
  - (a) Suction and oxygen outlets for each bed.
  - (b) Monitoring equipment appropriate to post anesthesia care.
- (3) Emergency medications and equipment shall be immediately accessible to the recovery area.
- (4) The care of the mother and newborn during the recovery period shall be under the direct observation of a registered nurse.
- (5) Provisions shall be made to maintain the family unit during the recovery period.

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) 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.

(B) The labor-delivery-recovery room may be located outside the labor-delivery suite but shall be within the maternity unit so the patient may be transferred to the cesarean/delivery room without having to pass through other functional areas of the hospital outside the maternity service and so that infant security is maintained.

(C) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 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.

(E) Each labor-delivery-recovery room shall contain or have access to private toilet and shower or tub facilities. If tub facilities are provided, there shall be at least a three foot clearance on two sides and at the end of the tub.



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- (F) Each labor-delivery-recovery room shall contain the following:
- (1) Nurse call system.
  - (2) Emergency call or intercommunication system.
  - (3) Oxygen outlet(s).
  - (4) Suction outlet(s).
  - (5) Sphygmomanometer with adult stethoscopes.
  - (6) Continuous vital sign monitoring equipment for the mother (when regional anesthesia is used).
  - (7) Equipment for the administration of local and regional anesthesia when these forms of anesthesia are indicated.
  - (8) Fetoscope or a means of evaluating fetal heart rate.
  - (9) Emergency delivery kit.
  - (10) Clock with sweep second hand.
  - (11) Adjustable lighting adequate for examinations.
  - (12) Bed.
  - (13) Adequate seating for family members.
  - (14) Functional source of emergency electric power.
- (G) (1) Each labor-delivery-recovery room shall have readily available:
- (a) Separate handwashing unit with hands free controls.
  - (b) Resuscitation medications and equipment for both mother and infant.
  - (c) Electronic fetal monitoring equipment.
  - (d) Oxygen and suction capabilities for the infant.
  - (e) Bassinet.
  - (f) Standard infant warming device.
  - (g) Equipment for the care of the newborn during the time period he/she remains in the labor-delivery-recovery room, as specified by hospital policy.
  - (h) Infant identification materials.
- (2) All equipment and medications for labor, delivery, anesthesia and resuscitation may be portable but shall be present in the room at the time of delivery.
- (H) All facilities, furnishings and equipment shall be washable.

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

- (A) 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.
- (B) The labor-delivery-recovery-postpartum room may be located outside the labor-delivery suite but shall be within the maternity unit so that the patient may be transferred to the cesarean/delivery birth room without having to pass through other functional areas outside the maternity service and so that infant security is maintained.
- (C) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide a minimum of 250 square feet of floor space for each labor-delivery-recovery-postpartum room.
- (D) The labor-delivery-recovery-postpartum room shall have single patient occupancy.
- (E) The labor-delivery-recovery-postpartum room shall have adequate soundproofing.
- (F) Each labor-delivery-recovery-postpartum room shall contain or have access to private toilet and shower or tub facilities. If tub facilities are provided, there shall be at least a three foot clearance on two sides and at the end of the tub.

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- (G) Each labor-delivery-recovery-postpartum room shall contain the following:
- (1) Nurse call system.
  - (2) Emergency call or intercommunication system.
  - (3) Oxygen outlet.
  - (4) Suction outlet.
  - (5) Sphygmomanometer with adult stethoscope.
  - (6) Continuous vital signs monitoring equipment for the mother (when regional anesthesia is used).
  - (7) Equipment for the administration of local and regional anesthesia when these forms of anesthesia are indicated.
  - (8) Fetoscope or a means of evaluating fetal heart rate.
  - (9) Emergency delivery kit.
  - (10) Clock with sweep second hand.
  - (11) Adjustable lighting adequate for examinations.
  - (12) Bed.
  - (13) Adequate seating for family members.
  - (14) Functional source of emergency electric power.
- (H) (1) Each labor-delivery-recovery-postpartum room shall have readily available:
- (a) Separate handwashing unit with hands free controls.
  - (b) Resuscitation medications and equipment for both mother and infant.
  - (c) Electronic-fetal monitoring equipment.
  - (d) Oxygen and suction capabilities for the infant.
  - (e) Bassinet.
  - (f) Standard infant warming device.
  - (g) Equipment for the care of the mother and normal newborn until discharge.
  - (h) Infant identification materials.
- (2) All equipment for labor, delivery, anesthesia and resuscitation may be portable but shall be present in the room at the time of delivery.
- (I) All facilities, furnishings and equipment shall be washable.

130.623: Postpartum Unit

- (A) Provisions shall be made to accommodate the mother and infant in the same room 24 hours a day as requested by the mother.
- (B) Equipment for each room in the postpartum unit shall include at least the following:
- (1) Suction and oxygen capabilities.
  - (2) Availability of resuscitation equipment and emergency medications for both the mother and infant.
  - (3) Sink with hands-free controls in or adjacent to the room.
  - (4) Available toilet with sink and shower facilities.
  - (5) Staff emergency call system.
- (C) Construction of new units or alterations or additions to existing maternal and newborn units begun on or after April 1, 2006 shall provide a minimum 124 square feet per bed in multiple bedrooms and 144 square feet in single bedrooms.

130.624: Nursery

- (A) Each service shall provide within its nurseries a minimum number of well-newborn bassinets that equals the number of maternity beds plus one bassinet per well-newborn nursery to accommodate at-home and enroute births, multiple births, retrotransfers and recovery infants. A lower number of bassinets may be acceptable, if the licensee demonstrates, through a statistical formula provided by the Department, that a 95% probability is achieved for the availability of bassinets, based on the projected number of births per year and the average length of stay.

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- (B) All newborns in the nursery shall at all times be in direct view of personnel accountable for them.
- (C) In the well-newborn nursery, each bassinet shall have an average of 24 square feet of floor space with a three foot distance between bassinets. Each bassinet shall be immediately accessible to the aisle.
- (D) The environment of the nursery shall provide:
  - (1) Adequate illumination with a system of variation of light intensities.
  - (2) Temperature of 72° to 78° F controlled by heating and air conditioning equipment.
  - (3) Humidity of 30-60% with regularly scheduled monitoring.
  - (4) Interior finish of off-white or colors that permit detection of cyanosis and jaundice.
  - (5) Windows, if provided, shall have clear glass and doublepane insulation. Window coverings shall be fire-proof and easy to clean.
  - (6) Floor finishes shall be washable.
- (E) 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.
- (F) At least one sink with hands-free controls shall be provided for every six bassinets.
- (G) The nursery shall include appropriate storage space for at least minimum daily quantities of infant care supplies.
- (H) Nursery equipment shall include at least the following:
  - (1) Individual bassinets capable of storing individual supplies of linen and infant care equipment.
  - (2) Suction, oxygen and compressed air.
  - (3) Washable infant scales.
  - (4) Covered receptacles for the disposal of soiled linen, diapers or waste, with removable linings or bags and with foot controls.
  - (5) Blanket warmer, readily available to the nursery.
  - (6) Staff emergency call system.
- (I) The following shall be readily available to the nursery:
  - (1) Emergency equipment and medications for infant resuscitation and stabilization prior to transfer.
  - (2) Oxygen administration capabilities with humidification, blending device and analyzer and oxygen saturation monitor.
  - (3) Cardio-respiratory monitor with high/low alarm.
  - (4) Commercially manufactured isolette with air filter or a radiant heat bed.
  - (5) Separate and secure refrigerator and freezer for storage of breast milk.
  - (6) Electric breast pump and collection kits.
  - (7) Appropriate facilities and necessary equipment for circumcision.
  - (8) Hearing screening equipment.

130.625: Additional Physical Plant Requirements

- (A) Electric outlets shall have a common ground.
- (B) Electrical equipment shall be checked for current leakage and grounding adequacy when first introduced and at periodic intervals thereafter, per hospital equipment maintenance policy.
- (C) Plugs shall be hospital grade. Adaptors, extension cords and junction boxes shall not be used.
- (D) Emergency electrical power shall be available in all areas serving mothers and newborns, including sufficient numbers of emergency electrical outlets to maintain life support systems.

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130.626: Infection Control

- (A) Each maternal and newborn unit shall have policies incorporating standard precautions as defined in guidelines issued by the Centers for Disease Control and Prevention. The guidelines can be found at [www.cdc.gov](http://www.cdc.gov).
- (B) Policies and procedures shall include a requirement for staff hand hygiene on arrival in the unit as well as before and after each patient contact.
- (C) Infection specific precautions shall be based on the identified or suspected pathogen and its known mode of transmission and shall be applied in accordance with guidance issued by the Centers for Disease Control and Prevention.
- (D) (1) The maternal and newborn service shall have a plan to manage the mother and/or the infant requiring physical isolation. Mothers and infants may be placed in isolation together 24 hours a day.
- (2) (a) The hospital shall define those infections for which separate isolation is required. However, if separate isolation is not provided, the following conditions shall be met:
- (i) An adequate number of nursing and medical personnel are on duty and have sufficient time for hand hygiene.
  - (ii) Sufficient space is available for a four to six foot aisle or area between newborn stations.
  - (iii) An adequate number of sinks for handwashing are available and conveniently located to the "isolated" patient in each nursery room or area.
  - (iv) Continuing instruction is given to personnel about the mode of transmission of infections.
- (b) When the criteria specified in 105 CMR 130.626(D)(2)(a) are not met or the physician determines separation of the infant is indicated, a separate nursery with handwashing facilities shall be used to house the infant.
- (3) Forced air incubators may be used for limited protective or reverse isolation of newborns and infants, i.e., to protect these infants from others who may be infectious. Forced air incubators shall not be relied on as a means of preventing transmission from infected incubator patients to others.
- (E) The hospital policy shall establish maternal and newborn service staff dress requirements. At a minimum such policy shall include:
- (1) Provision for a clean barrier at the point of infant-caregiver contact.
  - (2) Requirements for when cover gowns should be used.
  - (3) A requirement that the hair of personnel shall be restrained in a manner that prevents its coming in contact with the patient.
- (F) Staff assigned to maternal and newborn areas shall have:
- (1) Demonstrated immunity to rubella either via rubella titer or physician-documented rubella vaccine received on or after 12 months of age.
  - (2) Demonstrated immunity to measles (rubeola) either via measles titer, physician-diagnosed disease or physician-documented live measles vaccine received on or after 12 months of age.
  - (3) Tuberculin skin testing, repeat skin testing, and x-ray follow-up of staff with positive findings as defined by hospital infection control policy. At a minimum staff shall be tested at time of hiring, unless a previously significant reaction can be documented.
- (G) Exclusion of personnel with communicable diseases shall be defined by hospital policy and consistent with 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements.
- (H) Policies and procedures for cleaning, disinfecting or sterilization of patient care areas, equipment, supplies and infant linen shall be established, approved and periodically reviewed by the hospital's infection control officer or equivalent.

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.
- (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.
  - (i) Method of feeding including feeding plan of care.
  - (ii) 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/her physician designee.

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- (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 or pediatric 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 develop policies and procedures consistent with Massachusetts General Laws related to maternal and newborn care.
  
- (B) Each maternal and newborn service shall maintain a daily patient care log that documents the information required by the Massachusetts Department of Public Health, Division of Health Statistics and Research annual report.
  
- (C) 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 shall be reported within 48 hours to the Department by the hospital in which the death occurs.
  
- (D) Each hospital with a maternal and newborn service and each pediatric hospital with a neonatology subspecialty service shall submit patient-specific data reports that include practice benchmarks such as transfers, retro-transfers, and maternal and newborn medical conditions to the Massachusetts Department of Public Health in accordance with Department guidelines.
  
- (E) Each hospital with a Level III maternal and newborn service shall develop and maintain quality improvement initiatives through participation in the Vermont Oxford Network's Very Low Birth Weight (VLBW) Database and shall make Vermont Oxford Network data reports available to the Department upon request.

130.629: Universal Newborn Hearing Screening Programs

(A) Definitions.

Audiologist shall mean 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 et seq., who meets such requirements for additional experience as defined by the Department in the Universal Newborn Hearing Screening Guidelines.

Birth Center shall mean either a free-standing or hospital-affiliated birth center, as defined at 105 CMR 142.000 et seq..

Birth Hospital shall mean, for the purposes of regulations regarding universal newborn hearing screening programs in 105 CMR 130.000 et seq. and 105 CMR 142.000 et seq., a hospital with a maternal and newborn service, as designated by the Department pursuant to 105 CMR 130.000 et seq., 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 et seq., from which an infant may be initially discharged to home.

Hearing Screening shall mean a test to detect hearing thresholds of 30 decibels or greater in either ear in the speech frequency range. The methodology shall be one that is 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.

Newborn Infant shall mean, for the purposes of regulations regarding universal newborn hearing screening programs in 105 CMR 130.000 et seq. and 105 CMR 142.000 et seq., an infant less than three months of age.

(B) Information and Screening Requirements.

- (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.
  - (a) This information shall be readily available in the major languages as identified through the acute hospital's language needs assessment required under 105 CMR 130.1103(A) and literacy levels of the population served by the maternal and newborn service.
  - (b) Translation of the information to languages used by a smaller percentage of the obstetrical population shall be provided prior to the hearing screening to the maximum extent possible, but in no event later than discharge.
  - (c) For a hospital without a maternal newborn service from which a newborn infant may be initially discharged to home, the hospital shall ensure that translation of the hearing screening information is provided to non-English speaking parents or guardians of a newborn infant prior to discharge to the maximum extent possible.
- (2) Each birth hospital and birth center shall ensure that a hearing screening is performed on all newborn infants before the newborn infant is initially discharged to home.
  - (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.
  - (b) By the age of three months, 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.
  - (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. This information shall include at a minimum the time and location of the screening appointment that has been scheduled, the telephone number of the screening site, a list of diagnostic test centers approved by the Department, as well as information about the importance of screening and follow-up. The information shall be provided to the parent or guardian in writing in the language understood by the parent or guardian.
- (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.
  - (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. This information shall include at a minimum the time and location of the diagnostic test appointment that has been scheduled, the telephone number of the diagnostic test site, a list of diagnostic test centers approved by the Department, as well as information about the importance of follow-up. The information shall be provided to the parent or guardian in writing in the language understood by the parent or guardian.

(C) Screening Protocols.

(1) 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.

(2) A licensed audiologist shall oversee the provision of screening services and shall train the persons performing the screening.

(3) Within 120 days of the effective date of 105 CMR 130.629, each birth hospital and birth center shall submit to the Department for its approval a protocol for newborn hearing screening. The protocol shall, at a minimum, to the satisfaction of the Department:

(a) Identify the staffing of the program and outline the responsibilities of each staff member;

(b) Describe the training and supervision of screening personnel by a licensed audiologist;

(c) Identify the screening methods and equipment to be used to conduct the screening, including provisions for readily available back-up equipment in the event of an equipment malfunction;

(d) Outline infection control procedures;

(e) Provide samples of information to be provided to parents/guardians regarding the screening, including but not limited to information about coverage of the costs of the screening by third party payers, the potential risks of hearing loss, and the benefits of early detection and intervention;

(f) Outline the procedure for documenting the results of the screening;

(g) Identify the procedure for communicating that the infant did not pass, was unsuccessfully screened or missed the screening to the parent or guardian, primary care physician, and the Department. See 105 CMR 130.629(B)(5) and (B)(7);

(h) Describe the training and supervision of individuals with responsibility to inform parents or guardians of screening results;

(i) Identify the procedure to ensure an infant who missed a screening or was unsuccessfully screened will receive a screening. See 105 CMR 130.629(B)(4) and (B)(5);

(j) Identify the procedure to ensure the parent or guardian of an infant who did not pass the screening will receive information about follow-up and an appointment for diagnostic services. See 105 CMR 130.629(B)(6) and (B)(7);

(k) Identify the procedure for reporting data on an annual basis or as otherwise required by the Department, 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;

(l) Describe the screening program's Quality Assurance review process; and

(m) Include a provision for the review of hearing screening status in the discharge plan for all newborn infants required at 105 CMR 130.630(E)(2)(e), 130.640(B)(4)(p), 130.650(B)(4)(i), and 130.663 and in the information concerning the condition at discharge or transfer required at 105 CMR 142.504(D)(7).

(4) Prior to implementing a significant change in a hearing screening protocol approved by the Department, a hospital or birth center must request and have received written approval of the change from the Department.



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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. Provides for the care and management of well newborns, stable infants born at  $\geq 35$  weeks gestation, including stable retro-transferred infants not needing Level IB, IIA, IIB or III services.

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) Collaboration/Transfer Agreements. The Level I service shall establish formal written collaboration/transfer agreements with at least one Level III hospital within geographic proximity and other hospitals to which the service regularly refers patients.

(B) Administration and Staffing.

- (1) An obstetrician either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology shall be designated as medical director of the maternal service. The medical director or his/her designee shall be available on-call 24 hours a day.
- (2) A pediatrician either certified or an active candidate for certification 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/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 either certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available on-call 24 hours a day.
- (5) A pediatrician either certified or an active candidate for certification by the American Board of Pediatrics with newborn privileges or board certified or an active candidate for certification by the American Board of Family Practice with newborn 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.

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

- (1) Social risk assessment and social work services by a licensed social worker(s) with experience in social assessment of high risk perinatal patients (mother/infant dyad), patient education, discharge planning, community follow-up programs, referrals and home care arrangements. These services may be provided by the hospital social service department or through written arrangements with public or private social service agencies.
- (2) Nutritional consultation by a dietician registered by the American Dietetic Association and experienced in maternal and newborn nutritional needs available seven days a week.
- (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) Emergency management of maternal patients, including the capacity to resuscitate and stabilize the patient prior to transfer. In the event of the need for emergency resuscitation and/or stabilization of the mother, an obstetrician shall be either onsite or called to come in to manage the emergency prior to transport of the mother to a Level II or Level III service.
- (5) Emergency management of neonates, including the capacity to resuscitate and stabilize the patient prior to transfer. In the event of the need for emergency resuscitation and/or stabilization of the infant a pediatrician shall be either onsite or called to come in to manage the emergency prior to transport of the infant to a Level III service. All infants requiring ongoing mechanical ventilation shall be transferred to a Level III service.

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- (6) Arrangements for emergency transport to Level II and III services as stipulated in collaboration/transfer agreements. Infants shall be transferred to an appropriate service within geographic proximity except under unusual circumstances such as lack of available bed or by parental request.
- (7) Availability of continuous internal and external electronic fetal monitoring and auscultation.
- (8) Amniocentesis and ultrasound capabilities.
- (9) Blood for transfusions including O negative and fresh frozen plasma 24 hours a day.
- (10) Respiratory therapists shall be available on call 24 hours a day.
- (11) Radiology services, including portable x-ray and ultrasound on-call 24 hours a day.
- (12) Clinical laboratory services, including microchemistry, on-call 24 hours a day.
- (13) Care of the retrotransferred stable-growing or recovery infant who does not require the complex medical management needs provided by a Level II or III service.
- (14) The following care and services 24 hours a day for infants born in-house and for retrotransfers:
  - (a) Emergency management including newborn cardiopulmonary resuscitation, and emergent diagnostic placement of umbilical arterial and venous arterial catheter lines.
  - (b) Neonatal stabilization, including:
    - (i) oxygen administration and monitoring;
    - (ii) cardio-respiratory monitoring;
    - (iii) emergency packed red blood cells and fresh frozen plasma;
    - (iv) glucose management;
    - (v) intravenous fluid administration;
    - (vi) antibiotic administration;
    - (vii) sepsis evaluation, including lumbar puncture, and blood cultures;
    - (viii) thermoregulation; and
    - (ix) provision for parental contact prior to transfer.
  - (c) Care of the newborn:
    - (i) intramuscular injections;
    - (ii) phototherapy;
    - (iii) thermoregulation;
    - (iv) fluid management;
    - (v) infant feeding; and
    - (vi) pain assessment and management.
- (15) Registered pharmacist services with access to neonatal, pediatric and maternal pharmacological resources, at a minimum available by telephone consultation.
- (16) Provision for 24-hour access to emergency drugs.
- (17) Capability of beginning an emergency cesarean surgical birth within 30 minutes of the decision to perform the procedure.

(D) 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 the following:

- (1) Policies and procedures for consultation with and/or transfer of mother and/or newborn to level II and III facilities:
  - (a) The policies and procedures for maternal transfer shall encourage the delivery at a Level II or III facility of those mothers who are medically assessed as requiring such level of care or whose newborns are anticipated to require the services offered at such level.
  - (b) The policies and procedures for maternal transfer shall address the management of premature labor, isoimmunizations, medical complications of pregnancy, as well as antenatal and intrapartal complications of delivery.
- (2) Policies and procedures for management of medical and surgical complications of pregnancy that include, at a minimum, maternal diabetes, organic heart disorder and surgical abdomen.
- (3) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

Such policies shall be submitted to the Department upon request.

(E) 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  $\geq 35$  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/her designee shall be available on-call 24 hours a day.

(b) A physician who is either certified or an active candidate for certification by the American Board of Pediatrics with Continuing Care Nursery privileges shall be available on-call 24 hours a day.

(c) Nursing.

(i) 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.

(ii) 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 in addition to 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) Continuous involvement of parents in infant's care and opportunity for parents to room-in for predischarge education in caring for the infant.

(g) Where indicated, a plan for positive infant stimulation 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.

(h) Written discharge planning.

(i) 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.

(j) In-house clinical laboratory services including microchemistry 24 hours a day.

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

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

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

(3) Policies and Procedures for Transfer. 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,

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(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.

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

(a) Nursing orientation and ongoing education including theory and skills required to function in the Level IB Continuing Care Nursery.

(b) If therapeutic formulas are made on-site, preparation and sealing of containers to prevent tampering.

(c) Policy and procedures for the care and management of infants with mild apnea of prematurity, neonatal abstinence assessment and management, care and management of PICC line and oxygen therapy, feeding protocols, criteria for neonatology consult and transfer to level III service.

(d) 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 uncomplicated pregnancies 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 neonate: well newborns, premature infants  $\geq 34$  weeks gestation, and infants who require special care services (including retro-transferred infants).

A service shall be eligible 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 or the requirement of 105 CMR 130.640(A)(3).

(B) Level IIB Service. Level IIB capabilities include the care and management of uncomplicated pregnancies 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 neonate, well newborns, premature infants delivering at  $\geq 32$  weeks gestation, 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 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 or the requirement of 105 CMR 130.640(B)(3).

(C) The Level IIA or IIB Community-based Maternal-Newborn Service shall meet the requirements contained in 105 CMR 130.601 through 130.628 and 105 CMR 130.640(D) through (E), unless otherwise specified

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(D) Maternal Service.

- (1) Collaboration/Transfer Agreements. Each Level IIA or IIB service shall establish formal written collaboration/transfer agreements with at least one hospital with a Level III maternal service.
- (2) Administration and Staffing.
  - (a) A physician certified by the American Board of Obstetrics and Gynecology shall be designated medical director of the maternal service. This physician shall collaborate with the pediatrician responsible for newborn patients in the medical management of the entire maternal and newborn service.
  - (b) A physician certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full 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 maternal 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.
    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, 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.
  - (d) A licensed social worker with experience in maternal and child health shall be available to provide services to mothers.
  - (e) A dietician registered by the American Dietetic Association and with expertise in maternal care shall be available for consultation to both normal and high-risk mothers.
- (3) Services. Each Level II Maternal Service shall provide the following:
  - (a) Social risk assessment and social work services by a licensed social worker(s) with experience in social assessment of high risk perinatal patients (mother/infant dyad), patient education, discharge planning, community follow-up programs, referrals and home care arrangements.
  - (b) Nutritional consultation by a registered dietician experienced in maternal and newborn nutritional needs available seven days a week.
  - (c) Medical risk assessment, resuscitation and stabilization of the mother prior to transport to a Level III facility if required.
  - (d) Availability of continuous internal and external electronic-fetal monitoring and auscultation.
  - (e) Blood for transfusions, including O negative and fresh frozen plasma, 24 hours a day.
  - (f) Radiology, in-house, 24 hours a day.
  - (g) Clinical laboratory services including in-house capabilities for microchemical fetal blood sample monitoring 24 hours a day.
  - (h) Capability to perform ultrasound and amniocentesis in-house 24 hours a day.
  - (i) Subspecialty services for the mothers including, but not limited to, general surgery, cardiology, urology, internal medicine, hematology and neurology.
  - (j) Access to genetics counseling.
  - (k) Capability of beginning an emergency cesarean surgical birth within 30 minutes of the decision to perform the procedure.
- (4) 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) Policies and procedures for consultation with specialists for medical management and/or transfer of the mother to a Level III facility.
  - (i) Policies and procedures for maternal transfer shall address the management of premature labor, medical complications of pregnancy, as well as antenatal complications of delivery.
  - (ii) Policies and procedures for management of medical and surgical complications of pregnancy shall include but not be limited to maternal diabetes, iso-immunization, organic heart disease and surgical abdomen.
  - (iii) The policies for maternal transfer shall encourage the delivery at a Level III facility of those mothers who are medically assessed as requiring such level of care or whose newborn(s) are anticipated to require the services of such level.
- (c) 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) Collaboration/Transfer Agreements. Each hospital providing a Level II maternal and newborn service shall establish formal written collaboration/transfer agreements with at least one Level III service.
- (2) Administration and Staffing.
  - (a) A physician certified by the American Board of Pediatrics who has qualified to appear for the neonatology board shall be designated the medical director of the Special Care Nursery. A pediatrician meeting the requirements of 105 CMR 130.640(E)(2)(b) shall be designated to act in the absence of the director.
  - (b) A neonatologist who is either certified or an active candidate for 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.
  - (d) A masters-prepared social worker with a background in maternal and child health shall be available as needed.
  - (e) A dietician registered by the American Dietetic Association and with pediatric experience shall be available as needed.
  - (f) A respiratory therapist with pediatric experience shall be present in-house 24 hours a day to provide consultation on oxygen therapy and equipment maintenance.
  - (g) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written hospital policy.
- (3) 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 or a pediatrician who meets the requirements of 105 CMR 130.640(E)(3)(a) or neonatal nurse practitioner who meets the requirements of 105 CMR 130.640(E)(3)(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 first year of post-graduate residency training with at least two months neonatal intensive care unit rotations or a pediatrician who is certified or an active candidate for certification by the American Board of Pediatrics. 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).

(b) Neonatal Nurse Practitioner.

(i) A neonatal nurse practitioner qualified to provide on-site coverage in the special care nursery shall

- a. preferably have a master's degree but at a minimum have a baccalaureate degree;
- b. be certified as a neonatal nurse practitioner by a nationally recognized organization; and
- c. be authorized to practice as an advanced practice registered nurse by the Massachusetts Board of Registration in Nursing.

(ii) 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).

(iii) There shall be a planned schedule for the practitioner to rotate regularly to the Level III service with which the Level II service has a collaboration agreement. Rotation to the Level III service shall occur with such frequency as to assure that the neonatal nurse practitioner has the opportunity to maintain skills in the emergency procedures outlined in 105 CMR 130.640(E)(3)(a). At a minimum, the rotation shall occur annually. The practitioner shall be periodically evaluated by both the Level II and Level III services.

(iv) Neonatal nurse practitioners shall be credentialed through the hospital's nursing department and medical staff and function under approved written guidelines for practice. 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).

(v) 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.

(vi) 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.

(vii) 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.

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

- (a) Social work services.
- (b) Nutritional consultation.
- (c) Risk-assessment, stabilization and triage to a Level III services.
- (d) Provision of a neutral-thermal environment.
- (e) Continuous and long-term oxygen administration via nasal cannula and hood, including oxygen saturation monitoring.
- (f) Pharmacological treatment of apnea of prematurity.
- (g) Capabilities to insert and maintain intravenous therapy for hydration and medication administration 24 hours a day.
- (h) Umbilical artery and venous catheter insertion and maintenance.
- (i) Continuous electronic cardio-respiratory monitoring.
- (j) Blood transfusion capability (exchange transfusion optional).
- (k) Naso-gastric, oro-gastric and oro-jejunal feedings.
- (l) Sepsis evaluations including lumbar punctures and cultures.
- (m) Parenteral nutrition.
- (n) Phototherapy.
- (o) Continuous involvement of parents in infant's care and opportunity for parents to room-in for pre-discharge education in caring for the infant.

- (p) Where indicated, a plan for positive infant stimulation 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. (Attention shall also be given to elimination of negative or extraneous environmental stimuli.)
- (q) Written discharge planning.
- (r) Arrangements for transport between Level II and Level III facilities as stipulated in collaboration/transfer agreements.
- (s) Care of the retrotransferred infant from Level III after the acute phase of illness has passed, including infants who require care for ongoing medical supervision and management. Placement at a Level II service shall be jointly agreed upon at least by the medical staff responsible for the infant's care at the Level II and Level III facilities.
- (t) Radiology, including portable x-ray capabilities, in-house, 24 hours a day.
- (u) In-house clinical laboratory services including microchemistry 24 hours a day.
- (v) Respiratory therapy services, in-house, 24 hours a day.
- (w) Access within the facility or through arrangement with Level III facilities to subspecialty services or consultation with pediatric surgery, neurology, cardiology and genetics.
- (x) In addition, a Level II B service shall provide Continuous Positive Airway Pressure (CPAP) in compliance with guidelines established by the Department.

(5) Policies and Procedures for Transfer.

- (a) Each Level IIA or Level IIB Special Care Nursery shall have written policies and/or procedures for consultation with and/or transfer to a Level III unit. All infants in a designated Level II service requiring mechanical ventilation shall be transferred to a Level III Unit. Such policies shall be submitted to the Department upon request.
- (b) In a Level IIA service a mechanical ventilator or CPAP (Continuous Positive Airway Pressure) may be initiated and used in a Special Care Nursery prior to such transfer only when the Medical Director of the Special Care Nursery approves such use and only when all of the following conditions are met:
  - (i) A neonatologist remains at the infant's bedside at all times.
  - (ii) A respiratory therapist with experience in neonatal ventilation remains at the infant's bedside at all times.
  - (iii) The Special Care Nursery is arranging for transport of the infant to the Level III unit.
  - (iv) The mechanical ventilator is used only while the infant is awaiting the transport.
- (c) In a Level IIB service a mechanical ventilator may be initiated and used in a Special Care Nursery prior to such transfer only when the Medical Director of the Special Care Nursery approves such use and only when all of the following conditions are met:
  - (i) A neonatologist remains at the infant's bedside at all times.
  - (ii) A respiratory therapist with experience in neonatal ventilation remains at the infant's bedside at all times.
  - (iii) The Special Care Nursery is arranging for transport of the infant to the Level III unit.
  - (iv) The mechanical ventilator is used only while the infant is awaiting the transport.

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

- (a) Nursing orientation and ongoing education including theory and skills required to function in the Special Care Nursery.
- (b) If therapeutic formulas are made on-site, policies governing preparation and sealing containers to prevent tampering.
- (c) Other policies and procedures as deemed appropriate by the hospital perinatal committee.

(7) 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.



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- (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.
- (8) Environment and Equipment. The Special Care Nursery shall contain the following:
  - (a) Incubators.
  - (b) Cardio-respiratory monitors with high/low alarm.
  - (c) Warming table(s).
  - (d) Infusion pumps.
  - (e) Oxygen humidification and warming system. (The respiratory therapist shall check machine functioning and provide scheduled maintenance per written hospital policy.)
  - (f) Oxygen analyzer.
  - (g) Umbilical artery/vein catheterization equipment.
  - (h) Emergency medications and equipment.
  - (i) A separate formula preparation area if therapeutic formulas are made on-site. The preparation area shall have a work counter, sink for handwashing and storage facility.
  - (j) Availability of hospital grade breast pump and collection kits in numbers sufficient to meet needs and separate refrigerator/freezer for expressed breast milk.
- (9) 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 neonates: well newborns, premature infants, and infants who require neonatal intensive care services. The service provides newborn care to patients with routine medical needs, as well as to those with actual medical problems. The maternal service has the capabilities 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.

(C) The Level III service shall meet the 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) A physician certified or an active candidate for certification by the American Board of Obstetrics and Gynecology with full privileges shall be available in-house 24 hours a day.
- (c) An 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 and be Advanced Cardiac Life Support certified.

(f) A full time master's prepared nurse, preferably a clinical nurse specialist with clinical experience in neonatology or perinatology or a neonatal nurse practitioner, shall be available with dedicated responsibility for coordinating the in-service education for maternal and newborn staff.

(g) A master's-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 patients' needs.

(h) A dietician registered by the American Dietetics Association 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) Social work services.

(b) Nutritional consultation.

(c) Medical risk assessment and resuscitation.

(d) Availability of continuous internal and external electronic-fetal monitoring.

(e) Blood for transfusions, including O negative and fresh frozen plasma, 24 hours a day.

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

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

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

(i) 24 hours a day capability for ultrasound and amniocentesis.

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

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

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

(m) Capability of beginning an emergency cesarean surgical birth within 30 minutes of the decision to perform the procedure.

(3) Policies and Procedures. In addition to the policies and procedures required pursuant to 105 CMR 130.601 through 130.628 the level III Maternal Services 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.

(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/her designee shall be available on-call 24 hours a day.

(b) A board certified neonatologist or an active candidate for certification in neonatology by the American Board of Pediatrics shall be available in-house 24 hours a day.

(c) 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.

- (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 neonates 24 hours a day. The team of nurses shall demonstrate competencies in critical care 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 130.650(D)(1)(f).
- (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 dietician registered by the American Dietetics Association who has 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.
- (i) A respiratory therapist trained in the neonatology specialty area shall be available to the unit 24 hours a day.
- (j) A medical engineer shall be responsible for the maintenance and safe functioning of specialized equipment per written policy.
- (k) 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) Phototherapy.
- (g) Exchange transfusions.
- (h) Continuous cardio-respiratory monitoring including oxygen saturation monitoring.
- (i) Complex nutritional and metabolic management including total parenteral nutrition.
- (j) Full range of emergency pediatric radiology and subspecialty services available 24 hours a day.
- (k) Full range of laboratory services including microchemistry and full service blood bank available 24 hours a day.
- (l) Access to emergency surgical interventions in the neonate (or written agreements with other institutions providing subspecialty surgical procedures) available 24 hours a day.
- (m) Post-surgical care.
- (n) Access to pediatric subspecialty consultation and services including surgery, neurology, cardiology, gastroenterology, infectious disease, hematology and genetics available 24 hours a day.
- (o) Where indicated, a developmental plan 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. (Attention shall also be given to elimination of negative or extraneous environmental stimuli and to pain management and monitoring.)
- (p) Availability of developmental consultation, including occupational and physical therapies.
- (q) Continuous involvement of parents in infant's care and opportunity for mothers to room-in for pre-discharge education in caring for the infant.

- (r) 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.)
  - (s) Ongoing written discharge planning.
  - (t) Transport capabilities to return patients to a hospital with a Level I or II service.
  - (u) Ethics committee for review of complex patient care issues with focus on parental involvement in decision making.
  - (v) Professional education program.
  - (w) Availability of educational offerings to collaborating community hospitals.
  - (x) Parent education appropriate to meet the needs of the infant and family.
  - (y) Breastfeeding support.
- (3) Policies and Procedures. The neonatal intensive care unit shall have written policies and procedures for the following:
- (a) Nursing orientation and ongoing education in theory and skills required to function in the NICU.
  - (b) Admission, transfer and discharge of patients.
  - (c) Emergency transport of infants from collaborating hospitals. These policies shall require the presence of a physician or neonatology specialty-trained nurse on the transport team and access to telephone consultation with a neonatologist.
  - (d) Research on infants.
  - (e) Membership and functioning of the ethics committee.
  - (f) If therapeutic formulas are made on-site, policies for preparation and sealing of containers to prevent tampering.
  - (g) Newborn pain management.
  - (h) 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. The Neonatal Intensive Care Unit shall meet the following requirements:
- (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) A separate formula preparation area shall be provided when therapeutic formulas are made on-site. The preparation area shall have a work counter, sink for handwashing and storage facility.
  - (d) Availability of breastfeeding pump room.
- (6) Equipment. The Neonatal Intensive Care Unit shall contain at least the following equipment:
- (a) Isolettes.
  - (b) Cardio-respiratory monitors with high/low alarm.
  - (c) Warming tables.
  - (d) Infusion pumps.
  - (e) Oxygen humidification and warming system.
  - (f) Oxygen analyzer.
  - (g) Percutaneous oxygen monitor.
  - (h) Arterial and venous catheterization equipment.

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- (i) Neonatal resuscitation medications and equipment as described by the American Academy of Pediatrics Neonatal Resuscitation Program guidelines.
- (j) Ventilators with heated humidity and alarm systems. (The respiratory therapist shall check machine settings and functioning regularly per departmental policy.)
- (k) Transducers for invasive cardiac monitoring.
- (l) Immediate accessibility to microchemistry laboratory.
- (m) Transport isolette(s).
- (n) Electric breast pump(s) and collection kits.
- (o) 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. Model language for implementation of 105 CMR 130.662 will be provided by the Department.

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.

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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, payors 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, payors 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

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

General Pediatric Service (Level II), a service which provides care for pediatric patients with uncomplicated and complicated 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 to age 21, other than an infant in a newborn nursery, an intermediate or special care nursery, or a neonatal intensive care unit. Pediatric patients under the age of 15 must be admitted to a pediatric service. Pediatric patients 15 years of age and over may, at the option of the admitting physician, be cared for on a service other than the pediatric service.

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Pediatric Specialty Service, a hospital or a unit of a hospital which 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 which 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 which provides short-term acute care and/or stabilization for pediatric patients, and which may provide prolonged care to pediatric patients in appropriate cases. 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 in conjunction with the Pediatric Advisory Committee. A Level I service need not have a pediatric unit but it must admit all pediatric patients under 15 years of age to a room or rooms designated primarily for the use of pediatric patients. A Level I service shall exist only in an area where there is documented evidence of geographic isolation as defined in the acute care hospital component of the currently approved state health plan.

130.710: Department Establishment of Pediatric Advisory Committee

The Department shall establish a Pediatric Advisory Committee to advise the Department on issues related to 105 CMR 130.700 through 130.760 (Pediatric Services). This committee's membership shall be multidisciplinary. It shall include but not necessarily be limited to one or more members of the following groups: physicians, nurses, hospital administrators, and consumers. It shall be representative of the various parts of the state and all levels of pediatric care.

130.711: Department Designation of the Level of Pediatric Service in a Hospital

The Department shall designate the level of pediatric service of each hospital subject to Department licensure which has a pediatric service. The Department will base such designations upon documentation submitted by each such hospital of the nature of its pediatric service, followed by a survey of the service by Department staff and consultation with the Pediatric Advisory Committee. By July 1, 1981, each hospital with a pediatric service must file an application with the Department in which it proposes the level of care at which its pediatric services should be designated. This application shall be accompanied by documentation that the hospital's pediatric service complies with the requirements for that level. Thereafter, the Department will survey the hospital to check its compliance with the requirements for that level of care.

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 under 15 years of age 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 which cannot be provided in such a pediatric area, unit or sub-unit, such as obstetrics or other care designated by the Department. Pediatric patients 15 years of age and over may, at the option of the admitting physician, be cared for on a service other than the pediatric service.

130.720: continued

- (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 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 a 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) Every pediatric service shall establish an advisory multidisciplinary Pediatric Committee, chaired by the Chief of Pediatrics, to advise it on issues related to the service.
- (D) Each pediatric service shall have written policies and procedures for patients requiring transfer and/or consultation.
- (E) The hospital shall establish a policy identifying which patients must have a consultation by a pediatrician.
- (F) Each pediatric service shall develop a policy for the management of infectious disease and isolation.
- (G) At least one pediatric patient room shall be available for isolation use.
- (H) Each pediatric service shall have written protocols for the management of pediatric patients with known or suspected psychiatric, child abuse or neglect problems.
- (I) The pediatric service shall have a policy regarding parental involvement which allows for constant parental support of and contact with the pediatric patient throughout hospitalization. However, parental access to specialized areas like operating rooms may be denied.
- (J) 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.
- (K) 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.
- (L) Equipment sized appropriately for pediatric patients must be available in all areas and services providing care to pediatric patients.
- (M) All pediatric service equipment, including beds, cribs, wheelchairs, and toys, shall meet the minimum safety standards established by the hospital's Pediatric Committee.
- (N) Provision shall be made for the safe storage of drugs, external solutions, and other potentially toxic substances kept on pediatric services.
- (O) Laundry chutes on pediatric services must be locked.
- (P) All personnel providing direct care to pediatric patients shall participate in a pediatric orientation program which meets the needs of the hospital and its patients.



130.720: continued

(Q) Each pediatric service shall have pediatric emergency resuscitation equipment and medication readily available. A visible sign or chart listing pediatric doses for emergency drugs shall accompany such equipment.

(R) Only Level III pediatric services may have pediatric intensive care units. Ordinarily, patients under 15 years of age 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 board qualified or certified pediatrician for every pediatric patient under 15 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.
- (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.

(S) Every pediatric service shall make available informational material on chronic and other related conditions to families of pediatric patients with such conditions, and services to such families.

(T) Every pediatric service admitting a newborn infant, as defined under 105 CMR 130.629, 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 130.629.

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) There must be a registered nurse with clinical pediatric experience 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 under 15 years of age. 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 their existence must be made known to the families of pediatric patients.

(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:

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- (A) 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 under 15 years of age.
    - (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. The hospital has written policies specifying the types of diagnoses that adult patients may not have to be admitted to the adult care unit in which pediatric sub-unit is located. These policies are approved by the Department, with the advice of the Pediatric Advisory Committee, as assuring an adequate standard of care for pediatric patients admitted to the sub-unit.
    - (d) The pediatric sub-unit is situated in such a way that the flow of adult patients through it is discouraged.
- (B) The hospital must have a designated Chief of Pediatrics who is a board qualified or 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.
- (C) There must be a physician trained in pediatric resuscitation available in-hospital 24 hours a day.
- (D) Any pediatric residents and interns assigned to a Level II service shall be supervised by a staff pediatrician.
- (E) The head nurse or equivalent who has 24-hour responsibility for the direction and supervision of patient care on the general pediatric service shall be a registered nurse, preferably with a B.S. in nursing, and shall have had documented pediatric nursing experience within the past five years.
- (F) At least one registered nurse with pediatric nursing experience shall be assigned to work in each pediatric unit or sub-unit at all times. Nursing personnel regularly assigned to the pediatric unit or sub-unit shall have this as their primary patient care responsibility.
- (G) 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.
- (H) Physical and occupational therapy services shall be available in-hospital or through consultant arrangements.
- (I) The Chief of Pediatrics and the Laboratory Director shall determine what laboratory tests, including those utilizing microtechniques, the hospital must have the capacity to perform for pediatric patients. A technician to perform such tests shall be available on a 24-hour basis, in-hospital or on call within 15 minutes.
- (J) A radiology technician shall be available on a 24-hour basis, in-hospital or on call within 15 minutes.
- (K) When necessary, a registered dietitian shall be available to Level II service staff and the families of pediatric patients for consultation concerning pediatric nutrition.
- (L) The hospital shall provide documentation of training and experience in pediatric anesthesiology of anesthesiologists providing care to pediatric patients.

130.740: continued

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

(N) The pediatric service must have a protocol for a recreational and educational program sufficient to meet the needs of its patients.

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

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) There must be a designated Chief of Pediatrics and an alternate or alternates designated by the Chief who will assume the responsibilities of the Chief in the Chief's absence. Each must be a board qualified or certified pediatrician.

(B) A board qualified or certified pediatrician or pediatric resident with a minimum of two years' residency training must be in the hospital 24 hours a day.

(C) The pediatric service must have a supervisory level nursing coordinator, who has at least a B.S. in nursing and pediatric experience, and preferably an M.S. in pediatric nursing.

(D) 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.

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

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

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

(H) At least one radiologist and one radiology technician in the hospital 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.

(I) There must be a pediatric patient recreation program run 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.

(J) Each Level III service must have a pediatric intensive care unit (PICU), discrete from the adult ICU, which 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.

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- (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 registered nurse in charge of the nursing staff in the PICU shall have at least two years of pediatric nursing experience and documented education in the care and management of critically ill pediatric patients.
- (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.
- (9) Support personnel 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 for designation of the level of their pediatric service pursuant to 105 CMR 130.711. 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. However, if documentation submitted by the pediatric specialty service, a survey by the Department and Department consultation with the Pediatric Advisory Committee provide substantial evidence that any of these requirements should not apply, on the basis of the grounds for waiver of standards indicated in 105 CMR 130.970, the Department may waive the application of such a requirement to the service.

130.761: Emergency Service - Pediatric Patients

- (A) All hospitals providing emergency care for pediatric patients, as defined by 105 CMR 130.701, 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 have 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. A readily visible sign or chart listing pediatric doses for emergency drugs shall be posted in all rooms in which resuscitation is conducted.
  - (5) Names and phone number of consultants on call to provide emergency care to pediatric patients' shall be readily accessible.
  - (6) Radiology and laboratory services, including appropriately board-certified physicians and technicians, shall be available on call 24 hours a day.
  - (7) The emergency service shall have written policies and procedures for the management of pediatric problems, including:
    - (a) Cardiopulmonary resuscitation.

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- (b) Respiratory obstruction.
- (c) Burns.
- (d) Poison and ingestions.
- (e) Drug and alcohol abuse.
- (f) Child abuse.
- (g) Psychiatric disturbances.
- (h) Transfer of pediatric patients to other facilities.
- (i) Consent to treatment on behalf of pediatric patients.
- (j) Handling of special situations such as pediatric patients dead on arrival; or suspected rape, pregnancy, or venereal disease.

(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 qualified or certified 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.

130.770: Contact Person

Acute hospitals shall designate a contact person for receiving all notifications from the Department regarding appeals filed pursuant to 105 CMR 130.666. Said contact person shall immediately make available any patient information requested by the Department.

130.771: Advisory Committee

The Department shall establish an advisory committee, comprised of representatives of the medical, insurance, and consumer communities, so as to advise the Department on matters pertaining to hospital length of stay requirements and post-partum care benefits for mothers and newborns. Such advisory committee shall meet as often as necessary, but no less than once a year, in accordance with procedures established by the Department. The advisory committee shall advise the Department as to the following:

- (1) the adequacy and appropriateness of the current ACOG/AAP standards regarding early discharge and post-partum care services.
- (2) any matter affecting the implementation of St. 1995, c. 218 or 105 CMR 130.660 through 130.669.

130.800: Hospice Services

Licensing regulations applicable to a hospice service of a hospital are set forth in 105 CMR 141.000: The Licensure of Hospice Programs, which are incorporated herein by reference.

130.810: Birth Center Services

Licensing regulations applicable to the birth center services of a hospital set forth in 105 CMR 142.000 which are incorporated herein by reference.

130.820: Definitions

The following definitions apply in 105 CMR 130.820 through 130.836 when used with regard to satellite emergency facilities:

Satellite Emergency Facility (SEF) means 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).

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Emergency Department means the department of the hospital that provides emergency services as defined in 105 CMR 130.020 and is located on the main campus of the hospital that operates the SEF.

130.821: Approval

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 et seq., 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:

- (1) a statement of the type of care that will be provided at the SEF;
- (2) 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;
- (3) a description of the level of ambulance transport that will be appropriate at the proposed SEF; and
- (4) 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 cause a notice of the public meeting to be published in the legal notice section of local newspapers serving residents of the hospital's service area. The notice shall be in 14 point type and contain as its caption: "Public Announcement Concerning the Establishment of a Satellite Emergency Facility at (name of hospital)" The notice shall set forth the name and address of the hospital, 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:

130.827: continued

- (1) 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;
- (2) 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";
- (3) 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);
- (4) a list of meetings to be held with public officials and the affected parties listed in 105 CMR 130.823;
- (5) a clear and understandable description of the services available at the SEF and any changes in services previously provided at the SEF site;
- (6) 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;
- (7) a list of alternative facilities that provide emergency services to residents of the hospital's service area;
- (8) a plan to provide accurate and appropriate road signage in the hospital's service area;
- (9) notice of the date when the SEF will commence operations; and
- (10) 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 prepared 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 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 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 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

- (A) 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;
- (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

SEF's shall have:

- (1) on site basic diagnostic radiology available 24 hours per day;
- (2) the capability of performing on site basic laboratory testing with results available in less than one hour;
- (3) laboratory services capable of performing blood gas analysis and routine hematology and chemistry available 24 hours per day;
- (4) 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
- (5) plain film radiography available on site with technicians available 24 hours per day.

130.835: Clinical Services and Equipment

SEF's shall have:

- (1) monitored and unmonitored beds in sufficient quality to meet projected patient volume;
- (2) 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;
- (3) 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;
- (4) 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,
- (5) 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 and annually thereafter. The report shall include:

- (1) total patient volume, including the number of walk in patients and patients transported by either BLS or ALS ambulance;
- (2) the number of patients transferred to other facilities categorized by method of transport to the SEF;
- (3) if known, the number of patients admitted to a hospital within 72 hours of having been seen at the SEF;
- (4) deaths occurring at the SEF; and
- (5) detailed description of community education and training activities.

130.840: Definition

The following definition applies to 105 CMR 130.840 through 130.841.



130.840: continued

Diversion Status System shall mean 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.

(D) The Commissioner shall appoint a diversion status advisory committee to advise the Department on technical aspects of the diversion status system. The membership shall include hospital and pre-hospital representatives from each of the EMS regions.

130.850: Trauma Service

Licensing regulations 105 CMR 130.850 through 105 CMR 130.854 set forth standards for the licensure and designation of trauma services as mandated by M.G.L. c. 111C, § 11(a), which states that the Department shall develop a statewide coordinated trauma care system that at a minimum, by regulation and guidelines, shall provide for the designation of trauma centers at various levels.

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; or

(B) The hospital is recognized as a level 1, 2, or 3 adult trauma center or a level 1 or 2 pediatric trauma center in regional point-of-entry plans as of March 12, 2004 and is in the process of completing ASC verification as defined in Department guidelines.

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

(D) The hospital provides to the Division of Health Care Finance and Policy the designated trauma center data set to be specified in administrative requirements jointly developed by the Department and the Division of Health Care Finance and Policy, and promulgated by the Department; and

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

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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 the Division of Health Care Finance and Policy the trauma service hospital data set to be specified in administrative requirements jointly developed by the Department and the Division of Health Care Finance and Policy, 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 the printed 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, and the Department 90 days prior to the proposed effective date of such change.

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130.900: Standards for Operation of Hospital-based Cardiac Catheterization Services

105 CMR 130.900 through 130.982 set forth standards for the operation of hospital-based adult cardiac catheterization 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 request prior approval from the Department. Any hospital wishing to perform cardiac catheterization procedures on pediatric patients must apply to the Department for approval of a special project, as described under 105 CMR 130.051. The application process for the pediatric cardiac catheterization service special project is described in 105 CMR 130.921.

130.910: Definitions

Cardiac Catheterization Services means diagnostic and therapeutic services, other than cardiac surgery, which are not usually performed at the patient's bedside and which involve the introduction of physical objects (such as catheters) into the heart, its chambers, the pericardium, or the great vessels proximal to the heart. Examples of cardiac catheterization services are right heart and left heart cardiac catheterization, coronary angiography, ventriculography, and percutaneous coronary interventions. Excluded from this definition are: bedside cardiac and pulmonary artery catheterization using floating and/or indwelling catheters; the implantation, repair, and replacement of cardiac pacemaker devices; and cardiac radionuclide scanning procedures that do not require the use of the cardiac catheterization laboratory.

Electrophysiology Studies (EPS) means the recording of intracardiac electrogram, atrial or ventricular stimulation, intracardiac mapping or cardiac ablation.

Primary Operator means a physician who is scrubbed and provides hands-on participation in and has primary responsibility for all aspects of the cardiac catheterization service procedures. There is one primary operator per case. However, for the purpose of counting operator volume pursuant to 105 CMR 130.900 through 130.982, in a training situation a fellow and the attending physician may both be considered the primary operator for the case.

130.915: Department Approval to Provide Adult Cardiac Catheterization Services

(A) A hospital licensed pursuant to M.G.L. c. 111, § 51 that intends to provide cardiac catheterization services shall apply for and receive approval from the Department in order to provide cardiac catheterization services. The Department shall grant its approval if it finds that the hospital meets the standards and requirements in 105 CMR 130.900 through 130.982 for operating a cardiac catheterization laboratory. Upon determination that the hospital meets the relevant requirements, the Department shall cause the license issued to a hospital pursuant to 105 CMR 130.120 to indicate that the licensee is authorized to provide cardiac catheterization services as a specific service of the hospital. All cardiac catheterization laboratories shall obtain Department approval pursuant to 105 CMR 130.900 through 130.982 prior to operating such a program.

(B) A mobile cardiac catheterization service shall be organized and coordinated by a hospital licensed or operated by the Commonwealth pursuant to M.G.L. c. 111, § 51 (the sponsor or lead hospital), that has operated a fixed site cardiac catheterization service for at least one year immediately prior to filing an application, and shall meet all licensure requirements. Upon determination that the sponsor and host site hospitals meet the relevant requirements, the Department shall cause the license issued to the sponsor and host site hospitals pursuant to 105 CMR 130.120 to indicate that the licensees are authorized to provide mobile cardiac catheterization services as a specific service of the hospital.

130.920: Initial Application to Provide Adult Cardiac Catheterization Services

(A) As directed by the Department, each hospital seeking to provide cardiac catheterization services shall submit an application that documents how the hospital will meet the cardiac catheterization services standards. Every application shall be notarized and signed under the pains and penalties of perjury by the applicant or a person authorized to act on behalf of the applicant.

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130.920: continued

(B) Applicants shall list the specific procedures that are proposed to be provided by the cardiac catheterization service.

(C) Applicants for cardiac catheterization services shall document how the service will meet the facility volume minimums within the two year time frame required in 105 CMR 130.935: Minimum Workload Requirements.

130.921: Application to Provide Pediatric Cardiac Catheterization Services (Special Project)

(A) Any hospital that intends to provide pediatric cardiac catheterization services must request and receive from the Department written special project approval to provide pediatric cardiac catheterization services. Applicants should submit a written request to the Department. Pediatric cardiac catheterization procedures shall not be performed by a mobile cardiac catheterization service.

(B) All applicants shall at a minimum have the following:

- (1) a licensed Level III pediatric service, and
- (2) Determination of Need approval to perform open heart surgery.

130.922: Timing of Application

After the initial licensure of the cardiac catheterization service, the hospital shall reapply for licensure of the cardiac catheterization service each time that it applies for renewal of its hospital license.

130.924: Evaluation of Application

(A) The Department shall not approve an initial application to provide cardiac catheterization services unless the Commissioner or his designee has conducted an inspection or other investigation of the facility and has determined that the applicant complies with the requirements of 105 CMR 130.900 through 130.982.

(B) Applicants shall have demonstrated satisfactorily to the Department that the facility volume minimums will be met within 24 months of initial licensure.

130.926: Issuance of an Amended Hospital License

Upon approval of the application to provide cardiac catheterization services, the Department shall issue an amended hospital license which indicates that cardiac catheterization is an approved service provided by the hospital.

130.930: Establishment of Invasive Cardiac Services Advisory Committee

The Department shall establish an Invasive Cardiac Services Advisory Committee (ICSAC or the Committee) to advise the Department on issues related to invasive diagnostic and therapeutic 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.

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130.935: Minimum Workload Requirements

(A) Each cardiac catheterization service that performs only diagnostic procedures shall maintain a minimum caseload volume of 300 procedures per year.

(1) Any cardiac catheterization service providing fewer than 300 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 150 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 not have a practice based in Massachusetts and shall certify that he/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 licensed and, if applicable, subject to any conditions determined to be appropriate.

(4) New services shall reach the minimum number of procedures within 24 months of licensure of the service.

(5) For the purposes of measuring facility volume, a mobile cardiac catheterization service may aggregate the facility volume of participating hospitals.

(B) Cardiac catheterization services that perform therapeutic as well as diagnostic catheterizations shall perform a minimum of 600 catheterization procedures per year, of which 200 procedures shall be therapeutic.

(1) Any service performing therapeutic as well as diagnostic catheterizations that performs less than the volume minimums shall within 30 days of the end of the Department's fiscal year reporting period:

(a) 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); and

(b) 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 not have a practice based in Massachusetts and shall certify that he/she does not have any conflict of interest regarding the hospital and physicians to be reviewed.

(2) The results of the review shall be submitted to the Department within ten days of receipt.

(3) Based on a review of the QAPI and the results of the assessment of the quality of the cardiac catheterization service by an appropriately qualified professional peer review organization or individual(s) approved by the Department, the Department shall determine whether a facility will continue to be licensed and, if applicable, subject to any conditions determined to be appropriate.

(4) New services providing diagnostic and therapeutic catheterizations shall reach the minimum number of procedures within 24 months of licensure of the service.

(C) If a hospital is required to submit its quarterly reports of the QAPI under 105 CMR 130.935 (A) or (B), 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, or in the case of a mobile cardiac catheterization service, the sponsor or lead hospital, shall designate a licensed physician director who shall have responsibility for the cardiac catheterization service. The physician shall be board certified in cardiovascular disease. However, licensed physicians acting as the physician director of existing cardiac catheterization services as of July 25, 1997 who are not board certified in cardiovascular disease but who meet all other requirements in 105 CMR 130.900 through 130.982, shall be grandfathered. The physician director shall have training and experience in cardiac catheterization.

(1) The physician director of a cardiac catheterization service that performs therapeutic procedures shall be board certified in interventional cardiology. Experienced interventionalists who performed interventional procedures prior to 1998 and/or completed training prior to 1998 and did not seek board certification prior to 2003 are exempt from the board certification in interventional cardiology requirement, but must document that their volume and outcomes meet accepted national standards.

The physician director of a cardiac catheterization service that performs therapeutic procedures who is not board certified in interventional cardiology may meet the requirement of 105 CMR 130.940(A) by appointing a director of interventional cardiology who is board certified in interventional cardiology to assist with oversight.

(2) A hospital that performs diagnostic and interventional/therapeutic 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) and who has five years of post-fellowship experience and documented skill in performing electrophysiology procedures.

Any physician director of electrophysiology services who was in the position on February 11, 2009 but who does not meet the five year post-fellowship experience requirement shall be grandfathered regarding that five year requirement.

(B) (1) Prior to designation as physician director, the physician director of a catheterization service that performs only diagnostic catheterization procedures shall have had at least five years post-fellowship experience in performing cardiac catheterization procedures, including a minimum of 250 procedures in which he/she served as primary operator, and documented skill in performing cardiac catheterization procedures.

(2) Prior to designation as physician director, the director of a cardiac catheterization service that performs therapeutic procedures shall have at least five years post-fellowship experience in performing cardiac catheterization procedures, including at least 500 therapeutic cardiac catheterization procedures in which he/she served as primary operator, and documented skill in performing cardiac catheterization procedures.

(C) The cardiac catheterization service and EPS, if applicable, physician director(s) shall be responsible for at least the following:

- (1) Development and implementation of policies and procedures.
- (2) Development of 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.
- (3) Establishment and monitoring of quality control standards (including morbidity and mortality) for the cardiac catheterization/EPS laboratory and staff, including the development and implementation of the quality assessment and performance improvement program.
- (4) Supervision and training of all personnel, including in-service training and continuing education.
- (5) Procurement of equipment and supplies.
- (6) Proper safety, function, maintenance and calibration of all equipment.
- (7) Patient scheduling.
- (8) Maintenance of records of all hemodynamic angiographic and other diagnostic and therapeutic procedures performed.
- (9) Review and recommendations regarding the granting of physician privileges in cardiac catheterization service/EPS procedures.
- (10) Production of regular reports of cardiac catheterization/EPS laboratory activity and collection of pertinent patient data.

130.940: continued

(D) The physician director may delegate to appropriate staff the activities related to the responsibilities listed in 105 CMR 130.940(C)(1) through (10).

(E) The physician director for a mobile cardiac catheterization service shall designate a clinically trained Program Manager at each participating hospital site to coordinate the activities of the cardiac catheterization service, in collaboration with the host hospital's Directors of Medicine, Nursing, Medical Records, Pharmacy, Laboratory, Radiology Services, and Infection Control.

(F) The physician director, with the hospital administration, or in the case of a mobile cardiac catheterization service, with the sponsor or lead hospital and host sites' administrations, 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. Privileges shall be granted for one year. Each physician must apply for and be awarded privileges on a yearly basis. Renewal of privileges shall be contingent upon results of appropriateness, technical quality, review of patient outcomes and other quality assurance information for all procedures. The review shall include an assessment of procedure volume for consistency with recommended minimum volume(s) in American College of Cardiology/American Heart Association and Heart Rhythm Society guidelines, as applicable, for maintaining competency in performing procedures.

(G) Each cardiac catheterization service, and in the case of a mobile cardiac catheterization service each participating hospital site, shall have on staff at least two physicians who are board certified in cardiovascular disease. Each physician who performs cardiac catheterization/EPS procedures shall be a fully accredited member of the hospital staff. Criteria for privileges shall at a minimum ensure the following:

(1) After July 25, 1997, physicians who are granted privileges to perform cardiac catheterization procedures as primary operator shall have had a minimum of eight months training in a cardiac catheterization laboratory during which time the physician performed a minimum of 300 diagnostic procedures.

(2)(a) Physicians seeking initial privileges to perform cardiac catheterization and/or EPS procedures who completed their training more than 12 months prior to seeking privileges and who do not have cardiac catheterization and/or EPS privileges at any other hospital shall meet the supervised retraining standards set by the physician director to ensure competency to perform the procedures.

(b) The retraining standards shall ensure that an individualized plan is developed for each physician that includes but is not limited to a minimum number of procedural observations, assistance at procedures and independently performed procedures to be completed by the physician. The plan, compliance with the plan, and the evaluation of physician competency shall be documented in the physician credential file.

(3) Physicians who perform percutaneous coronary interventions (PCI) shall have additional experience as the primary operator in a minimum of 250 PCI procedures, and shall be board certified in interventional cardiology.

(a) 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/she passes the board certification exam.

(b) Experienced interventionalists who performed interventional procedures prior to 1998 and/or completed their training before 1998 and did not seek board certification prior to 2003 are exempt from the board certification in interventional cardiology requirement, but must document that their procedural volume and outcomes meet accepted national standards.

(4) All physicians who perform percutaneous coronary interventions shall annually perform a minimum of 75 PCI procedures per year, consistent with the national guidelines adopted by the American College of Cardiology/American Heart Association.

130.940: continued

(a) In a hospital where this volume minimum is not met, the physician director shall take measures acceptable to the Department to ensure the quality of the interventional procedures. This may include, but is not limited to, the establishment of a mentoring relationship between a physician(s) whose volume is less than 75 PCI procedures per year and a highly experienced and skilled operator performing more than 150 PCI procedures per year.

If an operator performs PCI procedures at more than one hospital and does not meet the total volume minimum, the physician directors at each site at which the operator performs PCI procedures shall consult and collaborate with each other to establish measures acceptable to the Department to ensure the quality of the interventional procedures.

(b) An assessment of all mentoring relationships or other measures taken to assure quality of individual operator performance shall be included in the quarterly QAPI reports required under 105 CMR 130.965(E).

(H) At least two persons shall assist the physician during the performance of all cardiac catheterization procedures. At least one assistant shall be clinically trained (either a Registered Nurse, Nurse Practitioner or Physician Assistant).

(1) Personnel shall operate within the scope of practice as defined by the appropriate licensing and/or certifying board. These personnel shall be trained and experienced in the use of all appropriate instruments and equipment.

(2) A mobile cardiac catheterization service shall use a staffing team that travels to each site.

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

(J) 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.

(K) 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.

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

(M) Hospitals participating in a mobile cardiac catheterization service shall, in collaboration with the appropriate tertiary facility, as required under 105 CMR 130.975(A), develop and implement initial and ongoing teaching, training and evaluation of participating hospital staff in the pre- and post-procedure care of cardiac catheterization patients.

130.950: Equipment and Supplies

Each cardiac catheterization service shall include at least the following:

(A) X-ray tube.

(B) Image intensifier or digital acquisition unit.

(C) Pulse generator.

(D) Collimator.

(E) TV system.

(F) Image processor.



130.950: continued

- (G) Data transfer.
- (H) Data storage (archival system).
- (I) Monitoring and recording equipment.
- (J) Pressure transducers.
- (K) Equipment for determining cardiac output.
- (L) Equipment for determining oxygen saturation, hemoglobin, blood gas analysis and pH.
- (M) Appropriate cardiac catheters and accessory equipment.
- (N) Resuscitation equipment and medications.
- (O) Intra-aortic balloon pump located within the hospital and available to the laboratory. For hospitals without cardiac surgery services, an intra-aortic balloon pump designed for ambulance transport. At a minimum, quarterly in-service training shall be performed with this equipment to ensure maintenance of staff skills.

130.955: Supportive Diagnostic Services

Each hospital that provides cardiac catheterization services, and in the case of a mobile cardiac catheterization laboratory, each participating hospital site, shall provide access to: services for hematology and coagulation disorders; electrocardiography; diagnostic radiology; clinical pathology; nuclear medicine and nuclear cardiology; doppler echocardiography; pulmonary function testing; microbiology; exercise stress testing; and cardiac pacemaker and defibrillator assessment.

130.960: Space

(A) A cardiac catheterization/EPs laboratory shall meet the cardiac catheterization laboratory standards in the current edition of Guidelines for Design and Construction of Health Care Facilities of the American Institute of Architects, as referenced in 105 CMR 130.107, and shall include provisions for each of the following:

- (1) Control, monitoring and recording equipment.
- (2) X-ray power and controls.
- (3) Work room.
- (4) Dressing area for staff.
- (5) Dressing area for outpatients.
- (6) Patient preparation, holding, and recovery areas.

The recovery area must be directly accessible from the procedure room and designed according to the standards applicable to recovery areas for ambulatory surgery from the *Guidelines for Design and Construction of Health Care Facilities* referenced in 105 CMR 130.960(A).

- (7) Waiting area and toilet room.
- (8) Storage area for supplies and medications.

(B) Cardiac catheterization laboratory space renovated or constructed after July 25, 1997 shall include a minimum floor area of 500 square feet for the procedure room.

(C) A mobile cardiac catheterization laboratory shall meet, in addition to the general cardiac catheterization laboratory standards in the American Institute of Architects' (AIA) guidelines cited in 105 CMR 130.960(A), the AIA standards for mobile units.

- (1) Each mobile cardiac catheterization laboratory site shall provide a temperature-controlled connection to the hospital.
- (2) Each mobile cardiac catheterization laboratory site shall provide safeguards to ensure protection of the mobile van (e.g., barriers, restricted traffic flow).

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130.962: Assurance of Continuity of Care

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

130.965: In-house Evaluation of Quality

(A) Each cardiac catheterization/EPS service shall establish and maintain an effective, ongoing, data-driven, 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 indicators, based on nationally accepted standards, that reflect the quality of care and patient safety,
- (2) Collect and maintain data pertaining to these indicators in a systematic manner,
- (3) Perform statistical analyses of the results for comparison with nationally accepted quality indicator benchmarks,
- (4) Prepare reports to document comparison results and identify areas for improvement, and
- (5) Develop an approach to implement quality improvement efforts and problem solving that includes feedback for catheterization service staff on the effectiveness of the solutions and/or triggers further opportunities for improvement.

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

- (1) Appropriate patient selection (according to pre-established selection criteria, consistent with nationally accepted standards);
- (2) The appropriateness of each cardiac catheterization/EPS procedure;
- (3) Technical quality of the catheterization/EPS studies;
- (4) Diagnostic accuracy and completeness of studies;
- (5) All catheterization/EPS procedure-related complications and adverse outcomes (including infections), during the patient's hospital stay or 24 hours post procedure, whichever is longer;
- (6) Number of cases requiring interhospital transfer and the reason for transfer;
- (7) Laboratory diagnostic and therapeutic procedure volume;
- (8) Physician therapeutic procedure volumes, including an assessment of all mentoring relationships established or other measures taken pursuant to 105 CMR 130.940 (G)(4)(a), if applicable;
- (9) The number/percent of diagnostic cardiac catheterization procedures determined to be normal (i.e., no disease or physiologically insignificant coronary stenoses);
- (10) Processes and criteria for staff credentialing;
- (11) Ongoing clinical staff training and education;
- (12) Patient satisfaction; and
- (13) Outcomes in comparison to national benchmarks.

Each cardiac catheterization service shall participate in a national data registry to help benchmark results and track complications.

(D) Cardiac catheterization/EPS and angiographic 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/electrophysiologic findings and clinical recommendations.

(E) A quarterly written report of QAPI findings, recommended actions, progress on implementation and supporting data shall be available for Department review.

130.970: Reporting to the Department of Public Health

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

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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 meet the following requirements:

(A) The hospital 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.

(B) The following procedures shall not be performed in a hospital that is not approved to perform cardiac surgery:

- (1) Percutaneous coronary interventions.
- (2) Percutaneous balloon valvuloplasty.
- (3) Myocardial biopsy.
- (4) Placement of any permanent cardiac devices other than cardiac pacemakers, defibrillators or implantable event monitors.

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

Hospitals shall not perform intracardiac electrophysiology studies unless the hospital is licensed to provide cardiac catheterization services.

130.982: Diagnostic and Interventional/Therapeutic Electrophysiology Studies

(A) Each hospital shall specifically define, based on nationally accepted standards of the American College of Cardiology/American Heart Association and the Heart Rhythm Society (HRS), the qualifications necessary for privileges to perform diagnostic and interventional/therapeutic EPS. Such policies shall ensure that EPS shall be performed by a physician board certified in cardiovascular disease who has a minimum of at least one additional year of specialized training in EPS and cardiac arrhythmias as defined by the Heart Rhythm Society (formerly known as the North American Society for Pacing and Electrophysiology (NASPE)).

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

Physicians who are within 12 months after completion of a fellowship in clinical cardiac electrophysiology, while awaiting board certification, may perform electrophysiology procedures under the supervision of a physician board certified in clinical cardiac electrophysiology, who performs more than 125 procedures per year, until he/she passes the board certification exam.

(2) Consistent with HRS guidelines, non-electrophysiologists wishing to implant cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRTs) devices must be trained in an American Council for Graduate Medical Education (ACGME) approved fellowship program and pass a competency exam offered by the International Board of Heart Rhythm Examiners.

(B) Renewal of physician privileges shall at a minimum include a review of all procedures for appropriateness, technical quality, patient outcomes and other quality assurance information developed through the Quality Assessment and Performance Improvement (QAPI) program. The review shall include an assessment of procedure volume for consistency with recommended minimum volumes in American College of Cardiology/American Heart Association and HRS guidelines, as applicable, for maintaining competency in performing procedures.

130.982: continued

(C) A registered nurse, Nurse Practitioner or Physician Assistant trained and experienced in advanced life support, cardiac drugs, and cardiac catheterization/EPS and a technician trained and experienced in cardiac catheterization/EPS shall be present during the procedure.

(D) Physician anesthesia services shall be available on site for emergencies.

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

(F) The following at a minimum shall be provided for the performance of diagnostic and interventional EPS procedures:

- (1) fluoroscopy unit,
- (2) programmable stimulator,
- (3) multi-channel physiologic recorder, and
- (4) resuscitative equipment.

(G) Provisions for pacing, defibrillation, and resuscitation must be immediately available.

(H) When requested by the Department, each hospital performing EPS shall submit information regarding patient outcomes and utilization.

130.1001: Definitions

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

Advisory Committee means 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 means the Commissioner of the Massachusetts Department of Public Health.

Department means the Massachusetts Department of Public Health.

Engineering and Work Practice Controls mean 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 means a plan that includes an effective procedure for identifying and selecting existing sharps injury prevention technology.

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

Health Care Worker means 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 means any hospital licensed by the Department pursuant to M.G.L. c. 111, § 51.

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

Sharp means 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.

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Sharps Injury Log means 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 means 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 C.F.R. 1910.1030 et seq. 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 C.F.R. 1910.1030 et seq.

130.1005: Exemption from the Inclusion of Sharps Injury Prevention Technology

(A) Sharps injury prevention technology may be excluded as engineering and 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,

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(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.

130.1008: Advisory Committee

The Department shall convene an advisory 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.

130.1009: List of Needleless Systems

The Department, in consultation with the advisory committee, shall compile, maintain and periodically update a list of needleless systems, with engineered injury protections meeting the purposes set forth in M.G.L. c. 111, § 53D. The list shall be available as a resource to assist hospitals in complying with 105 CMR 130.000.

130.1040: Definition of Emergency Contraception

For the purposes of 105 CMR 130.1041 through 130.1043, "emergency contraception" shall mean 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, § 12A 1/2.

(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.

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130.1101: Interpreter Service - Requirement

Each acute care hospital, as defined in M.G.L. c. 111, § 25B, which is licensed by the Department and which provides emergency services as defined in 105 CMR 130.020, 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 which 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 which includes input from community-based organizations, and which 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 which 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.

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(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.

(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 televising services, provided that telephonic or televising 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.



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130.1201: Definitions

As used in 105 CMR 130.1201 through 130.1203 the following definitions shall apply:

Cardiac Surgery means surgery on the heart and the thoracic great vessels performed on persons 18 years and older. 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 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.

Data Analysis Center (DAC) means the organization contracted by the Department to receive, process, analyze and report on the patient-specific cardiac surgery outcome data submitted by acute care hospitals.

STS National Database is a proprietary trademark owned by the Society of Thoracic Surgeons (STS), and means the cardiac surgery database developed and maintained by the STS.

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 Society of Thoracic Surgeons; 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 an advisory bulletin:

- (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 an advisory bulletin.

130.1301: Definitions

As used in 105 CMR 130.1301 through 130.1303 the following definitions shall apply:

Angioplasty means the procedure for remodeling a blood vessel through the introduction of an expandable balloon catheter and includes ant percutaneous intervention (PCI) on the heart. Examples of PCI include angioplasty, stents, atherectomy, brachytherapy, and/or local drug delivery.

Data Analysis Center (DAC) means the organization contracted by the Department to receive, process, analyze and report on the patient-specific angioplasty outcome data submitted by acute care hospitals.

NCDR™ National Database means the angioplasty database developed and maintained by the American College of Cardiology.

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130.1302: Angioplasty Patient Outcome Monitoring Requirements

Each hospital that provides angioplasty shall:

- (1) Submit patient-specific angioplasty outcome data for each patient who receives angioplasty services to the DAC as specified in 105 CMR 130.1303;
- (2) Require that each physician who performs angioplasty at the hospital is enrolled in and participates in the NCDR National Database of the American College of Cardiology; 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 National Database.

130.1303: Angioplasty Patient Outcome Data Requirements

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

- (1) Angioplasty data submitted by hospitals are subject to audit by the Department. All hospitals providing angioplasty 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 angioplasty services that the hospital provides. The Department shall set forth the formula and the procedures for disbursement to the DAC in an advisory bulletin.

130.1400: Purpose

The purpose of 105 CMR 130.1400 through 105 CMR 130.1413 is to establish standards for the designation of a Primary Stroke Service in a hospital with licensed Emergency Services.

130.1401: Definitions

Acute Hemorrhagic Stroke (a Subtype of Acute Stroke) means 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) means 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 means 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 means any 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;
- (3) five or more peer-reviewed publications on stroke;
- (4) eight or more continuing medical education (CME) credits each year in the area of cerebrovascular disease; or
- (5) other criteria approved by the governing body of the hospital.

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Acute Stroke Team means 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 means 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 means time frames established by the Department in an advisory bulletin 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 130.1400 through 130.1413.

130.1403: Evaluation of an Application

The Department shall designate a Primary Stroke Service upon demonstration satisfactory to the Department that the hospital meets the criteria in 105 CMR 130.1400 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. Written care protocols for acute stroke shall be available in the Emergency Department (ED) and other areas likely to evaluate and treat patients with acute stroke.

(B) Emergency Department (ED) Stroke Protocols.

(1) The hospital shall develop and implement written protocols for 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) The protocols shall include a method for 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) The hospital shall develop and implement 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.

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130.1406: Neuroimaging Services

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

(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).

130.1407: Other Imaging and Electrocardiogram Services

The hospital shall have the ability to promptly perform and evaluate chest x-rays and electrocardiograms consistent with time targets acceptable to the Department.

130.1408: Laboratory Services

The hospital shall have the ability to promptly perform and evaluate routine serum chemistry, hematology and coagulation studies for acute stroke patients, consistent with time targets acceptable to the Department.

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/her designee, and the Chief Executive Officer of each hospital or his/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 ischemic stroke who arrived within three hours of symptom onset, 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 an advisory bulletin.

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.

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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 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 130.1400 through 130.1413, including adherence to the time targets.

130.1500: Purpose

The purpose of 105 CMR 130.1500 through 130.1504 is to establish standards for those hospitals that provide medical control to licensed EFR and ambulance services.

130.1501: Definitions

The following definitions apply in 105 CMR 130.1500 through 130.1504:

Affiliate Hospital means 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 means an agreement between the hospital and a service that meets the requirements of 105 CMR 170.300.

Authorization to Practice means approval granted to EMS personnel as defined in 105 CMR 170.020.

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

EFR Service means 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 (EMS) means 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 means 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) means a person certified by the Department to provide emergency medical services pursuant to 105 CMR 170.000.

Medical Control means 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 means 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 means 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.

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

Regional EMS Council means 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 means a licensed ambulance service or EFR service as defined in 105 CMR 170.020.

Statewide Treatment Protocols means 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 with each service to which it provides medical control;
- (B) Make on-line medical direction available 24 hours a day, seven days a week to all services with which it has an affiliation agreement;
- (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;

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(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.

(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, as defined in M.G.L. c. 111, § 25B and 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:
  - (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:

Betsy Lehman Center means the Betsy Lehman Center for Patient Safety and Medical Error Reduction established pursuant to M.G.L. c. 6A, § 16E.

Healthcare-associated Infection (HAI), means 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; and
- (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.

National Healthcare Safety Network (NHSN) means the data collection network 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 and the Betsy Lehman Center, in accordance with guidelines of the Department, to:



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- (a) healthcare-associated infection data elements reportable to the NHSN; and
- (b) hospital-specific reports generated by 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 and the Betsy Lehman Center to healthcare-associated infection data elements.

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

130.1800: Patient and Family Advisory Council

(A) 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 establish a Council no later than October 1, 2010.
- (2) No later than September 30, 2009, a hospital shall prepare a written report outlining the hospital's plan to establish a Council by October 1, 2010.
- (3) No later than October 1, 2010 and annually thereafter, a hospital shall prepare a 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.
- (4) The hospital shall make the reports required in 105 CMR 130.1800(A)(2) and (3) 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:

- (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.

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(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.

REGULATORY AUTHORITY

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