* Section 405.1.* Introduction.

(a) General hospitals, hereinafter referred to as hospitals, shall comply with all of the requirements of this Part:

1. hospitals shall comply with construction standards contained in Article 2 of Subchapter C of this Chapter (Medical Facility Construction); and

2. hospitals shall notify the commissioner in writing within seven days after receipt of notice of the accreditation decision or notification of a tentative nonaccreditation by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association.

(b) The provisions of Parts 700, except for paragraphs (a)(21)-(22), (b)(25) and (c)(7), (35)-(41) of section 700.2; 702; 703, except for section 703.6; 706; and 707 of Article 1 of this Chapter shall not apply to general hospitals.

(c) Any person, partnership, stockholder, corporation or other entity with the authority to operate a hospital must be approved for establishment by the Public Health Council unless otherwise permitted to operate by the Public Health Law or as provided for by section 405.3 of this Part. For the purposes of this Part, a person, partnership, stockholder, corporation or other entity is an operator of a hospital if it has the decision-making authority over any of the following:

1. appointment or dismissal of hospital management-level employees and medical staff, except the election or removal of corporate officers by the members of a not-for-profit corporation;
2. approval of hospital operating and capital budgets;
3. adoption or approval of hospital operating policies and procedures;
4. approval of certificate of need applications filed by or on behalf of the hospital;
5. approval of hospital debt necessary to finance the cost of compliance with operational or physical plant standards required by law;
6. approval of hospital contracts for management or for clinical services; and
7. approval of settlements of administrative proceedings or litigation to which the hospital is party, except approval by the members of a not-for-profit corporation of settlements of litigation that exceed insurance coverage or any applicable self-insurance fund.

(d) Nothing in subdivision (c) of this section shall require the establishment of any member of a not-for-profit corporation, which operates a hospital, based upon such member's reservation and exercise of the power to require that the hospital operate in conformance with the mission and philosophy of the hospital corporation.

10 NY ADC 405.1
10 NY ADC 405.1
2008 WL 75295863
10 NY ADC 405.1

* Section 405.2.* Governing body.

(a) The established operator shall be legally responsible for the quality of patient care services, for the conduct and obligations of the hospital as an institution and for ensuring compliance with all Federal, State and local laws.

(b) Organization and operation.

1. The hospital shall have a governing body legally responsible for directing the operation of the hospital in accordance with its mission. If a hospital does not have an organized governing body, then the person or persons legally responsible for the conduct of the hospital shall carry out the functions specified in this Part that pertain to the governing body. Hospitals operated by governmental
organizations, with the exception of those sponsored by the Federal government, shall provide written notification to the commissioner of their designated governing bodies and the legal authority establishing these designations. No contracts/arrangements or other agreements may limit or diminish the responsibility of the governing body in any way.

(2) The governing body, in order to achieve and maintain generally accepted standards of professional practice and patient care services in the hospital, shall establish, cause to implement, maintain and, as necessary, revise its practices, policies and procedures for the ongoing evaluation of the services operated or delivered by the hospital and for the identification, assessment and resolution of problems that may develop in the conduct of the hospital.

(3) All officers, directors, trustees, partners, or sole proprietors of the governing body shall participate in orientation and continuing education programs addressing the mission of the institution, their roles and responsibilities, patients’ rights, and the organization, goals and operation of the hospital’s quality assurance program.

(4) The governing body shall adopt written bylaws reflecting its legal responsibility and accountability to the patients and its obligation to the community it was established to serve. The bylaws shall specify at least the following:
   (i) the role and purpose of the hospital;
   (ii) the duties and responsibilities of the governing body;
   (iii) the responsibilities of any governing body committees including the requirement that minutes reflect all business conducted, including findings, conclusions and recommendations;
   (iv) the relationships and responsibilities of the governing body, hospital administration, and the medical staff, and the mechanism established by the governing body for holding such parties accountable;
   (v) the mechanisms for adopting, reviewing and revising governing body bylaws; and
   (vi) the mechanisms for formal approval of the organization, bylaws, rules and regulations of the medical staff and its departments in the hospital.

(5) Meetings of the governing body shall be held in order for the governing body to evaluate the conduct of the hospital, including the care and treatment of patients as well as its own performance. Based on these evaluations, the governing body shall take necessary actions sufficient to correct noted problems. A record of all governing body proceedings which reflects all business conducted, including findings, conclusions and recommendations, shall be maintained for review and analysis.

(6) The governing body shall establish and maintain a coordinated program which integrates the review activities of all hospital services for the purpose of enhancing the quality of patient care and identifying and preventing malpractice.

(c) Compliance with Federal, State and local laws.

(1) The hospital shall comply with all applicable Federal, State and local laws, including the New York State Public Health Law, Mental Hygiene Law, and the Education Law.

(2) The governing body shall take all appropriate and necessary actions to monitor and restore compliance when deficiencies in the hospital’s compliance with statutory and/or regulatory requirements are identified, including but not limited to monitoring the chief executive officer’s submission and implementation of all plans of correction.

(d) Chief executive officer. The governing body shall appoint a chief executive officer who is responsible to the governing body for the management of the hospital. This function shall not be delegated to or shared with any organization except under a management authority contract approved by the commissioner pursuant to section 405.3 of this Part.

(1) The chief executive officer shall be qualified for his/her responsibilities through education and experience.

(2) The governing body shall assure the chief executive officer’s effective performance through ongoing documented monitoring and evaluation of that performance against written criteria developed for the position. Such criteria shall include the hospital’s compliance with statutory and regulatory requirements, the corrective actions required and taken to achieve such compliance, and the maintenance of corrective actions to achieve continued compliance in previously deficient areas.

(e) Medical staff. The governing body shall:

(1) determine, in accordance with State law, which categories of health care practitioners are eligible candidates for appointment to the medical staff;

(2) appoint a physician, referred to in this Part as the medical director, who is qualified for membership on the medical staff and who shall be responsible for directing the medical staff organization in accordance with provisions of section 405.4 of this Part. Such appointment shall be made after consultation with the medical staff. In making such appointment the governing body may
consider an individual who is a clinical department chairperson, an elected president of the medical staff, a medical staff committee chairperson, or any other person who meets the requirements for appointment set forth in this paragraph. The medical director may carry out his or her duties on either a full or part-time basis and on a salaried or nonsalaried basis as determined by the governing body and may report to the governing body directly, or to the governing body through the chief executive officer or through another route as determined by the governing body;

(3) ensure the implementation of written criteria for selection, appointment and reappointment of medical staff members and for the delineation of their medical privileges. Such criteria shall include standards for individual character, competence, training, experience, judgment, and physical and mental capabilities;

(4) ensure that staff membership or professional privileges in the hospital are not dependent solely upon certification, fellowship, or membership in a specialty body or society;

(5) appoint members of the medical staff after considering the recommendations of the existing members of the medical staff in accordance with written procedures, as established by hospital and medical staff bylaws;

(6) ensure that actions taken on applications for medical staff appointments and reappointments including the delineation of privileges are put in writing;

(7) ensure that the medical staff has written bylaws;

(8) approve medical staff bylaws and any other medical staff rules and regulations;

(9) require that members of the medical staff abide by the rules, regulations and bylaws of the hospital;

(10) ensure that the medical staff is accountable to the governing body for the quality of care provided to patients; and

(11) require that members of the medical staff practice only within the scope of privileges granted by the governing body.

(f) Care of patients. The governing body shall require that the following patient care practices are implemented, shall monitor the hospital's compliance with these patient care practices, and shall take corrective action as necessary to attain compliance:

(1) every patient of the hospital, whether an inpatient, emergency service patient, or outpatient, shall be provided care that meets generally acceptable standards of professional practice;

(2) every patient is under the care of a health care practitioner who is a member of the medical staff;

(3) patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted to admit patients to a hospital;

(4) a physician, or a registered physician’s assistant under the general supervision of a physician, or a nurse practitioner in collaboration with a physician, is on duty at all times in the hospital except that the commissioner may approve substitute coverage, for all or part of each day, by each patient's attending physician when these physicians are immediately available to the hospital by telephone, and available in person within 20 minutes as needed, upon a hospital demonstrating to the commissioner that:

(i) all patients are medically stable and patients who become medically unstable are promptly transferred to an appropriate receiving hospital in accordance with section 400.9 of this Title;

(ii) the hospital does not operate an emergency service; and

(iii) the entire hospital has less than 25 approved beds;

(5) a physician shall be responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization;

(6) hospitals which conduct, or propose to conduct, or otherwise authorize human research on patients or other human subjects shall adopt and implement policies and procedures pursuant to the provisions of Public Health Law, article 24-A for the protection of human subjects; and

(7) hospitals shall have available at all times personnel sufficient to meet patient care needs.

(g) Physical plant. The governing body is responsible for providing a physical plant equipped and staffed to maintain the needed facilities and services for patients in compliance with construction standards contained in Article 2 of Subchapter C of this Chapter (Medical Facility Construction), and for correcting deficiencies cited by regulatory agencies.

(h) Hospital service contracts. The governing body shall be responsible for services furnished in the hospital whether or not they are furnished by outside entities under contracts. The governing body shall ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable codes, rules and regulations.
The governing body shall ensure that the services performed under a contract are provided in a 
safe and effective manner, in accordance with the requirements of section 400.4 of this Subchapter.
(2) The hospital shall maintain a list of all contracted services, including the scope and nature of the 
services provided.

(i) As used in this Part to describe the duties or obligations of the governing body of a hospital, the 
words "assure" or "ensure" shall not affect the standard of liability in damages of a hospital 
corporation's board of directors, or the board's individual members, beyond the standard set forth in 
statutory and/or case law applicable in this State.

RESEARCH REFERENCES AND PRACTICE AIDS:
65 NY Jur 2d, Hospitals and Related Health Care Facilities §  7(supp).
10 NY ADC 405.2
10 NY ADC 405.2
2008 WL 75295864
10 NY ADC 405.2

* Section 405.3.* Administration.

The hospital shall be managed effectively and efficiently in accordance with hospital bylaws and 
policies and procedures. The daily management and operational affairs of the hospital shall be the 
responsibility of the chief executive officer.

(a) The chief executive officer shall be responsible for the development, submission and 
implementation of all plans to correct operational deficiencies identified by regulatory agencies on a 
timely basis and shall report to the governing body progress in developing and carrying out plans of 
correction.

(b) Personnel. The chief executive officer develops and implements personnel policies and practices 
with regard to at least the following:

(1) the employment of personnel, without regard to sex, race, creed, sexual orientation, disability, 
or national origin, whose qualifications are commensurate with anticipated job responsibilities;
(2) the identification of all hospital personnel, including students and volunteers, through the use of 
identification name tags which are clearly visible and are worn at all times;
(3) the orientation of all new employees to the hospital and to hospital and personnel policies;
(4) the development and implementation of a written plan for inservice training, including 
orientation and training for the governing body;
(5) effective July 1, 1989, the provision, at all times, of intravenous services, phlebotomy services, 
messenger services, transporter services, nurse aides, housekeeping services and other ancillary 
support services in a manner sufficient to meet patient care needs and to prevent adverse impact on 
the delivery of medical and nursing care;
(6) the maintenance of an accurate, current, and complete personnel record for each hospital 
employee;
(7) the verification of all applicable current licensure/certification;
(8) a periodic performance evaluation, based on a written job description, of each employee;
(9) the verification of employee health services, in consultation with the medical staff; and
(10) the provision for a physical examination and recorded medical history for all personnel 
including all employees, members of the medical staff, students and volunteers, whose activities are 
such that a health impairment would pose a potential risk to patients. The examination shall be of 
sufficient scope to ensure that no person shall assume his/her duties unless he/she is free from a 
health impairment which is of potential risk to the patient or which might interfere with the 
performance of his/her duties, including the habituation or addiction to depressants, stimulants, 
narcotics, alcohol or other drugs or substances which may alter the individual's behavior. The hospital 
is required to provide such examination without cost for all employees who are required to have such 
examination. For personnel whose activities are such that a health impairment would neither pose a 
risk to patients nor interfere with the performance of his/her duties, the hospital shall conduct a health 
status assessment in order to determine that the health and well-being of patients are not jeopardized 
by the condition of such individuals. The hospital shall require the following of all personnel as a 
condition of employment or affiliation:

(i) a certificate of immunization against rubella which means:
(a) a document prepared by a physician, physician’s assistant, specialist’s assistant, nurse practitioner, licensed midwife or a laboratory possessing a laboratory permit issued pursuant to Part 58 of this Title, demonstrating serologic evidence of rubella antibodies; or
(b) a document indicating one dose of live virus rubella vaccine was administered on or after the age of 12 months, showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization; or
(c) a copy of a document described in clause (a) or (b) of this subparagraph which comes from a previous employer or the school which the employee attended as a student; and
(ii) a certificate of immunization against measles for all personnel born on or after January 1, 1957 which means:
(a) a document prepared by a physician, physician's assistant, specialist's assistant, nurse practitioner, licensed midwife or a laboratory possessing a laboratory permit issued pursuant to Part 58 of this Title, demonstrating serologic evidence of measles antibodies; or
(b) a document indicating two doses of live virus measles vaccine were administered with the first dose administered on or after the age of 12 months and the second dose administered more than 30 days after the first dose but after 15 months of age showing the product administered and the date of administration, and prepared by the health practitioner who administered the immunization; or
(c) a document, indicating a diagnosis of the employee as having had measles disease prepared by the physician, physician's assistant/specialist's assistant, licensed midwife or nurse practitioner who diagnosed the employee's measles; or
(d) a copy of a document described in clause (a), (b) or (c) of this subparagraph which comes from a previous employer or the school which the employee attended as a student;
(iii) if any licensed physician, physician's assistant, specialist's assistant, licensed midwife or nurse practitioner certifies that immunization with measles and/or rubella vaccine may be detrimental to the employee's health, the requirements of subparagraph (i) and/or (ii) of this paragraph relating to measles and/or rubella immunization shall be inapplicable until such immunization is found no longer to be detrimental to such employee's health. The nature and duration of the medical exemption must be stated in the employee's employment medical record and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the American Academy of Pediatrics and the Immunization Practices Advisory Committee of the U.S. Department of Health and Human Services); and
(iv) ppd (Mantoux) skin test for tuberculosis prior to employment or affiliation and no less than every year thereafter for negative findings. Positive findings shall require appropriate clinical follow-up but no repeat skin test. The medical staff shall develop and implement policies regarding positive outcomes;
(v) documentation of preemployment and annual vaccination(s) against influenza, in accordance with Part 66 of this Title.
(11) the reassessment of the health status of all personnel as frequently as necessary, but no less than annually, to ensure that personnel are free from health impairments which pose potential risk to patients or personnel or which may interfere with the performance of duties;
(12) the provision for emergency health care for all personnel;
(13) the maintenance of medical records for all personnel including the dates, extent and results of all health assessments and physical examinations; the results of laboratory tests and X-ray reports; and records of immunizations, illnesses or injuries;
(14) the requirement that all personnel report immediately to their supervisor any signs or symptoms of personal illness. All personnel making such report shall be referred to an appropriate health care professional for assessment of the potential risk to patients and personnel. Based on this assessment, the hospital shall authorize appropriate measures to be taken, including but not limited to removal, reassignment or return to duty;
(15) the safety and protection of all personnel and advice to personnel concerning the nature of toxic substances which they may encounter in the workplace in the course of their employment or affiliation, in accordance with article 28 of the New York State Labor Law; and
(16) a policy that no hospital employee or member of a hospital medical staff shall be required by the hospital or a member of the hospital staff to participate in an induced termination of pregnancy who has informed the hospital of his or her decision not to participate in such act or acts;
(c) The hospital shall have a written agreement which defines the respective roles and responsibilities of the hospital and any educational program which utilizes the clinical facilities of the hospital for the education of students. Such agreement shall recognize the responsibility of the hospital for activities of the educational program and students which affect the care of patients.
(d) Records and reports. Any information, records or documents provided to the department shall be subject to the applicable provisions of the Public Health Law, Mental Hygiene Law, Education Law, and the Public Officers Law in relation to disclosure. The hospital shall maintain and furnish to the Department of Health, immediately upon written request, copies of all documents, including but not limited to:

1. All records related to patient care and services;
2. The certificate of incorporation or the partnership agreement and, the certificate of conducting business under an assumed name as required by General Business Law, section 130;
3. The reports of hospital inspections and surveys of outside agencies with statements attached specifying the steps taken to correct any hazards or deficiencies or to carry out the recommendations contained therein;
4. All contracts, leases and other agreements entered into by the governing authority pertaining to the ownership of the land, building, fixtures and equipment used in connection with the operation of the hospital;
5. All licenses, permits and certificates required by law for the operation of the hospital and also for those departments and staff members, where required;
6. Operating procedure manuals for all services or units of the hospital organization. These manuals shall be reviewed at least biennially by the hospital or more frequently as determined appropriate by each service or unit and be made available to all services and units of the hospital;
7. All bylaws, rules and regulations of the hospital and all amendments thereto; a listing of the names and addresses and titles of offices held for all members of the governing authority and revisions thereof; a copy of the bylaws, rules and regulations of the medical staff and all amendments of the medical staff and revisions thereof; a copy of the current annual report and financial statements of the hospital;
8. Copies of complaints received regarding patient care and documentation of the follow-up actions taken as a result of the investigation of these complaints;
9. Copies of all incident reports completed pursuant to section 405.8 of this Part;
10. A listing of the names and titles of the members of each committee of the hospital;
11. Written minutes of each committee's proceedings. These minutes shall include at least the following:
   i. Attendance;
   ii. Date and duration of the meeting;
   iii. Synopsis of issues discussed and actions or recommendations made; and
12. Any record required to be kept by the provisions of this Part.

(e) Other reporting requirements.

1. The hospital shall report in writing to the Office of Professional Medical Conduct with a copy to the appropriate area administrator of the department’s Office of Health Systems Management within 30 days of the occurrence of denial, suspension, restriction, termination or curtailment of training, employment, association or professional privileges or the denial of certification of completion of training of any physician, registered physician’s assistant or registered specialist’s assistant licensed/registered by the New York State Department of Education for reasons related in any way to any of the following:
   i. Alleged mental or physical impairment, incompetence, malpractice, misconduct or endangerment of patient safety or welfare;
   ii. Voluntary or involuntary resignation or withdrawal of association or of privileges with the hospital to avoid the imposition of disciplinary measures;
   iii. The receipt of information concerning a conviction of a misdemeanor or felony. The report shall contain:
      a. The name and address of the individual;
      b. The profession and license number;
      c. The date of the hospital's action;
      d. A description of the action taken; and
      e. The reason for the hospital's action or the nature of the action or conduct which lead to the resignation or withdrawal and the date thereof; and
   iv. The hospital shall establish policies and implement procedures to ensure compliance with these reporting requirements.
2. The hospital shall furnish to the Department of Education within 30 days of occurrence, a written report of any denial, withholding, curtailment, restriction, suspension or termination of any membership or professional privileges in, employment by, or any type of association with a hospital
relating to an individual who is a health profession student serving in a clinical clerkship, an unlicensed health professional serving in a clinical fellowship or residency, or an unlicensed health professional practicing under a limited permit or a state licensee, such as an audiologist, certified social worker, dental hygienist, dentist, nurse, occupational therapist, ophthalmic dispenser, optometrist, pharmacist, physical therapist, podiatrist, psychologist, or speech-language pathologist for reasons related in any way to any of the following reasons:

(i) alleged mental or physical impairment, incompetence, malpractice, misconduct or endangerment of patient safety or welfare;
(ii) voluntary or involuntary resignation or withdrawal of association, employment or privileges with the hospital to avoid imposition of disciplinary measures; or
(iii) the receipt of information concerning a conviction of a misdemeanor or felony. The report shall contain:

(a) the name and address of the individual;
(b) the profession and license number;
(c) the date of the hospital's action;
(d) a description of the action taken; and
(e) the reason for the hospital's action or the nature or the action or conduct which lead to the resignation or withdrawal and the date thereof.

(3) At the time that a physician on a hospital's staff is granted admitting privileges or before or at the time the physician admits his or her first patient, each hospital shall furnish to such physician the following notice, which each physician on the hospital staff must sign and date. The signed notices shall be kept on file by the hospital. The notice to physicians shall state:

"Notice to physicians. Payment to hospitals for inpatient services is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, and for neonates, upon birthweight or admission weight as well. This data must be documented by the patient's medical record. Anyone who misrepresents, falsifies, or conceals this information may be subject to fine, imprisonment, or civil penalty under applicable Federal and New York State laws."

(4) At the time of discharge, for categories of patients determined by the commissioner, the chief executive officer shall provide the department information in a manner and on a form specified by the department.

(f) Hospital management contracts.

(1) For the purposes of this Part, a management contract is an agreement between a hospital governing body and a contracting entity for the contracting entity to assume the primary responsibility for managing the day-to-day operations of an entire facility or a defined patient care unit of the facility. A management contract shall not include:

(i) a contract solely for the provision of professional clinical services;
(ii) an employment contract; or
(iii) a contract for the provision of administrative services to a defined patient care unit of a facility where all of the following factors are present:

(a) the hospital retains responsibility for the day-to-day operations of the defined patient care unit;
(b) the contracting entity has no authority to hire or fire any hospital employee;
(c) the contracting entity does not maintain and control the books and records of the defined patient care unit;
(d) the contracting entity has no authority to incur any liability on behalf of the facility; and
(e) the contracting entity has no authority to adopt or enforce policies regarding the operation of the defined patient care unit.

(2) Management contracts shall be effective only with the prior written consent of the commissioner and shall include the following:

(i) a description of the proposed roles of the governing body during the period of the proposed management contract. The description shall clearly reflect retention by the governing authority of ongoing responsibility for statutory and regulatory compliance;
(ii) a provision that clearly recognizes that the responsibilities of the facility's governing body are in no way obviated by entering into a management contract and that any powers not specifically delegated to the contracting entity through the provisions of the contract remain with the governing body; and
(iii) a plan for assuring maintenance of the fiscal stability, the level of services provided and the quality of care rendered by the facility during the term of the management contract.

(3) The governing body shall retain sufficient authority and control to discharge its responsibility under this Part. The following elements of control shall not be delegated to a managing authority:
(i) direct independent authority to appoint and discharge the chief executive officer or other key management employees;
(ii) independent control of the books and records;
(iii) authority over the disposition of assets and the authority to incur on behalf of the facility liabilities not normally associated with the day-to-day operation of a facility; and
(iv) independent adoption of policies affecting the delivery of health care services.

(4) A governing body wishing to enter into a management contract shall submit a proposed written contract to the department, at least 60 days prior to the intended effective date, unless a shorter period is approved in writing by the commissioner, due to extraordinary circumstances. In addition, the governing body shall also submit, within the same time frame, the following:

(i) documentation demonstrating that the proposed managing authority holds all necessary approvals to do business in New York State;

(ii) documentation of the goals and objectives of the management contract including a mechanism for periodic evaluation by the governing body of the effectiveness of the arrangement in meeting those goals and objectives;

(iii) evidence of the managing authority's financial stability;

(iv) information necessary to determine that the character and competence of the proposed managing authority, and its principals, officers and directors, is satisfactory, including evidence that all facilities it has managed in New York State have provided a substantially consistent high level of care in accordance with section 600.2 of this Title, during the term of their management contract or operating certificate; and

(v) evidence that it is financially feasible for the facility to enter into the proposed management contract for the term of the contract and for a period of one year following expiration, recognizing that the costs of the contract are subject to all applicable provisions of Part 86 of this Title. To demonstrate evidence of financial feasibility, the facility shall submit projected operating and capital budgets for the required periods. Such budgets shall be consistent with previous certified financial statements and be subject to future audits.

(5) During the period between a facility's submission of a request for initial approval of a management contract and disposition of that request, a facility may not enter into any arrangement for management contract services other than a written interim consultative agreement with the proposed managing authority. Any interim agreement shall be consistent with the provisions of this section and shall be submitted to the department no later than five days after its effective date.

(6) The term of a management contract shall be limited to three years and may be renewed for additional periods not to exceed three years only when authorized by the commissioner. The commissioner shall approve an application for renewal provided that compliance with this section and the following provisions can be demonstrated:

(i) that the goals and objectives of the contract have been met within specified time frames;

(ii) that the quality of care provided by the facility during the term of the contract has been maintained or has improved; and

(iii) that the level of service to meet community needs and patient access to care and services has been maintained or improved.

(7) A contract for which an application for renewal has been submitted on a timely basis to the commissioner may be extended on an interim basis until the commissioner approves or disapproves the application for renewal.

(8) A facility's governing body shall, within the terms of the contract, retain the authority to discharge the managing authority and its employees from their positions at the facility with or without cause on not more than 90 days' notice. In such event, the facility shall notify the department in writing at the time the managing authority is notified. The facility's governing body shall provide a plan for the operation of the facility subsequent to the discharge to be submitted with the notification to the department.

RESEARCH REFERENCES AND PRACTICE AIDS:
65 NY Jur 2d, Hospitals and Related Health Care Facilities §§ 20(supp), 22(supp), 25(supp).
10 NY ADC 405.3
2008 WL 75295865
10 NY ADC 405.3
The hospital shall have an organized medical staff that operates under bylaws approved by the governing body.

(a) Medical staff accountability. The medical staff shall be organized and accountable to the governing body for the quality of the medical care provided to all patients.

(1) The medical staff shall establish objective standards of care and conduct to be followed by all practitioners granted privileges at the hospital. Those standards shall:
   (i) be consistent with prevailing standards of medical and other licensed health care practitioner standards of practice and conduct; and
   (ii) afford patients their rights as patients in accordance with the provisions of this Part.

(2) The medical staff shall establish mechanisms to monitor the ongoing performance in delivering patient care of practitioners granted privileges at the hospital, including monitoring of practitioner compliance with bylaws of the medical staff and pertinent hospital policies and procedures.

(3) The medical staff shall review and, when appropriate, recommend to the governing body, the limitation or suspension of the privileges of practitioners who do not practice in compliance with the scope of their privileges, medical staff bylaws, standards of performance and policies and procedures, and assure that corrective measures are developed and put into place, when necessary.

(b) Organization.

(1) The medical staff shall be organized in a manner appropriate to the size of the institution and the services provided.

(2) The responsibility for organization and conduct of the medical staff shall be developed and defined in writing in consultation with the medical staff and assigned to the medical director who is a physician appointed by the governing body in accordance with section 405.2(e)(2) of this Part, based upon written qualifications for the position.

(3) The medical staff shall be composed of persons practicing medicine as defined in article 131 of title 8 of the State Education Law, and may also be composed of other licensed and currently registered health care practitioners appointed by the governing body.

(4) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with the provisions of this Part and the New York State Public Health Law. Following the initial appointment of medical staff members, the medical staff shall conduct periodic reappraisals of its members, on at least, a biennial basis.

(5) Medical staff appointments, and reappointments shall be made in accordance with the privilege review procedures of the hospital's quality assurance committee, as contained in section 405.6 of this Part.

(6) In order that the working conditions and working hours of physicians and postgraduate trainees promote the provision of quality medical care, the hospital shall establish the following limits on working hours for certain members of the medical staff and postgraduate trainees:

   (i) In hospitals with over 15,000 unscheduled visits to an emergency service per year, assignment of postgraduate trainees and attending physicians shall be limited to no more than 12 consecutive hours per on-duty assignment in the emergency service. The commissioner may approve alternative schedule limits of up to 15 hours for attending physicians in a hospital emergency service upon a determination that:
      (a) the alternative schedule contributes to the hospital's ability to meet its community's need for quality emergency services;
      (b) the volume of patients examined and treated during the extended period is substantially less than for other hours of the day; and
      (c) adequate rest time is provided between assignments and during each week to prevent fatigue.

   (ii) Effective July 1, 1989, schedules of postgraduate trainees with inpatient care responsibilities shall meet the following criteria:
      (a) the scheduled work week shall not exceed an average of 80 hours per week over a four week period;
      (b) such trainees shall not be scheduled to work for more than 24 consecutive hours;
      (c) for departments other than anesthesiology, family practice, medical, surgical, obstetrical, pediatric or other services which have a high volume of acutely ill patients, and where night calls are infrequent and physician rest time is adequate, the medical staff may develop and document scheduling arrangements other than those set forth in clauses (a) and (b) of this subparagraph; and
(d) "on call" duty in the hospital during the night shift hours by trainees in surgery shall not be included in the 24-limit contained in clause (b) of this subparagraph and the 80-hour limit contained in clause (a) of this subparagraph if:

(1) the hospital can document that during such night shifts postgraduate trainees are generally resting and that interruptions for patient care are infrequent and limited to patients for whom the postgraduate trainee has continuing responsibility;
(2) such duty is scheduled for each trainee no more often than every third night;
(3) a continuous assignment that includes night shift "on call" duty is followed by a nonworking period of no less than 16 hours; and
(4) policies and procedures are developed and implemented to immediately relieve a postgraduate trainee from a continuing assignment when fatigue due to an unusually active "on call" period is observed.

(iii) The medical staff shall develop and implement policies relating to postgraduate trainee schedules which prescribe limits on the assigned responsibilities of postgraduate trainees, including but not limited to, assignment to care of new patients, as the duration of daily on-duty assignments progress.

(iv) In determining limits on working hours of postgraduate trainees as set forth in subparagraphs (i) and (ii) of this paragraph, the medical staff shall require that scheduled on-duty assignments be separated by not less than eight nonworking hours. Postgraduate trainees shall have at least one 24 hour period of scheduled nonworking time per week.

(v) Hospitals employing postgraduate trainees shall adopt and enforce specific policies governing dual employment. Such policies shall require at a minimum, that each trainee notify the hospital of employment outside the hospital and the hours devoted to such employment. Postgraduate trainees who have worked the maximum number of hours permitted in subparagraphs (i)-(iv) of this paragraph shall be prohibited from working additional hours as physicians providing professional patient care services.

(c) Medical staff bylaws. The medical staff shall adopt and enforce bylaws to carry out its responsibilities. The bylaws shall at a minimum:

(1) be approved by the governing body;
(2) include a statement of the obligations and prerogatives of each category of medical staff membership;
(3) describe the organization of the medical staff;
(4) describe the qualifications and performance standards to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;
(5) set forth criteria and procedures for recommending the privileges to be granted to individual practitioners, contain a procedure for applying the criteria and procedures to individuals requesting privileges, and be consistent with the requirements contained in section 405.6 of this Part;
(6) set forth criteria and procedures for determining the need for consultation with a specialist physician to provide for the diagnosis and treatment of patient conditions in accordance with generally accepted standards of patient care. Such criteria and procedures shall not preclude postgraduate trainees, nurses, or other health care practitioners involved in the care of the patient from requesting such consultations in an emergency;
(7) describe the responsibilities of members of the medical staff for participation in the malpractice prevention program and the quality assurance program;
(8) exempt from the requirement to obtain medical staff privileges those practitioners from outside organ procurement organizations designated by the Secretary, U.S. Department of Health and Human Services, engaged solely at the hospital in the harvesting of tissues and/or other body parts for transplantation, therapy, research or educational purposes pursuant to the Federal Anatomical Gift Act and the requirements of section 405.25 of this Part;
(9) exempt from liability by the hospital any physician who shall inform a patient that he or she refuses to give advice with respect to, or participate in, any induced termination of pregnancy; and
(10) set forth criteria and procedures that ensure appropriate and confidential use of electronic or computer transmissions and authentications, including the identification of those categories of practitioners and hospital personnel who are authorized to utilize electronic or computer generated transmissions, if the hospital elects to utilize an electronic or computer system for transmitting or authenticating medical records entries, orders and/or other patient specific records.

d) Dental services.

(1) The attending dentist shall be responsible for the admission, management and discharge of dental patients, including all related written documentation.
The admission history and physical examination for dental patients shall be completed by a dentist qualified to perform a history and physical examination or by another member of the medical staff so qualified. A dentist qualified to perform a history and physical examination shall mean a dentist who:

(i) has successfully completed a postgraduate program of study incorporating training in physical diagnosis at least equivalent to that received by one who has successfully completed a postgraduate program of study in oral and maxillofacial surgery accredited by a nationally recognized body approved by the United States Education Department; and

(ii) as determined by the medical staff, is currently competent to conduct a complete history and physical examination to determine a patient's ability to undergo a proposed dental procedure.

Dental patients with medical comorbidities or complications present upon admission or arising during hospitalization shall be referred to appropriate medical staff for consultation and/or management.

Registered physician's assistants and registered specialist's assistants. Hospitals employing or extending privileges to registered physician's assistants or registered specialist's assistants shall comply with the provisions of this subdivision and Part 94 of this Title.

1. General standards. Hospitals shall:

(i) employ or extend privileges only to registered physician's assistants and registered specialist's assistants who are currently registered with the New York State Education Department;

(ii) designate in writing the licensed and currently registered staff physician or physicians responsible for the supervision and direction of each registered physician's assistant and registered specialist's assistant employed or extended privileges;

(a) no physician shall be designated to supervise and direct more than six registered physician's assistants or registered specialist's assistants or a combination thereof;

(b) when more than one physician is designated as responsible for registered physician's assistants or registered specialist's assistants, written policies and procedures shall delineate the specific physician charged with supervision of care of each patient for whom the registered physician's assistant or registered specialist's assistant is to render care;

(iii) employ or extend privileges only to registered physician's assistants and registered specialist's assistants whose training and experience are within the scope of practice for which the physician or physicians to whom they are assigned are qualified; and

(iv) be approved for providing the specialized medical services for which the registered specialist's assistant is employed or extended privileges and employ and extend privileges only to registered specialist's assistants whose training and experience are appropriate to the delivery of the specialized service.

2. Medical staff responsibility. The medical staff shall adopt, with governing body approval, bylaws, rules and regulations:

(i) which provide formal procedures for the evaluation of the application and credentials of registered physician's assistants and registered specialist's assistants applying for employment or privileges in the facility for the purpose of providing medical services under the supervision of a physician; and

(ii) which set forth in writing, the mechanism or mechanisms by which the supervising physicians shall exercise continuous supervision over the registered physician's assistants or registered specialist's assistants for whom he or she is responsible.

Postgraduate trainees. Patient care services may be provided by physicians in postgraduate training programs accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or an equivalent accrediting agency approved by the New York State Education Department, only if the following conditions are met:

1. all postgraduate trainees prior to entering a postgraduate training program, have received adequate and appropriate medical education as defined in subparagraphs (i) and (ii) of this paragraph:

(i) effective January 1, 1986 and thereafter, hospitals shall permit only the following to be assigned into a postgraduate training position:

(a) a graduate of a medical school offering a medical program accredited by the Liaison Committee on Medical Education or the American Osteopathic Association or registered with the New York State Education Department or by an accrediting organization acceptable to the New York State Education Department; or
(b) a graduate of a foreign medical school who has been certified by the Educational Commission for Foreign Medical Graduates (ECFMG) as meeting the requirements of the ECFMG and has been awarded the ECFMG certificate;

(ii) except for individuals eligible for licensure under section 6528 of the State Education Law, a graduate of a foreign medical school who enrolled in such medical school after October 1, 1983 shall have completed the clinical component of a program of medical education which:

(a) included no more than 12 weeks of clinical clerkships in a country other than the country in which the medical school is located;

(b) included clinical clerkships of greater than 12 weeks in a country other than the country in which the medical school is located if the clinical clerkships were offered by a medical school approved by the State Education Department for the purposes of clinical clerkships;

(2) the medical staff shall review the licensure, education, training, physical and mental capacity, and experience of individuals in approved postgraduate medical training programs in relation to the patient care services to be provided by such individuals in such training programs where such individuals do not otherwise have active medical staff privileges.

(i) such individuals may provide patient care services only as part of a training program accredited by the Accreditation Council for Graduate Medical Education or American Osteopathic Association, or an equivalent training program approved by the State Education Department;

(ii) the medical staff shall, based on written criteria, recommend privileges that are specific to treatments/procedures for each individual in such program prior to delivery of patient care services;

(iii) the medical staff shall develop and implement written policies and procedures which set forth a clear set of principles governing medical practice by postgraduate trainees, including guidelines on circumstances requiring supervision and consultation;

(iv) postgraduate trainee privileges, regardless of whether the individual is full-time, part-time, or rotating status, shall be modified based upon written criteria and individual review and approval of each trainee;

(v) the specific treatments/procedures that each individual is authorized to perform shall be stated in writing and that authorization shall specify:

(a) those treatments/procedures that may be performed under the general control and supervision of the patient's attending physician or another physician credentialed to provide the specific treatment/procedures; and

(b) those that may only be performed under direct visual supervision of the patient's attending physician or another physician credentialed to provide the specific treatment/procedures;

(3) the medical staff monitors and supervises postgraduate trainees assigned patient care responsibilities as part of an approved medical training program including:

(i) providing written documentation of privileges granted to such individuals to appropriate medical and other hospital patient care staff;

(ii) continuously monitoring patient care services provided by such individuals to assure provision of quality patient care services within the scope of privileges granted;

(iii) effective July 1, 1989 for postgraduate trainees in the acute care specialties of anesthesiology, family practice, medicine, obstetrics, pediatrics, psychiatry, and surgery, supervision shall be provided by physicians who are board-certified or admissible in those respective specialties or who have completed a minimum of four postgraduate years of training in such specialty. There shall be a sufficient number of these physicians present in person in the hospital 24 hours per day, seven days per week to supervise the postgraduate trainees in their specific specialties to meet reasonable and expected demand. In hospitals that can document that the patients' attending physicians are immediately available by telephone and readily available in person when needed, the onsite supervision of routine hospital care and procedures may be carried out in accordance with paragraph (2) of this subdivision by postgraduate trainees who are in their final year of postgraduate training, or who have completed at least three years of postgraduate training;

(iv) supervision by attending physicians of the care provided to surgery patients by postgraduates in training must include as a minimum:

(a) personal supervision of all surgical procedures requiring general anesthesia or an operating room procedure;

(b) preoperative examination and assessment by the attending physician; and

(c) postoperative examination and assessment no less frequently than daily by the attending physician;
(v) taking disciplinary action and other corrective measures against the individual providing service and/or the attending/supervising physician when services provided exceed scope of privileges granted; and

(vi) taking disciplinary action or other corrective measures against any individual providing service in violation of the physician's working hour limits set forth in subparagraph (b)(6)(iv) of this section.

(g) Unlicensed physicians. Patient care services may be provided by unlicensed physicians only under the following circumstances:

(1) physicians not licensed by New York State but who practice within the exemptions authorized by section 6526 of the State Education Law; or

(2) physicians who possess limited permits to practice medicine issued by the New York State Education Department pursuant to section 6525 of the State Education Law if such physicians are under the supervision of a physician licensed and currently registered to practice medicine in the State of New York and if the physicians possessing limited permits are:

(i) graduates of medical school offering a medical program accredited by the Liaison Committee on Medical Education or the American Osteopathic Association, or registered with the State Education Department or accredited by an accrediting organization acceptable to the State Education Department, and have satisfactorily completed one year of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department;

(ii) graduates of a foreign medical school and have satisfactorily completed three years of graduate medical education in a postgraduate training program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, their predecessors or successors or an equivalent accrediting agency acceptable to the State Education Department; or

(iii) graduates of a foreign medical school who have satisfactorily completed three years in a postgraduate training program and who are receiving advanced training as part of an official exchange visitor program approved by the United States Information Agency and the Educational Commission for Foreign Medical Graduates (ECFMG);

(3) the medical staff shall:

(i) review the licensure, education, training, physical and mental capacity, and experience of individuals practicing under the provisions of this subdivision;

(ii) based on written criteria, recommend privileges that are specific to treatments/procedures for each individual prior to delivery of patient care services;

(iii) continuously monitor patient care services provided by such individuals to assure provision of quality patient care services within the scope of privileges granted; and

(iv) take disciplinary action or other corrective measures against the individual providing service and/or the attending/supervising physician when services provided exceed the scope of privileges granted.

(h) Medical students. Medical students, in the course of their educational curriculum, may take patient histories, perform complete physical examinations and enter findings in the medical record of the patient with the approval of the patient's attending physician. All medical student entries must be countersigned within 24 hours by an appropriately privileged physician. Medical students may be assigned and directed to provide additional patient care services under the direct in person supervision of an attending physician or authorized postgraduate trainee. The hospital, in cooperation with the medical staff and the medical school, shall provide such appropriate supervision and documentation of all procedures performed by medical students. In addition, specific identified procedures may be performed by medical students under the general supervision of an attending physician or authorized senior postgraduate trainee provided that the medical staff and the medical school affirm in writing each individual student's competence to perform such procedures. Documentation of supervision and competence of medical students shall be incorporated into the quality assurance program of the hospital and its affiliation agreement with the medical school. In all such patient care contacts, the patient shall be made aware that the individual performing the procedure is a student.

(i) Autopsies. The medical staff shall attempt to secure permission for autopsies in all cases of unusual deaths and deaths of medical-legal and educational value. The mechanism for documenting permission to perform an autopsy shall be defined in writing. There shall be a system for notifying the medical staff, and specifically the attending physician, when an autopsy is to be performed.

RESEARCH REFERENCES AND PRACTICE AIDS:
65 NY Jur 2d, Hospitals and Related Health Care Facilities §§ 20(supp),
Section 405.5.* Nursing services.

The governing body shall ensure that the hospital has an organized nursing service that provides 24-hour services and that meets the care needs of all patients in accordance with established standards of nursing practice. The nursing services for all patients shall be provided or supervised by a registered professional nurse who is on duty and available at all times.

(a) Organization and staffing.

(1) The hospital shall have a written nursing service plan of administrative authority and delineation of responsibilities. The director of the nursing service shall be a licensed registered professional nurse who is qualified by training and experience for such position. He or she shall be responsible for the operation of the service, including developing a plan to be approved by the hospital for determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(2) The hospital shall employ licensed and currently registered professional nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. The hospital shall provide supervisory and staff personnel for each department or nursing unit to ensure, when needed in accordance with generally accepted standards of nursing practice, the immediate availability of a registered professional nurse for bedside care of any patient.

(3) Job descriptions for each position classification of registered professional nurses and ancillary nursing personnel shall specify standards of performance and delineate the functions, responsibilities, and specific qualifications of each classification.

(4) A written evaluation of the performance, credentials, and competence of registered professional nurses and ancillary nursing personnel shall be conducted on at least a biennial basis.

(5) When nursing services are provided by nursing students, nurses with limited permits, or by personnel from outside sources, the hospital shall retain full responsibility for the quality of nursing care rendered in the hospital.

(i) Nursing students, nurses with limited permits, and registered professional nurses from outside sources who are working in the hospital shall adhere to the policies and procedures of the hospital.

(ii) The director of nursing services shall provide for the supervision and evaluation of the clinical activities of all nursing personnel.

(6) All nursing services personnel, including nursing students and nonemployee licensed nurses who are working in the hospital, shall receive a basic orientation to prepare them for their specific duties and responsibilities prior to performing any nursing functions within a patient care area. For employee nurses and nursing students, the hospital shall provide or arrange for the provision of training programs to augment their knowledge of pertinent new developments in patient care. The hospital shall also require that nonemployee licensed nurses obtain education and training pertinent to the clinical duties to which they are assigned.

(b) Delivery of services.

(1) There shall be working relationships among medical staff, nursing staff and staff of other departments or services to assure that all patient care needs are met.

(i) Nursing services personnel shall execute the orders of physicians and other practitioners, authorized by the governing body to order such services.

(ii) Registered professional nurses shall confer with the responsible practitioner relative to patient care on an ongoing basis and relative to significant changes in the patient’s condition as necessary.

(iii) The hospital shall develop and implement policies and procedures for prompt review and correction, as necessary, of health care practitioner orders which have, or have the likely potential for having, negative impact on patient care and safety and which should not be carried out.

(2) There shall be continuous review and evaluation of the adequacy and appropriateness of nursing care provided for patients.

(i) Nursing care policies and procedures shall be written and consistent with generally accepted standards of nursing practice.

(ii) A registered professional nurse shall plan, supervise, and evaluate the nursing care for each patient. A registered professional nurse shall assign the nursing care of each patient to other nursing
personnel in accordance with the patient's needs and the preparation and competence of such other nursing personnel.

(3) Written nursing care plans shall be kept current. Such plans shall indicate what nursing care is needed, how it is to be provided, and the methods, approaches and mechanisms for ongoing modifications necessary to ensure the most effective and beneficial results for the patient. Patient education and patient/family knowledge of care requirements shall be included in the nursing plan.

(4) Nursing documentation shall describe the nursing care given and include information and observations of significance so that they contribute to the continuity of patient care. Nursing interventions and patient responses shall be documented.

(c) Administration of drugs. All drugs and biologicals shall be administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care as specified under section 405.2 of this Part, and generally accepted standards of practice. They shall be administered by a licensed physician or a registered professional nurse, or other personnel in accordance with applicable licensing requirements of title 8 of the New York State Education Law and in accordance with approved hospital policies and procedures.

(1) All orders for drugs and biologicals shall be authenticated by the practitioner or practitioners responsible for the care of the patient as specified under section 405.2 of this Part.

(2) Blood transfusions and intravenous medications shall be administered in accordance with approved medical staff and nursing service policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than physicians, such personnel shall have completed specific training to prepare them for this duty.

(3) There shall be a hospital procedure and nursing policies and procedures for the reporting and review of transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(d) Nasogastric tube feedings. Following consideration of possible alternatives for short-term nutritional therapy, nasogastric tubes and feeding formulations may be used for feeding purposes when determined clinically appropriate by the attending practitioner. Nasogastric tube feedings shall be used to promote a therapeutic program to maintain adequate nutrition and hydration and include a plan to help the patient develop or regain eating skills.

(1) Nasogastric tube feeding formulations shall be given in accordance with the manufacturer's instructions or at a rate appropriate to the physical size of the resident and the amount of fluid and nutrients necessary to meet the assessed caloric and fluid needs of the patient.

(2) To minimize patient discomfort, nasogastric tubes used for patient feeding purposes shall:
   (i) be the smallest gauge appropriate for the patient and shall not exceed 3.96 millimeters (#12 French) in outside diameter unless medically indicated;
   (ii) be made of a soft, flexible material such as medical grade polyurethane or silicone; and
   (iii) be specifically manufactured for nasogastric feeding purposes.

(3) Patients receiving nasogastric tube feedings shall be periodically evaluated for the ability to return to normal feeding function. If nasogastric feedings are to be continued longer than three months, permanent enteral feeding procedures such as surgical gastrostomy or jejunostomy shall be considered. If the nasogastric feeding is continued, the reasons for continuation shall be documented in the patient's medical record.

(4) The facility shall develop and implement policies and procedures for inpatient nasogastric tube feedings which are written in accordance with prevailing standards of professional practice and in consultation with the medical, nursing, dietary and pharmacy services of the facility. Medical practitioners shall be informed of such policies and procedures governing the use of nasogastric tubes for patient feeding. The policies and procedures shall address as a minimum:
   (i) types and sizes of nasogastric tubes and the various types of feeding formulations available at the facility;
   (ii) the need to assess each patient's clinical and nutritional status to determine the size of the nasogastric tube and type of feeding appropriate for that individual;
   (iii) standard techniques for inserting a nasogastric tube and confirming the correct placement of the tube;
   (iv) procedures for administering nasogastric feedings including positioning the patient and the need for patient observation and monitoring before, during and following the feeding; and
   (v) infection control practices related to tube feedings.

(e) Quality assurance. The nursing service shall monitor and evaluate the quality and appropriateness of patient care and the resolution of identified problems. This process shall be integrated with the quality assurance committee in accordance with hospital policies and procedures.
(1) Nursing service personnel shall meet as often as necessary to identify and resolve problems and potential problems in the provision of nursing care, taking into consideration the findings from relevant nursing care monitoring and evaluation activities.

(2) Documentation of such reviews shall include findings, conclusions, recommendations and actions taken in conjunction with the hospital-wide quality assurance program and shall be maintained for review and analysis.

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* Section 405.6.* Quality assurance program.

The governing body shall establish and maintain a coordinated quality assurance program which integrates the review activities of all hospital services to enhance the quality of patient care and identify and prevent medical, dental and podiatric malpractice.

(a) The governing body shall establish a quality assurance committee, at least one member to be a member of the governing body of the hospital and who is not otherwise affiliated with the hospital in an employment or contractual capacity. The quality assurance committee shall report its activities, findings and recommendations to the governing body as often as necessary, but no less often than four times a year. The quality assurance committee shall:

(1) develop a written plan which details:
   (i) the establishment and implementation of a medical, dental and podiatric malpractice prevention program;
   (ii) the manner in which the committee will relate to the medical staff executive committee, if any, the hospital governing body and the chief executive officer;
   (iii) the manner in which the medical, dental and podiatric malpractice program will relate to other hospital administrative mechanisms and procedures;
   (iv) the role and responsibility of each service or department in the quality assurance process; and
   (v) the authority of the committee regarding recommendation or implementation of corrective action;

(2) administer the hospital quality assurance program to assure:
   (i) the identification of actual or potential problems concerning patient care and clinical performance;
   (ii) the assessment of the cause and scope of problems identified;
   (iii) the development and recommendation of proposed courses of action to address problems identified;
   (iv) the use, in the revision of hospital policies and procedures, of information gathered regarding problems identified;
   (v) the implementation, through established mechanisms, of actions necessary to correct the identified problems;
   (vi) the monitoring and evaluation of actions taken and the implementation of remedial action to ensure effectiveness; and
   (vii) the documentation of all measures taken pursuant to this section in the quality assurance program.

(b) The activities of the quality assurance committee shall involve all patient care services and shall include, as a minimum:

(1) review of the care provided by the medical and nursing staff and by other health care practitioners employed by or associated with the hospital;
(2) review of mortalities;
(3) review of morbidity in circumstances other than those related to the natural course of disease or illness;
(4) review of infections, complications, errors in diagnosis, transfusions and results of treatments;
(5) review of medical records, medical care evaluation studies, complaints, incidents and staff suggestions regarding patient care and safety, utilization review findings, profile analysis and other pertinent data sources;
(6) the maintenance and continuous collection of information concerning the hospital's experience with negative health care outcomes and incidents injurious to patients, patient grievances,
professional liability premiums, settlements, awards, costs incurred by the hospital for patient injury prevention and safety improvement activities; and

(7) the committee shall oversee and coordinate the following:

(i) the establishment of a medical, dental and podiatric staff privileges review procedure through which credentials, physical and mental capacity, and competence in delivering health care services are reviewed at least biennially as part of an evaluation of staff privileges and in accordance with section 405.4 of this Part. These procedures shall include the collection of the following information from a physician, dentist or podiatrist prior to granting or renewing professional privileges or association in any capacity with the hospital:

(a) the name of any hospital or facility with which the physician, dentist or podiatrist has had any association, employment, privileges or practice and, if such association, employment, privileges or practice have been suspended, restricted, terminated, curtailed or not renewed, the reasons for such action;

(b) the substance of any pending malpractice actions or professional misconduct proceedings in this or any other state and any report made pursuant to section 405.3(e) of this Part;

(c) any judgment or settlement of any professional malpractice action and any finding of professional misconduct in this or any other state; and

(d) any information relative to findings pertinent to violations of patients' rights as set forth in section 405.7 of this Part;

(ii) upon initial application for or renewal of hospital staff privileges, the receipt of a waiver by the physician, dentist or podiatrist of any confidentiality provisions concerning the information set forth in subparagraph (i) of this paragraph and a sworn statement by the physician, dentist or podiatrist that the information is complete, true and accurate;

(iii) prior to granting or renewing privileges or association to any physician, dentist, or podiatrist, or hiring a physician, dentist or podiatrist, the hospital shall request from any hospital with or at which such physician, dentist or podiatrist has or had privileges, was associated or was employed during at least the preceding 10 years the following information concerning the physician, dentist or podiatrist:

(a) any pending professional misconduct proceedings or any professional malpractice actions in New York or another state;

(b) any judgment or settlement of a malpractice action and any finding of professional misconduct in New York or another state; and

(c) any information required to be reported by hospitals pursuant to section 405.3(e) of this Part;

(iv) the provision by the hospital, within 45 days, in response to requests from any other hospital or facility performing credentials review for medical staff appointment or reappointment, of information related to the physician's, dentist's, or podiatrist's professional practice within the facility for at least 10 years;

(v) the maintenance of a file on each physician, dentist and podiatrist granted privileges or otherwise associated with the hospital which shall contain the information collected pursuant to subparagraphs (i) through (iii) of this paragraph, to be updated at least on a biennial basis, and all other relevant information gathered in accordance with the hospital's quality assurance program and as required by this section;

(vi) a biennial review of credentials, physical and mental capacity and competence in delivering health care services of all clinical staff who are employed or associated with the hospital which for physicians, dentists and podiatrists shall include a comprehensive review of the information maintained in accordance with subparagraph (v);

(vii) a procedure for the prompt resolution of grievances by patients or their representatives related to accidents, injuries, treatment and other events that may result in claims of medical, dental or podiatric malpractice;

(viii) education programs dealing with patient safety, patients' rights, injury prevention, staff responsibility to report professional misconduct, legal aspects of patient care, improved communication with patients and causes of malpractice claims for staff personnel engaged in patient care activities; and

(ix) continuing education programs for medical, dental and podiatric staff in their areas of speciality.
The hospital shall ensure that all patients including inpatients, outpatients and emergency service patients, are afforded their rights as set forth in subdivision (b) of this section. The hospital’s responsibility for assuring patients’ rights includes both providing patients with a copy of these rights as set forth in subdivision (c) of this section and providing assistance to patients to understand and exercise these rights. Each general hospital patient who has been removed but not discharged from a hospital for the mentally ill operated or licensed under the Mental Hygiene Law shall maintain his or her status and rights as a patient pursuant to article 9 of the State Mental Hygiene Law and 14 NYCRR Part 527 (Rights of Patients).

(a) Procedural requirements. In order to assure that patients are made aware of, understand and can exercise their rights, the hospital shall meet the following requirements:

1. each patient or the patient representative shall be given a copy of their rights as set forth in subdivision (c) of this section at the time of admission;
2. for outpatients and emergency service patients, copies of these rights shall be provided to each patient or his/her representative;
3. a copy of these rights shall also be posted in clearly viewed areas of the hospital, at readable heights, including the admitting office, patient floors and outpatient department and the emergency service waiting areas;
4. inservice training shall be provided to all patient care staff to assure their knowledge and understanding of patients’ rights requirements;
5. the hospital shall communicate effectively to each inpatient or patient representative after admission an explanation of those rights and provide information on how these rights can be exercised. Patients shall be offered a choice at admission to have or to decline an in-person explanation of these rights. The hospital shall maintain documentation of such communication;
6. the hospital shall make available designated staff to answer questions regarding patients’ rights for outpatients and emergency service patients. Patients shall be notified of the availability of these services; and
7. the hospital shall develop a language assistance program to ensure meaningful access to the hospital’s services and reasonable accommodation for all patients who require language assistance. Program requirements shall include:
   (i) the designation of a language assistance coordinator who shall report to the hospital administration and who shall provide oversight for the provision of language assistance services;
   (ii) policies and procedures that assure timely identification and ongoing access for patients in need of language assistance services;
   (iii) the development of materials that will be made available for patients and potential patients that summarize the process and method to access free language assistance services;
   (iv) ongoing education and training for administrative, clinical and other employees with direct patient care contact regarding the importance of culturally and linguistically competent service delivery and how to access the hospital’s language assistance services on behalf of patients;
   (v) signage, as designated by the Department of Health, regarding the availability of free language assistance services in public entry locations and other public locations;
   (vi) identification of language of preference and language needs of each patient upon initial visit to the hospital;
   (vii) documentation in the medical record of the patient’s language of preference, language needs, and the acceptance or refusal of language assistance services;
   (viii) a provision that family members, friends, or non-hospital personnel may not act as interpreters, unless:
      (a) the patient agrees to their use;
      (b) free interpreter services have been offered by the hospital and refused; and
      (c) issues of age, competency, confidentiality, or conflicts of interest are taken into account. Any individual acting as an interpreter should be 16 years of age or older; individuals younger than 16 years of age should only be used in emergent circumstances and their use documented in the medical record;
   (ix) management of a resource of skilled interpreters and persons skilled in communicating with vision and/or hearing-impaired individuals;
      (a) interpreters and persons skilled in communicating with vision and/or hearing-impaired individuals shall be available to patients in the inpatient and outpatient setting within 20 minutes and to patients in the emergency service within 10 minutes of a request to the hospital administration by the patient, the patient’s family or representative or the provider of medical care. The Commissioner
of Health may approve time limited alternatives to the provisions of this subparagraph regarding interpreters and persons skilled in communicating with vision and/or hearing-impaired individuals for patients of rural hospitals; which:
(1) demonstrate that they have taken and are continuing to take all reasonable steps to fulfill these requirements but are not able to fulfill such requirements immediately for reasons beyond the hospital's control; and
(2) have developed and implemented effective interim plans addressing the communications needs of individuals in the hospital service area;
(x) an annual needs assessment utilizing demographic information available from the United States Bureau of the Census, hospital administrative data, school system data, or other sources, that will identify limited English-speaking groups comprising more than one percent of the total hospital service area population. Translations/transcriptions of significant hospital forms and instructions shall be regularly available for the languages identified by the needs assessment; and
(xi) reasonable accommodation for a family member or patient's representative to be present to assist with the communication assistance needs for patients with mental and developmental disabilities.
(b) Hospital responsibilities. The hospital shall afford to each patient the right to:
(1) exercise these rights regardless of the patient's language or impairment of hearing or vision. Skilled interpreters shall be provided to assist patients in using these rights;
(2) treatment without discrimination as to race, color, religion, sex, national origin, disability, sexual orientation, or source of payment;
(3) considerate and respectful care in a clean and safe environment;
(4) receive emergency medical care as indicated by the patient's medical condition upon arrival at the hospital;
(5) limit the use of physical restraints to those patient restraints authorized in writing by a physician after a personal examination of the patient, for a specified and limited period of time to protect the patient from injury to himself or to others. In an emergency, the restraint may be applied only by or under the supervision of and at the direction of a registered professional nurse who shall set forth in writing the circumstances requiring the use of restraints. In such emergencies, a physician shall be immediately summoned and pending the arrival of the physician, the patient shall be kept under continuous supervision as warranted by the patient's physical condition and emotional state. At frequent intervals while restraints are in use the patient's physical needs, comfort and safety shall be monitored. An assessment of the patient's condition shall be made at least once every 30 minutes or at more frequent intervals if directed by a physician;
(6) the name of the medical staff member who has the responsibility for coordinating his/her care and the right to discuss with his/her practitioner the type of care being rendered;
(7) the name, position and function of any person providing treatment to the patient;
(8) obtain from the responsible medical staff member complete current information concerning his/her diagnosis, treatment and prognosis in terms the patient can be reasonably expected to understand. The patient shall be advised of any change in health status, including harm or injury, the cause for the change and the recommended course of treatment. The information shall be made available to an appropriate person on the patient's behalf and documented in the patient's medical record, if the patient is not competent to receive such information;
(9) receive information necessary to give informed consent prior to the start of any nonemergency procedure or treatment or both. An informed consent shall include, as a minimum, the specific procedure or treatment or both, the reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatment, if any, as a reasonable practitioner under similar circumstances would disclose. Documented evidence of such informed consent shall be included in the patient's medical record;
(10) refuse treatment to the extent permitted by law and to be informed of the reasonably foreseeable consequences of such refusal;
(11) receive from the responsible medical staff or designated hospital representatives information necessary to give informed consent prior to the withholding of medical care and treatment;
(12) privacy consistent with the provision of appropriate care to the patient;
(13) confidentiality of all information and records pertaining to the patient's treatment, except as otherwise provided by law;
(14) a response by the hospital, in a reasonable manner, to the patient's request for services customarily rendered by the hospital consistent with the patient's treatment;
be informed by the responsible medical staff member or appropriate hospital staff of the patient's continuing health care requirements following discharge, and before any transfer to another facility, all relevant information about the need for and all reasonable alternatives to such a transfer; prior to discharge, receive an appropriate written discharge plan and a written description of the patient discharge review process available to the patient under Federal or State law; the identity of any hospital personnel including students that the hospital has authorized to participate in the patient's treatment and the right to refuse treatment, examination and/or observation by any personnel; refuse to participate in research and human experimentation in accordance with Federal and State law; examine and receive an explanation of his/her bill, regardless of source of payment; be informed of the hospital rules and regulations that apply to a patient's conduct; be admitted to a nonsmoking area; register complaints and recommend changes in policies and services to the facility's staff, the governing authority and the New York State Department of Health without fear of reprisal; express complaints about the care and services provided and to have the hospital investigate such complaints. The hospital shall provide the patient or his/her designee with a written response if requested by the patient indicating the findings of the investigation. The hospital shall notify the patient or his/her designee that if the patient is not satisfied with the hospital's oral or written response, the patient may complain to the New York State Department of Health's Office of Health Systems Management. The hospital shall provide the telephone number of the local area office of the Health Department to the patient; obtain access to his/her medical record pursuant to the provisions of Part 50 of this Title. The hospital may impose reasonable charges for all copies of medical records provided to patients, not to exceed costs incurred by the hospital. A patient shall not be denied a copy of his/her medical record solely because of inability to pay; and receive supportive services to meet the changing care needs of the patient and the patient's family/representative provided by qualified individuals who collectively have expertise in assessing the special needs of hospital patients and their families. (c) Patients' Bill of Rights. For purposes of subdivision (a) of this section, the hospital shall utilize the following Patients' Bill of Rights:

Patients' Bill of Rights

As a patient in a hospital in New York State, you have the right, consistent with law, to:
(1) Understand and use these rights. If for any reason you do not understand or you need help, the hospital must provide assistance, including an interpreter.
(2) Receive treatment without discrimination as to race, color, religion, sex, national origin, disability, sexual orientation, or source of payment.
(3) Receive considerate and respectful care in a clean and safe environment free of unnecessary restraints.
(4) Receive emergency care if you need it.
(5) Be informed of the name and position of the doctor who will be in charge of your care in the hospital.
(6) Know the names, positions, and functions of any hospital staff involved in your care and refuse their treatment, examination or observation.
(7) A no smoking room.
(8) Receive complete information about your diagnosis, treatment and prognosis.
(9) Receive all the information that you need to give informed consent for any proposed procedure or treatment. This information shall include the possible risks and benefits of the procedure or treatment.
(10) Receive all the information you need to give informed consent for an order not to resuscitate. You also have the right to designate an individual to give this consent for you if you are too ill to do so. If you would like additional information, please ask for a copy of the pamphlet. Do Not Resuscitate Orders--A Guide for Patients and Families.
(11) Refuse treatment and be told what effect this may have on your health.
(12) Refuse to take part in research. In deciding whether or not to participate, you have the right to a full explanation.
(13) Privacy while in the hospital and confidentiality of all information and records regarding your care.

(14) Participate in all decisions about your treatment and discharge from the hospital. The hospital must provide you with a written discharge plan and written description of how you can appeal your discharge.

(15) Review your medical record without charge and obtain a copy of your medical record for which the hospital can charge a reasonable fee. You cannot be denied a copy solely because you cannot afford to pay.

(16) Receive an itemized bill and explanation of all charges.

(17) Complain without fear of reprisals about the care and services you are receiving and to have the hospital respond to you and if you request it, a written response. If you are not satisfied with the hospital’s response, you can complain to the New York State Health Department. The hospital must provide you with the Health Department telephone number.

(18) Authorize those family members and other adults who will be given priority to visit consistent with your ability to receive visitors.

(19) Make known your wishes in regard to anatomical gifts. You may document your wishes in your health care proxy or on a donor card, available from the hospital.

RESEARCH REFERENCES AND PRACTICE AIDS:
52 NY Jur 2d, Employment Relations § 504(supp).
10 NY ADC 405.7
10 NY ADC 405.7
2008 WL 75295869
10 NY ADC 405.7

* Section 405.8.* Incident reporting.

(a) Any incident required to be reported pursuant to subdivision (b) of this section shall be reported to the department’s Office of Health Systems Management on a telephone number maintained for such purpose. Hospitals shall report such incidents within 24 hours of when the incident occurred or when the hospital has reasonable cause to believe that such an incident has occurred and shall take no more than seven calendar days to determine whether an incident defined in paragraph (b)(1) of this section is reportable and subject to the requirements of this section. The hospital shall give written notification within seven calendar days of the initial notification. This notification shall be submitted in a format specified by the department and shall record the nature, classification and location of the incident; medical record numbers of all patients directly affected by the incident; the full name and title of physicians and hospital staff directly involved in the incident as well as their license, permit, certification or registration numbers; the effect of the incident on the patient; follow-up treatments and evaluations planned; the expected completion date for the hospital’s investigation and identification information required by the department.

(b) Incidents to be reported are:
   (1) patients’ deaths in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards. Injuries and impairments of bodily functions, in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards and that necessitate additional or more complicated treatment regimens or that result in a significant change in patient status, shall also be considered reportable under this subdivision;
   (2) fires or internal disasters in the facility which disrupt the provision of patient care services or cause harm to patients or personnel;
   (3) equipment malfunction or equipment user error during treatment or diagnosis of a patient which did or could have adversely affected a patient or personnel;
   (4) poisoning occurring within the facility;
   (5) patient elopements and kidnappings;
   (6) strikes by personnel;
   (7) disasters or other emergency situations external to the hospital environment which affect facility operations; and
   (8) unscheduled termination of any services vital to the continued safe operation of the facility or to the health and safety of its patients and personnel, including but not limited to the termination of
telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food, or contract services.

c) The hospital shall conduct an investigation of incidents described in paragraphs (b)(1)-(6) of this section and those incidents in paragraphs (7)-(9) deemed appropriate by the department.

d) The hospital shall provide a copy of its investigative report to the area administrator within 24 hours of its completion. This report shall document all hospital efforts to identify and analyze the circumstances surrounding the incident and to develop and implement appropriate measures to improve the overall quality of patient care. This report shall contain all information required by the department including:

1. an explanation of the circumstances surrounding the incident;
2. an updated assessment of the effect of the incident on the patient(s);
3. a summary of current patient status including follow-up care provided and post-incident diagnosis;
4. a chronology of steps taken to investigate the incident that identifies the date(s) and person(s) or committee(s) involved in each review activity;
5. the identification of all findings and conclusions associated with the review of the incident;
6. summaries of any committee findings and recommendations associated with the review of the incident; and
7. a summary of all actions taken to correct identified problems, to prevent recurrence of the incident and/or to improve overall patient care and to comply with other requirements of this Part.

e) This section does not replace other reporting required by this Part.

f) Nothing in this section shall prohibit the department from investigating any incident included in subdivision (b) of this section.

10 NY ADC 405.8
2008 WL 75295870
10 NY ADC 405.8

*Section 405.9.* Admission/discharge.

(a) General.

1. The governing body shall establish and implement written admission and discharge policies to protect the health and safety of the patients and shall not assign or delegate the functions of admission and discharge to any referral agency and shall not permit the splitting or sharing of fees between a referring agency and the hospital.

(b) Admission.

1. Each patient shall be advised of their rights pursuant to section 405.7 of this Part and, as appropriate, the criteria for Medicaid eligibility.

2. No person shall be denied admission to the hospital because of race, creed, national origin, sex, disability within the capacity of the hospital to provide treatment, sexual orientation or source of payment.

3. Except in emergencies, patients shall be admitted only upon referral and under the care of a licensed and currently registered practitioner who is granted admitting privileges by the governing body. The patient's condition and provisional diagnosis shall be established on admission by the patient's admitting practitioner and shall be noted in the patient's medical record.

4. Except in emergencies, a hospital shall admit as patients only those persons who require the type of medical services authorized by the hospital's operating certificate.

5. Except as provided in section 405.2(f)(4) of this Part, the hospital shall have a licensed and currently registered physician, or a registered physician's assistant under the general supervision of a physician, or a nurse practitioner in collaboration with a physician, available on the premises at all times who shall be responsible for receiving patients for care in accordance with policies established by the hospital and for the appropriate disposition of requests to admit patients.

6. Insofar as it is practicable, the admitting practitioner shall request of each person being admitted, information concerning signs or symptoms of recent exposure to communicable diseases as defined in Part 2 of this Title. Whenever there are positive findings of exposure to such communicable disease, the patient shall be isolated and managed in accordance with the hospital's infection control policies and the provisions of Part 2 of this Title.

(i) The facility shall establish a separate pediatric unit if the hospital regularly has 16 or more pediatric patients or if pediatric patients cannot be adequately and safely cared for in other than separately certified pediatric beds.

(ii) Hospitals maintaining certified pediatric beds shall assure that admission to those beds is limited to patients who have not yet reached their 21st birthday except in instances when there are no other available beds within the hospital. In such instances, the hospital shall afford priority admission to the pediatric bed to patients 20 years of age or younger.

(iii) Children under the age of 14 shall not be admitted to a room with patients 21 years of age or over except with the knowledge and agreement of the child's attending practitioner and parent or guardian and the concurrence of the other patients occupying the room and their attending practitioners.

(iv) Infants shall not be kept in the same nursery or room with older children or with any adult patient unless their own healthy mothers occupy the same room and the concurrence of the other patients and their attending practitioners has been obtained.

(v) In the event a separate unit is not available, arrangements for the admission of all children shall be made consistent with written policies and procedures to ensure the safety of each patient.

8 The hospital shall require that a member of the medical staff who has privileges to admit patients shall assume the principal obligation and responsibility for managing the patient's medical care. Postgraduate trainees and supervising physicians shall consult with and be directed by the attending practitioner with regard to therapeutic decisions and changes in patient status. Direct patient care may be provided by postgraduate trainees and medical students, within their permitted scope of responsibility and privileges with supervision as required in section 405.4 of this Part with the concurrence of the attending practitioner. Occurrence of urgent or emergent situations may preclude the attending or admitting practitioner from direct participation in decisionmaking regarding patient care. In such circumstances, the supervising physician shall concur in the decision, and the attending practitioner shall be notified as soon as possible. Responsibility for such decisions made in the absence of consultation with the responsible attending practitioner resides with the involved postgraduate trainees and supervising physicians.

9 The hospital shall provide for the assignment, management, and disposition of patients who are not admitted as private patients of members of the medical staff. The hospital shall develop and implement policies and procedures which provide for the continuity of care of such patients and shall include a procedure by which each patient is assigned to a member of the medical staff, who shall be the personal practitioner to the patient and assume professional responsibility for his/her care in the hospital and for a proper plan of care after discharge.

10 No hospital shall be required to admit any patient for the purpose of performing an induced termination of pregnancy, nor shall any hospital be liable for its failure or refusal to participate in any such act, provided that the hospital shall inform the patient of its decision not to participate in such an act or acts. The hospital in such event shall inform the patient of appropriate resources for services or information.

11 A complete and permanent record shall be maintained of all patients admitted, including but not limited to the date and time of admission, name and address, date of birth, the next of kin or sponsor, veteran status (insofar as these are obtainable), the admitting diagnosis, condition, the name of the referring practitioner, the hospital attending practitioner or service, and as to discharge, the date and time, condition and principal diagnosis.

(i) If a patient is identified as a veteran, the hospital shall notify such veteran of the possible availability of services at a hospital operated by the Veteran's Administration. For the purposes of this paragraph, a veteran shall be defined as a person who served in the United States Military, who received a discharge other than a dishonorable discharge and who is eligible for benefits provided by the Veteran's Administration.

(ii) If a patient eligible for transfer to a hospital operated by the Veteran's Administration requests such transfer, hospital staff shall make such arrangements. Transfer shall be effected in accordance with paragraph (f)(7) of this section.

12 Every patient shall have a complete history and physical examination performed by an appropriately credentialed practitioner within seven days before or 24 hours after admission. If recorded in the patient's medical record by an individual other than the attending practitioner, the history and physical examination shall be reviewed and countersigned by the attending practitioner.

(i) Such examination shall include a screening uterine cytology smear on women 21 years of age and over, unless such test is medically contraindicated or has been performed within the previous
three years, and palpation of breast, unless medically contraindicated, for all women over 21 years of age. These examinations shall be recorded in the medical record.

(ii) Insofar as it is possible to identify patients who may be susceptible to sickle cell anemia, all such presumptively susceptible patients, including infants over six months of age, shall be examined for the presence of sickle cell hemoglobin unless such test has been previously performed and the results recorded in the patient's medical record or otherwise satisfactorily recorded, such as on an identification card.

(13) No patient 18 years of age or older shall be detained in a hospital against his will, nor shall a minor be detained against the will of his parent or legal guardian, except as authorized by law. This provision shall not be construed to preclude or prohibit attempts to persuade a patient to remain in the hospital in his/her own interest, nor the temporary detention of a mentally disturbed patient for the protection of himself/herself or others, pending prompt legal determination of his/her rights. In no event shall a patient be detained solely for nonpayment of his/her hospital bill or practitioner's statement for medical services.

(14) The hospital shall adopt and make public the following admission notices to be provided to all patients receiving inpatient hospital care. Medicare patients shall be given the notice set forth in subparagraph (i) and all other inpatients shall be given the notice set forth in subparagraph (ii) of this paragraph.

(i) Hospital Admission Notice for Medicare Patients
You have the following rights under the New York State law:

Before you are discharged, you must receive a written Discharge Plan. You or your representative have the right to be involved in your discharge planning.

Your written Discharge Plan must describe the arrangements for any future health care that you may need after discharge. You may not be discharged until the services required in your written Discharge Plan are secured or determined to be reasonably available.

If you do not agree with the Discharge Plan or believe the services are not reasonably available, you may call the New York State Health Department to investigate your complaint and the safety of your discharge. The hospital must provide you with the Health Department's telephone number if you ask for it.

For important information about your rights as a Medicare patient, see the "IMPORTANT MESSAGE FROM MEDICARE," which you must receive when admitted to a hospital.

(ii) Hospital Admission Notice
An Important Message Regarding Your Rights as a Hospital Inpatient
Your Rights While a Hospital Patient

You have the right to receive all of the hospital care that you need for the treatment of your illness or injury. Your discharge date is determined only by YOUR health care needs, not by your DRG category or your insurance.

You have the right to be fully informed about decisions affecting your care and your insurance coverage. ASK QUESTIONS. You have the right to designate a representative to act on your behalf.

You have the right to know about your medical condition. Talk to your doctor about your condition and your health care needs. If you have questions or concerns about hospital services, your discharge date or your discharge plan, consult your doctor or a hospital representative (such as the nurse, social worker, or discharge planner).

Before you are discharged you must receive a written DISCHARGE NOTICE and a written DISCHARGE PLAN. You and/or your representative have the right to be involved in your discharge planning.

You have the right to appeal the written discharge plan or notice you receive from the hospital. IF YOU THINK YOU ARE BEING ASKED TO LEAVE THE HOSPITAL TOO SOON

Be sure you have received the written notice of discharge that the hospital must give you. You need this discharge notice in order to appeal.

This notice will say who to call and how to appeal. To avoid extra charges you must call to appeal by 12 noon of the day after you receive the notice. If you miss this time you may still appeal. However, you may have to pay for your continued stay in the hospital, if you lose your appeal.

DISCHARGE PLANS

In addition to the right to appeal, you have the right to:

Receive a written discharge plan that describes the arrangements for any future health care you may need after discharge. You may not be discharged until the services required in your written
discharge plan are secured or determined by the hospital to be reasonably available. You also have
the right to appeal this discharge plan.

PATIENTS' RIGHTS

A general statement of your additional rights as a patient must be provided to you at this time.

FOR ASSISTANCE/HELP

The Independent Professional Review Agent (IPRA) for your area and your insurance coverage is:
(Hospitals are permitted to use a checklist to indicate the IPRA that the patient should contact.)

(15) In conjunction with the requirements for complete history and physical examination as
established in this section, hospitals approved by the Office of Alcoholism and Substance Abuse
Services (OASAS) or the Division of Alcoholism and Alcohol Abuse, a predecessor agency, shall provide
a health intervention services (HIS) program to screen all admitted patients for signs of alcoholism or
alcohol abuse that may relate to the condition requiring hospital admission. Specifically, such hospitals
shall:

(i) maintain a dedicated staff that are adequate in number and trained, including continuing
education and inservice training, to perform all the activities required of the HIS program;
(ii) identify patients who exhibit signs of alcoholism or alcohol abuse through a comprehensive
screening protocol; and
(iii) offer patients intervention and referral services consistent with their assessed needs.

(c) Treatment of sexual offense survivors and maintenance of sexual offense evidence.

(1) Treatment of survivors. Hospital shall:

(i) maintain current protocols regarding the care of patients reporting sexual assault;
(ii) provide patients who are suspected or confirmed victims of sexual offenses appropriate
assessment, emergency treatment and referrals to meet the health care needs of such individuals, to
provide emotional support to them and to minimize further trauma;
(iii) advise patients of the availability of services provided by a local rape crisis or victim assistance
organization and, unless the patient declines such services, contact such organization with information
concerning the age and sex of the victim, language spoken by the victim if other than English, and any
other information that may impact the assignment of a victim advocate, such as mental retardation,
etc., so that a representative may offer the patient the services that the organization provides;
(iv) as provided by the department and consistent with current standards of professional practice,
provide to patients written and verbal information necessary to make an informed choice in regard to
treatment options, including pregnancy prophylaxis;
(v) provide to patients, upon request, prophylaxis against pregnancy, sexually transmitted diseases,
hepatitis B and HIV, as medically indicated;
(vi) discuss with patients the option of reporting the sexual offense to the police, and upon consent
of the patient, report the offense to the local law enforcement agency; and
(vii) reasonably assure patients an appropriate and safe discharge.

(2) Maintenance of sexual offense evidence. The hospital shall provide for the maintenance of
evidence of sexual offenses. The hospital shall establish and implement written policies and
procedures that are consistent with the requirements of this section and that shall apply to all service
units of the hospital which treat victims of sexual offenses, including but not limited to medicine,
surgery, emergency, pediatric and outpatient services.

(i) The sexual offenses subject to the provisions of this subdivision shall be sexual misconduct, rape,
sodomy, sexual abuse and aggravated sexual abuse as defined in article 130 of the Penal Law.
(ii) The sexual offense evidence shall include, as appropriate to the injuries sustained in each case,
slides, cotton swabs, clothing or portion thereof, hair combings, fingernail scrapings, photographs, and
other items specified by the local police agency and forensic laboratory in each particular case.
(iii) The hospital shall preserve items of sexual offense evidence and ensure that clothes and
samples or swabs are dried, stored in paper bags and labeled, and shall mark and log each item of
evidence with a code number corresponding to the patient's medical record number.
(iv) Privileged sexual offense evidence shall mean evidence collected or obtained from the patient
during the hospital examination and treatment of injuries sustained as a result of a sexual offense.
(v) Sexual offense evidence that is not privileged shall mean evidence which is obtained from
victims of suspected child abuse or maltreatment, and that derived from other alleged crimes,
attendant to or committed simultaneously with the sexual offense, which are required to be reported
to a police agency, such as bullet or gunshot wounds, powder burns, burn injuries, which may also be required to be reported to the state fire administrator, or other injuries arising from or caused by the discharge of a gun or firearm, or wounds which may result in death and which are inflicted by a knife, ice pick or other sharp or pointed instrument in accordance with sections 265.25 and 265.26 of the Penal Law. Nothing in this paragraph shall prevent the reporting of diseases or medical conditions required by law to be reported to health authorities.

(vi) Upon admission of a patient who is an alleged sexual offense survivor, the hospital shall seek patient consent, or consent of the person authorized to act on the patient's behalf, for collection and storage of the sexual offense evidence and shall explain the specific rights of the patient and obligations of the hospital as outlined in this paragraph. The hospital shall store the sexual offense evidence in a locked, separate and secure area for not less than 30 days unless:
   (a) the patient or person authorized to act on the patient's behalf signs a statement directing the hospital not to collect and keep privileged evidence; or
   (b) such evidence is privileged and the patient or person authorized to act on the patient's behalf signs a statement directing the hospital to surrender the evidence to the police before the 30-day period has expired; or
   (c) the evidence is not privileged and the police request its surrender before 30-day period has expired.

(vii) If none of the above acts have occurred within 30 days from commencement of treatment, the evidence shall be discarded and the patient's possessions shall be returned upon the patient's request.

(viii) The hospital shall designate a staff member to coordinate the required actions and to contact the local police agency and forensic laboratory to determine their specific needs and requirements for the maintenance of sexual offense evidence.

(d) Child abuse and maltreatment. The hospital shall provide for the identification, assessment, reporting and management of cases of suspected child abuse and maltreatment. The hospital shall establish and implement written policies and procedures which are consistent with the requirements of this section and which shall apply to all service units of the hospital which treat victims of child abuse and maltreatment, including but not limited to medicine, surgery, emergency, pediatrics and outpatient services.

(1) The hospital shall provide orientation and continuing education to the nursing, medical and social work personnel of, at least, the hospital's emergency, pediatric and outpatient services in the recognition of indicators of domestic violence and suspected child abuse and maltreatment and in the individual's responsibilities in dealing with such case.

(2) A staff member shall be designated to coordinate the required reporting to the New York State Central Register of Child Abuse and Maltreatment and the hospital's actions taken with respect to such cases in accordance with procedures set forth in article 6, title 6 of the State Social Services Law.

(e) Domestic violence. The hospital shall provide for the identification, assessment, treatment and appropriate referral of cases of suspected or confirmed domestic violence victims. The hospital shall establish and implement written policies and procedures consistent with the requirements of this section which shall apply to all service units of the hospital.

(f) Discharge.

(1) The hospital shall ensure that each patient has a discharge plan which meets the patient's post-hospital care needs. No patient who requires continuing health care services in accordance with such patient discharge plan may be discharged until such services are secured or determined by the hospital to be reasonably available to the patient.

(2) The hospital shall have a discharge planning coordinator responsible for the coordination of the hospital discharge planning program. The discharge planning coordinator shall be an individual with appropriate training and experience as determined by the hospital to coordinate the hospital discharge planning program.

(3) The hospital shall ensure:
   (i) that discharge planning staff have available current information regarding home care programs, institutional health care providers, and other support services within the hospital's primary service area, including their range of services, admission and discharge policies and payment criteria;
   (ii) the utilization of written criteria as part of a screening system for the early identification of those patients who may require post-hospital care planning and services. Such criteria shall reflect the hospital's experience with patients requiring post-hospital care and shall be reviewed and updated annually;
   (iii) that upon the admission of each patient, information is obtained as required to assist in identifying those patients who may require post-hospital care planning;
(iv) that each patient is screened as soon as possible following admission in accordance with the written criteria described in subparagraph (ii) of this paragraph and that this screening is coordinated with the utilization review process;

(v) that each patient identified through the screening system as potentially in need of post-hospital care is assessed by those health professionals whose services are appropriate to the needs of the patient to determine the patient's post-hospital care needs. Such assessment shall include an evaluation of the extent to which the patient or patient's personal support system can provide or arrange to provide for identified care needs while the patient continues to reside in his/her personal residence;

(vi) that for each patient determined to need assistance with post-hospital care, the health professionals whose services are medically necessary, together with the patient and the patient's family/representative shall develop an individualized comprehensive discharge plan consistent with medical discharge orders and identified patient needs;

(vii) that each patient determined to need assistance with post-hospital care and the patient's family/representative receive verbal and written information regarding the range of services in the patient’s community which have the capability of assisting the patient and the patient's family/representative in implementing the patient’ s individualized discharge plan which is appropriate to the patient's level of care needs;

(viii) that the patient and the patient’s family/representative shall have the opportunity to participate in decisions regarding the selection of post-hospital care consistent with and subject to any limitations of Federal and State laws. Planning for post-hospital care shall not be limited to placement in residential health care facilities for persons assessed to need that level of care, but shall include consideration of nonpatient services such as home care, long-term home health care, hospice, day care and respite care;

(ix) that when residential health care facility placement is indicated, the patient and the patient's family/representative shall be afforded the opportunity, consistent with and subject to any limitations of Federal and State laws, to participate in the selection of the residential health care facilities to which applications for admission are made.

(x) that contact with appropriate providers of health care and services is made as soon as possible, but no later than the day of assignment of alternate level of care status and that each patient's record contains a record of all such contacts including date of contact and provider response as well as a copy of any standard assessment form, including but not limited to any hospital/community patient review instrument as contained in section 400.13 of this Title and any home health assessment, completed by the hospital for purposes of post-hospital care;

(xi) that relevant discharge planning information is available for the utilization review committee; and

(xii) the development and implementation of written criteria for use in the hospital emergency service indicating the circumstances in which discharge planning services shall be provided for a person who is in need of post emergency care and services but not in need of inpatient hospital care.

(4) The hospital shall establish and implement written policies and procedures governing the admissions and discharge process which ensure compliance with State and Federal antidiscrimination laws which apply to the operator. Such laws include, but need not be limited to, the applicable provisions of this Part; Public Health Law, section 2801-a(9); the New York State Civil Rights Law, sections 40 and 40-c; article 15 (Human Rights Law) of the State Executive Law, sections 291, 292 and 296; and title 42 of the United States Code, sections 1981, 2000a, 2000a-2, 2000d, 3602, 3604 and 3607. Copies of the cited State and Federal statutes are available from West Publishing Company, P.O. Box 64526, St. Paul, MN 55164-0526, the publisher of McKinney's Consolidated Laws of New York annotated and the United States Code annotated. Copies of such statutes are also available for public inspection and copying at the Records Access Office, New York State Department of Health, Corning Tower Building, Governor Nelson A. Rockefeller Empire State Plaza, Albany, NY 12237.

(5) Discharge planners shall inform each patient and his/her family of the admission policies of the residential health care facilities to which they are referred.

(6) The requirements of this subdivision relating to a patient's family/representative participating in the discharge planning process and in receiving an explanation of the reason for a patient's transfer or discharge shall not apply in the following circumstances:

(i) when a competent adult patient objects to such participation by, or to an explanation regarding transfer or discharge being given to, any family/representative. Any such objections shall be noted in the patient's medical record; or
(ii) when the hospital has made a reasonable effort to contact a patient's family/representative in order to provide an opportunity to participate in the discharge planning process or to explain the reason for transfer or discharge, and the hospital is unable to locate a responsible family member/representative, or, if located, such individual refuses to participate. The reasons a patient's family/representative did not participate in the discharge planning process or did not receive an explanation of the reason for a patient's transfer or discharge shall be noted in the patient's medical record. A reasonable effort shall include, but not be limited to, attempts to contact a patient's family/representative by telephone, telegram and/or mail.

(7) The hospital shall ensure that no person presented for medical care shall be removed, transferred or discharged from a hospital based upon source of payment. Each removal, transfer or discharge shall be carried out after a written order made by a physician that, in his/her judgment, such removal, transfer or discharge will not create a medical hazard to the person or that such removal, transfer or discharge is considered to be in the person's best interest despite the potential hazard of movement. Such a removal, transfer or discharge shall be made only after explaining the need for removal, transfer or discharge to the patient and to the patient's family/representative and prior notification to the medical facility expected to receive the patient.

(i) The hospital shall maintain a record of all removals, discharges and transfers from the hospital, including the date and time of the hospital reception or admission, name, sex, age, address, presumptive diagnosis, treatment provided, clinical condition, reason for removal, transfer or discharge and destination. A copy of such information shall accompany any person transferred or discharged to a health care facility or a certified or licensed home care services agency and, where applicable become a part of the person's medical record.

(ii) Patients discharged from the hospital by their attending practitioner shall not be permitted to remain in the hospital without the consent of the chief executive officer of the hospital except in accordance with provisions of subdivision (g) of this section.

(iii) In the absence of a written order of an attending practitioner discharging a patient, with respect to a patient who insists upon discharging himself from the hospital, the hospital shall obtain, where practicable, a written release from the patient absolving the hospital and the patient's attending practitioner of liability and damages resulting from such discharge.

(8) Unless otherwise provided by law, the hospital shall ensure that a minor shall be discharged only in the custody of his parent, a member of his immediate family or his legal guardian or custodian, unless such parent or guardian shall otherwise direct.

(9) A dead body, including a stillborn infant or fetus estimated by an attending physician to have completed 20 weeks of gestation, shall be delivered only to a licensed funeral director or undertaker or his/her agent. If, at the time of death, the patient was diagnosed as having a specific communicable or infectious disease, including but not limited to those diseases designated in Part 2 of this Title, a written report of such disease shall accompany the body when it is released to the funeral director or his/her agent.

(g) Hospital inpatient discharge review program.

(1) A hospital inpatient discharge review program applicable to all patients other than beneficiaries of title XVIII of the Federal Social Security Act (Medicare) shall be established in accordance with this subdivision. No hospital inpatient subject to the provisions of this subdivision may be discharged on the basis that inpatient hospital service in a general hospital is no longer medically necessary and that an appropriate discharge plan has been established unless a written notice of such determinations and a copy of the discharge plan have been provided to the patient or the appointed personal representative of the patient. The patient or the appointed personal representative of the patient shall have the opportunity to sign the notice and a copy of the discharge plan and receive a copy of both signed documents. Every hospital shall use the common notice set forth in paragraph (9) of this subdivision. The patient, or the appointed personal representative of the patient may request a review of such determinations by the appropriate independent professional review agent or review agent in accordance with paragraph (4) of this subdivision. Notwithstanding that the patient discharge review process provided in accordance with Federal law and regulation shall apply to beneficiaries of title XVIII of the Federal Social Security Act (Medicare), a written copy of the discharge plan, and discharge notice shall be provided to the beneficiary or the appointed personal representative of the beneficiary. The beneficiary or the appointed personal representative of the beneficiary shall have the opportunity to sign the documents and receive a copy of the signed documents.

(i) For patients eligible for payments by state governmental agencies for hospital inpatient services as the patient's primary payor an independent professional review agent shall mean the commissioner or his designee. In conducting hospital inpatient discharge reviews in accordance with this paragraph,
the commissioner may utilize the services of department personnel or other authorized representatives, including a review agent approved in accordance with subparagraph (ii) of this paragraph.

(ii) For patients who are not beneficiaries of title XVIII of the Federal Social Security Act (Medicare) nor eligible for payments by state governmental agencies as the patient's primary payor, an independent professional review agent shall mean a third-party payor of hospital services or other corporation approved by the commissioner in writing for purposes of conducting hospital inpatient discharge reviews in accordance with this subdivision. For a third-party payor of hospital services or other corporation to be approved as an independent professional review agent in accordance with this subparagraph, such third-party payor or other corporation must meet the following approval criteria:

(a) the review agent shall employ or otherwise secure the services of adequate medical personnel qualified to determine the necessity of continued inpatient hospital services and the appropriateness of hospital discharge plans;
(b) the review agent shall demonstrate the ability to render review decisions in a timely manner as provided in this subdivision;
(c) the review agent shall agree to provide ready access by the commissioner to all data, records and information it collects and maintains concerning its review activities under this subdivision;
(d) the review agent shall agree to provide to the commissioner such data, information and reports as the commissioner determines necessary to evaluate the review process provided pursuant to this subdivision;
(e) the review agent shall provide assurances that review personnel shall not have a conflict of interest in conducting a discharge review for a patient based on hospital or professional affiliation; and
(f) the review agent meets such other performance and efficiency criteria regarding the conduct of reviews pursuant to this subdivision established by the commissioner.

The commissioner may withdraw approval of an independent professional review agent where such review agent fails to continue to meet approval criteria established pursuant to this subparagraph.

(iii) Each hospital shall enter into contracts with one or more independent professional review agents approved by the commissioner in accordance with subparagraph (ii) of this paragraph for purposes of conducting hospital inpatient discharge reviews in accordance with this subdivision for patients, including uncompensated care patients, who are not beneficiaries of title XVIII of the Federal Social Security Act (Medicare) nor eligible for payments by State governmental agencies as the patient's primary payor; provided, however, a payor of hospital service authorized under article 43 of the State Insurance Law or certified as health maintenance organizations under article 44 of the Public Health Law, may designate the review agent for their subscribers or beneficiaries or enrolled members and shall reimburse such designated review agent for costs of the discharge review program.

(i) If a hospital and the attending physician agree that inpatient hospital service in a hospital is no longer medically necessary for a patient, other than a beneficiary of title XVIII of the Federal Social Security Act (Medicare), and an appropriate discharge plan has been established for such patient, at that time the hospital shall provide the patient or the appointed personal representative of the patient with a written discharge notice and a copy of the discharge plan, meeting the requirements of paragraph (1) of this subdivision.

(ii) If a hospital has determined that inpatient hospital service in a hospital is no longer medically necessary for a patient, other than a beneficiary of title XVIII of the Federal Social Security Act (Medicare), and an appropriate discharge plan has been established for such patient but the attending physician has not agreed with the hospital's determinations, the hospital may request by telephone a review of the validity of the hospital's determinations by the appropriate independent professional review agent. Such review agent shall conduct a review of the hospital's determinations and prior to the conclusion of the review shall provide an opportunity to the treating physician and an appropriate representative of the hospital to confer and provide information which may include the patient's clinical records if requested by the review agent. Such review agent shall notify the hospital of the results of its review not later than one working day after the date the review agent has received the request, the records required to conduct such review, and the date of such conferring and receipt of any additional information requested. The hospital shall provide notice to the attending physician of the results of the review. If the review agent concurs with the hospital's determinations, the hospital shall provide the patient or his appointed personal representative with a written notice of such determinations and notice that the patient shall be financially responsible for continued stay, and with a copy of the proposed discharge plan. The patient or the appointed personal representative of the patient shall have the opportunity to sign the notice and a copy of the proposed discharge plan and receive a copy of both signed documents. Every hospital shall use the notice set forth in paragraph
(10) of this subdivision which shall indicate the determinations made, shall state the reasons therefor
and that the patient's attending physician has disagreed, and shall state that the patient or the
appointed personal representative of the patient may request a review of such determinations by the
appropriate review agent.

(4) A patient in a hospital, or the appointed personal representative of the patient, who receives a
written notice in accordance with subparagraph (3)(i) or (3)(ii) of this subdivision, may request a
review by the appropriate review agent of the determinations set forth in such notice related to
medical necessity of continued inpatient hospital service, the appropriateness of the discharge plan
and the availability of required continuing health care services.

(i) If a patient while still hospitalized or while no longer an inpatient, or the appointed personal
representative of such patient, requests a review by the appropriate review agent, the hospital shall
promptly provide to the review agent the records required to review the determinations. Such request
for a patient no longer an inpatient shall take place no later than 30 days after receipt of a notice
provided in accordance with paragraph (3) of this subdivision or seven days after receipt of a complete
bill for all inpatient services rendered, whichever is later. The review agent shall conduct a review of
such determinations, and shall provide the treating physician and an appropriate representative of the
hospital with an opportunity to confer and provide information prior to the conclusion of the review.
The review agent shall provide written notice to the patient, or the appointed personal representative
of the patient, and the hospital of the results of the review within three working days of receipt of the
requests for review and the records required to review the determinations. The hospital shall provide
notice to the attending physician of the results of the review.

(ii) If a patient while still an inpatient in the hospital, or the appointed personal representative of the
patient, requests a review by the appropriate review agent not later than noon of the first working day
after the date the patient, or the appointed personal representative of the patient, receives the written
notice, the hospital shall provide to the appropriate review agent the records required to review the
determinations by the close of business of such working day. The appropriate review agent shall
conduct a review of such determinations and provide written notice to the patient, or the appointed
personal representative of the patient, and the hospital of the results of the review not later than one
full working day after the date the review agent has received the request for review and such records.
The hospital shall provide notice to the attending physician of the results of the review.

(5) If the appropriate review agent, upon any review conducted pursuant to subparagraph (3)(ii) or
pursuant to paragraph (4) of this subdivision does not concur in the determinations, continued stay in
a hospital shall be deemed necessary and appropriate for the patient for purposes of payment for such
continued stay.

(6) If a patient eligible for payment for inpatient hospital services under the casebased payment per
discharge system or the appointed personal representative of the patient, requests a review by the
appropriate review agent in accordance with subparagraph (4)(ii) of this subdivision, the hospital may
not demand or request any payment for additional inpatient hospital services provided to such patient
subsequent to the proposed time of discharge and prior to noon of the day after the date the patient
or the appointed personal representative of the patient receives notice of the results of the review by
the review agent except deductibles, copayments, or other charges that would be authorized for a
patient for whom inpatient hospital services in a hospital continue to be necessary and appropriate.

(7) In any review conducted pursuant to subparagraph (3)(ii) or pursuant to paragraph (4) of this
subdivision, the review agent shall solicit the views of the patient involved, or the appointed personal
representative of the patient, and the attending physician.

(8) Each patient, or the appointed personal representative of the patient, provided a notice by a
hospital in accordance with paragraph (3) of this subdivision shall be provided at such time by the
hospital with a notice of such patient's right to request a discharge review in accordance with this
subdivision. The patient or the appointed personal representative of the patient shall have the
opportunity to sign this form and receive a copy of the signed form.

(9) Notice that inpatient hospital service is no longer medically necessary. For purposes of
subparagraph (3)(i) of this subdivision, the hospital shall utilize the following notices:

(i) The following form shall be used for patients covered under the case payment system:

DISCHARGE NOTICE

DATE:/________/________

READ THIS LETTER CAREFULLY--IT CONCERNS YOUR PRIVATE INSURANCE
Dear Patient:

Your doctor and the hospital have determined that you no longer require care in the hospital and will be ready for discharge on:

Day of Week ________/ _____

Date /__________

IF YOU AGREE with this decision, you will be discharged. Be sure you have already received your written discharge plan which describes the arrangements for any future health care you may need.

IF YOU DO NOT AGREE and think you are not medically ready for discharge or feel that your discharge plan will not meet your health care needs, you or your representative may request a review. Contact the review agent indicated on the reverse side of this letter if you would like a review of the discharge decision.

IF YOU WOULD LIKE A REVIEW, you should immediately, but not later than noon of (Day and Date) call the telephone number checked off on the reverse side of this page.

IF YOU CANNOT REQUEST THE REVIEW YOURSELF, and you do not have a family member or friend to help you, you may ask the hospital representative at extension , who will request the review for you.

IF YOU REQUEST A REVIEW, the following will happen:

1. The review agent will ask you or your representative why you or your representative think you need to stay in the hospital and also will ask your name, admission date and telephone number where you or your representative can be reached.

2. After speaking with you or your representative and your doctor and after reviewing your medical record, the review agent will make a decision which will be given to you in writing.

3. While this review is being conducted, you will not have to pay for any additional hospital days until you have received the review agent's decision.

IF THE REVIEW AGENT AGREES WITH THE DISCHARGE DECISION, you will be financially responsible for your continued stay after noon of the day after you or your representative has been notified of the review agent's decision.

IF THE REVIEW AGENT AGREES THAT YOU STILL NEED TO BE IN THE HOSPITAL: for Medicaid patients, Medicaid benefits will continue to cover your stay; for private health insurance patients, coverage for your continued stay is limited to the scope of your private health insurance policy.

NOTE: If you miss the noon deadline mentioned on the first page of this notice, you may still request a review. However, if the review agent disagrees with you, you will be financially responsible for the days of care beginning with the proposed discharge date.

If you would like a review of your hospital stay after you have been discharged, you may request a review by the review agent within 30 days of the receipt of this notice or seven days after receipt of a complete bill from the hospital, whichever is later, by writing to the review agent.

I have received this notice on behalf of myself as the patient or as the representative of the patient:

________________________
Signature /__________

________________________
Date /__________

________________________
Time

________________________
Relationship

(ii) The following form shall be used for patients covered under a per diem reimbursement system:
DISCHARGE NOTICE

DATE /________/________

READ THIS LETTER CAREFULLY--IT CONCERNS YOUR PRIVATE INSURANCE
BENEFITS OR MEDICAID BENEFITS OR IF YOU ARE UNINSURED

PATIENT NAME: ________ PRIMARY PAYOR
AT DISCHARGE:____________
ATT. PHYS.: ________MR NO.:____________
ADM DATE:________/ ________/________

Dear Patient:

Your doctor and the hospital have determined that you no longer require care in the hospital and will be ready for discharge on:

Day of Week ________/

Date /________

IF YOU AGREE with this decision, you will be discharged. Be sure you have already received your written discharge plan which describes the arrangements for any health care you may need when you leave the hospital.

IF YOU DO NOT AGREE and think you are not medically ready for discharge or feel that your discharge plan will not meet your health care needs, you or your representative may request a review of the discharge decision by contacting your review agent indicated on the reverse side of this page.

IMPORTANT NOTICE ABOUT THE PAYMENT FOR YOUR CARE

• If your hospital care is covered by private health insurance, you may be charged directly while you remain in the hospital while the discharge review is being conducted. Whether you have to pay during this period will depend on your private health insurance benefits and if the review agent agrees with you that you need to stay in the hospital.
• If your hospital care is covered under the Medicaid program, Medicaid will pay for the days you remain in the hospital while the discharge review is being conducted.

IF YOU WOULD LIKE A REVIEW, you should immediately, but not later than noon of (Day and Date) call the telephone number checked off on the reverse side of this page.

IF YOU CANNOT REQUEST THE REVIEW YOURSELF, and you do not have a family member or friend to help you, you may ask the hospital representative at extension , who will request the review for you.

IF YOU REQUEST A REVIEW, the following will happen:
1. The review agent will ask you or your representative why you or your representative think you need to stay in the hospital and also will ask your name, admission date and telephone number where you or your representative can be reached.
2. After speaking with you or your representative and your doctor and after reviewing your medical record, the review agent will make a decision which will be given to you in writing.
   IF THE REVIEW AGENT AGREES WITH THE DISCHARGE DECISION, you will be financially responsible for your continued stay after noon of the day you or your representative has been notified of the review agent's decision.
   IF THE REVIEW AGENT AGREES THAT YOU STILL NEED TO BE IN THE HOSPITAL: for Medicaid patients, Medicaid benefits will continue to cover your stay; for private health insurance patients, coverage for your continued stay is limited to the scope of your private health insurance policy.
   NOTE: If you miss the noon deadline mentioned on the first page of this notice, you may still request a review. However, if the review agent disagrees with you, you will be financially responsible for the days of care beginning with the proposed discharge date.

If you would like a review of your hospital stay after you have been discharged, you may request a review by the review agent within 30 days of the receipt of this notice or seven days after receipt of a complete bill from the hospital, whichever is later, by writing to the review agent.

I have received this notice on behalf of myself as the patient or as the representative of the patient:
(10) Notice that inpatient hospital services is no longer medically necessary. For purposes of subparagraph (3)(ii) of this subdivision, a hospital shall utilize the following notice:

HOSPITAL LETTERHEAD

DATE /________/________

CONTINUED STAY DISCHARGE NOTICE

(ATTENDING PHYSICIAN AGREES/REVIEW AGENT AGREES)

READ THIS LETTER CAREFULLY--IT CONCERNS YOUR INSURANCE BENEFITS OR MEDICAID BENEFITS

PATIENT NAME: ____________ PRIMARY PAYOR: ____________
ADDRESS: ____________
ATT. PHYS.: ____________ MR NO.: ____________ ADM. DATE: ________/_______/_______

Dear Patient:

After careful review of your medical record and consideration of your own views regarding medical condition, the (name of review agent) (the review agent approved by the Department of Health) has agreed with the hospital that you no longer require care in the hospital because you are ready for discharge.

IF YOU AGREE with this decision, you should discuss with your doctor the arrangements for any further health care you may need. This means if you have health insurance benefits or Medicaid benefits, these benefits will no longer pay for any additional hospital days as of:

Day of Week ________/_______

IF YOU DO NOT AGREE THAT YOU ARE READY FOR DISCHARGE, IMMEDIATELY AFTER RECEIPT OF THIS NOTICE YOU OR YOUR REPRESENTATIVE MAY CALL THE (name of review agent) AT (phone no.) TO REQUEST AN IMMEDIATE REREVIEW OF YOUR MEDICAL RECORD.

If you cannot request the reconsideration yourself and you do not have a representative to help you, you may notify the hospital representative at extension ________ to request the reconsideration to you. In either case, the individual review agent approved by the Department of Health will request your name, admission date, and telephone number where you or your representative can be reached. If the individual review agent approved by the Department of Health did not ask your views before, it must do so now.

IF YOU REQUEST A REVIEW, the following will happen:
(1) You or your representative will be informed in writing of the results of the review.
(2) IF THE REVIEW AGENT AGREES WITH THE HOSPITAL’s DECISION that you are ready for discharge or that your condition could be safely treated in another setting and you have health insurance benefits or Medicaid benefits, your health insurance benefits or Medicaid benefits will PAY FOR YOUR STAY ONLY UNTIL NOON OF THE NEXT DAY AFTER YOU OR YOUR REPRESENTATIVE HAVE BEEN NOTIFIED.
If the review agent determines that you still need to be in the hospital, for purposes of payments under health insurance or Medicaid benefits, your continued stay will be considered necessary and appropriate.

IN EITHER CASE (2 OR 3), YOU WILL NOT HAVE TO PAY FOR ANY ADDITIONAL HOSPITAL DAYS UNTIL YOU HAVE BEEN NOTIFIED OF THE REVIEW AGENT DETERMINATION.

NOTE: If you miss the noon deadline mentioned on the reverse side of this notice, you may still request a review during your hospital stay. However, if the review agent rules against you, you will be financially responsible starting on the date you receive the notice. Of course, if the review agent determination is in your favor, you are not liable for payment for the extra days.

If you would like a review of your hospital stay after you have been discharged, you may request an individual review agent review within 30 days of receipt of this notice or seven days after receipt of a complete bill from the hospital, whichever is later, by writing to the review agent.

(REVIEW AGENT NAME/ADDRESS)

________________________

(Hospital Representative Signature)

(Date)

(Time)

If your hospital stay is not covered under the per case payment system, you may still request a discharge review. However, you will continue to be charged for hospital services during the review process.

IF YOU HAVE ANY DIFFICULTY UNDERSTANDING THIS NOTICE OR IF YOU NEED MORE INFORMATION, YOU MAY CALL THE REVIEW AGENT DIRECTLY AT:

________________________

(Telephone No.)

I have received this notice on behalf of myself as the patient or as a representative of the patient to whom it is addressed:

Signature / ______________________

Date / ______________________

Time

Relationship

cc: Attending Physician
Hospital Billing Office

(11) The provisions of this subdivision shall apply to hospital inpatients admitted on and after January 1, 1988.

10 NY ADC 405.9
10 NY ADC 405.9
2008 WL 75295871
10 NY ADC 405.9

* Section 405.10.* Medical records.
The hospital shall have a department that has administrative responsibility for medical records. An accurate, clear, and comprehensive medical record shall be maintained for every person evaluated or treated as an inpatient, ambulatory patient, emergency patient or outpatient of the hospital.

(a) General requirements.

(1) Medical records shall be legibly and accurately written, complete, properly filed, retained and accessible in a manner that does not compromise the security and confidentiality of the records.

(2) The hospital shall establish, implement and monitor an effective system of author identification for medical records and/or medical orders to ensure the integrity of the authentication and protect the security of all transmissions, records and record entries. This system shall identify those categories of practitioners and personnel who are authorized to utilize electronic or computer authentication systems.

(3) The hospital shall ensure that all medical records are completed within 30 days following discharge.

(4) Medical records shall be retained in their original or legally reproduced form for a period of at least six years from the date of discharge or three years after the patient’s age of majority (18 years), whichever is longer, or at least six years after death.

(5) The hospital shall have a system of coding and indexing medical records. The system shall allow for timely retrieval by diagnosis and procedure, in order to support quality assurance studies.

(6) The hospital shall ensure the confidentiality of patient records. Original medical records, information from or copies of records shall be released only to hospital staff involved in treating the patient and individuals as permitted by Federal and State laws.

(7) The hospital shall allow patients and other qualified persons to obtain access to their medical records and to add brief written statements which challenge the accuracy of the medical record documentation to become a permanent part of the medical record, in accordance with the provisions of Part 50 of Chapter II of this Title and the provisions of Public Health Law, section 18(4).

(b) Content.

(1) The medical record shall contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.

(2) All records shall document, as appropriate, at least the following:

   (i) evidence of a physical examination, including a health history, performed no more than seven days prior to admission or within 24 hours after admission and a statement of the conclusion or impressions drawn;

   (ii) admitting diagnosis;

   (iii) results of all consultative evaluations of the patient and findings by clinical and other staff involved in the care of the patient;

   (iv) documentation of all complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia;

   (v) properly executed consent forms for procedures and treatments;

   (vi) all practitioners’ diagnostic and therapeutic orders, nursing documentation and care plans, reports of treatment, medication records, radiology, and laboratory reports, vital signs and other information necessary to monitor the patient’s condition;

   (vii) discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care; and

   (viii) final diagnosis.

(c) Authentication of medical records, record entries and medical orders.

(1) Upon completion of ordering or providing or evaluating patient care services, each such action shall be recorded and promptly entered in the patient medical record. All entries shall be legible and complete and shall be authenticated by the person entering, ordering or completing such action. Legible and signed facsimile orders may be accepted and shall be filed in the patient medical record.

(2) Written signatures, or initials and electronic signatures or computer generated signature codes shall be acceptable as authentication when utilized in accordance with hospital policy.

(3) Each electronic or computer entry, order or authentication shall be recorded in the medical record as to date, time, category of practitioner, mode of transmission and point of origin.

(4) Safeguards to ensure security and confidentiality shall include but not be limited to:

   (i) the assignment, as appropriate, of a unique identifier that is assigned in a confidential manner;

   (ii) the certification in writing by the hospital’s designee and the user that each identifier assigned is confidential and is available and accessible only to the person authorized to use the electronic or computer authentication system;
(iii) policies and procedures to ensure the security of electronic or computer equipment from unwarranted access;
(iv) policies and procedures that restrict access to information and data to those individuals who have need, reason and permission for such access; and
(v) the implementation of an audit capability to track access by users.

(5) Hospitals shall implement an ongoing verification process to ensure that electronic communications and entries are accurate, including but not limited to:
   (i) protocols for ensuring that incomplete entries or reports or documents are not accepted or implemented until reviewed, completed and verified by the author; and
   (ii) a process implemented as part of the hospital's quality assurance activities that provides for the sampling of records for review to verify the accuracy and integrity of the system.

(6) Written notice from the author shall be required should the author/user wish to terminate participating in the electronic or computer authentication system.

(7) The hospital shall have procedures in place to modify or terminate use of any assigned identifier in cases of abuse or misuse or if practice privileges are suspended, restricted, terminated or curtailed or employment or affiliation ends.

(8) The hospital shall implement procedures regarding the use and authentication of telephone orders. Such orders shall be used sparingly, shall be accepted and recorded only in accordance with applicable scope of practice provisions for licensed, certified or registered practitioners, consistent with Federal and State law, and with hospital policies and procedures and shall be authenticated by the prescribing practitioner as soon as possible, also in accordance with such policies and procedures.

(9) All orders for controlled substances shall be carried out in accordance with provisions of Part 80 of this Title.

RESEARCH REFERENCES AND PRACTICE AIDS:
44 NY Jur 2d, Disclosure § 341(supp).
52 NY Jur 2d, Employment Relations § 504(supp).
10 NY ADC 405.10
10 NY ADC 405.10
2008 WL 75295872
10 NY ADC 405.10

* Section 405.11.* Infection control.

The hospital shall provide a sanitary environment to avoid sources and transmission of nosocomial infections and of communicable diseases which may lead to morbidity or mortality in patients and hospital personnel. The hospital shall establish an effective infection control program for the prevention, control, investigation and reporting of all communicable disease and increased incidence of infections, including nosocomial infections, consistent with current acceptable standards of professional practice. The hospital-wide infection control program shall be reviewed as frequently as necessary but not less than once per year, and updated as necessary to promote optimal effectiveness.

(a) Organization. The hospital shall designate an infection control professional who is responsible for the development and implementation of a hospital-wide infection control program. This individual shall be qualified by training in infection surveillance, prevention and control and also have knowledge or job experience in epidemiological principles, infectious diseases and infection control practices.

(b) Nosocomial surveillance, prevention and control. The hospital-wide infection control program shall include processes designed to reduce the risk of endemic and epidemic nosocomial infections and communicable diseases in patients and hospital personnel. Such processes shall include methods to:
   (1) collect and analyze surveillance data including case findings and identification of epidemiologically important nosocomial infections and communicable disease;
   (2) prevent or reduce the risk of nosocomial infections; and
   (3) control the spread of infection and communicable diseases and epidemiologically important organisms.

(c) Reporting of infections and communicable diseases. There shall be written policies and procedures for identifying, reporting and investigating infections, and communicable disease of patients and hospital personnel both community acquired and nosocomial. The professional responsible for the hospital-wide infection control program shall report to the Department of Health, in a manner specified by the Commissioner of Health, any increased incidence of nosocomial infections,
as designated in section 2.2 of this Title and defined by the department, or nosocomially acquired communicable disease designated in section 2.1 of this Title. This individual shall also report, immediately, the presence of any communicable disease as defined in section 2.1 of this Title, to the city, county, or district health officer.

(d) Integration with the quality assurance program. The professional responsible for the hospital-wide infection control program shall ensure that all hospital infection control activities are integrated with the quality assurance program required by section 405.6 of this Part, including identification, assessment and correction of problems related to infection and communicable disease control.

(e) Infection control education. The hospital shall require compliance with written requirements for orientation and ongoing education programs that are relevant to the hospital's infection control program for all personnel whose activities are such that they are at risk of directly or indirectly contributing to the transmission of infection or communicable disease from or to patients, other health care personnel or themselves.

(f) Corrective action plans. The hospital shall be responsible for the implementation of acceptable corrective action plans related to infection control and resulting from problems identified through quality assurance or regulatory oversight activities and the professional responsible for the hospital-wide infection control program shall report to the chief executive officer progress in correcting identified problems.

* Section 405.12.* Surgical services.

If surgery is provided, the service shall be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice.

(a) Organization and direction. The surgical service shall be directed by a physician who shall be responsible for the clinical aspects of organization and delivery of all in-patient and ambulatory surgical services provided to hospital patients. That physician or another individual qualified by training and experience shall direct administrative aspects of the service.

(1) The operating room shall be supervised by a registered professional nurse or physician who the hospital finds qualified by training and experience for this role.

(i) Nursing personnel shall be on duty in sufficient number for the surgical suite in accordance with the needs of patients and the complexity of services they are to receive.

(ii) Licensed practical nurses and surgical technologists may perform scrub functions under the supervision of a registered professional nurse; they may assist in circulatory duties under the supervision of a registered professional nurse who is immediately available to respond to emergencies in accordance with policies and procedures established by the medical staff and the nursing service and approved by the governing body.

(2) Surgical privileges shall be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner as required by section 405.4 of this Part. The surgical service shall maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(3) In accordance with written policies and procedures developed and implemented by the medical staff and approved by the governing body, in any procedure presenting unusual hazard to life based on the individual patient risk factors and complexity of the procedure, there shall be present and scrubbed as first assistant a physician designated by the medical staff and the governing body as being qualified to assist in major surgery.

(4) The surgical service policies shall clearly outline requirements for orientation and continuing education programs for all staff and compliance with such requirements shall be considered at the time of performance evaluation. Such training or continuing education programs will be established that are relevant to care provided, but will, at a minimum include instruction in safety precautions, equipment usage and inspections, infection control requirements, cardiopulmonary resuscitation and patients’ rights requirements pertaining to surgical/anesthesia consents.

(5) The director shall, in conjunction with the medical staff, monitor the quality and appropriateness of patient care and ensure that identified problems are reported to the quality assurance committee and are resolved.

(6) Precautions shall be clearly identified in written policies and procedures specific to the department and include but are not limited to:
(i) safety regulations posted;
(ii) routine inspection and maintenance of equipment;
(iii) availability in the operating room suites of a call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, thoracotomy set and tracheotomy set; and
(iv) control of traffic in and out of the operating room suites and accessory services to eliminate through traffic.
(b) Operation and service delivery. Policies governing surgical services shall be designed to assure the achievement and maintenance of generally accepted standards of medical practice and patient care.
   (1) The operating room register shall be kept complete and up-to-date.
   (2) There shall be a complete history and physical work-up in the chart of every patient prior to any surgery except emergency surgery. Each record shall document a review of the patient's overall condition and health status prior to any surgery including the identification of any potential surgical problems and cardiac problems. If this has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient. Such reports shall be signed to attest to the adequacy and currency of the history and physical or countersigned by the attending surgeon, prior to surgery.
   (3) Informed consent shall be obtained from the patient, and a properly executed informed consent form for the operation that includes the identification of the practitioner(s) performing the surgical procedure(s) shall be in the patient's chart before surgery except in emergencies in accordance with section 405.7 of this Part.
   (4) An operative report describing techniques, findings, complications, tissues removed or altered and the general condition of the patient shall be written or dictated immediately following surgery and signed by the surgeon.
   (5) Findings of any pathology reports shall be recorded in the patient's medical record and a procedure established and implemented for reporting unusual findings to the patient's attending practitioner or surgeon.
   (6) All infections of clean surgical cases shall be recorded and reported to the infection control officer. A procedure shall be developed and implemented for the investigation of such cases.
(c) Voluntary termination of pregnancy.
   (1) No termination of pregnancy shall be performed until a woman has had a complete physical examination with appropriate tests for a positive pregnancy and a determination of gestational age including the use of sonography where there is a question of gestational age.
   (2) The standards for preprocedure examination, post-procedure evaluation, counseling for family planning services and birth control options, evaluation, treatment, and determination of blood group and Rh type established in section 756.3 of this Title shall be applicable to all terminations of pregnancy performed in hospitals.
   (3) When a patient is admitted for an induced termination of pregnancy, the determination of blood group and Rh type shall have been made prior to the admission and shall have been recorded in the patient's chart. If not done, such determination shall be made as soon after admission as practicable, and prior to the termination of pregnancy. The patient shall be evaluated for the risk of sensitization to Rho(D) antigen, and if the use of Rh immune globulin is indicated, and the patient consents, an appropriate dosage thereof shall be administered to her as soon as possible within 72 hours after the termination of pregnancy.

* Section 405.13.* Anesthesia services.

If anesthesia services are provided within a hospital, the hospital shall develop, implement and keep current effective written policies and procedures regarding staff privileges, the administration of anesthetics, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care.
(a) Organization and direction. Anesthesia services shall be directed by a physician who has responsibility for the clinical aspects of organization and delivery of all anesthesia services provided by
the hospital. That physician or another individual qualified by education and experience shall direct administrative aspects of the service.

1. The director shall be responsible, in conjunction with the medical staff, for recommending to the governing body privileges to those persons qualified to administer anesthetics, including the procedures each person is qualified to perform and the levels of required supervision as appropriate. Anesthesia shall be administered in accordance with their credentials and privileges by the following:
   (i) anesthesiologists;
   (ii) physicians granted anesthesia privileges;
   (iii) dentists, oral surgeons, or podiatrists who are qualified to administer anesthesia under State law;
   (iv) certified registered nurse anesthetists (CRNA’s) under the supervision of an anesthesiologist who is immediately available as needed or under the supervision of the operating physician who has been found qualified by the governing body and the medical staff to supervise the administration of anesthetics and who has accepted responsibility for the supervision of the CRNA; or
   (v) a student enrolled in a school of nurse anesthesia accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs may administer anesthesia as related to such course of study under the direct personal supervision of a certified registered nurse anesthetist or an anesthesiologist.

2. Anesthesia service policies shall clearly outline requirements for orientation and continuing education programs for all staff, and staff compliance with such requirements shall be considered at the time of reappointment or performance evaluation. Such training and continuing education programs shall be established that are relevant to care provided but must, at a minimum, include instruction in safety precautions, equipment usage and inspections, infection control requirements and any patients’ rights requirements pertaining to surgical/anesthesia consents.

3. The director shall, in conjunction with the medical staff, monitor the quality and appropriateness of anesthesia related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved.

(b) Operation and service delivery. Policies governing anesthesia services shall be designed to ensure the achievement and maintenance of generally accepted standards of medical practice and patient care.

1. All anesthesia machines shall be numbered and reports of all equipment inspections and routine maintenance shall be included in the anesthesia service records. Policies and procedures shall be developed and implemented regarding notification of equipment disorders/malfunctions to the director, to the manufacturer and, in accordance with section 405.8 of this Part, to the department.

2. Written policies regarding anesthesia procedures shall be developed and implemented which shall clearly delineate pre-anesthesia and post-anesthesia responsibilities. These policies shall include, but not be limited to, the following elements:
   (i) Pre-anesthesia physical evaluations shall be performed by an individual qualified to administer anesthesia and recorded within 48 hours, prior to surgery.
   (ii) Routine checks shall be conducted by the anesthetist prior to every administration of anesthesia to ensure the readiness, availability, cleanliness, sterility when required, and working condition of all equipment used in the administration of anesthetic agents.
   (iii) All anesthesia care shall be provided in accordance with accepted standards of practice and shall ensure the safety of the patient during the administration, conduct of and emergence from anesthesia. The following continuous monitoring is required during the administration of general and regional anesthetics. Such continuous monitoring is not required during the administration of anesthetics administered for analgesia or during the administration of local anesthetics unless medically indicated.
      (a) An anesthetist shall be continuously present in the operating room throughout the administration and the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care. If there is a documented hazard to the anesthetist which prevents the anesthetist from being continuously present in the operating room, provision must be made for monitoring the patient.
      (b) All patients must be attended by the anesthetist during the emergence from anesthesia until they are under the care of qualified post-anesthesia care staff or longer as necessary to meet the patient’s needs.
      (c) During all anesthetics, the heart sounds and breathing sounds of all patients shall be monitored through the use of a precordial or esophageal stethoscope. Such equipment or superior equipment shall be obtained and utilized by the hospital.
      (d) During the administration and conduct of all anesthesia the patient’s oxygenation shall be continuously monitored to ensure adequate oxygen concentration in the inspired gas and the blood through the use of a pulse oximeter or superior equipment. During every administration of general
anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm.

(e) All patients' ventilation shall be continuously monitored during the conduct of anesthesia. During regional anesthesia, monitored anesthesia care and general anesthesia with a mask, the adequacy of ventilation shall be evaluated through the continual observation of the patient's qualitative clinical signs. For every patient receiving general anesthesia with an endotracheal tube, the quantitative carbon dioxide content of expired gases shall be monitored through the use of endtidal carbon dioxide analysis or superior technology. In all cases where ventilation is controlled by a mechanical ventilator, there shall be in continuous use an alarm that is capable of detecting disconnection of any components of the breathing system.

(f) The patient's circulatory functions shall be continuously monitored during all anesthetics. This monitoring shall include the continuous display of the patient's electrocardiogram, from the beginning of anesthesia until preparation to leave the anesthetizing location, and the evaluation of the patient's blood pressure and heart rate at least every five minutes.

(g) During every administration of anesthesia, there shall be immediately available a means to continuously measure the patient's temperature.

(iv) Intraoperative anesthesia records shall document all pertinent events that occur during the induction, maintenance, and emergence from anesthesia. These pertinent events shall include, but not be limited to, the following: intraoperative abnormalities or complications, blood pressure, pulse, dosage and duration of all anesthetic agents, dosage and duration of other drugs and intravenous fluids, and the administration of blood and blood components. The record shall also document the general condition of the patient.

(v) With respect to inpatients a post-anesthetic follow-up evaluation and report by the individual who administered the anesthesia or by an individual qualified administer anesthesia shall be written not less than three or more than 48 hours after surgery and shall note the presence or absence of anesthesia related abnormalities or complications, and shall evaluate the patient for proper anesthesia recovery and shall document the general condition of the patient.

(vi) With respect to outpatients, a post-anesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff shall be documented for each patient prior to hospital discharge.

(3) Safety precautions shall be clearly identified in written policies and procedures specific to the department and include, but not be limited to:

(i) safety regulations posted;
(ii) routine inspection and maintenance of equipment;
(iii) use and maintenance of shockproof equipment;
(iv) proper grounding; and
(v) infection control.

10 NY ADC 405.13
10 NY ADC 405.13
2008 WL 75295875
10 NY ADC 405.13

* Section 405.14.* Respiratory care services.

Respiratory care services shall be provided in a manner which assures the safe and effective operation and management of staff and services necessary to provide respiratory care to hospital patients at all times. The service shall have effective and current written policies and procedures regarding staff assignments, the administration of medication, diluents and oxygen, the maintenance of safety controls and the integration of such services with other related services of the hospital.

(a) Organization and direction. The services shall be directed by a physician who shall be responsible for the clinical aspects of organization and delivery of all respiratory care services. The physician, or another individual qualified by training and experience shall direct administrative aspects of the service.

(1) Respiratory care services shall be provided by staff who possess the necessary qualifications specified by the medical staff, consistent with provisions of the New York State Education Law.

(i) Each individual who provides respiratory care services shall be competent to provide such services as evidenced by education, training and experience and where applicable demonstrated adherence to hospital policies and procedures.
(ii) A sufficient number of qualified competent professional and support personnel shall be available to meet the respiratory care needs of the patient.

(2) Written policies and procedures shall describe mechanisms for effective management of the service, including the nature and the amount of supervision required for personnel to carry out specific procedures, as well as mechanisms governing interdepartmental relationships and communications.

(3) Staff orientation and inservice training shall be required, provided and documented in accordance with written hospital policies and procedures.

(b) Operation and service delivery. Respiratory care services shall be provided in a manner which assures the achievement and maintenance of generally accepted standards of professional medical practice and patient care.

(1) Respiratory care services shall only be provided in accordance with specific hospital protocols/policies or upon the orders of members of the medical staff. The orders for respiratory care services shall specify the type, frequency and duration of treatment, and, as appropriate, the type and dose of medication, the type of diluent, and the oxygen concentration.

(2) All respiratory care services provided shall be documented in the patient's medical record, including the type of therapy, date and time of administration, effects of therapy, and any adverse reactions.

(3) If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit shall meet the requirements for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control as set forth in section 405.16 of this Part.

(4) The service shall implement a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of patient care and for the resolution of identified problems. The process shall involve the reporting of findings, conclusions and recommendations to the quality assurance committee in accordance with hospital policies and procedures.

10 NY ADC 405.14
10 NY ADC 405.14
2008 WL 75295876
10 NY ADC 405.14

* Section 405.15.* Radiologic and nuclear medicine services.

(a) General provisions for diagnostic and therapeutic radiologic services. The hospital shall maintain or have available diagnostic radiologic services defined for purposes of this subdivision as imaging services utilizing diagnostic radiation equipment or devices which emit radiation by virtue of the application of high voltage. If therapeutic services are provided, they shall meet the requirements established in subdivision (b) of this section in addition to the requirements of this subdivision. In addition, the hospital shall meet the standards of Part 16 of the State Sanitary Code.

(1) The hospital shall maintain or have available radiologic services according to the needs of the patients as determined by the governing body in consultation with the medical staff and the administration.

(2) Radiologic services shall be provided only on the order of physicians or, consistent with State law, of those other practitioners authorized by the medical staff and governing body to order such services.

(3) Safety for patients and personnel. The radiologic services shall be free from hazards for patients and personnel. Written policies and procedures affecting safety shall be implemented and available for inspection.

(i) Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards and radiation hazards. This includes adequate shielding for patients and personnel, as well as appropriate storage, use and disposal of radioactive materials.

(ii) Any existing or potential hazards identified through periodic inspection by local or State health authorities shall be corrected promptly.

(iii) Personnel shall be instructed in radiation safety principles; and radiation monitoring practices shall be adequate to ensure compliance with all regulatory requirements.

(iv) Radiologic procedures requiring the use of contrast media or fluoroscopic interpretation and control shall be performed with the active participation of a qualified specialist in diagnostic radiology or a physician qualified in a medical specialty related to the radiographic procedure. Emergency equipment and staff trained in its use shall be available for anaphylactic shock reactions from contrast media.
(4) Personnel. The hospital shall provide qualified personnel adequate to supervise and conduct the services. For radiologic tests, the following personnel standards shall apply for the purposes of this subdivision:

   (i) a full-time or part-time radiologist who is board certified or board admissible in radiology shall direct the clinical aspects of the organization and delivery of radiologic services. That radiologist or another individual qualified by education and experience shall direct the administrative aspects of the services;

   (ii) radiologic tests shall be interpreted by a board certified or board admissible radiologist, except that radiologic tests may be interpreted by practitioners within their field of specialization who are granted privileges to interpret such tests by the governing body and the medical staff in consultation with the director of radiologic services pursuant to the credentialing process in the hospital;

   (iii) the services of qualified radiologists, qualified practitioners, and licensed radiologic technologists shall be sufficient and available to meet the needs of the patients. A licensed technologist shall be on duty or available at all times and function in accordance with article 35 of the Public Health Law and Part 89 of this Title;

   (iv) use of the radiologic equipment and administration of radiologic procedures shall be limited to personnel who are currently licensed and designated as qualified by the hospital in accordance with any applicable licenses and regulations.

(5) Records. Records of radiologic services including interpretations, consultations and therapy shall be filed with the patient's record, and duplicate copies shall be kept in the radiology department/service. All films, scans and other image records shall be referenced in the patient's medical record and retained in the patient's medical record, radiology department/service or in another central location accessible to appropriate staff.

   (i) Requests by the attending practitioner for X-ray examination shall contain a concise statement of reasons for the examination which shall be authenticated by the requestor.

   (ii) The radiologist or other practitioner who performs radiology services shall authenticate reports of his or her interpretations.

   (iii) The hospital shall retain films, scans and other image records which have not been incorporated in the medical record for at least six years or three years after a minor patient reaches the age of majority.

(b) Therapeutic radiology or radiation oncology. Therapeutic radiology or radiation oncology services shall be provided in accordance with the following:

   (1) no facility providing the service shall refuse treatment of a patient on the basis of the referring practitioner or practitioner's facility affiliation, if any;

   (2) institutions shall provide services for patients who cannot attend treatment sessions during normal day shift working hours;

   (3) therapeutic radiology or radiation oncology services shall utilize four or more megavoltage (MEV) or cobalt teletherapy units with a source-axis distance of 80 or more centimeters and rotational capabilities as the primary unit in a multi-unit radiotherapy service or as the sole unit in a smaller radiotherapy unit;

   (4) a therapeutic radiology service shall be headed by a board admissible or board certified radiation therapist or a general radiologist who devotes at least 80 percent of his/her time to the practice of therapeutic radiology and who treats not fewer than 175 patients per year;

   (5) a therapeutic radiology service shall have on staff:

      (i) one full-time New York State licensed radiation therapy technologist for every MEV unit; and

      (ii) a full-time registered professional nurse with appropriate education and experience;

   (6) a facility with a therapeutic radiology service shall have on staff or through formal arrangements:

      (i) a board admissible or board certified medical oncologist, hematologist or other specialist who devotes at least 80 percent of his/her practice to medical oncology and who treats not fewer than 175 oncology patients per year; and

      (ii) a radiological physicist who will be involved in treatment, planning and dosimetry as well as calibrating the equipment, and who holds a degree in physics and who is either certified or admissible for certification by the American Board of Radiology or the American Board of Health Physicists; or

         (a) a person holding a degree in physics and having full-time radiation therapy experience; or

         (b) a physicist in training or a dosimetrist supervised by a part-time radiological physicist;

   (7) the therapeutic radiology service shall be part of a multidisciplinary approach to the management of cancer patients, involving a variety of specialists in a joint treatment program, either through formal arrangement or in the facility;
(8) each patient shall have a treatment plan in his/her medical records;

(9) each therapeutic radiology service shall have access, either through formal arrangements or in the facility, to a full range of diagnostic services, including ultrasound, hematology, pathology, CT scanners nuclear medicine and diagnostic radiology;

(10) each facility providing therapeutic radiology services shall have access to the full range of rehabilitation therapies, including but not limited to physical therapy, occupational therapy, vocational training, and psychological counseling services for its radiotherapeutic patients;

(11) a radiation therapy program operating an MEV unit with photon or electron beam energies greater than 10 MEV's must be a part of a comprehensive program of cancer care which includes surgical oncology, medical oncology, pathology and diagnostic radiology. In addition such program shall meet the following standards:

(i) there shall be two full-time equivalent radiation oncologists on staff who are board-certified in radiation oncology or have equivalent training and experience and whose professional practices are limited to radiation oncology;

(ii) there shall be a full-time medical radiation physicist assigned to the radiation therapy program for the treatment planning of patients; and

(iii) there shall be a simulator available within the radiation therapy program used for producing precise mock-ups of geometric relationships of treatment equipment to a patient and yielding high quality diagnostic radiographs of the treatment portals.

(c) Nuclear medicine services. If the hospital provides nuclear medicine services, those services shall meet the needs of the patients in accordance with generally acceptable standards of practice. Nuclear medicine services shall be ordered only by a physician whose Federal or State licensure and staff privileges allow such referrals.

(1) Organization and staffing. The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.

(i) The clinical aspect of the organization and delivery of nuclear medicine services shall be directed by a physician who is qualified in nuclear medicine and named in the facility's New York State Health Department or New York City Health Department radioactive materials license as authorized to use radioactive materials in humans. The administrative aspects of these services shall be directed by that physician or another individual qualified for such duties by education and experience.

(ii) The qualifications, training, functions and responsibilities of all nuclear medicine personnel shall be specified by the clinical service director in accordance with applicable regulations and approved by the medical staff and the hospital.

(2) Delivery of service. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with generally acceptable standards of practice and pertinent laws, rules and regulations.

(i) In-house preparation of radiopharmaceuticals shall be by, or under the direct supervision of, an appropriately trained registered pharmacist or a physician whose use of radioactive materials is authorized in the facility's New York State Health Department or New York City Health Department radioactive materials license.

(ii) If clinical laboratory tests are performed in the nuclear medicine service, the service shall meet the requirement for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control in accordance with the requirements of section 405.16 of this Part.

(3) Facilities. The hospital shall provide equipment and supplies which are appropriate for the types of nuclear medicine services offered and shall maintain such for safe and effective performance. The equipment shall be:

(i) maintained in safe operating condition; and

(ii) inspected, tested, and calibrated at least annually by qualified personnel and at the intervals specified in the hospital's quality assurance program.

(4) Records. The hospital shall maintain authenticated and dated reports of nuclear medicine interpretations, consultations and procedures.

(i) The hospital shall maintain copies of nuclear medicine reports which have not been incorporated into the patient's medical record for at least six years or three years after the patient reaches the age of majority.

(ii) Interpretation of the results of nuclear medicine procedures shall be made by a physician authorized in the facility's New York State Health Department or New York City Health Department radioactive materials license, or a physician under his/her tutelage. Interpretations may be made in
consultation with the referring practitioner or other practitioners. The authorized physician, or physicians in tutelage, shall authenticate and date the interpretations of these tests.

10 NY ADC 405.15
10 NY ADC 405.15
2008 WL 75295877
10 NY ADC 405.15

* Section 405.16.* Laboratory services.

The hospital shall provide laboratory services that meet the needs of the patients as determined by the medical staff and the hospital.

(a) The hospital shall ensure that all clinical laboratory services provided or arranged for by the hospital comply with article 5, title V of the New York State Public Health Law and with Subpart 58-1 (Clinical Laboratories) of this Title, or for facilities located in New York City, with article 13 of the New York City Health Code. Hospitals shall ensure that all blood banks and transfusion services comply with article 31 of the New York State Public Health Law and Subpart 58-2 (Blood Banks) of this Title.

(b) The hospital shall maintain an adequately organized and supervised clinical laboratory with the necessary staff, space, facilities and equipment to meet the needs of its patients.

(1) Emergency laboratory services shall be available 24 hours a day, seven days a week, including holidays.

(2) For emergency situations, the hospital shall have immediately available a minimum blood supply.

(3) A written description of all laboratory services provided shall be available to the medical staff.

(4) The laboratory shall make provision for the proper receipt and reporting of tissue specimens.

(c) Personnel. The hospital shall provide personnel qualified to direct and staff the laboratory.

(1) The hospital shall ensure that all laboratory services are conducted under the supervision of a director who holds a certificate of qualification issued by the New York State Department of Health or, where applicable, the New York City Department of Health.

(2) The laboratory director shall:
   (i) provide technical supervision of all laboratory services, regardless of site;
   (ii) assure that all tests, examinations and procedures are properly performed, recorded and reported;
   (iii) assure that all tests for hospital patients are ordered by a practitioner so authorized by the hospital;
   (iv) assure that appropriate signatures are on all cytology and histopathology reports and that all reports are filed with the patient’s medical record and duplicate copies kept in a manner which permits ready identification and accessibility;
   (v) assure that the laboratory staff:
      (a) have appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently;
      (b) are sufficient in number for the scope and complexity of the services provided; and
   (vi) assure that there is a documented quality control program in effect for all laboratory services in accordance with the requirements outlined in Part 58 of this Title and in conjunction with the hospital-wide quality assurance program required by section 405.6 of this Part.

(d) Tissue examination. Tissue pathology services shall be provided by and under the direction of a pathologist possessing a certificate of qualification issued by the New York State Department of Health or, where appropriate, the New York City Department of Health. The medical staff and the pathologist shall identify which tissue specimens require a macroscopic examination only and which tissue specimens require both macroscopic and microscopic examinations. Policies and procedures pertaining to the receipt and holding of tissue specimens shall be developed and implemented and shall, at a minimum, include the following:

(1) a pathologist shall be responsible for verifying the receipt of tissues for examinations;

(2) a plan is established in the absence of a pathologist for sending all tissues requiring examination to a qualified pathologist outside the hospital; and

(3) provisions for maintaining a tissue file in the hospital.

(e) Blood, blood products and transfusion services. The hospital shall ensure that there are facilities provided or readily available for the acquisition, safekeeping, transfusion and distribution of blood and
that storage and use of blood products is under the direction of a blood bank director possessing a certificate of qualification issued by the New York State Department of Health, or where applicable, the New York City Department of Health.

(1) The hospital shall maintain, as a minimum, proper blood storage facilities under control and supervision of the blood bank director.

(2) In the case of services provided by an outside blood bank, the hospital shall have an agreement governing the acquisition, transfer and availability of blood and blood products, including plasma derivatives, that is reviewed and approved by the blood bank director, transfusion committee and administration.

(3) There shall be provision for prompt blood grouping, antibody detection, and compatibility testing, and for laboratory investigation of transfusion reactions.

(4) Blood storage facilities in the hospital shall have a temperature alarm system that is regularly inspected.

(5) Records shall be kept on file indicating the receipt and disposition of all blood and blood products acquired by the hospital.

(6) Samples of each unit of transfused blood and blood products, including plasma derivatives, shall be retained for further testing the event of reactions. The hospital shall promptly dispose of all blood not retained for further testing that has exceeded its expiration date.

(7) The hospital, according to its established procedure, shall review all transfusions of blood or blood derivatives and promptly investigate and report all transfusion reactions. Procedures shall be established and implemented for ensuring that reports of all acute hemolytic transfusion reactions are made to the hospital-wide quality assurance program and to the department pursuant to section 405.8 of this Part and that, as appropriate, recommendations are made to the medical staff regarding improvements in transfusion procedures and practices.

10 NY ADC 405.16
10 NY ADC 405.16
2008 WL 75295878
10 NY ADC 405.16

* Section 405.17.* Pharmaceutical services.

The hospital shall provide pharmaceutical services that are available at all times on the premises to meet the needs of the patients. The hospital shall have a pharmacy that is registered and operated in accordance with article 137 of the New York State Education Law and is directed by a registered pharmacist trained in the specialized functions of hospital pharmacy.

(a) Organization and direction. The pharmacy shall be responsible, in conjunction with the medical staff, for ensuring the health and safety of patients through the organization, management and operation of the service in accordance with accepted professional principles and the proper selection, storage, preparation, distribution, use, control, disposal and accountability of drugs and pharmaceuticals.

(1) The director shall be employed on a full-time or part-time basis based on the needs of the hospital.

(2) The director, in conjunction with designated members of the medical staff, shall ensure that:

(i) information relating to drug interactions, drug therapies, side effects, toxicology, dosage, indications for use, and routes of administration is available to the professional staff;

(ii) a formulary is established and reviewed at least annually and updated as necessary to meet the needs of the patients for use in the hospital to assure quality pharmaceuticals at reasonable costs;

(iii) standards are established concerning the use and control of investigational drugs and research in the use of recognized drugs;

(iv) clinical data are evaluated concerning new drugs or preparations requested for use in the hospital; and

(v) the list of floor stock medication is reviewed and recommendations are made concerning drugs to be stocked on the nursing unit floors and by other services.

(3) The director shall be responsible for developing and implementing written policies and procedures for the intrahospital distribution of drugs.

(4) Effective October 1, 1990, each hospital shall have implemented a unit-dose distribution system.

(5) The pharmaceutical service shall have an adequate number of registered pharmacists and other qualified personnel to ensure the availability of quality services including emergency services, 24 hours per day, seven days per week.
(6) All drug storage, preparation and dispensing shall be under the supervision of the director and shall be monitored for adherence to hospital policies and procedures. Monitoring reports shall be documented and available for inspection.

(7) The director shall ensure that current and accurate records are kept of the transactions of the pharmacy, including but not limited to:
   (i) a system of records and bookkeeping in accordance with the policies of the hospital for:
      (a) maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies; and
      (b) charging patients for drugs and pharmaceutical supplies;
   (ii) a record of inventory and dispensing of all controlled substances maintained in accordance with article 33 of the Public Health Law and Part 80 of this Title; and
   (iii) the labeling of all inpatient and outpatient medications in accordance with article 137 of the State Education Law and 8 NYCRR section 29.7.

(8) The director shall ensure that drug monitoring services are provided appropriate to each inpatient's needs. This shall include, but not be limited to, the maintenance of a medication record or drug profile for each inpatient which is based on available drug history and current therapy.

(9) The director will ensure that there is a quality assurance program to monitor personnel qualifications, training, performance, equipment and facilities.
   (i) The director shall require and document the participation of pharmacy personnel in relevant education programs, including orientation of new employees as well as inservice and outside continuing education programs.
   (ii) The quality assurance program shall include policies and procedures to minimize drug errors.
   (iii) The director in conjunction with the medical staff shall ensure the monitoring and evaluation of the quality and appropriateness of patient services provided by the pharmaceutical service.

(10) The director shall participate in those aspects of the hospital's overall quality assurance program that relate to drug utilization and effectiveness.

(b) Operation and service delivery. All drugs and biologicals shall be controlled and distributed in accordance with written policies and procedures.

(1) The compounding, preparation, labeling or dispensing of drugs shall be performed by a licensed pharmacist or pharmacy intern in accordance with applicable State and Federal laws.

(2) All packing and repacking of medications shall be performed in the pharmacy by or under the direct supervision of a pharmacist in accordance with article 137 of the State Education Law.
   (i) Written policies and procedures shall indicate how such packages shall be labeled to identify the lot number or reference code and manufacturer's or distributor's name for proper identification and safety.
   (ii) Repacking and inventory records shall be maintained by the pharmacy.
   (iii) Written policies and procedures shall specify those medications which will not be obtained from manufacturers or distributors in single unit packages and those which will not be repackaged as single units in the facility.

(3) Policies and procedures for the unit-dose drug distribution system shall be developed and implemented and shall include, but not be limited to:
   (i) each patient shall have his or her own receptacle, such as a tray, bin, box cassette, drawer or compartment, appropriately labeled as to patient, and containing his or her own medications. Each single unit package of medication shall be labeled in accordance with requirements set forth in article 137 of the State Education Law;
   (ii) delivery and exchange of patient medications shall occur as scheduled and as specified in the service's written policies and procedures. Not more than a 72-hour supply of prescribed medications shall be delivered to or available in the patient care area at any time;
   (iii) methods for procuring drugs on a routine basis, in emergencies and in the event of disaster shall be identified in the service's written policies and procedures; and
   (iv) written policies and procedures shall be developed and implemented regarding emergency kits and emergency carts including provisions for ensuring that emergency kits are secure and accessible and are specific to service locations, but are not kept under lock and key;
      (a) locations and contents shall be identified and approved by the pharmaceutical service and the medical staff;
      (b) frequency of checking contents and expiration dates shall be specified in written policies and procedures.

(4) Outdated, mislabeled, discontinued, expired or otherwise unusable drugs and biologicals shall not be available for patient use.
(5) A procedure shall be developed to provide for the availability of drugs and biologicals during periods of time when a pharmacist may not be immediately available.

(6) Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after a time that is specified in the service's policies and procedures as determined by the medical staff.

(7) Policies and procedures shall be developed and implemented for documenting, reviewing and, as appropriate, reporting dispensing errors, adverse drug reactions and drug defects.

(c) Physical facilities. The hospital shall provide facilities for the storage, safeguarding, preparation, and dispensing of drugs.

(1) Floor stock medications shall be issued to floor units in accordance with the facility's written policies and procedures:

(i) all floor stocks must be properly controlled and shall be limited to those medications identified on an approved floor stock list;

(ii) floor stock will be checked at least monthly by or under the direct supervision of a pharmacist for outdated and unauthorized medications.

(2) All drugs and biologicals shall be stored in locked storage areas and all controlled substances shall be stored in accordance with the storage requirements set forth in article 33 of the Public Health Law and Part 80 of this Title.

(3) All abuses and losses of controlled substances shall be reported to the director, and to the medical staff, as appropriate, in accordance with applicable Federal and State laws.

10 NY ADC 405.17
10 NY ADC 405.17
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* Section 405.18.* Rehabilitation services.

The hospital shall make available rehabilitation services consistent with the needs of the patients, which shall be designed to provide individualized, goal-oriented, comprehensive and coordinated services to minimize the effects of physical, mental, social and vocational disadvantages and to effect a realization of the patient's potential for useful and productive activity while ensuring the health and safety of the patient. Such services include but are not limited to audiology, occupational therapy, physical therapy and speech-language pathology and shall be delivered in accordance with a written plan for treatment. Hospitals providing general rehabilitation services but not providing comprehensive inpatient physical medicine and rehabilitation programs shall meet the provisions of subdivisions (a) and (b) of this section. Hospitals which do provide comprehensive inpatient physical medicine and rehabilitation programs shall meet the provisions of subdivisions (a) and (c) of this section. Hospitals which provide a spinal cord injury program shall meet the provisions of subdivisions (a), (c) and (d) of this section. Hospitals which provide a traumatic head injury program shall meet the provisions of subdivisions (a), (c) and (e) of this section.

(a) Organization and staffing.

(1) There shall be a director of the service who shall have administrative responsibility for the delivery of patient care and for the supervision of the service. The director shall have the necessary knowledge, experience and capabilities to properly supervise and administer the service.

(2) Physical therapy, occupational therapy, speech-language pathology, or audiology services, if provided, shall be provided by staff who meet the qualifications specified by the governing body, and who are licensed and currently registered by the New York State Education Department.

(i) Each individual who provides rehabilitation services shall be competent to provide such services by reason of education, training, experience and demonstrated performance.

(ii) A sufficient number of qualified competent professional and support personnel shall be available to meet the needs of the patient population and the objectives of the service.

(iii) Sufficient space, equipment and facilities shall be available to support the clinical and administrative functions of the service.

(3) Written policies and procedures which describe the mechanism for the management of the rehabilitation service as well as interdepartmental relationships and communications shall be implemented.

(4) Staff orientation and inservice training shall be required, provided and documented in accordance with hospital policies and procedures.

(b) Delivery of services.
(1) The hospital shall assure that patients who require rehabilitation services are identified and that appropriate services are provided in accordance with the orders of attending physicians or other practitioners as authorized by the governing body, consistent with the New York State Education Law, to order such services. Working relationships among medical staff, nursing staff and rehabilitation service staff shall be established to ensure the identification of patients and delivery of appropriate services.

(2) Rehabilitation services shall be ordered by the attending physician or authorized practitioners and provided in accordance with a written multidisciplinary treatment plan which is based upon a functional assessment and evaluation performed and documented by a professional who is qualified under the provisions of the New York State Education Law, and shall include the diagnosis or diagnoses, precautions and contraindications, and goals of the prescribed therapy.

(i) The multidisciplinary treatment plan shall identify patient needs, establish realistic and measurable goals and identify specific therapeutic interventions by type, amount and frequency needed to maintain, restore and/or promote the patient's functioning and health, within stated time frames for achievement.

(ii) The multidisciplinary treatment plan shall be prepared by rehabilitation service staff with the involvement of the practitioner who ordered the services, the nursing staff, as well as the patient and the family to the extent possible.

(iii) The patient's progress and response to treatment shall be assessed on a timely and regular basis, in accordance with hospital policies and procedures, and documented in the patient's medical record.

(iv) Multidisciplinary treatment plans and goals shall be revised as appropriate in accordance with the assessment of the patient's progress and the results of treatment.

(v) The rehabilitation service shall monitor and evaluate the quality and appropriateness of patient care and resolve identified problems through implementation of a planned and systematic process. The process shall involve reporting to the quality assurance committee in accordance with hospital policies and procedures.

(vi) In accordance with the provisions of section 405.9(f) of this Part, rehabilitation therapy staff shall work with the attending practitioner, the nursing staff, other health care providers and agencies as well as the patient and the family, to the extent possible, to assure that all appropriate discharge planning arrangements have been made prior to discharge to meet the patient's identified needs.

(c) Comprehensive inpatient physical medicine and rehabilitation programs, if provided, shall be approved by the department and shall be organized and operated in accordance with the following:

(1) the beds shall be in a designated area forming a distinct organizational unit, shall be staffed and equipped for the specific purpose of providing a comprehensive physical medicine and rehabilitation program, and shall be used exclusively for such purpose;

(2) patients exhibiting conditions, including but not limited to the following, shall be considered as candidates for admission to a comprehensive inpatient physical medicine and rehabilitation program: severe disabling impairments of recent onset or recent progression, those being readmitted for such conditions, or those with such conditions who previously have not received comprehensive rehabilitation services;

(3) the program shall be directed by a chief of physical medicine and rehabilitation who shall be full-time with the physical medicine and rehabilitation program. The chief of physical medicine and rehabilitation shall be a board certified physiatrist or a physician who by training and experience is knowledgeable in physical and rehabilitative medicine;

(4) the attending physician for a patient admitted to the program shall be a rehabilitation physician, a physician who is board certified in physical medicine and rehabilitation or a physician who by training and experience is knowledgeable in physical medicine and rehabilitation;

(5) nursing care shall be provided under the direction of a registered professional nurse who has appropriate training and experience in rehabilitation nursing as determined by the program and the hospital;

(6) the program shall provide a core of services which includes: rehabilitation nursing, physical therapy, occupational therapy, medical social work, psychology and speech-language pathology;

(7) dependent upon the needs of the patients served, the program shall provide or make formal arrangements for the following services: dental, vocational rehabilitation, education, orthotics, prosthetics, respiratory therapy, rehabilitation engineering, driver education, audiology and therapeutic recreation;

(8) physician consultation shall be available, including but not limited to: general surgery, internal medicine, neurology, neurosurgery, ophthalmology, orthopedic surgery, otorhinolaryngology,
pediatrics, physical medicine and rehabilitation, plastic surgery, psychiatry, pulmonary medicine and urology;

(9) patient care services shall be provided through a coordinated interdisciplinary team approach. Participation of members of the core team in the direct care of each patient will vary dependent upon individual patient needs. Patients shall receive a comprehensive evaluation within seven days following admission followed by regular team conferences at intervals appropriate to the treatment goals established for the patient. These conferences shall result in documentation of decisions on rehabilitation goals that meet professional standards of care, identification of services needed for the patients to progress toward those goals, and evaluation of progress toward meeting established goals;

(10) each program shall develop and implement written policies and procedures for the following: patient admission and orientation, assessment and evaluation, program management, discharge planning and follow-up;

(11) the program shall establish formalized relationships with other area hospitals and providers of comprehensive rehabilitation services, regardless of setting, which shall include provisions for consultation, inservice education, and the evaluation of common treatment protocols;

(12) programs shall have written agreements in place for the transfer of patients who need medical or specialty care not available at the hospital of admission. Transfer agreements shall be mutually agreed upon by both the transferring and receiving facility and shall be reviewed on at least an annual basis;

(13) there shall be an organized outpatient physical medicine and rehabilitation program at the hospital which shall provide a range of services equal in scope to that of the inpatient program including spinal cord and head injury programs where they are provided; and

(14) there shall be an organized program for follow-up care to maintain or improve patient health status and functioning following discharge.

(d) A spinal cord injury program, if provided, shall provide coordinated and integrated services for spinal cord injured persons, whether from trauma or disease, enabling those patients served to achieve optimal functioning;

(1) The spinal cord injury program shall be a designated unit for spinal cord injured people with a designated staff to serve the spinal cord injured patients.

(2) The spinal cord injury program shall be directed by a physician with special interest and competence in the care of those with spinal cord injury.

(3) Nursing services for the spinal cord injury program shall be provided under the direction of a registered professional nurse who has appropriate training and experience in the provision of rehabilitation nursing for spinal cord injured individuals.

(4) The following shall be available seven days a week, 24 hours per day: registered professional nurses, trained personnel capable of provided intermittent catheterization, as required, and respiratory therapy services.

(5) There shall be a formally organized program for patient and family spinal cord injury education regarding bladder management, bowel management, pulmonary care, skin care, instruction in medications, nutrition, access to follow-up medical care, care of equipment, and sexual counseling.

(e) A traumatic head injury program, if provided, shall be designed specifically to serve medically stable, traumatically brain injured individuals. The program shall provide goal-oriented, comprehensive, interdisciplinary and coordinated services directed at restoring the individual to the optimal level of physical, emotional, cognitive and behavioral functioning.

(1) General requirements. The hospital shall ensure:

(i) the development and consistent application of written admission and continued stay criteria for this service which include but are not limited to the use of a generally recognized classification system for measuring each individual's physical, behavioral and cognitive level of functioning and the family's capabilities and functioning, and are consistent with the following requirements:

(a) a patient admitted for active rehabilitation shall be a person who has suffered a traumatic brain injury with structural nondegenerative brain damage, is medically stable, is not in a persistent vegetative state, demonstrates potential for physical, behavioral and cognitive rehabilitation and may evidence moderate to severe behavior abnormalities. The patient must be capable of exhibiting at least localized responses by reacting specifically but inconsistently to stimuli;

(b) a patient admitted for active coma stimulation shall be a person who has suffered a traumatic brain injury with structural nondegenerative brain damage and is in a coma. The patient may be completely unresponsive to any stimuli or may exhibit a generalized response by reacting inconsistently and nonpurposefully to stimuli in a nonspecific manner; and
(c) a patient who has diffuse brain damage caused by anoxia, toxic poisoning, cerebral vascular accident, or encephalitis may be considered appropriate for admission to this program either for active coma stimulation or active rehabilitation;

(ii) records shall be maintained for at least two years identifying persons who were determined by the facility to be ineligible for admission under the head injury program. The records shall indicate the reason for ineligibility and any referral action taken;

(iii) inservice and continuing education programs which address the medical, physical, cognitive, psychosocial and behavioral needs of head injured patients shall be conducted on a regular basis for all personnel caring for such patients;

(iv) educational programs shall be conducted for personnel not providing direct care but who come in contact on a regular basis with head injured patients. The programs should familiarize personnel with the specific needs of these patients; and

(v) education and counseling services shall be available and offered to the patient and families as needed.

(2) Program management and staffing. There shall be distinct staffing for the direct care services in the head injury program unit.

(i) The program shall be administered by a program director who has at least two years of clinical or administrative experience in head injury rehabilitation programs. The program director shall have specific responsibilities which include, but are not limited to:

(a) administrative direction and oversight of the program;

(b) ongoing review of the program and implementation of program changes as identified; and

(c) development and implementation of educational programs on an ongoing basis for staff working with head injured patients.

(ii) A physician who has advanced training and experience in the care of the head injured shall be responsible for the medical direction and medical oversight of the head injury program and may serve as the program director.

(iii) A qualified specialist in physical medicine and rehabilitation or a physician who has training and experience in the care and rehabilitation of head injured patients shall be responsible for the care of each patient.

(iv) A primary interdisciplinary team of health care professionals with special interest, training, experience and expertise in head injury rehabilitation shall be responsible for the assessment, coordinated program and care planning, and direct services for each head injured patient. The interdisciplinary team members shall be specifically assigned to serve head injured patients and the team shall include as a minimum the following types of health care professionals:

(a) physician;

(b) registered professional nurse;

(c) physical therapist;

(d) occupational therapist;

(e) speech-language pathologist;

(f) social worker;

(g) dietitian;

(h) therapeutic recreation specialist; and

(i) clinical psychologist with training and experience in neuropsychology.

(v) Nursing services for the head injury unit shall be provided under the direction of a registered professional nurse who is certified or eligible for certification in rehabilitation nursing or who has demonstrated appropriate clinical competency, training and experience in the provision of rehabilitation nursing for head injured patients as determined by the program and the hospital.

(vi) There shall be at least one registered professional nurse with experience in rehabilitation nursing assigned to each shift on the head injury unit.

(vii) Depending upon types of patients being served and individual patient's need, the program shall provide or make formal arrangements for vocational rehabilitation services and special education services.

(3) Interdisciplinary care planning.

(i) A member of the interdisciplinary team managing the patient shall be designated to:

(a) coordinate the overall plan of care and services and identify unmet needs for each patient including discharge and follow-up plans;

(b) serve as a liaison among patient, family and staff to ensure that patient and family concerns are addressed; and
(c) serve as a liaison with the educational, social and vocational resources in the community which are serving the patient.

(ii) A written, comprehensive care plan shall be developed and implemented which establishes rehabilitation goals for each patient. The plan shall be developed on admission by the interdisciplinary team and the attending physician in consultation with the patient, the patient's family and outside agencies, as necessary. The care plan shall be reviewed at least every 14 days and modified according to the patient's needs by the interdisciplinary team. The comprehensive care plan is based upon initial and ongoing integrated, interdisciplinary assessments which shall address as a minimum, medical, dental and neurological status, nutritional status, sensorimotor capacity, the developmental needs of children and adolescents, cognitive, perceptual and communicative capacity, affect and mood, activities of daily living skills, educational or vocational capacities, sexuality issues and concerns, family unity counseling and community reintegration needs and recreation and leisure time interests.

(iii) Findings from the comprehensive care plan reviews shall be integrated into the utilization review program of the facility.

(iv) A written discharge plan shall be developed for each patient as part of the overall care plan and shall include input from all professionals caring for the patient, the patient's family, the patient if capable and, as appropriate, any outside agency or resource that will be involved with the patient following discharge.

(v) The family and patient shall receive preparation for discharge through the facility's educational and counseling services.

(vi) There shall be effective provision for follow-up care and post discharge care which shall include as a minimum, formal linkages to other sources of care and services for head- or brain-injured patients including outpatient services, residential health care facility-based services, home care service agency services and vocational education and rehabilitation services.

4) Utilization review monitoring. The facility shall participate with the commissioner or his designee in a program of patient care and services monitoring which shall include, but not be limited to: review of admissions, care and services provided, continued stays, and discharge planning. The facility shall furnish such records and reports at such frequency as the commissioner or his designee may require and shall make available members of the interdisciplinary patient care team for case conferences as the commissioner or his designee deems necessary.

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* Section 405.19.* Emergency services.

(a) General.

(1) Emergency services shall be provided in accordance with this subdivision or subdivisions (b) through (e) of this section as appropriate.

(2) If emergency services are not provided as an organized service of the hospital, the governing body and the medical staff shall assure:

(i) prompt physician evaluation of patients presenting emergencies;

(ii) initial treatment and stabilization or management; and

(iii) transfer, where indicated, of patients to an appropriate receiving hospital. The hospital shall have a written agreement with local emergency medical services (EMS) to accommodate the need for timely inter-hospital transfer on a 24 hours a day, 7 days a week, 365 days a year basis.

(b) Organization.

(1) The medical staff shall develop and implement written policies and procedures approved by the governing body that shall specify:

(i) the responsibility of the emergency services to evaluate, initially manage and treat, or admit or recommend admission, or transfer patients to another facility that can provide definitive treatment. Such policies and procedures shall include a written agreement with one or more local emergency medical services (EMS) to accommodate the need for timely inter-facility transport on a 24 hours a day, 7 days a week, 365 days a year basis;

(ii) the organizational structure of the emergency service, including the specification of authority and accountability for services; and

(iii) explicit prohibition on transfer of patients based on their ability or inability to pay for services.
(2) The emergency service shall be directed by a licensed and currently registered physician who is board-certified or board-admissible for a period not to exceed five years after the physician first attained board admissibility, in emergency medicine, surgery, internal medicine, pediatrics or family practice and who is currently certified in advanced trauma life support (ATLS) or has training and experience equivalent to ATLS. Such physician shall also have successfully completed a course in advanced cardiac life support (ACLS) or have had training and experience equivalent to ACLS. A licensed and currently registered physician who is board-certified or board-admissible in psychiatry for a period not to exceed five years after the physician first attained board admissibility, in psychiatry may serve as psychiatrist director of a separately operated psychiatric emergency service. Directors of separately operated psychiatric emergency services need not be qualified to perform ACLS and ATLS.

(3) An emergency service shall have laboratory and X-ray capability, including both fixed and mobile equipment, available 24 hours a day, seven days a week, to provide test results to the service within a time considered reasonable by accepted emergency medical standards.

(c) General policies and procedures.

(1) The location and telephone number of the State Department of Health designated poison control center, shall be maintained at the telephone switchboard and in the emergency service.

(2) All cases of suspected child abuse or neglect shall be treated and reported immediately to the New York State Central Register of Child Abuse and Maltreatment pursuant to procedures set forth in article 6, title 6 of the Social Services Law.

(3) Domestic violence. The emergency service shall develop and implement policies and procedures which provide for the management of cases of suspected or confirmed domestic violence victims in accordance with the requirements section 405.9(e) of this Part.

(4) The emergency service shall establish and implement written policies and procedures for the maintenance of sexual offense evidence as part of the hospital-wide provisions required by this Part. An organized protocol for survivors of sexual offenses, including medical and psychological care shall be incorporated into such policies and procedures. These policies, procedures and protocols shall be consistent with the standards for patient care and evidence collection established in section 405.9(c) of this Part.

(5) The emergency service, in conjunction with the discharge planning program of the hospital, shall establish and implement written criteria and guidelines specifying the circumstances, the actions to be taken, and the appropriate contact agencies and individuals to accomplish adequate discharge planning for persons in need of post emergency treatment or services but not in need of inpatient hospital care;

(6) An admission and discharge register shall be current and shall include at least the following information for every individual seeking care:

(i) date, name, age, gender, ZIP code;

(ii) expected source of payment;

(iii) time and means of arrival, including name of ambulance service for patients arriving by ambulance;

(iv) complaint and disposition of the case; and

(v) time and means of departure, including name of ambulance service for patients transferred by ambulance.

(7) There shall be a medical record that meets the medical record requirements of this Part for every patient seen in the emergency service. Medical records shall be integrated or cross-referenced with the inpatient and outpatient medical records system to assure the timely availability of previous patient care information and shall contain the prehospital care report or equivalent report for patients who arrive by ambulance.

(8) Review of the hospital emergency service shall be conducted at least four times a year as a part of the hospital's overall quality assurance program. Receiving hospitals shall report to sending hospitals and emergency medical systems, as appropriate, all patients that die unexpectedly within 24 hours upon arrival at the receiving hospitals. These patient mortalities shall be included in both hospital's quality assurance review.

(d) Staffing. The following requirements are applicable to all organized emergency services:

(1) Emergency service physician services shall meet the following requirements:

(ii) The emergency services attending physician shall meet the minimum qualifications set forth in either clause (a) or (b) of this subparagraph.

(a) The emergency services attending physician shall be a licensed and currently registered physician who is board-certified in emergency medicine, surgery, internal medicine, pediatrics or family practice and who is currently certified in advanced trauma life support (ATLS) or has training
and experience equivalent to ATLS. Such physician shall also have successfully completed a course in advanced cardiac life support (ACLS) or have had training and experience equivalent to ACLS. A licensed and currently registered physician who is board-certified in psychiatry may serve as psychiatrist attending in a separately operated psychiatric emergency service. A licensed and currently registered physician who is board-admisible in one of these specialty areas and is currently certified in ATLS or who has training and experience equivalent to ATLS and has successfully completed a course in ACLS or has had training and experience equivalent to ACLS may be designated as attending physician for a period not to exceed five years after the physician has first attained board admissibility except that the requirement to be qualified to perform ATLS and ACLS shall not be applicable to qualified psychiatrist attendings in a separately operated psychiatric emergency service. Physicians who are board-certified or admissible, for a period not to exceed five years after the physician first attained board admissibility, in other specialty areas may be designated as attending physicians for patients requiring their expertise.

(b) The emergency services attending physician shall be a physician who:

1. is licensed and currently registered;
2. has successfully completed one year of postgraduate training;
3. has, within the past five years, accumulated 7,000 documented patient contact hours or hours of teaching medical students, physicians in-training, or physicians in emergency medicine. Up to 3,500 hours of documented experience in hospital-based settings or other settings in the specialties of internal medicine, family practice, surgery or pediatrics may be substituted for the required hours of emergency medicine experience on an hour-for-hour basis;
4. has acquired in each of the last three years, an average of 50 hours or more per year of continuing medical education pertinent to emergency medicine or to the specialties of practice which contributed to meeting the 7,000 hours requirement specified in subclause (3) of this clause;
5. is currently certified in ATLS or has training and experience equivalent to ATLS; and
6. has successfully completed a course in advanced cardiac life support (ACLS) or has had training and experience equivalent to ACLS.

(ii) There shall be at least one emergency service attending physician on duty 24 hours a day, seven days a week. For hospitals that exceed 15,000 unscheduled visits annually, the attending physician shall be present and available to provide patient care and supervision in the emergency service. As necessitated by patient care needs, additional attending physicians shall be present and available to provide patient care and supervision. Appropriate subspecialty availability as demanded by the case mix shall be provided promptly in accordance with patient needs. For hospitals with less than 15,000 unscheduled emergency visits per year, the supervising or an attending physician need not be present but shall be available within 20 minutes.

(iii) Other medical staff practitioner services provided in the emergency service shall be in accordance with the privileges granted the individual.

(iv) Every medical-surgical specialty on the hospital's medical staff which is organized as a department or clinical service and where practitioner staffing is sufficient, shall have a schedule to provide coverage to the emergency service by attending physicians in a timely manner, 24 hours a day, seven days a week, in accordance with patient needs.

(2) Nursing services:

(i) There shall be at least one supervising emergency services registered professional nurse present and available to provide patient care services in the emergency service 24 hours a day, seven days a week.

(ii) Emergency services supervising nurses shall be licensed and currently registered and possess current, comprehensive knowledge and skills in emergency health care. They shall have at least one year of clinical experience, be able to demonstrate skills and knowledge necessary to perform basic life support measures, have successfully completed a course in ACLS or have had training and experience equivalent to ACLS and maintain current competence in ACLS as determined by the hospital.

(iii) Registered professional nurses in the emergency service shall be licensed and currently registered professional nurses who possess current, comprehensive knowledge and skills in emergency health care. They shall have at least one year of clinical experience, have successfully completed an emergency nursing orientation program and be able to demonstrate skills and knowledge necessary to perform basic life support measures. Within one year of assignment to the emergency service, each emergency service nurse shall have successfully completed a course in ACLS or have had training and experience equivalent to ACLS and shall maintain current competence in ACLS as determined by the hospital.
Additional registered professional nurses and nursing staff shall be assigned to the emergency service in accordance with patient needs. If, on average:

(a) the volume of patients per eight-hour shift is under 25, an additional registered professional nurse shall be available as needed to assist the supervising registered professional nurse with delivery of direct patient care; or

(b) the volume of patients per eight-hour shift is over 25, there shall be a minimum of two registered professional nurses per shift assigned to provide direct patient care. As patient volume and intensity increases, the total number of available registered professional nurses shall also be increased to meet patient care needs.

(3) Registered physician's assistants and nurse practitioners:

(i) Patient care services provided by registered physician's assistants shall be in accordance with section 405.4 of this Part.

(ii) Patient care services provided by certified nurse practitioners shall be in collaboration with a licensed physician whose professional privileges include approval to work in the emergency service and in accordance with written practice protocols for these services.

(iii) the registered physician assistants and the nurse practitioners shall meet the following standards:

(a) the registered physician assistants and the nurse practitioners in the emergency service shall have successfully completed a course in ACLS or have had training and experience equivalent to ACLS when determined necessary by the hospital to meet anticipated patient needs or when a physician assistant or nurse practitioner is serving as the sole practitioner on duty in a hospital with less than 15,000 unscheduled emergency visits per year;

(b) registered physician assistants and nurse practitioners in the emergency service shall have had training and experience equivalent to ATLS when determined necessary by the hospital to meet anticipated patient needs or when a physician assistant or nurse practitioner is serving as the sole practitioner on duty in a hospital with less than 15,000 unscheduled emergency visits per year.

(4) Support personnel. There shall be sufficient support personnel assigned to the emergency service to perform the following duties on a timely basis: patient registration, reception, messenger service, acquisition of supplies, equipment, delivery and labelling of laboratory specimens, responsible for the timely retrieval of laboratory reports, obtaining records, patient transport and other services as required.

(e) Patient care.

(1) The hospital shall assure that all persons arriving at the emergency service for treatment receive emergency health care that meets generally accepted standards of medical care.

(2) Every person arriving at the emergency service for care shall be promptly examined, diagnosed and appropriately treated in accordance with triage and transfer policies and protocols adopted by the emergency service and approved by the hospital. Such protocols must include written agreements with local emergency medical services (EMS) in accordance with subparagraph (b) (1)(i) of this section. All patient care services shall be provided under the direction and control of the emergency services director or attending physician. In no event shall a patient be discharged unless evaluated and treated as necessary by an appropriately privileged physician, physician's assistant, or nurse practitioner. Hospitals which elect to use physician's assistants or nurse practitioners shall develop and implement written policies and treatment protocols subject to approval by the governing body that specify patient conditions that may be treated by a registered physician's assistant or nurse practitioner without direct visual supervision of the emergency services attending physician.

(3) Hospitals that have limited capability for receiving and treating patients in need of specialized emergency care shall develop and implement standard descriptions of such patients, and have triage and treatment protocols and formal written transfer agreements with hospitals that are designated as being able to receive and provide definitive care for such patients. Patients in need of specialized emergency care shall include, but not be limited to:

(i) trauma patients and multiple injury patients;

(ii) burn patients with burns ranging from moderate uncomplicated to major burns as determined by use of generally acceptable methods for estimating total body surface area;

(iii) high risk maternity patients or neonates or pediatric patients in need of intensive care;

(iv) head injured or spinal cord injured patients;

(v) acute psychiatric patients;

(vi) replantation patients;

(vii) dialysis patients; and

(viii) acute myocardial infarction patients including but not limited to patients with ST elevation.
(4) Hospitals shall verbally request ambulance dispatcher services to divert patients with life threatening conditions to other hospitals only when the chief executive officer or designee appointed in writing, determines that acceptance of an additional critical patient would endanger the life of that patient or another patient. Request for diversion shall be documented in writing and, if warranted, renewed at the beginning of each shift.

(5) Where observation beds are used, they shall be for observation and stabilization and they shall not be used for longer than eight hours duration. Patients in these beds shall be cared for by sufficient staff assigned to meet the patients needs. At the end of eight hours observation or treatment the patient must be admitted to the inpatient service, be transferred in accordance with paragraph (6) of this subdivision, or be discharged to self-care or the care of a physician or other appropriate follow-up service.

(6) Patients shall be transferred to another hospital only when:
(i) the patient's condition is stable or being managed;
(ii) the attending practitioner has authorized the transfer; and
(iii) administration of the receiving hospital is informed and can provide the necessary resources to care for the patient; or
(iv) when pursuant to paragraph (2) of this subdivision, the patient is in need of specialized emergency care at a hospital designated to receive and provide definitive care for such patients.

(7) Hospitals located within a city with a population of one million or more persons shall apply, and if accepted, participate to the full extent of their capability, in the emergency medical service which is operated by such city or such city's health and hospitals corporation.

(f) Quality assurance.
(1) Quality assurance activities of the emergency service shall be integrated with the hospital-wide quality assurance program and shall include review of:
(i) arrangements for medical control and direction of prehospital emergency medical services;
(ii) provisions for triage of persons in need of specialized emergency care to hospitals designated as capable of treating those patients;
(iii) emergency care provided to hospital patients, to be conducted at least four times a year, and to include prehospital care providers, emergency services personnel and emergency service physicians; and
(iv) adequacy of staff training and continuing education.
(2) hospitals as represented by emergency department practitioners and other clinical practitioners relevant to the care provided should also collaborate, as provided under Public Health Law section 3006, in the quality improvement programs of their local EMS to review prehospital care issues including review of specific patient cases.

* Section 405.20.* Outpatient services.

Outpatient services, including ambulatory care services and extension clinics, shall be provided in a manner which safely and effectively meets the needs of the patients.

(a) General requirements. As a minimum when provided, outpatient services shall comply with the rules and regulations set forth in this Part as well as the outpatient care provisions of sections 752.1 and 753.1 and Parts 756, 757 and 758 of Subchapter C of this Title.
(1) The provision of this section shall apply to hospital-sponsored ambulatory services, including part-time and off-site clinics, which accept primary responsibility for health supervision and medical care of patients.
(2) The hospital shall ensure that all care provided by its ambulatory services is in accordance with prevailing standards of professional practice.
(3) The hospital shall conduct periodic reviews of the care rendered by its ambulatory services as part of its overall quality assurance program.
(b) The hospital shall assign a physician to be responsible for the professional services of the outpatient department. Either this physician or an administrator qualified by training and experience shall be responsible for administration of the outpatient services.
(c) Patient care. The hospital shall effectively meet outpatient patient care needs by:
(1) the provision of patient care in a continuous manner by the same health care practitioner, whenever possible;
(2) the appropriate referral to other health care facilities or health care practitioners for services not available;
(3) the identification, assessment, reporting and referral of cases of suspected child abuse or neglect as required by section 405.9(d) of this Part;
(4) compliance with the domestic violence provisions of section 405.9(e) of this Part; and
(5) the development of a written plan of treatment. When treatment is provided it is revised, as necessary, in consultation with other health care professionals.

(d) Hospital-based ambulatory surgery service. In a hospital maintaining an on-site hospital-based ambulatory surgery service, the following requirements supplement existing applicable requirements of sections 405.12 (Surgical services) and 405.13 (Anesthesia services) of this Part. Hospital-based ambulatory surgery services shall mean a service organized to provide surgical procedures which shall be performed for reasons of safety in an operating room on anesthetized patients requiring a stay of less than 24 hours' duration. These procedures do not include outpatient surgical procedures which can be performed safely in a private physician's office or in an outpatient treatment room.

(1) The hospital-based ambulatory surgery service shall be directed by a physician found qualified by the governing body to perform such duties.

(2) The governing body and the medical staff shall develop, maintain and periodically review a list of surgical procedures which may be performed in the service. The medical staff shall assure that procedures performed in the service conform with generally accepted standards of professional practice, in accordance with the competencies of the medical and professional staff who have privileges in the hospital-based ambulatory surgery service, and are appropriate in the facilities and consistent with the equipment available. The medical staff shall, based upon its review of individual medical staff qualifications, recommend to the governing body specific surgical procedures which each practitioner is qualified to perform in the hospital-based ambulatory surgery service.

(3) Hospital-based ambulatory surgery services may be located at the same site as the hospital (on-site) or apart from the hospital (off-site), pursuant to section 709.5 of this Title.

(i) Recovery rooms adequate for the needs of hospital-based ambulatory surgery patients, conveniently located to the operating room, shall be provided.

(ii) Waiting rooms adequate for the needs of patients and responsible persons accompanying patients shall be provided.

(4) Prior to surgery, each patient shall have a timely history and physical examination, appropriate to the patient's physical condition and the surgical procedure to be performed, which shall be recorded in the patient medical record.

(5) Each postsurgery patient shall be observed for postoperative complications for an adequate time period as determined by the attending practitioner and the anesthesiologist. The service shall have written policies for hospital admission of patients whose postoperative status prevents discharge or necessitates inpatient admission.

(6) Detailed verbal instructions understandable to the patient, confirmed by written instructions, and approved by the medical staff of the hospital-based ambulatory surgery service shall be provided to each patient at discharge, to include at least the following:

(i) information about complications that may arise;
(ii) telephone number(s) to be used by the patient should complications or questions arise;
(iii) directions for medications prescribed, if any;
(iv) date, time and location of follow-up visit or return visit; and
(v) designated place to go for treatment in the event of an emergency.

(7) The hospital-based ambulatory surgery service staff shall develop written policies, approved by the medical staff, for documentation of the patient's postoperative course of treatment. The policies must be reviewed and adopted by the governing board of the hospital prior to implementation. The policies must provide a mechanism to assure that complications of surgery or anesthesia, which occur before and after discharge, are identified and documented in the patient's medical record.

(8) The hospital-based ambulatory surgery service shall have an organized system of quality assurance approved by the medical staff and the governing body which undertakes investigations into operative results of surgical procedures performed on the service and maintains statistics on operative failures and complications.

(9) Notwithstanding anything herein to the contrary, an off-site hospital-based ambulatory surgery service shall be operated in accordance with the provisions of Part 755 of this Title.
Section 405.21.* Perinatal services.

(a) Applicability. This section shall apply to all general hospitals having maternity and newborn services and providing pregnancy-related care for women who are pregnant at any stage, parturient or within six weeks from delivery and for infants 28 days of age or less or, regardless of age, who are less than 2,500 grams (51/2 pounds).

(b) Definitions. For the purposes of this section:

(1) Perinatal services shall mean those services provided in a particular hospital where, as a regular practice, maternity patients and newborn infants receive care on a continuum ranging from preconception services to care during all stages of pregnancy, parturition, postpartum and neonatal care.

(2) Perinatal regionalization system shall mean the statewide organization of maternal and newborn health care services, designed as set forth in Part 721 of this Title, to ensure that mothers and newborns receive the care they need in a timely, safe and effective manner.

(3) Labor room shall mean a room for parturient patients in labor, distinct from patient bedrooms and from operating or delivery rooms.

(4) Delivery room shall mean a room distinct from patient bedrooms and set apart for the delivery of parturient patients.

(5) Single unit maternity or labor-delivery-recovery-postpartum model shall mean a model for family-centered maternity and newborn care in which labor, delivery, nursery and postpartum care are all provided in a single room and movable equipment is introduced and withdrawn from the room as required to provide services and care to the mother and neonate.

(6) Rooming-in shall mean an arrangement which allows the mother and her newborn infant to be cared for together, so that the mother may have access to her infant during all or a substantial part of the day and night, not limited to feeding times.

(7) Newborns shall mean all infants 28 days of age or less.

(8) Premature infant shall mean an infant whose gestational age at birth calculated from the first day of the last menstrual period, or using another reliable method for patients with an unreliable history, is less than 37 completed weeks or 258 completed days.

(9) Low birth weight infant shall mean an infant weighing less than 2,500 grams (51/2 pounds) at birth.

(10) Normal newborn nursery shall mean a room for housing newborns who do not need intensive care and are not suspected of nor diagnosed as having any communicable condition.

(11) Neonatal intensive care unit (NICU) shall mean a room at Level II, Level III and Regional Perinatal Center perinatal care services for housing newborns, including premature infants and low birth weight infants, who require specialized care and who are not suspected of nor diagnosed as having any communicable condition.

(12) Observation nursery shall mean a room, physically separate from the normal newborn nursery, where newborns exposed to potential sources of infection and newborns suspected of but not diagnosed as having any communicable condition may be observed pending diagnosis.

(13) Isolation nursery shall mean a room, physically separate from other nurseries, for the isolation of newborns diagnosed as having any communicable condition.

(14) Family planning shall mean the planning and spacing of children by medically acceptable methods to achieve pregnancy, or prevent unintended pregnancy.

(15) Level I perinatal care service shall mean a comprehensive maternal and newborn service as defined by section 721.2(a) of this Title.

(16) Level II perinatal care service shall mean a comprehensive maternal and newborn service as defined by section 721.2(b) of this Title.

(17) Level III perinatal care service shall mean a comprehensive maternal and newborn service as defined by section 721.2(c) of this Title.

(18) Regional perinatal center (RPC) shall mean a hospital or hospitals housing a Level III perinatal care service as defined in section 721.2(d) of this Title.

(19) Perinatal affiliates shall mean Level I, Level II and Level III hospitals which have a current perinatal affiliation agreement as defined in Part 721 of this Title.
Birth center shall mean a place, other than a traditional hospital childbirth unit or birthing room, where births are planned to occur away from the mother's usual residence following a normal uncomplicated pregnancy.

Birthing room shall mean a hospital room designed as a homelike setting which serves as a combined labor/delivery/recovery room and where family members or other supporting persons may remain with a woman as much as possible throughout the childbirth process.

Quality improvement shall mean improvement of the quality of care provided by the RPC or affiliate hospitals through initiatives and analyses designed to identify and then address potential problem areas in care in its own hospital or in affiliated hospitals, or in the region as a whole, through review of either sentinel cases or patterns of care.

(c) General requirements.

(1) Hospitals providing perinatal services shall provide such services in accordance with current standards of professional practice. Written policies and procedures shall be developed and implemented which address the following:

(i) the professional qualifications of the hospital's obstetric and pediatric staff;

(ii) the requirements for consultation with a qualified specialist when required by specific medical conditions;

(iii) the establishment and implementation of rooming-in at the option of each patient unless the establishment or implementation of such program for that patient is medically contraindicated or unless the hospital does not have sufficient facilities to accommodate all such requests;

(iv) protocols and resources available to stabilize and assess newborns for their need of neonatal intensive care; and

(v) the daily care of maternity patients and infants in the perinatal service.

(2) Medical record for each maternity patient. The medical record for each maternity patient admitted to the perinatal service shall be maintained in accordance with section 405.10 of this Part and also shall include the following:

(i) a copy or abstract of the prenatal record, if existing, including a maternal history and physical examination as well as results of maternal and fetal risk assessment, results of maternal HIV, Hepatitis B and Group B strep testing if done, and ongoing assessments of fetal growth and development and maternal health;

(ii) the results of a current physical examination performed by staff granted privileges to perform such examination that meets the requirements of section 405.9(b)(11) of this Part; and

(iii) labor and birth information including records of fetal monitoring and postpartum assessment.

(3) Medical record for each newborn. The medical record for each newborn shall be cross-referenced with the mother's medical record and contain the following additional information:

(i) newborn physical assessment, including APGAR scores, presence or absence of three cord vessels, ability to feed, vital signs and accommodation to extrauterine life;

(ii) newborn care, including the administration of eye prophylaxis and vitamin K;

(iii) description of maternal-newborn interaction; and

(iv) orders for newborn screening tests, including arrangements for screening for hearing.

(4) The hospital shall ensure the transfer to the newborn's medical records of a mother's HIV test result, if one exists.

(5) The hospital shall maintain in a timely manner in the perinatal service area, a register of births, in which shall be recorded the name of each patient admitted, date of admission, date and time of birth, type of delivery, names of personnel present in the delivery room, sex, weight and gestational age of infant, location of delivery and outcome of delivery. Any delivery for which the institution is responsible for filing a birth certificate shall be listed in this register.

(6) Control of infection or other communicable condition. The provisions of section 405.11 of this Part shall apply to the perinatal service. In addition, the following requirements relating to the control of infection or other communicable conditions in the perinatal service shall be met:

(i) each patient admitted to the labor-delivery unit shall be screened for signs of, or exposure to, infection. Those with suspected or confirmed communicable conditions shall be reported to the responsible attending practitioner and the infection control officer for observation or isolation as required;

(ii) isolation precautions shall be carried out for patients in labor with confirmed or suspected infection. There shall be at least one room readily available for the use of a maternity patient requiring isolation. The hospital shall implement safe and effective isolation precautions to prevent the spread of infection and assign professional and other staff in the perinatal service in a manner that will prevent
Preconception services. The hospital shall develop and implement written policies and procedures for preconception services either onsite or through referral arrangements. Services shall include but not be limited to family planning, nutritional assessment and counseling, genetic screening and counseling, and identification and treatment of medical conditions that could adversely affect a future pregnancy.

(8) Hospital prenatal care activities.

(i) The hospital shall participate in and shall provide or arrange for effective prenatal care activities including conducting effective community outreach programs either directly or in collaboration with community-based providers and practitioners who provide prenatal care and services to women in the hospital service area. Activities and services of a prenatal care program shall include but not be limited to the following:

(a) active promotion of prenatal care for pregnant women during the first trimester of pregnancy and making services available to patients seeking initial care during each trimester;
(b) the initial prenatal care visit shall include a complete history, physical examination, pelvic examination, laboratory screening, initiation of patient education, screening for nutritional status, nutrition counseling and use of a standardized prenatal risk assessment tool;
(c) arrangements for repeat visits for follow-up prenatal care and education;
(d) nutrition counseling;
(e) psychosocial support services as needed;
(f) ongoing maternal and fetal risk assessment;
(g) prebooking for delivery; and
(h) providing HIV counseling and a clinical recommendation for testing to pregnant women. Counseling and/or testing, if accepted, shall be provided pursuant to Public Health Law, article 27-F. Information regarding the woman's HIV counseling and HIV status must be transferred as part of her medical history to the labor and delivery site. Women with positive test results shall be referred to the necessary health and social services within a clinically appropriate time.

(ii) To perform the activities and provide the services in subparagraph (i) of this paragraph, the perinatal service shall accommodate and coordinate services with primary care providers as follows:

(a) the hospital shall develop a memorandum of understanding with each diagnostic and treatment center, prenatal care provider who is not a member of the medical staff and prenatal care assistance program in the hospital service area. These memoranda shall establish protocols for the provision of prenatal care, testing, prebooking arrangements, timely transfer of records and other necessary services; and
(b) the hospital shall require as a condition of continuing medical staff membership that medical staff members provide to maternity patients under their care prenatal care, prebooking arrangements, testing, timely transfer of records and other necessary services. Written policies and procedures implementing this requirement shall be developed.

(iii) Hospitals shall assure the availability of prenatal childbirth education classes for all prebooked women which address as a minimum the anatomy and physiology of pregnancy, labor and delivery, infant care and feeding, breastfeeding, parenting, nutrition, the effects of smoking, alcohol and other drugs on the fetus, what to expect if transferred, and the newborn screening program with the distribution of newborn screening educational literature.

(iv) The hospital shall assure that each prebooked woman receives the hospital's maternity information leaflet as described in PHL section 2803-j, which includes a written description of available options for labor, delivery and postpartum services. The attending practitioner shall:

(a) advise the woman of options for treatment, care and technological support that are expected to be available at the time of labor and delivery together with the advantages and disadvantages of each option;
(b) answer fully any questions the woman may have regarding the options available; and
(c) obtain from the woman her informed choice of mode of treatment, care and technological support that are expected to be necessary.
Hospitals in consultation with the medical staff shall develop memoranda of understanding with free-standing birth centers in their service area, upon request from such centers, for the prompt admission of women and newborns and transfer of records of any birth center patient whose assessed condition necessitates admission to the level of perinatal service provided by such hospital.

(i) Such transfer shall be accomplished in accordance with the provisions of sections 754.2(e) and 754.4 of this Title.

(ii) Unless already performed at a free-standing birth center, newborns transferred to a hospital shall have newborn screening performed at the hospital in accordance with Part 69 of this Title.

(iii) The hospital, as part of its quality improvement activities, shall review all maternal and/or newborn transfers from birth centers to ensure adequacy of risk assessment and care, that each transfer has been appropriately arranged, and that reasons for the transfer have been documented clearly.

(10) Quality improvement activities. In addition to the quality assurance provisions of section 405.6 of this Part, the hospital shall, in conjunction with the medical staff and the nursing staff, monitor the quality and appropriateness of patient care and ensure that identified problems are reported to the quality assurance committee together with recommendations for corrective action. In accordance with section 721.9 of this Title, the hospital shall also perform quality improvement activities in accordance with its perinatal affiliation agreement.

(11) Functioning of perinatal services.

(i) Inpatient perinatal services shall be operated as closed units with limited access to unnecessary hospital traffic.

(ii) The perinatal service shall have available: services for the identification of high-risk mothers and fetuses, continuous electronic fetal monitoring, Cesarean delivery capabilities within 30 minutes of determination of need for such procedure, anesthesia services available on a 24-hour basis, radiology and ultrasound examination, with at least one ultrasound machine immediately available for use by the labor and delivery service.

(12) Laboratory services. The perinatal service shall have immediate access to the hospital's laboratory services including a 24-hour capability to provide blood group, Rh type and cross-matching, and basic emergency laboratory evaluations. Either ABO Rh-specific or O-Rh-negative blood and fresh frozen plasma shall be available at the facility at all times. Such other procedures as may be required by the perinatal service shall be performed on a timely basis.

(13) Admissions.

(i) Women in need of medical care and services pertaining to pregnancy, delivery and the puerperal period shall be admitted to the maternity service. Such admission shall be consistent with section 405.9 of this Part.

(a) Each patient shall be attended by a licensed and currently registered obstetrician, family practitioner or licensed midwife who will be responsible for the patient’s care.

(b) A patient may not be sent home without the prior knowledge and approval of her attending physician or licensed midwife.

(ii) Admission of nonobstetric patients.

(a) The hospital shall develop and implement written policies and procedures for the admission of nonobstetric female patients to the perinatal service area. The hospital shall ensure that obstetric patients take precedence over nonobstetric patients and that the safety and physical and psychological well-being of obstetric patients are not jeopardized.

(b) The following nonobstetric patients shall not be admitted to the maternity service:

(1) patients undergoing radiation therapy while they retain radioactive materials that have been administered for, or that result from, such treatment; and

(2) patients in an acute, infectious state or with signs and symptoms which may denote infection.

(c) If an acute or chronic infection or any other condition which would have contraindicated admission to the perinatal service is found during surgery or during any other period of hospitalization, the patient shall be removed from the perinatal service area.

(14) Voluntary acknowledgement of paternity for a child born out of wedlock.

(i) If a child is born to an unmarried woman and the putative father is readily identifiable to the responsible hospital staff and available, the hospital shall:

(a) provide to the child's mother and putative father documents and oral and written instructions and information necessary for such mother and father to complete an acknowledgement of paternity form in compliance with section 4135-b of the Public Health Law and section 111-k of the Social Services Law; and
(b) file the executed acknowledgement of paternity with the registrar at the same time at which the certificate of live birth is filed, if possible.

(ii) The hospital shall not be required to seek out or otherwise locate a putative father who is not readily identifiable or available.

(15) Hospitals with a perinatal care service shall participate in the perinatal regionalization system in accordance with their level of care designations under Part 721 of this Title.

(16) Each hospital providing Level I, II or III perinatal care services shall enter into a perinatal affiliation agreement with its designated RPC in accordance with Part 721 of this Title. Level I and II hospitals may also enter into transfer agreements in accordance with Part 721 with Level III hospitals.

(d) High-risk antepartum services at Level II, Level III and RPC perinatal services.

(i) Level II, Level III and/or RPC perinatal services shall develop and implement written policies and procedures to indicate where pregnant patients with obstetric, medical, or surgical complications are to be assigned to provide for their continuous observation and care.

(ii) Maternal intensive care services.

(a) Hospitals providing Level I or II perinatal care services shall develop, enter into and implement written agreements with hospitals providing Level III and RPC perinatal care services for the transfer of obstetric patients whose physical conditions are evaluated as needing such higher level of care.

(b) Hospitals which provide multiple levels of perinatal care services shall develop and implement written protocols and procedures for the in-house transfer of patients who are evaluated as requiring a level of care other than the level being provided in the area where the patient is currently located.

(c) Evaluation of the patient's condition and need care for intensive care services shall be conducted in accordance with standardized risk assessment criteria based on generally accepted standards of practice which shall be adopted in writing and implemented uniformly throughout the perinatal service.

(iv) Level II, Level III and RPC perinatal care services shall maintain a nursing staff that is appropriately trained and adequate in size to provide specialized care to distressed mothers and infants. The number of patient care staff on duty during any shift shall reflect the volume and nature of patient services being provided during that shift.

(v) An RPC shall:

(a) offer education and training to its perinatal affiliates and associated birth centers. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures and technological advances;

(b) review, in conjunction with its perinatal affiliates, all cases of patients transferred to a higher level of care to determine whether such transfers were appropriate and accomplished according to established transfer agreements; and

(c) participate in case conferences with its perinatal affiliates and associated birth centers to determine whether any non-transferred high-risk cases were handled appropriately and whether the transfer guidelines were adequate to address such circumstances;

(d) for purposes of participation in such activities, the RPC representative or representatives shall be deemed member(s) of the perinatal affiliate's quality assurance committee. RPC representatives may only access confidential patient information for quality improvement purposes through their roles on the affiliate hospitals' quality assurance committees as set forth in the affiliation agreements and these regulations. Members of hospitals' quality assurance committees must maintain the confidentiality of patient information and are subject to the confidentiality restrictions of Public Health Law section 2805-m.

(e) Intrapartum services.

(1) The hospital shall develop and implement written policies and procedures that indicate the areas of responsibility of both medical and nursing personnel for normal, high-risk, and emergency deliveries. These policies and procedures shall be reviewed yearly and made available to all staff. There also shall be written policies for the care of pregnant patients when all antepartum and postpartum beds are occupied.

(2) Written policies and procedures shall be developed and implemented governing restrictions of entry to the closed labor and delivery unit and the hospital shall ensure that, unless medically contraindicated, the patient may choose to be accompanied during labor and delivery by the father and/or other supportive person(s) who can provide emotional comfort and encouragement. Any such contraindications shall be noted in the medical record.

(3) Evaluation and preparation.

(i) In conjunction with the required updated history and physical exam, the hospital shall provide for the following:
(a) laboratory data including serologic tests for blood group, Rh type, syphillis and rubella titer;
   (1) if the woman's serology is positive, a cord blood serology shall be obtained. If the sample could
not be taken prior to the pregnancy's end, the serology shall be taken at the time of termination of the
pregnancy;
   (2) the woman shall be evaluated for the risk of sensitization to Rho (D) antigen and if the use of Rh
immune globulin is indicated, an appropriate dosage thereof shall be administered to her as soon as
possible within 72 hours after delivery or termination of pregnancy;
   (b) an assessment of the woman's HIV status and the provision of testing in accordance with section
69-1.3(l) of this Title;
   (c) an admitting physical examination which shall include the woman's blood pressure, pulse and
temperature, the fetal heart rate, the frequency, duration and evaluation of the quality of the uterine
contractions and which shall be recorded in the patient's medical record. An evaluation of any
complications should be made. If there is suspected leakage of amniotic fluid or any unusual bleeding,
the attending physician or licensed midwife shall be notified immediately before a pelvic examination
is performed. When there are no complications or contraindications, qualified nursing personnel may
perform the initial pelvic examination to evaluate labor status and the imminence of delivery. The
physician or licensed midwife responsible for the woman's care shall be informed of her status, so that
a decision can be made regarding further management; and
   (d) interval assessments including physical and psychological status of the woman and fetal status.
   (ii) Pharmacological or surgical induction or augmentation of labor.
   (a) Qualified practitioner as referred to in this section shall mean a practitioner functioning within his
or her scope of practice according to State Education Law who meets the hospital's criteria for
privileging and credentialing practitioners in management of labor and delivery in accordance with the
hospital's policies and procedures.
   (b) Pharmacological or surgical induction or augmentation of labor may be initiated only after a
qualified practitioner has evaluated the woman, determined that induction or augmentation is
medically necessary for the woman or fetus, recorded the indication, obtained informed consent for
induction or augmentation of labor, and established a prospective plan of management acceptable to
the woman. If the qualified practitioner initiating these procedures does not have privileges to perform
cesarean deliveries, a physician who has such privileges shall be contacted directly prior to initiation of
the induction or augmentation and a determination made that he or she shall be available within 30
minutes of determination of the need to perform a cesarean delivery. If the patient has had a previous
cesarean delivery, a physician with cesarean privileges must be immediately available during
pharmacological induction or augmentation of labor.
   (c) Pharmacological or surgical induction or augmentation shall be initiated by a qualified
practitioner. A qualified practitioner shall initiate the induction or augmentation and shall remain with
the woman for a period of time sufficient to ensure that the procedures or medication has been well-
tolerated and has caused no adverse reaction. A physician capable of managing any reasonably
foreseeable complications from the induction or augmentation of labor shall be available within a
timeframe appropriate to the woman's needs.
   (d) For pharmacological induction or augmentation of labor, the hospital shall develop and
implement a written protocol for the preparation and administration of the oxytocic agent and/or other
substances used to induce or augment labor.
   (e) During the entire time of the labor induction or augmentation, the woman shall be monitored by
staff who are trained and competent in both the monitoring of fetal heart rate and uterine contractions
and interpretation of such monitoring. The monitoring shall be by either electronic fetal monitoring or
auscultation. Where auscultation is used in lieu of electronic fetal monitoring, it shall be performed no
less frequently than every 15 minutes during the first stage of labor and every five minutes during the
second stage of labor.
   (iii) No attempt shall be made to delay birth of an infant by physical restraint or anesthesia.
   (iv) Each maternity patient, when present in a labor, delivery, birthing room or birth center shall be
under the care of a registered professional nurse available in accordance with the patient's needs.
   (v) The medical record shall be updated to note whenever the woman's choice of position for labor,
use of drugs or technological support devices or mode of treatment and care cannot be honored due
to medical contraindications. Standing orders for drugs or technological support devices may only be
implemented after the nature and consequences of the intervention have been explained to the
woman, and the woman agrees to such implementation.

(4) Delivery.
(i) Hospitals shall develop and implement policies and procedures for the delivery room that shall require at least the following:
(a) regular evaluation of maternal blood pressure and pulse both during and after delivery; and
(b) fetal heart evaluation.
(ii) Section 405.13 of this Part concerning anesthesia services shall apply to the clinical perinatal service. The anesthetist shall be informed in advance if complications with the delivery are anticipated.
(iii) The perinatal service and the medical staff shall designate in writing those situations which require consultation with and/or transfer of responsibility from a licensed midwife or a family practice physician to an obstetrician.
(iv) Alternative arrangements for the organization of the perinatal service, including but not limited to birthing rooms, birth centers or single unit maternity models, shall conform to pertinent requirements of this section and Parts 711 and 712 of this Title. Birth centers shall also conform to the patient care provisions of Part 754 of this Title.
(v) Immediate care of the newborn. The practitioner who delivers the baby shall be responsible for the immediate postdelivery care of the newborn until another qualified person assumes this duty. At all times, the newborn shall be attended by a physician or licensed midwife and shall be under the care of a registered professional nurse.
   (a) Resuscitation of a distressed newborn. The hospital shall develop and implement policies and procedures for the recognition and immediate resuscitation of a distressed newborn. Level I and II perinatal care services shall accomplish this in consultation with, and with assistance of, the RPC with which the hospital has a perinatal affiliation agreement. The policies and procedures shall include the following elements:
      (1) the designation of a physician to assume primary responsibility for the establishment of standards of care, review of practices, maintenance of appropriate drugs and training of personnel;
      (2) approval of these policies and procedures by the directors of maternity and newborn services, anesthesia, pediatrics, nursing and by the medical staff;
      (3) requirement for immediate availability of needed resuscitative equipment and personnel;
      (4) presence in the delivery room of a member of the professional staff specifically qualified in newborn resuscitation;
      (5) capability to provide short-term respiratory support including bag and mask ventilation;
      (6) procedures for the stabilization of the distressed newborn;
      (7) capability to perform endotracheal intubation and umbilical vessel catheterization. For a Level I perinatal care service, the perinatal affiliation agreement with its designated RPC shall provide for staff training to develop current staff competence in these procedures; and
      (8) procedures for the preparation and transfer of the distressed newborn to a Level III or RPC perinatal care service when medically indicated.
   (b) The hospital shall administer eye prophylaxis and vitamin K in accordance with sections 12.2 and 12.3 of this Title, test for phenylketonuria and other diseases and provide or arrange for newborn hearing in accordance with Part 69 of this Title.
   (c) The hospital shall conduct expedited HIV testing of a newborn whose mother's HIV status is unknown at delivery in accordance with section 69-1.3(l) of this Title;
   (d) A professional staff person in attendance at a delivery shall ensure proper identification of a newborn before it leaves the room where the delivery has occurred.
      (1) The hospital shall ensure continuous identification of the newborn infant during the entire period of hospitalization including verification of identity after each separation and reunion of mother and newborn. In addition to the development and implementation of written policies and procedures for continuous identification, further policies and procedures shall set forth steps to be taken when the means of identification which has been placed on the newborn becomes separated from the newborn. Newborns born of different mothers shall not be present at the same time in the room where delivery/recovery takes place, unless each has previously been identified by the methods prescribed in this clause.
      (2) Newborns born of different mothers shall not be present at the same time in the room where delivery/recovery takes place, unless each has previously been identified by the methods prescribed in this clause.
   (e) Circumcision, which shall be an elective procedure, shall not be performed during the newborn stabilization period after birth.
   (f) Postpartum care of mother. Appropriate nursing care shall be available to the mother during the period of recovery after delivery. At all times after delivery, the mother shall have maximum access to her baby unless such access is medically contraindicated and recorded in the appropriate medical record.
The mother shall be transferred to the postpartum area only after her vital signs have stabilized. The hospital shall adopt and implement policies and procedures for identifying any postpartum complications that arise and informing the responsible practitioner who shall manage complications.

(2) Postpartum monitoring shall include the following:
   (i) vital signs shall be recorded on a regular basis;
   (ii) fluid intake and output shall be recorded. The uterine fundus shall be frequently examined to determine if it is well contracted and whether there is excessive bleeding;
   (iii) the patient's practitioner shall be notified of any unusual findings;
   (iv) nursing personnel qualified to recognize postpartum emergencies and problems shall be immediately available to the patient;
   (v) the father or other support person shall be allowed to remain with the mother during the recovery period unless medically contraindicated or unless the nursing staff determines that the continued presence of the individual would interfere with the continuing care of the mother or other patients;
   (vi) a physical assessment of the mother shall be conducted in accordance with established protocols; and
   (vii) unless medically contraindicated or unacceptable to the mother, the newborn shall remain with the mother who shall provide a preferred source of body warmth for the newborn. During this period the newborn shall be closely observed for any abnormal signs and breastfeeding shall be encouraged.

(3) Education and orientation of the mother who is planning to raise the baby.
   (i) The hospital shall provide instruction and assistance to each maternity patient who has chosen to breastfeed and shall provide information on the advantages and disadvantages of breastfeeding to women who are undecided as to the feeding method for their infants. As a minimum:
      (a) the hospital shall designate at least one person who is thoroughly trained in breastfeeding physiology and management to be responsible for ensuring implementation of an effective breastfeeding program. At all times, there should be available at least one staff member qualified to assist and encourage mothers with breastfeeding;
      (b) written policies and procedures shall be developed and implemented to assist and encourage the mother to breastfeed which shall include, but not be limited to:
         (1) prohibition of the application of standing orders for antilactation drugs;
         (2) placement of the newborn for breastfeeding immediately following delivery, unless contraindicated;
         (3) restriction of the newborn's supplemental feedings to those indicated by the medical condition of the newborn or of the mother;
         (4) provision for the newborn to be fed on demand; and
         (5) provision for distribution of discharge packs of infant formula only upon a specific order by the attending practitioner or at the request of the mother;
      (c) the hospital shall provide an education program as soon after admission as possible which shall include but not be limited to:
         (1) the importance of scheduling follow-up care with a pediatric care provider within the timeframe following discharge as directed by the discharging pediatric care provider.
         (2) the nutritional and physiological aspects of human milk;
         (3) the normal process for establishing lactation, including care of breasts, common problems associated with breastfeeding and frequency of feeding;
         (4) dietary requirements for breastfeeding;
         (5) diseases and medication or other substances which may have an effect on breastfeeding;
         (6) sanitary procedures to follow in collecting and storing human milk; and
         (7) sources for advice and information available to the mother following discharge; and
      (d) for mothers who have chosen formula feeding or for whom breastfeeding is medically contraindicated, hospitals shall provide training in formula preparation and feeding techniques.
   (ii) The hospital shall provide to the mother instructions in caring for herself and her baby. Topics to be covered shall include but not be limited: to self-care, nutrition, breast examination, exercise, infant care including taking temperature, feeding, bathing, diapering, infant growth and development and parent-infant relationships.
   (iii) The hospital shall determine that the maternity patient can perform basic self-care and infant care techniques prior to discharge or make arrangements for postdischarge instruction.
   (iv) Each maternity patient shall be offered a program of instruction and counseling in family planning, if requested by the patient, the hospital shall provide the patient with a list, compiled by the department and made available to the hospital, of providers offering the services requested.
(4) Visiting. The hospital shall develop and implement written policies and procedures regarding visiting that:
   (i) do not unreasonably restrict fathers or other primary support person(s) from visitation to the mother during the recovery period;
   (ii) promote family bonding by allowing regular visitation for the newborn's siblings in a manner consistent with safety and infection control; and
   (iii) permit visitations by other family members and friends in a manner consistent with efficient hospital operation and acceptable standards of care.

(5) Discharge planning. The discharge of mother and newborn shall be performed in accordance with section 405.9 of this Part. In addition prior to discharge, the hospital shall determine that:
   (i) sources of nutrition for the infant and mother will be available and sufficient and if this is not confirmed, the attending practitioner and an appropriate social services agency shall be notified;
   (ii) follow-up medical arrangements for mother and infant have been made;
   (iii) the mother has been instructed regarding normal postpartum events, care of breasts and perineum, care of the urinary bladder, amounts of activity allowed, diet, exercise, emotional response, family planning, resumption of coitus and signs of common complications;
   (iv) the mother has been advised on what to do if any complication or emergency arises;
   (v) the newborn has had a documented and complete physical examination and verification of a passage of stool and urine;
   (vi) the means of identification of mother and newborn are matched. If the newborn is discharged in the care of someone other than the mother, the hospital shall ensure that the person or persons are entitled to the custody of the newborn; and
   (vii) the newborn is stable; sucking and swallowing abilities are normal. Routine medical evaluation of the neonate's status at two to three days of age shall have been conducted or arranged as well as newborn screening at time of discharge, provided discharge is greater than 24 hours after the birth, or between the third and fifth day of life, whichever occurs first, in accordance with Part 69 of this Title.

(g) High-risk neonatal care.
   (1) Each hospital providing Level I, II or III perinatal care services shall enter into a perinatal affiliation agreement with its designated RPC in accordance with Part 721 of this Title. Level I and II hospitals may also enter into transfer agreements in accordance with Part 721 of this Title with Level III hospitals.
   (i) The perinatal affiliation agreements and transfer agreements shall include provisions for standardized risk assessment based on generally accepted standards of practice, stabilization and resuscitation of newborns as necessary, newborn screening in accordance with Part 69 of this Title, consultation, patient transport, transfer of maternal and newborn records and any other features needed to ensure prompt and efficient transport of newborns that minimize risks and provide the newborn with needed services.
   (ii) Unless medically contraindicated, mothers shall be permitted to accompany distressed newborns to receiving perinatal care facilities.
   (iii) The perinatal affiliation agreements and transfer agreements shall provide for the return of the distressed newborn to the sending hospital when the condition has been stabilized and return is medically appropriate.
   (iv) If transfer necessitates separating the mother and newborn, mothers who have chosen to breastfeed should be encouraged to maintain lactation and breast milk should be available to the newborn.

(2) Placement in nurseries.
   (i) Healthy newborns shall be placed in a normal newborn nursery. If a newborn in a normal newborn nursery is removed temporarily from the perinatal service for any reason, the newborn may be returned to the normal newborn nursery only if infection control measures established by the hospital have been followed.
   (ii) Newborns requiring specialized care shall be placed in a NICU and hospitals shall develop and implement protocols for all phases of treatment of such newborns. Newborns who are delivered in perinatal care services that are not capable of providing all necessary care and services shall be transferred to perinatal care services at hospitals that can meet the newborns' needs.
   (h) Neonatal intensive care services.
   (1) Neonatal intensive care services shall be provided by Level II, Level III and RPC perinatal care hospitals.
(2) Decisions regarding the appropriate level of care and the need for transport of a neonate to a higher level of care shall be made consistent with generally accepted standards of care and the hospital's perinatal affiliation agreement.

(3) Treatment of severely ill, injured, or handicapped infants with life-threatening conditions.
   (i) Severely ill, injured or handicapped infants exhibiting life-threatening conditions shall be transferred to and/or treated at RPCs or other hospitals having Level III perinatal care services after consultation with that service has established that the infant might benefit from such transfer.
   (ii) Level III perinatal care services and RPCs shall consult with the hospital's bioethical review committee which shall assist the service and provide guidance to staff and families in the resolution of issues affecting the care, support and treatment of severely ill, injured, or handicapped infants with life-threatening conditions. The committee:
      (a) shall consist of such members of the medical staff, nursing staff, social work staff and administration as designated by the governing body and such other community-based individuals with experience in bioethical matters as may be chosen by the governing body;
      (b) shall operate in accordance with written policies and procedures developed by the hospital. Such policies shall establish the protocols for organization and functioning of the committee and scope of responsibility for specified cases as well as development of general review policies governing bioethical matters. The hospital shall:
         (1) ensure that the parents are fully advised regarding the infant's condition, prognosis, options for treatment, likely outcomes of such treatment and options, if any, for the discontinuance of heroic life maintenance efforts; and
         (2) ensure that any decision by competent parents to continue life-sustaining efforts is implemented by the hospital; and
      (c) shall, in conjunction with the attending physician(s), child protective services, the medical staff and the governing body, recommend that the hospital obtain an appropriate court order to undertake a course of treatment, in all cases when in the judgment of the committee:
         (1) the parents do not have the capacity to make a decision; or
         (2) the parents' decision on a course of action is manifestly against the infant's best interest.

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* Section 405.22.* Critical care and special care services.

   (a) General provisions. Critical care and special care services are those services which are organized and provided for patients requiring care on a concentrated or continuous basis to meet special health care needs. Each service shall be provided with a concentration of professional staff and supportive services that are appropriate to the scope of services provided.
   (1) The direction of each service, unless otherwise specified in this section, shall be provided by a designated member of the medical staff who has received special training and has demonstrated competence in the service related to the care provided.
   (2) The provision of all critical care and special care services shall be in accordance with generally accepted standards of medical practice. The hospital shall ensure that written policies are developed by the medical staff and the nursing service and implemented for all special care and critical care services.
      (i) The written policies and procedures shall be reviewed at least annually and revised as necessary and shall include at a minimum the following: infection control protocols, safety practices, admission/discharge protocols and an organized program for monitoring the quality and appropriateness of patient care, with identified problems reported to the hospital-wide quality assurance program and resolved.
      (ii) The written protocols for patient admission to and discharge from a critical care or special care unit shall include:
         (a) criteria for priority admissions;
         (b) alternatives for providing specialized patient care to those patients who require such care but who, due to lack of space, or other specified reasons such as infection or contagious disease, are not eligible for admission according to unit policy; and
         (c) guidelines for the timely transfer and referral of patients who require services that are not provided by the unit.
(3) Each critical care unit shall be organized as a physically and functionally distinct entity within the hospital.

(i) Access shall be controlled in order to regulate traffic, including visitors, in the interest of infection control.

(ii) Emergency equipment and an emergency cart within each unit shall contain appropriate drugs and equipment, as determined by the medical staff and pharmacy service.

(4) When critical or special care services are provided to pediatric patients, opportunities shall be provided for education, socialization, and play pertinent to the growth and development needs of these patients, unless medically contraindicated.

(b) Organ transplant center.

(1) Definitions. For purposes of this subdivision, unless the context indicates otherwise, the following terms shall have the following meanings:

(i) Organ means a human kidney, heart, heart valve, liver, lung, or pancreas.

(ii) Organ procurement organization (OPO) means a person, facility, or institution engaged in procuring organs for transplantation or therapy purposes, but does not include:

(a) facilities or institutions which permit procurement activities to be conducted on their premises by employees or agents of an approved organ procurement organization; or

(b) facilities or consortia of facilities which conduct transplantation activities in accordance with article 28 of this chapter when the organ is procured through an approved organ procurement organization, licensed bank or storage facility, or a living donor. A bank or storage facility shall not constitute an organ procurement organization solely by virtue of procuring heart valves.

(iii) Service area of an organ procurement organization means the geographic area of service approved by the Secretary, U.S. Department of Health and Human Services, or, in the absence of such approval, by the department.

(iv) Patient shall generally refer to both the donor patient and recipient patient except that subparagraphs (2)(iv), (v) and clause (vi)(a) of this subdivision shall refer to a recipient only.

(2) General requirements.

(i) Organ transplantation shall be performed only in hospitals approved by the commissioner pursuant to Part 710 of this Title.

(ii) The hospital shall be a member of the Organ Procurement and Transplantation Network approved by the Secretary, U.S. Department of Health and Human Services and shall abide by its rules and requirements.

(iii) When fully operational, to ensure quality of care and cost effectiveness, the hospital shall perform at least 20 liver transplants per year if an approved liver transplant center, or at least 14 human heart transplants if an approved heart transplant center, or at least 20 kidney transplants a year if an approved kidney transplant center.

(iv) The hospital shall participate in a patient registry program with an organ procurement organization designated by the Secretary, U.S. Department of Health and Human Services. Each facility performing transplant services shall inform a patient awaiting transplantation of the prohibition against being placed on multiple facility waiting lists before arranging for the placement of the patient on the waiting list.

(v) Every hospital performing organ transplants shall maintain written criteria for the selection of patients for transplant services which shall be consistent with professional standards of practice, applied consistently, and made available to the public.

(vi) The hospital shall maintain a record of:

(a) all patients who are referred for transplantation and the date of their referral;

(b) the results of the evaluation of all candidates for transplantation which documents the reasons a candidate is determined to be either suitable or unsuitable for transplantation;

(c) the date a suitable candidate is selected for transplantation;

(d) the reasons for, and date of, any declination of a matching organ offered to a potential donee;

(e) the date transplantation surgery occurred;

(f) the organs utilized; and

(g) the donor’s United Network for Organ Sharing (UNOS) identification number.

(vii) There shall be an organized system for follow-up of patients after discharge which maintains records on the long-term survival of persons who have received a transplant or who have made a live adult liver donation.

(viii) The hospital shall ensure that written procedures are maintained and implemented for the receipt, identification, and verification of all organs for transplantation.
(ix) Written infection control policies and procedures specific to the transplant services shall be developed and implemented as an integral part of the hospital's infection control program.

(x) The infectious disease program shall have sufficient professional and laboratory resources needed to address donor organ issues dealing with transmissible infections and necessary resources to discover, identify and manage complications from organisms associated with transplants which are commonly or uncommonly encountered.

(3) Organization and staffing.
   (i) The director of the transplant center, in addition to the requirements of paragraph (a)(1) of this section, shall be a qualified specialist with previous experience and demonstrated competence in the transplant service. The director shall oversee the quality assurance program in the transplant center.
   (ii) Each transplant center shall have on-site a qualified transplant physician and a qualified transplant surgeon who may also fulfill the requirement as director of the service. An infectious disease physician shall be on-site or available to address donor organ issues dealing with transmissible infections and issues described in subparagraph (2)(x) of this subdivision.
   (iii) The hospital shall provide a clinical transplant coordinator and sufficient staff to coordinate the activities of the transplant program, including patient follow-up after discharge.
   (iv) The hospital shall ensure that all staff providing care to transplant patients are prepared for their responsibilities through education, experience, demonstrated competence and completion of inservice education programs as needed.
   (v) From admission to discharge, patient care evaluation, planning and management shall be performed by the professional health care team involved with the care of the patient, and shall include plans for follow-up of the patient into the community. The patient and patient's family shall be involved and have input into the patient's care plan.
   (vi) Psychiatric and social services shall be made available to the transplant center to assist with psychosocial problems of the patients and their families and to participate as members of the health care team responsible for the patient's care.

(4) Quality assurance and improvement.
   (i) As part of the hospital's quality assurance or quality improvement program, the hospital shall implement and maintain a system for continuously evaluating the quality and appropriateness of patient care and patient outcomes including survival rates and any complications.
   (ii) Reports summarizing the experience of the transplantation service shall be submitted to the department as requested by the commissioner.
   (iii) The patient specific data reported to the Health Resources and Services Administration contractor, as required by the Organ Procurement and Transplantation Network, shall be reported to the department periodically as requested by the commissioner. The hospital may designate the Health Resources and Services Administration Organ Procurement and Transplantation Network contractor as an agent of the hospital for the purpose of complying with this requirement.

(5) Organ acceptance criteria.
   (i) In conjunction with an organ procurement organization, the hospital shall adopt and uniformly apply organ acceptance criteria and establish written policies and procedures to ensure the medical suitability of organs to be transplanted. The organ acceptance criteria shall be consistent with professional standards of practice. Specific medical conditions of the donor shall be confirmed by the transplant surgeon through the donor's medical history, appropriate clinical laboratory testing and other confirmation methods and documented in the recipient's medical record.
   (ii) Written organ acceptance criteria shall be specific for each type of organ and shall describe those medical conditions which would make the potential donor ineligible under any circumstance.
   (iii) Written organ acceptance criteria shall describe those medical conditions for which medical discretion may be exercised regarding organ acceptance with specified limits on this discretion, when the potential organ recipient is fully informed of the issues posed by the particular donor and organ.

(6) Hospitals performing live adult liver donation transplants shall comply with the standards established in subdivision (l) of this section.

(c) Burn unit/center.
   (1) Personnel and staffing.
      (i) A burn unit/center shall designate a director who is a board-certified or board-admissible general or plastic surgeon with one additional year of specialized training in burn therapy or equivalent experience in burn patient care.
      (ii) Staff for the burn unit/center shall include:
         (a) a head nurse of the facility who is a registered professional nurse, with two years intensive care unit or equivalent training and a minimum of six months burn experience;
(b) one registered professional nurse for every two intensive care patients at all times;
(c) one registered professional nurse for every three non-intensive care patients at all times;
(d) on staff, or through formal arrangement, a physical therapist and occupational therapist with a
minimum of three months training or six months experience in burn treatment available as needed;
(e) staff or through formal arrangement a registered dietician available as needed;
(f le, on staff, or through formal arrangement, a medical social worker responsible for referral and
follow-up care and individual and group counseling available as needed; and
(g) a psychologist and/or psychiatrist available as needed.
(iii) The burn unit/center shall be responsible for training facility staff and other personnel within the
service area on emergency treatment procedures, assessment of total body surface area affected, and
the classification of burns and triage protocols.
(2) Operation and service delivery.
(i) Each burn unit/center shall have a minimum of six beds.
(ii) Each burn unit/center shall treat a minimum of 50 patients with major burn injury to moderate
uncomplicated burn injury per year.
(iii) The burn unit/center shall refer patients for whom there are no available beds to another burn
unit/center which can provide the care needed.
(iv) Each burn unit/center shall have available, either through direct control or through a network of
clearly identified relationships, a system of land and/or air transport which will bring severe burn
victims to the unit/center.
(v) Each burn unit/center shall have a designated area for providing specialized intensive care and
an operating room easily accessible within the hospital.
(vi) Reviews of each patient with major burn injury or moderate uncomplicated burn injury shall be
undertaken on a weekly basis by the burn care team.
(d) Alternate level of care.
(1) Organization and staffing.
(i) Patients on each service of the hospital who have been assigned alternate level of care status
shall be congregated on a single care unit when there are 10 or more such persons on the service.
Patients for whom discharge is anticipated within 14 days and patients whose identified needs cannot
be safely and effectively met on this unit need not be transferred to the congregate unit and shall not
be counted in the 10-patient threshold.
(ii) If the hospital can demonstrate to the department that it can fully meet the needs of patients
assigned alternate level of care status without congregating such patients, it may provide such
services in accordance with a plan approved by the department in lieu of meeting the requirements of
subparagraph (i) of this paragraph.
(iii) The hospital shall appoint a staff person who has administrative responsibility for the delivery of
patient care services to patients assigned alternate level of care status and for the supervision of the
services whether or not they are provided by congregate care units.
(iv) The appointed staff person shall monitor and evaluate the quality and appropriateness of care
provided to alternate level of care patients and shall ensure that identified problems are resolved and
are reported, as appropriate, to the hospital-wide quality assurance program.
(2) Delivery of services.
(i) The hospital shall provide each patient assigned to alternate level of care status care and services
in accordance with a multidisciplinary assessment of needs in order to promote the patient's
independence and health.
(a) A written individualized, comprehensive care plan based upon the patient’s assessed needs shall
include, but not be limited to:
(1) medical and nursing care;
(2) assistance and/or supervision, when required, with activities of daily living, such as toileting,
feeding, ambulation, bathing including routine skin care, care of hair and nails, and oral hygiene;
(3) rehabilitation therapy services as the patient's needs indicate;
(4) a activities program appropriate to the needs and interests of each patient to sustain physical
and psychosocial functioning; and
(5) other clinical care and supportive services to meet the needs of patients.
(b) The written individualized comprehensive care plan shall be developed and implemented by all of
the qualified professionals whose services are required by the patient under the supervision and
coordination of the patient's attending physician and with the involvement of the patient and the
family to the extent possible, in accordance with the patient's wishes.
(c) The comprehensive care plan shall establish realistic and measurable goals for short- and long-term care needs, and shall identify the type, amount and frequency of care and services needed to maintain, restore and/or promote the patient’s functioning and health within stated time frames for achievement.

(e) Acquired immune deficiency syndrome (AIDS) centers.

(1) Definition. An AIDS center shall mean a hospital approved by the commissioner pursuant to Part 710 of this Title as a provider of designated, comprehensive and coordinated services for AIDS patients in accordance with the requirements of this section. These services shall include inpatient, outpatient, community and support services for the screening, diagnosis, treatment, care and follow-up of patients with AIDS.

(2) Administrative requirements. The hospital shall ensure that:

(i) integrated and comprehensive services are provided onsite to include, as a minimum, the following:

(a) a designated patient care unit for AIDS patients, except that the commissioner may waive this requirement, under a plan acceptable to the commissioner for placing patients in other than a designated unit, if the AIDS center meets all other requirements of this section and the hospital can demonstrate:

(1) that it is unable, due to structural or space limitations, to place the AIDS patients in a designated unit; or

(2) specific programmatic or operational reasons why it is preferable not to use a designated unit or not practicable to have a designated unit for AIDS patients;

(b) an outpatient clinic program for screening, diagnostic and treatment services for AIDS patients; and

(c) emergency services, available 24 hours a day, for treatment of AIDS patients;

(ii) other health care services, as appropriate, are provided directly or through contract for AIDS patients, to include at least the following:

(a) home health care, provided through a home care services agency licensed or certified under article 36 of the Public Health Law, made available 24 hours a day, 7 days a week; and

(b) personal care services;

(iii) all reasonable efforts are made to provide or arrange for the following services and programs to meet the needs of the AIDS patients:

(a) residential health care;

(b) hospice services provided through a hospice certified under article 40 of the Public Health Law; and

(c) residential living programs;

(iv) diagnostic and therapeutic radiology services and other specialized services are made available to meet the needs of AIDS patients;

(v) inservice education programs which address the medical, psychological and social needs specific to AIDS patients are conducted for all hospital personnel caring for AIDS inpatients;

(vi) infection control policies and procedures pertinent to AIDS are developed and implemented as an integral part of the hospital-wide infection control program;

(vii) a quality assurance program, which includes a review of the appropriateness of care for patients with AIDS, is developed and implemented as an integral part of the overall quality assurance program;

(viii) at the request of the department, it shall participate in clinical research programs approved by the hospital's institutional review board/human research review committee;

(ix) resource information about AIDS shall be available to the public, and educational programs are provided for particular high-risk populations in their service area; and

(x) a crisis intervention program shall be made available in coordination with other existing community services.

(3) Patient referral, admission and discharge. The hospital shall ensure that:

(i) policies and procedures are developed and implemented which address admission criteria for AIDS patients, referral mechanisms and coordinated discharge planning;

(ii) only patients who meet the admission criteria for AIDS are admitted to the designated patient care unit;

(iii) services which the center provide are available to all persons regardless of age, race, color, creed, sex, sexual orientation, disability, national origin or ability to pay;
(iv) there are transfer agreements in effect with other hospitals in accordance with section 400.9 of this Title for the acceptance of referrals or the transfer of AIDS patients in need of specialized services available at the center; and

(v) professional staff responsible for planning patient discharges, referrals or transfers shall have available current information regarding home care programs, institutional health care providers and other support services within the hospital's primary service area.

(4) Patient management plan. The hospital shall ensure that:
(i) a multidisciplinary team, whose composition reflects inpatient and outpatient care services, operating in conjunction with the attending physician:
(a) shall be responsible for each AIDS patient;
(b) shall include, as appropriate to the needs of the AIDS patient, health care professionals from nursing, nutritional, mental health and social work services; and
(c) whenever practicable, the AIDS patient is assigned to the same multidisciplinary team;
(ii) a comprehensive patient management plan is developed by the multidisciplinary professional team, the patient, and when appropriate, home health care or other nonacute long-term care representatives, in consultation with the patient's family and other individuals with significant personal ties to the patients, which:
(a) shall reflect the ongoing psychological, social, functional and financial needs of the patient and is oriented to posthospital, ambulatory care and community support services;
(b) shall be based on the patient's illness, prescribed treatments and the individual patient's needs and choices;
(c) shall be reviewed and updated to reflect the patient's changing needs and current status;
(d) shall include transfer or discharge and follow-up plans coordinated by the multidisciplinary team or the case manager;
(e) shall be forwarded with the patient upon discharge or transfer for posthospital care; and
(f) shall evaluate the extent to which the patient or patient's personal support system can provide or arrange to provide for identified care needs of the patient in the home situation;
(iii) a case manager shall be designated from the multidisciplinary team to be responsible for coordinating the health care services and plan for each AIDS patient; and
(iv) a mechanism shall be established to assure periodic reviews and updates of the patient management plan in conjunction with other agencies involved with, or responsible for, the care of the AIDS patient.

(5) Medical director. The hospital shall appoint a physician who:
(i) shall be a qualified physician with special training in infectious diseases, oncology or other appropriate subspecialty;
(ii) shall direct and coordinate all medical services provided in the AIDS center;
(iii) shall ensure the implementation of the quality assurance program as specified in subparagraph (2)(vii) of this subdivision;
(iv) shall ensure that all members of the health care team participate in the quality assurance program;
(v) shall ensure that interdisciplinary rounds that include the health care professionals responsible for the patient's total care are made on a timely and sufficiently frequent basis as determined by each patient's needs;
(vi) shall ensure that other qualified physician specialists are available for consultation as indicated by the patient's condition; and
(vii) shall ensure that routine dental services are available for AIDS patients.

(6) Quality assurance monitoring.
(i) The commissioner shall monitor and evaluate the quality and appropriateness of care provided to AIDS patients by the AIDS center through mechanisms which include, but are not limited to, the monitoring and evaluation of patient management plans, utilization reviews and quality assurance programs.
(ii) The department and its AIDS Institute shall develop criteria for assessing the effectiveness of AIDS centers in providing care that meets the special needs of AIDS patients.

(7) Construction requirements. The designated patient care unit shall be a discrete unit which complies with the requirements of section 712.2 of this Title, except as modified by the following:
(i) maximum patient room capacity shall be two beds, except that more than two beds per room may be allowed under a protocol based on patient diagnosis and approved by the commissioner;
(ii) patient room temperature shall be capable of being maintained between 70 and 80° F. Individual room air-conditioning units may be used; and
(iii) each patient care unit shall have at least one functional dayroom with space commensurate with the needs of the patients.

(f) Comprehensive and extended screening and monitoring services for epilepsy.

(1) Definition. Comprehensive and extended screening and monitoring services for epilepsy shall mean a planned combination of services including inpatient and outpatient care which shall include, but not be limited to: electroencephalographic monitoring, selection of appropriate anticonvulsant medication through neuropharmacological monitoring, surgical interventions, if indicated, and management of a patient's psychological and social needs through a coordinated interdisciplinary team approach. For purposes of this section, extended screening and monitoring services are considered rehabilitative care.

(2) Comprehensive and extended screening and monitoring services for epilepsy shall be provided in a hospital approved by the commissioner pursuant to Part 710 of this Title as a provider of such services. The purpose of these services is to treat and rehabilitate patients with uncontrolled seizures in order to restore and promote them to their optimal level of functioning.

(3) Administrative requirements. The hospital shall ensure that:

(i) policies and procedures be developed and implemented which address the provision and coordination of care between the inpatient unit and the outpatient unit for comprehensive and extended screening and monitoring services for patients with epilepsy;

(ii) a physician is appointed to direct the service, who is a qualified neurologist and who has demonstrated competence in the services and care provided to patients with epilepsy;

(iii) an interdisciplinary team of health care professionals with training and experience in the treatment of epilepsy shall be responsible for assessing patients and planning, providing and coordinating care. The interdisciplinary team shall include as a minimum the following types of health care professionals: neurologist, neurosurgeon, registered professional nurse, pharmacist, psychiatrist with training in neuropsychiatry, psychologist with training in neuropsychology, social worker, dietician, physical therapy, occupational therapist, and dentist;

(iv) consultative services of a neurologist with experience in pediatrics shall be made available as needed;

(v) the service shall provide or make formal arrangements for vocational rehabilitation services and special education services for patients who can benefit from such services;

(vi) comprehensive and extended screening and monitoring services for epilepsy shall include clinical services with staff specialized in electroencephalography, cable telemetry and neuropharmacological monitoring of anticonvulsant drugs; and

(vii) as part of the hospital's quality assurance program, the comprehensive epilepsy service shall implement a system for evaluating the quality and appropriateness of patient care and patient outcomes. Reports summarizing the outcomes from the quality assurance program for these services shall be submitted to the department on an annual basis.

(g) Pediatric and maternal human immunodeficiency virus (HIV) services.

(1) Applicability.

(i) AIDS centers designated in accordance with subdivision (g) of this section which have pediatric and/or maternity services shall provide specialized services for infants, children, adolescents, and pregnant women who are infected with human immunodeficiency virus (HIV) or who are antibody positive and comply with the pertinent provisions of this subdivision as well as those in subdivision (g).

(ii) Hospitals not designated as AIDS centers in accordance with subdivision (g) may be approved to provide specialized services for infants, children, adolescents, and pregnant women who are infected with human immunodeficiency virus (HIV) or who are antibody positive, if the hospital:

(a) is in an area of high prevalence of HIV infection in children and women as evidenced by the hospital's newborn HIV seropositivity rate and the hospital's discharge rate for pediatric and maternal HIV related disorders;

(b) provided care in the past to pediatric and maternal HIV patients;

(c) demonstrates that it is unable to meet the requirements for full designation under subdivision (g) of this section; and

(d) complies with the requirements of this subdivision and subdivision (g) of this section, except for the definition of AIDS center in paragraph (g)(1) and except for the administrative requirement regarding designated patient care units in clause (g)(2)(i)(a).

(iii) A patient shall be eligible for services if the patient is an infant, child, adolescent or a pregnant woman who is infected with HIV or is HIV antibody positive, whether or not the patient has progressed to symptomatic HIV related illness.
(iv) For purposes of these regulations, family shall include the patient's immediate kin, legal guardian or anyone with significant personal ties to and who resides with the patient. 

(2) Organization of services. The hospital shall ensure that:
   (i) patients who require HIV related services are identified and referred for care by the pediatric and maternal HIV services;
   (ii) obstetrical, pediatric and medical services develop and implement procedures to coordinate the clinical care of pediatric and maternal HIV patients to ensure the voluntary identification of potentially affected patients and family members and the delivery of appropriate services;
   (iii) an organizational plan and policies and procedures are developed and implemented which address interdepartmental relationships and communications between the pediatric and maternal HIV services;
   (iv) patient care services are provided through a coordinated interdisciplinary team approach. Inpatient and outpatient services shall be organized to preclude unnecessary hospitalization and to ensure continuity of care. A member of the interdisciplinary team managing the patient shall be designated as the individual patient's and family's case manager and shall be responsible for serving as a liaison among patient, family, staff and resources in the community and responsible for coordinating the comprehensive family management plan;
   (v) services are family-centered and, in addition to the inpatient services, include the following ambulatory care and community support services: dental, substance abuse treatment, family planning, infusion therapy, mental health, neurodevelopmental evaluation, nutrition, rehabilitation therapies, prenatal care and primary care services;
   (vi) other health and related human services are provided or arranged for as appropriate to meet the personal, social, educational, developmental and financial needs of these patients, including as a minimum:
      (a) personal services such as caregiver support, day care, homemaker, housekeeper, transitional residential living programs, respite and transportation to and from needed services;
      (b) referral for legal services as appropriate to the needs of the patient;
      (c) identification and referral of children and adolescents in need of foster care and adoption services;
      (d) financial services such as emergency support, food stamps, housing assistance, medical assistance, public assistance, Social Security Disability, Supplemental Security Income and Special Supplemental Food Program for Women, Infants and Children; and
      (e) education and developmental services such as early intervention and therapeutic day care services;
   (vii) a comprehensive family management plan is developed and implemented to address the medical, nursing, nutritional, functional, developmental, educational, psychological, social and financial needs of the patient and family, which plan:
      (a) integrates the patient management plans as specified in subdivision (g) of this section with plans addressing the needs of the family; and
      (b) documents the assessment and the monitoring of the patient's and family's needs with reassessment as necessary.

(3) Patient referral, admission and discharge. The hospital shall ensure that:
   (i) services begin at the time of the patient's entry into the pediatric and maternal HIV service program and continue until the patient chooses not to participate in the pediatric and maternal HIV service; or relocates outside the pediatric and maternal HIV service catchment area; or transfers to another AIDS center or pediatric and maternal HIV service; or expires;
   (ii) admission criteria include provisions for the assignment of pediatric and adolescent patients to a unit appropriate for the developmental needs of the patient; and
   (iii) written policies and procedures are established and implemented for the pediatric and maternal HIV service to include voluntary HIV counseling and testing.

(h) Secure units for tuberculosis patients including detainees.

(1) Definition. Secure unit for tuberculosis patients including detainees shall mean a designated patient care unit specifically designed to treat patients who have been diagnosed with active tuberculosis. Hospitals shall provide such patients with safe and adequate care within such unit in accordance with procedures approved by the commissioner. Patients eligible for admission to such units shall include:
   (i) patients who have been found to be noncompliant with medical regimens and legally remanded to such unit who shall receive priority admission to and retention in such unit. The rights of such
patients to leave such units shall be restricted in accordance with the order legally remanding them to such units; and

(ii) other patients requiring acute care for active tuberculosis but not legally remanded for treatment, including intensified treatment for those individuals with multiple drug resistant tuberculosis. Such patients shall retain rights to voluntary egress from and entrance to such units in accordance with generally accepted medical practice and consistent with the rights of patients in other units of the hospital.

(2) Staffing and operation. A secure unit for tuberculosis patients including detainees shall:

(i) maintain staff that are adequate in number and trained, including continuing education and inservice training, to perform all necessary activities related to the treatment and care of such patients with tuberculosis;

(ii) implement procedures to identify, diagnose and treat patients who exhibit signs and symptoms of infectious disease including the use of appropriate isolation practices;

(iii) consist of an environmentally sound physical plant in accordance with current, generally accepted standards of infection control practices specifically relating to tuberculosis. Such practices shall address ventilation, air dilution, and the provision of adequate and appropriate isolation facilities; and

(iv) provide adequate and effective personal protective devices to any persons at risk of exposure to infectious tuberculosis. Such protective devices shall be utilized and monitored through a respiratory program which shall ensure training, proper use and/or fit of such appropriate devices in accordance with generally accepted standards of practice.

(3) Approval. Hospitals wishing to operate secure units for tuberculosis patients including detainees, for which construction approval pursuant to Part 710 of this Title is not otherwise required, shall apply to the Commissioner of Health for approval to operate such units pursuant to section 710.1(c)(5) of such Part specifically requiring a prior review of architectural and engineering matters.

(1) Tuberculosis treatment center--for legally detained tuberculosis patients.

(a) Tuberculosis treatment center for legally detained tuberculosis patients shall mean a designated patient unit or site specifically designed to treat and contain those patients who have been remanded pursuant to applicable statute, for treatment, care, and observation for active tuberculosis. Hospitals shall be equipped and staffed with safeguards approved by the commissioner as adequate to contain these patients and prevent elopement or escape.

(b) Admission, transfer and discharge.

(i) Patients shall be admitted to such center only when:

(a) such patients require a reduced level of medical care with such care needs expected to continue for an extended period of time;

(b) such patients do not require the greater intensity of services provided by a secure unit for tuberculosis patients as defined in subdivision (j) of this section; and

(c) such center has the capability to meet the ongoing medical, nursing and psycho-social needs of the patient.

(ii) Patients shall be transferred from such center to a secure unit for tuberculosis patients at a hospital operating such unit when:

(a) a change in the patient's medical condition necessitates movement to a unit providing more intense services;

(b) security for the legally remanded patient during transfer can be assured; and

(c) the patient and the patient's designated representative have been notified of the pending transfer. Such notification shall be given as soon as possible after the need for transfer has been documented.

(iii) Patients shall be discharged from such center only when treatment goals have been met in accordance with the order legally remanding them to the center.

(2) Staffing and operation. A tuberculosis treatment center for legally detained tuberculosis patients shall:

(i) maintain staff that are adequate in number and qualifications to perform all necessary activities related to the care and treatment of such patients with active tuberculosis. The staff shall be from those disciplines that provide the training necessary to meet the medical/nursing and psycho-social aspects of the care necessary for these patients;

(ii) implement procedures to diagnose, treat and monitor patients who exhibit signs and symptoms of infectious disease, including the use of appropriate isolation practices;

(iii) consist of an environmentally sound physical plant in accordance with current, generally acceptable standards of infection control specifically relating to tuberculosis. Such plant design shall
include adequate dilutional ventilation, safe exhaust/discharge of potentially contaminated air, and the
provision of adequate isolation facilities with appropriate directional air flow;
(iv) provide adequate and effective security control systems which will safely contain the legally
detained patient and prevent elopement or escape of such patient;
(v) provide adequate and effective personal protective devices to any persons at risk of exposure to
an infectious tuberculosis patient. Such protective devices shall be utilized and monitored through a
respiratory program which shall adequately train individuals in the proper use and/or fit of such
appropriate devices in accordance with generally accepted standards of practice;
(vi) monitor employees for tuberculosis infection on an ongoing basis and review aggregate results
of such monitoring; and
(vii) monitor environmental controls to ensure proper functioning.
(4) Approval. Hospitals wishing to operate a tuberculosis treatment center for legally detained
tuberculosis patients for which construction approval pursuant to Part 710 of this Title is not otherwise
required, shall apply to the Commissioner of Health for approval to operate such centers pursuant to
section 710.1(c)(5) of such Part, which provides for a prior review limited to architectural and
engineering matters.
(j) Live adult liver transplantation services. Hospitals performing live adult liver transplants shall
comply with the requirements of this subdivision.
(1) Independent donor advocate team. An independent donor advocate team shall be established for
any live adult liver transplantation program. This team's interests shall be centered on the well-being
of the live donor.
(i) Composition of the team. The independent donor advocate team shall consist of, at a minimum,
an internal medicine physician, a transplant coordinator/nurse clinician, a licensed master social
worker, and a psychiatrist assigned to evaluate the live donor. The team shall include the participation
of an ethicist, as appropriate.
(ii) Team responsibilities. The team’s main responsibility is to support the donor, beginning with the
donor evaluation process and continuing through donation, the postoperative period, to discharge and
postdischarge. The team shall assist the donor in making informed decisions and balance
external/family pressures to donate. Team members should evaluate the donor and make a
recommendation concerning donor suitability and ensure that the needs of the donor are fulfilled
promptly and in accordance with best medical practice. The team shall:
(a) structure the process of informed choice (specifically stating informed "choice" instead of
preordained "consent") and emphasize that the decision to donate is not a foregone conclusion;
(b) safeguard the interests of and well-being of the donor;
(c) explain the evaluation process, what to expect, what it means to be a donor;
(d) evaluation whether any choice made by the donor is informed and not coerced by:
(1) evaluating whether there is monetary or property enrichment for the donor;
(2) evaluating whether there is coercion to donate by family or others;
(3) providing adequate information to the recipient to ensure his or her understanding regarding the
risks to the donor;
(4) assessing the donor’s intellectual and emotional capability of participating in a balanced
discussion of potential risks and benefits;
(5) providing information to the donor about the medical, psychosocial and financial implications of
the live donation for the potential donor and about the recipient's options for cadaveric transplant,
including risks and outcomes;
(6) ensuring the donor understands that he or she may decline to donate at any time prior to his or
her surgery; and
(7) if requested by the donor, assisting the donor in the preparation of a general statement of
unsuitability for donation which shall not include falsified medical information;
(e) consult with the surgical team regarding donor suitability before issuing a formal
recommendation;
(f) transmit its findings in writing to the surgical team. The transmittal shall include the reasons for
the independent donor advocate team's recommendation and annex any documents and consultations
considered by the team in its deliberations. The final determination of donor suitability rests with the
attending surgeons of the surgical team;
(g) determine jointly with the attending surgeons of the surgical team who shall meet with the
potential donor to advise him or her of the final determination of donor suitability. At least one of the
attending surgeons of the surgical team shall participate in such meeting. The potential donor will be
advised of the independent donor advocate team's recommendation. Regardless of whether they
participate in such meeting, all members of the independent donor advocate team shall make
themselves available to the potential donor upon his or her request to discuss the independent donor
advocate team's recommendation; and

(h) assure there is continuity of care during hospitalization and assure that there are appropriate
referrals for postdischarge care including follow-up from medicine, psychiatry or social work, as
needed.

(iii) Team characteristics.
(a) The independent donor advocate team shall not receive direct financial or personal gains from
recommending continuation of the donor's participation.
(b) The status of the independent donor advocate team or its members at the transplant center may
not be affected by any activities undertaken on behalf of the donor, including recommending for or
against donation.
(c) The independent donor advocate team shall be medically sophisticated in transplantation and
aware of relevant statistics such as center volume and outcome data, and be able to explain such
information to the potential donor.
(d) Each member of the team shall have sufficient preparation in his or her role to recommend that
a specific donor not be a candidate when appropriate.
(1) All team members shall have a comprehensive working knowledge of liver disease and
transplantation.
(2) The licensed master social worker shall be skilled in individual and family counseling, shall
understand the entire donation process, and be able to provide information on financial issues and
community resources.
(e) Once team members are designated by the center to serve on the independent donor advocate
team, they shall participate in at least three donor evaluation processes per year.

(iv) Education of the donor. In order to ensure that the potential donor has the knowledge and
capacity to exercise an informed choice, the team shall do the following:
(a) thoroughly evaluate the intellectual and emotional capacity of the potential donor to exercise
legally and ethically adequate informed choice as described in paragraph (2) of this subdivision;
(b) devise a process appropriate for each individual potential donor to inform him or her orally and
in writing about the risks and benefits of medical interventions;
(c) evaluate whether there is a thorough understanding of the elements of the decision;
(d) evaluate whether the potential donor's decision is voluntary;
(e) inform the potential donor that the donor advocate team members may recommend against
donation and that the team's recommendation will be given significant consideration in the surgical
team's decision. The reasons for the team's decision shall be explained to the donor; and
(f) advise the potential donor of the opportunity to discuss donation with others who have donated
in the past and assist in making arrangements to do so, if requested by the donor.

(2) Informed choice. A person who gives consent to be a live adult liver donor shall be competent,
willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks
and benefits as a donor, fully informed of the risks, benefits and any alternative treatments available
to the recipient, have a vital emotional relationship with the recipient, and be likely to benefit in a way
not involving the transfer of money or property. The following factors shall be present:
(i) Informed understanding:
(a) All information shall be presented to the potential donor in a language or manner understandable
to him or her, consistent with his or her education level.
(b) The potential donor shall be able to demonstrate that he or she understands the essential
elements of the donation process, especially the risks associated with the procedure.
(c) Adequate time shall be allowed for the potential donor to understand and assimilate the
information provided, ask questions and have questions answered.
(d) The donor's family/loved ones shall be given the opportunity to discuss openly with the
independent donor advocate and surgical teams their concerns in a safe and nonthreatening
environment.
(e) The potential donor shall understand the need for and agree and commit to postoperative, long-
term follow-up and testing by the transplant center.
(ii) Disclosure requirements:
(a) The donation process shall be explained to the potential donor and shall include:
(1) donor evaluation procedure;
(2) surgical procedure;
(3) recuperative period;
short- and long-term follow-up care;
alternative donation and transplant procedures;
potential psychological benefits and detriments to donor;
transplant center and surgeon-specific statistics of donor and recipient outcomes;
confidentiality of the donor's information and decision;
donor's ability to opt out at any point in the process; and
information about how the transplant center will attempt to follow the health of the donor for life.

(b) The transplant team and the independent donor advocate team shall disclose their institutional affiliations to the potential donor.

(c) There shall be a two-week period of reflection and reaffirmation of the decision to donate subsequent to the completion of the medical work-up and the surgical team's final approval to proceed before the potential donor signs the consent for the donation procedure.

(d) Consistent with the patients' rights provisions of section 405.7(a)(7) of this Part, non-English speaking candidates and hearing-impaired candidates shall be provided with a non-family interpreter who understands their language and culture.

(e) A member of the independent donor advocate team shall witness the potential donor signing the consent document for the procedure.

(iii) Risks. Risks shall be fully explained to the potential donor. The explanation shall include:

(a) physical:
(1) potential for surgical complications including risk of donor death;
(2) potential for liver failure and the need for liver transplant, including increased risks associated with advanced age, such as reduced regeneration;
(3) potential for other medical complications including long-term complications;
(4) scars;
(5) pain;
(6) fatigue; and
(7) abdominal and/or bowel symptoms such as bloating and nausea;

(b) psychosocial:
(1) potential for problems with body image;
(2) possibility of recipient death;
(3) possibility of recipient rejection and need for retransplantation;
(4) possibility of recurrent disease in recipient such as hepatitis C or hepatocellular carcinoma;
(5) possibility of adjustment disorder postsurgery;
(6) impact on donor’s family;
(7) impact on recipient’s family; and
(8) potential impact of donation on the donor’s lifestyle;

(c) financial:
(1) out-of-pocket expenses;
(2) child care costs;
(3) possible loss of employment;
(4) potential impact on ability to obtain future employment;
(5) potential for disability benefits and need for assistance completing relevant paperwork; and
(6) impact on ability to obtain health and life insurance.

(iv) Documentation. The entire disclosure and consent process shall be documented in the donor's medical record, which shall be maintained separate and distinct from the recipient's medical record.

(3) Primary medical evaluation. A medical evaluation of the potential donor shall be made by a qualified attending physician member or members of the medical staff. The following are minimum criteria that the donor must meet:

(i) absence of systemic disease or probable future occurrence;
(ii) absence of current or past impairment to any vital organ;
(iii) absence of vulnerability to infection or blood loss or delayed wound healing; and
(iv) be 18 years of age or older.

(4) Psychiatric and social work requirements.

(i) The donor should have a vital emotional relationship with the recipient and be likely to benefit in a way not involving the transfer of money or property.

(ii) A psychiatric and psychosocial evaluation of the potential donor shall be made by the psychiatrist and social worker members of the donor advocate team. The evaluation shall include, but not be
limited to, consideration of the donor's current and past history of psychiatric illness, physical abuse, sexual abuse, alcohol abuse and substance abuse.

(iii) Social work services shall be provided in accordance with section 405.28 of this Part as well as any additional requirements established in this subdivision.

(5) Recipient criteria. The transplant center must establish written policies and procedures governing recipient eligibility for live adult liver donation. At a minimum, such policies and procedures shall:

(i) ensure the patient is listed on the cadaveric liver transplant waiting list developed in accordance with the national eligibility criteria for cadaveric donation;

(ii) ensure the recipient has received information regarding specific risks and benefits, alternative treatments and expected outcome of the transplantation;

(iii) establish conditions which require recipient exclusion; and

(iv) ensure that the benefits to both the donor and the recipient outweigh the risks before any living liver transplant is performed.

(6) Perioperative care requirements.

(i) The donor surgeon shall have the primary responsibility for the donor's care and welfare throughout his or her hospital stay.

(a) The donor surgeon is responsible for making the final determination regarding a donor's suitability after reviewing and considering the donor's medical, psychological, and social history; the donor's current medical, psychological and social status; the recommendation of the independent donor advocate team; all consultative reports; and the standards set forth in this subdivision.

(b) If the donor surgeon decides to proceed with a donation after receiving an adverse recommendation from the independent donor advocate team, the physician shall document the reasons for doing so in the patient's medical record.

(ii) Transplant centers shall have the ability to allow donors to bank a minimum of one unit of blood before surgery.

(iii) Surgeries may be scheduled only when sufficient staffing will be available for the postoperative period.

(iv) The transplant coordinator, or another team member, shall provide regular updates to the families/significant others of both the donor and recipient during the surgical procedures.

(v) Surgical team requirements.

(a) At least two liver transplant attending surgeons with experience as established in clause (e) of this subparagraph shall participate in the surgery on the donor. These two surgeons shall be present for the critical parts of the surgery including the liver parenchymal transection. They both shall be available and scrubbed if needed for complications, however, only one surgeon need be present for the remainder of the donor operation.

(b) A third liver transplant attending surgeon shall be present in the recipient operating room. This surgeon must have experience in cadaveric liver transplantation but does not necessarily need expertise in live donor resectional surgery.

(c) All three surgeons shall be board certified or board admissible in general surgery or have foreign certification determined to be equivalent by the New York State Department of Health.

(d) All three surgeons shall have demonstrated experience in liver transplant surgery.

(e) Except as provided in clause (f) of this subparagraph, each of the two surgeons required to participate in the critical parts of the surgery shall have demonstrated experience in live donor hepatectomy (15 procedures) or demonstrated experience in major hepatobiliary resectional surgery (20 procedures) or surgical fellowship at an American Society of Transplant Surgeons (ASTS) approved liver transplant fellowship program (or an equivalent acceptable to the department) with demonstrated experience (15 procedures) with live donor hepatectomy. This shall include written verification by the fellowship program director or by the director of the supervising transplant program of hands-on training at an institution performing live donor hepatectomy.

(f) For a new program with no experience in live donor adult liver transplantation, surgeons shall have demonstrated experience in major hepatobiliary resectional surgery (20 procedures). Surgeons shall also visit an established program and observe a minimum of five cases. Written verification shall be obtained from the director of the hosting program and retained in the surgeon's personnel file.

(vi) Anesthesia requirements.

(a) There shall be two separate attending anesthesiologists; one each for the live adult liver transplantation donor and recipient operations. These anesthesiologists shall be present for the critical anesthetic and surgical portions of the procedures and immediately available at all other times. As one case is completed, either anesthesiologist may take responsibility for the ongoing case. The
anesthesiologists shall have experience in liver transplant anesthesia and/or major hepatic resection surgery and/or cardiac surgery anesthesia.

(b) There shall be two separate anesthesia teams in two operating rooms (one for the donor, one for the recipient).

(c) These teams shall each be directed by a separate attending anesthesiologist for the live donor and the recipient procedure. In addition to the attending anesthesiologist who shall be present as specified in clause (a) of this subparagraph, at least one member of the anesthesia team who is an anesthesiologist, chief resident, fellow (postgraduate year 3, 4 or 5), and/or qualified certified registered nurse anesthetist shall be present and responsible, under the direction of the attending anesthesiologist, for the evaluation and care of the patient through all phases of the procedure pertaining to the administration of, and recovery from, anesthesia. All team members shall have ongoing education and training in liver and/or cardiac surgery and have had anesthesia responsibility for major liver resections.

(7) Postoperative care requirements. Donors shall receive postoperative care consistent with the following:

(i) day 0-1: live adult liver donors shall receive intensive care (ICU or PACU);

(ii) day 2: if stable and cleared for transfer by the transplant team. donors shall be cared for in a hospital unit that is dedicated to the care of transplant recipients or a hospital unit in which patients who undergo major hepatobiliary resectional surgery are cared for. Liver donors should not at any time be cared for on any other unit unless a specific medical condition of the donor warrants such a transfer and the transfer is documented in the donor's medical record;

(iii) the donor shall be evaluated at least daily by one of the qualified liver transplant attending physicians with documentation in the medical record;

(iv) the transplant team shall be responsible for the pain management of the donor. In institutions where a pain management team is available, the transplant team may delegate its responsibility to this team. However, there shall be a written protocol in place for assessment and management of donor pain;

(v) if there is an identified member of the anesthesia care team with specific education and training in pain management of liver donors, that person shall be available for consultation with the transplant team regarding the pain control of the donor;

(vi) the patient care staff shall be familiar with the common complications associated with the donor and recipient operations and have appropriate monitoring in place to detect these problems should they arise; and

(vii) if there is an emergent complication requiring reoperation, these patients shall be prioritized by the hospital for access to the operating room by the institution.

(8) Medical minimum staffing requirements.

(i) There shall be 24-hour/seven-day-a-week continuous coverage of the transplant service by general surgery residents at the postgraduate year 2 level or higher, transplant fellows, nurse practitioners or physician assistants. Between the hours of 6 p.m. and 8 a.m. and at all times on weekends and holidays, the covering residents, fellows, nurse practitioners, or physician assistants should be dedicated to the transplant service and not covering other surgical or nonsurgical patients. An attending transplant surgeon should be available immediately as a resource for the residents, fellows, nurse practitioners or physician assistants at all times.

(ii) Any patient with abnormal vital signs or unusual symptoms as identified by the registered professional nurse shall be evaluated immediately by the medical staff. Notification to the appropriate senior medical staff member (fellow, chief resident, attending) shall be made within 30 minutes in accordance with written hospital policies and procedures.

(9) Nursing minimum staffing requirements.

(i) Nursing staff shall have ongoing education and training in live donor liver transplantation nursing care (donor and recipient). This shall include education on the pain management issues particular to the donor. The registered professional nursing ratio shall be at least one registered professional nurse for every two patients (1:2) in the ICU/PACU level setting, increased as appropriate for the acuity level of the patients.

(ii) After the donor is transferred from the ICU/PACU, the registered professional nursing ratio shall be at least 1:4 on all shifts, increased as appropriate for the acuity level of the patients.

(iii) The same registered professional nurse shall not take care of both the donor and the recipient.

(iv) The nursing service shall provide the potential donor with pre-surgical information and shall offer the potential donor a tour of the unit before surgery.
The names and beeper numbers of the transplant team shall be posted on all units receiving transplant donors.

10) Radiology service requirements.
(i) Hospitals performing live adult liver transplantation shall have adequate radiological staff support including:
(a) a radiologist with demonstrated experience in evaluating preoperative imaging studies of a potential liver donor including computerized tomography (CT scan) or magnetic resonance imaging (MRI) with respect to liver volume estimates (right and left lobe) and detailed vascular and biliary anatomy;
(b) a radiologist with expertise in reviewing imaging studies in liver transplant recipients; and
(c) radiologists with experience in interventional procedures (angiography) and ultrasound imaging studies in the live donor and liver transplant recipient (who should be available at all times including weekends and between the hours of 6 p.m. and 8 a.m.).
(ii) If there is an emergent complication requiring radiology services, these patients should be prioritized for access to radiology services by the hospital.

11) Discharge planning requirements. The hospital shall comply with the discharge planning requirements contained in section 405.9 of this Part as well as the following:
(i) Representatives of the independent donor advocate team shall be available to the donor from pre-admission to postdischarge.
(ii) A detailed, written discharge plan shall be developed, given to the donor and provided to all health care professionals involved in the donor's case, including the donor's primary care physician.
(iii) This plan shall be reviewed with the donor by a health care professional such as the primary care nurse, social worker or transplant coordinator.
(iv) The plan shall include, at a minimum, instructions on:
(a) activities;
(b) diet;
(c) medication for pain; and
(d) wound care.
(v) The patient shall be provided with a 24-hour contact number that he/she can call with questions. The responder shall be available when needed and knowledgeable about live adult liver donation.
(vi) Information shall include the name, address and telephone number of the surgeon and instructions for the follow-up visit.
(vii) Instructions for family members or caregivers shall be provided.

12) Post-discharge requirements.
(i) Medical follow-up shall meet generally accepted standards for someone who has undergone a major liver resection procedure. This follow-up shall include:
(a) postoperative visits with the donor's surgeon(s);
(b) follow-up coordinated with the donor's primary care physician to assess wound healing and liver function and to monitor for signs/symptoms of infection;
(c) serum liver chemistry tests at discharge or at six weeks (whichever is sooner) and six months and annually for the first five years; three dimensional liver scan with volume assessment at one year shall be performed on all donors of full right or full left lobes; and
(d) written summary of the donor's condition, which shall be provided to the donor and his or her primary care physician upon the donor's discharge from the hospital.
(ii) The hospital shall provide or arrange for follow-up social/psychological supports as needed, which may include measures such as:
(a) visits with a social worker with familiarity with organ transplantation issues;
(b) visits with a psychologist or psychiatrist with familiarity with organ transplantation issues;
(c) participation in a professionally run support group, similar to support groups for cadaveric donor families;
(d) participation in a center-sponsored computer donor listserve or bulletin board to share patient concerns; and
(e) invitation to a donor recognition event, such as an annual recognition ceremony or presentation of a donor medal.
(iii) There shall be follow up on financial/insurance concerns, possibly by the transplant center's financial coordinator.
(iv) Hospitals shall periodically report to the commissioner, or his or her designee, such information as the commissioner shall require to assist the department in assessing the quality of care provided; determining routine or unusual complications or outcomes; and identifying potential improvements to
donor education, screening, consent, preoperative, surgical and postoperative care and follow-up. Such information shall include, but not limited to, donor demographics, preoperative medical and psychosocial information; surgical information and complications; hospital staff training and experience; recipient outcome; and immediate and long-term postoperative care, complications, and impact on quality of life.

(v) Regardless of department reporting requirements, hospitals shall attempt to track the donor and his or her condition for the donor's lifetime to determine if there are any long-term health issues associated with the donation.

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* Section 405.23.* Food and dietetic services.

The hospital shall have an organized dietary department that is directed and staffed by an adequate number of qualified personnel. The hospital shall ensure that each patient's dietary needs are considered and correlated with physician's orders and with the patient's overall health status and that quality nutritional care is provided to patients.

(a) General.

(1) The hospital food and dietetic services, including cafeterias and snack bars, shall be operated in conformance with the sanitary requirements of Part 14 (Service Food Establishments) of Chapter I (State Sanitary Code) of this Title.

(2) Nutritional needs of patients shall be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(b) Organization. The department shall be directed on a full-time basis by an individual who, by education or specialized training or experience, is knowledgeable about food service management.

(1) The director shall be responsible to the chief executive officer or his/her designee for the daily management of the dietary services, including quality food production, service and staff supervision and management.

(2) The director shall ensure that:

(i) overall coordination and integration of the therapeutic and administrative aspects of dietetic services are maintained; and

(ii) the quality, safety and appropriateness of the dietetic department/service functions are monitored, evaluated and that appropriate actions based upon findings are taken.

(3) The director shall ensure that relevant orientation and inservice education programs are conducted for dietetic personnel and, as appropriate, for other hospital personnel that shall include, at a minimum, personal hygiene, safety and infection control requirements and proper methods of waste disposal.

(4) The director shall be responsible for the development and implementation of policies and procedures concerning the scope and conduct of dietetic services which include:

(i) nutritional care policies and procedures which are developed by a qualified dietitian;

(ii) personal hygiene and health of dietetic personnel; and

(iii) infection control measures to minimize the possibility of contamination and transfer of infection.

(5) A dietitian, full-time, part-time or on a consultant basis shall supervise the nutritional aspects of patient care and assure that quality nutritional care is provided to patients.

(6) Dietetic services shall be provided by a sufficient number of administrative and technical personnel competent in their respective duties.

(c) Diets. There shall be a systematic record of diets and menus, consistent with the physician's orders which meet the needs of the patients.

(1) Therapeutic diets shall be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing and food services personnel.
The hospital shall be operated and maintained to ensure the safety of patients.

(a) Building and grounds. Facility grounds and physical plant shall be maintained in a manner to assure a safe and suitable environment for patients.

1. Grounds and buildings shall be maintained in functional condition and to meet design intent, free of safety hazards, excessive noise, odors and environmental pollutants as may adversely affect the health or welfare of patients.

2. There shall be facilities for emergency provision of adequate fuel and water supplies during any period in which the supply of fuel and/or water from usual sources temporarily becomes disrupted.

(b) Life safety from fire.

(1) Buildings and equipment shall be so maintained as to prevent fire.

(2) The hospital shall have a written master fire plan that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and visitors; evacuation; and cooperation with firefighting authorities.

(3) Personnel shall be trained in procedures to be followed in emergencies, including but not limited to the use of firefighting equipment, evacuation of patients and personnel and all other duties in the master fire plan.

(4) Fire drills shall be conducted at irregular intervals at least 12 times per year covering all shifts.

(5) The hospital shall ensure the thorough investigation of all fires. A written report of the investigation shall be produced and shall remain on file for not less than six years.

(c) Engineering and maintenance.

(1) Water supplies of medical facilities. All water used in operation shall be provided in conformance with Part 5 of the State Sanitary Code and section 702.1(a) of this Title.

(2) Preventive maintenance. A written preventive maintenance program shall be established and implemented to insure that all equipment and buildings are operative, safe, sanitary and maintained in good repair.

(i) Hospitals shall develop and adhere to schedules for testing, maintenance and calibration of all patient care and life safety equipment. Such maintenance schedules shall, at a minimum, be conducted in accordance with manufacturer's specifications.

(ii) Written reports documenting such tests, maintenance and calibration shall be retained on file for not less than three years after the date of such tests, maintenance or calibration.

(d) Waste. Hospitals shall develop and implement infectious waste management programs as required by the provisions of title XIII of article 13 of the Public Health Law.

(e) Housekeeping.

(1) The entire facility, including but not limited to the floors, walls, windows, doors, ceilings, fixtures, equipment and furnishings, shall be kept clean and maintained in good repair.

(2) The facility shall be kept free of insects and rodents.

(3) All cleaning shall be done in a manner which will not spread dust or other particulate matter.

(4) Supplies and equipment for housekeeping functions shall be provided with cleaning compounds and hazardous substances properly labeled and stored.

(f) Linen and laundry.

(1) Clean linen shall be provided to meet the requirements of patients.

(2) All linen shall be handled, stored, laundered and processed, and transported in a manner that will prevent infection and assure the maintenance of linen that is clean and in good repair. The hospital shall ensure that any use of inks or dyes contained aniline oil (aminobenzene) or oil of mirbane (nitrobenzene) or other benzene derivatives by such hospital, laundry or diaper service conforms to the requirements in section 12.10 of the State Sanitary Code.

(3) All linen, including blankets, shall be laundered between patient use.

(4) To prevent the spread of infection, all soiled linen shall be enclosed in containers within the patient care unit for transportation to the laundry.

(5) All linen from isolation rooms, infectious patients and the pathology service shall be enclosed in identifiable containers distinguishable from other laundry.

(g) Emergency and disaster preparedness. The hospital shall have a written plan, rehearsed and updated at least twice a year, with procedures to be followed for the proper care of patients and personnel, including but not limited to the reception and treatment of mass casualty victims, in the event of an internal or external emergency or disaster arising from the interruption of normal services resulting from earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences. Personnel responsible for the hospital's accommodation to
extraordinary events shall be trained in all aspects of preparedness for any interruption of services and for any disaster.

(h) Animals. Animals, exclusive of those required for laboratory purposes, shall only be allowed in a hospital in the following instances:

1. service dogs or other service animals which have been individually trained to do work or perform tasks for the benefit of an individual with a disability when the presence of such animal will not pose a significant risk to the health or safety of others that cannot be eliminated by reasonable accommodation and is not medically contraindicated. However, if the safe operation of the hospital would be jeopardized, a service animal need not be allowed to enter. A finding by appropriate medical personnel at the hospital that the presence or use of a service animal would pose a significant health risk in certain designated areas of a hospital may serve as a basis for excluding service animals in those areas;

2. when a hospital chooses to initiate and operate an organized animal visitation or animal-assisted therapy program that is jointly developed, approved and monitored by the hospital's quality assurance, risk management and infection control committees or designees. In each such approved program, the hospital must at a minimum ensure that:

   i. participating animals meet the qualifications set by the hospital including:
      a. certification of current vaccinations and being free of communicable diseases or infections;
      b. documentation of having training and temperament acceptable to the hospital;
   ii. each participating patient signs a patient consent form that includes an assessment of the risks and benefits of program participation;
   iii. hospital personnel and non-participating patients in proximity to the program are not negatively impacted by the presence of such animals;
   iv. the well-being of the participating animals is considered and maintained;
   v. patient and staff satisfaction is assessed, ensuring that participating patients and staff as well as a representative sample of non-participating patients and staff are routinely sampled for feedback; and
   vi. infection control protocols established for the program include a comparative assessment of infections for participating and non-participating patients.

(i) Central supply services. The hospital shall ensure the provision of central supply services for the preparation, storage, handling and distribution of sterile supplies and other patient care items. The hospital shall conform to current, acceptable standards of practice for central services.

1. Central services shall be under the direction of an individual qualified by education, training and experience to supervise the personnel and functions of central services, and who shall be responsible to the chief executive officer either directly, or through a designated department head.

2. Central services shall be evaluated as part of the hospital's ongoing quality assurance program.

3. The functional design and workflow patterns in central services shall provide for the separation of soiled and contaminated supplies from those that are clean and sterile.

4. There shall be written policies and procedures for the decontamination and sterilization activities performed in central services and elsewhere in the hospital, and for related requirements. These policies and procedures shall include, but not be limited to provisions for:

   i. the decontamination, cleaning, preparation and sterilization of patient care supplies and equipment;
   ii. the separation of soiled or contaminated supplies and equipment from clean and sterilized supplies and equipment;
   iii. the assembly, wrapping, storage, handling and distribution of sterile supplies and equipment in central services and all other areas of the hospital as applicable;
   iv. requirements for aeration of gas-sterilized items;
   v. maintaining and recording time and temperature for each sterilization cycle and aeration cycle, if any, with provisions for records to be kept at least one year;
   vi. the labeling of each sterilized item with the date sterilized, cycle and expiration date indicating the shelf life of the sterilized item if the hospital chooses to use time-related sterility criteria with established expiration dating of in-house reprocessed and sterilized supplies and equipment;
   vii. event-related sterility assurance if the hospital chooses to use such criteria for sterility assurance. Such sterility assurance shall:
      a. comply with generally accepted standards for sterility assurance such as those endorsed by the Association for the Advancement of Medical Instrumentation, the Joint Commission on the Accreditation of Healthcare Organizations or other such entities recognized as appropriate by the commissioner;
(b) be based on the results of an evaluation of current hospital policies and procedures for handling sterile supplies;
(c) be reflected in the hospital’s written policies which detail the process and responsibilities and which have been approved by the infection control officer and Infection Control Committee, if any;
(d) be addressed through inservice education of staff; and
(e) provide for quality assurance monitoring to evaluate effectiveness;
(viii) the use of chemical indicators with each cycle and weekly bacteriological spore monitoring for all sterilizers;
(ix) the rotation and reprocessing of sterile equipment and supplies; and
(x) the routine checking and removal of outdated or damaged sterile supplies and equipment or supplies which no longer meet the sterility standards of the event-related sterility assurance criteria and the recall of such supplies and equipment from all areas of the hospital.
(j) Injury control. The hospital shall:
(1) have a safety education program which shall include both orientation of new employees and continuing inservice training programs;
(2) develop and implement programs designed to eliminate safety hazards; and
(3) maintain, during any construction, alterations or repairs, a safe environment and safe access.

10 NY ADC 405.24
10 NY ADC 405.24
2008 WL 75295886
10 NY ADC 405.24

* Section 405.25.* Organ and tissue donation (anatomical gifts).

(a) Definitions. For the purposes of this section, the following terms shall have the following meanings:
(1) designated requestor shall mean a person selected by the hospital to discharge the responsibilities of requesting the spouse, next of kin or guardian of the decedent to consent to an anatomical gift. The designated requestor shall be a trained hospital employee, or an employee of an organ procurement organization, eye bank or other tissue bank. Designated requestors, at a minimum, must complete a course, that meets the criteria set forth in subdivision (e) of this section, provided or approved by an organ procurement organization and designed in consultation with the eye bank or other tissue bank community, whichever is applicable, on how to approach potential donor families and request organ, eye or other tissue donation. The hospital administrator may select more than one designated requestor;
(2) suitability for organ, eye and other tissue donation shall mean that the organ procurement organization, eye bank or other tissue bank in consultation with the hospital, after appropriate medical screening (which may include serological testing if applicable) determines that the patient meets the medical criteria for donation;
(3) organ procurement organization (OPO) shall mean an organization which is designated by the Secretary, U.S. Department of Health and Human Services, to perform or coordinate the performance of retrieving, preserving and transporting organs and to maintain a system of locating prospective recipients for available organs; and
(4) tissue bank shall mean a tissue bank licensed under Part 52, which includes eye banks.

(b) The hospital shall assure that written policies and procedures are established, implemented and maintained for notifying an organ procurement organization and/or appropriate tissue banks including eye banks, licensed pursuant to Part 52 when death of a patient has occurred or is imminent, designating the requestor(s) to approach the family, selecting eye bank(s) and other applicable tissue bank(s) for referrals, causing a timely request to be made by the designated requestor and monitoring the implementation of these functions. These policies and procedures shall be developed in consultation with organ procurement organizations and licensed eye banks and other tissue banks selected by the hospital. Written policies and procedures to be established shall include:
(1) protocol for notification of the organ procurement organization, eye bank or other tissue bank upon the death or imminent death of every patient, including provisions specifying that for ventilator patients declared brain dead, the organ procurement provider must be notified and able to determine suitability for donation prior to removal of such patients from the ventilator;
(2) procedures for seeking consent by the designated requestor so that requests are made only when the candidate meets the medical criteria for screening potential donors, and that no requests are made when the conditions listed in paragraph (d)(1), (2) or (3) of this section are present;
(3) a procedure for documenting in the patient’s medical record notification of the organ procurement organization, eye bank or other applicable tissue bank(s), and the results of such notification and requests for consent or absence of a request;

(4) an ongoing system for monitoring compliance with routine referral of potential donors including the outcomes of such referrals and any resulting requests. When a hospital contracts with an outside organization to review hospital policies, procedures, patient records and outcomes to assess compliance with this section, the contract shall be written and executed in accordance with section 400.4 of this Title and shall require the contractor to be held to the same standards of patient confidentiality as the hospital; and

(5) a method for hospitals to select at least one eye bank(s) and all applicable tissue bank(s) for the procurement of tissue and any policies and procedures the hospital has adopted concerning the rotation of referrals.

(c)

(1) Where a patient is a suitable candidate for organ, eye or other tissue donation and where the patient has not properly executed an organ donor card, or other authorization for organ, eye or other tissue donation, the designated requestor shall, in a timely manner, at the time of death of a hospital patient, request the persons listed below, in the order of priority stated, to consent to the gift of all useful organs, tissues and/or other body parts of the decedent’s body:

(i) the spouse;
(ii) a son or daughter 18 years of age or older;
(iii) either parent;
(iv) a brother or sister 18 years of age or older; or
(v) a guardian of the person of the decedent at the time of his/her death.

(2) Consent or refusal need only be obtained from any person in the highest priority class available when persons in prior classes have been sought with due diligence and are not available at the time of death. Any consent to an anatomical gift by a person designated in this subdivision shall be given by a document signed by him/her or given by his/her telegraphic, recorded telephonic or other recorded message.

(3) A designated requestor may also request consent to an anatomical gift from any other person who is authorized or under the obligation to dispose of the body including, but not limited to, a person named in a decedent's will, a commissioner of a social services district, a coroner, a medical examiner, or a hospital administrator.

(d) Anatomical donations shall not be requested when any one of the following conditions are present:

(1) actual notice of contrary intentions by the decedent;
(2) actual notice of opposition by a member of the highest priority class available specified in subparagraphs (c)(1)(i)-(v) of this section; or
(3) other reason to believe that an anatomical gift is contrary to the decedent’s religious or moral beliefs. The medical record shall document the evidence that served as the basis for the "reason to believe."

(e) The designated requestor shall be selected by the hospital based on his/her ability to relate to families in a sensitive and caring manner and shall complete a course provided by a tissue bank and approved by the organ procurement organization, or provided by the organ procurement organization and designed in consultation with community eye bank or other tissue bank, whichever is applicable, to have demonstrated proficiency in the following areas:

(1) psychological and emotional considerations when dealing with bereaved families and particularly with individuals with diminished mental capacity;
(2) social, cultural, ethical and religious factors affecting attitudes toward organ donation;
(3) general medical concepts involved in organ and tissue transplantation and the use of organs and tissues in research and education;
(4) procedures for declaring death, and collecting and preserving organs, tissues and/or other body parts and how these procedures are most appropriately explained to the decedent’s family;
(5) the cost implications to the family for organ and tissue donation, if any;
(6) the existing networks for the procurement of organs and the systems for allocating donated organs, tissues and other body parts to suitable recipients; and
(7) the routine referral law and the hospital's policies and procedures regarding requests for consent to anatomical gifts.

10 NY ADC 405.25
10 NY ADC 405.25
Section 405.26.* Utilization review.

(a) Hospitals shall comply with Federal regulations regarding utilization review. Such regulations shall include section 482.30 of the Code of Federal Regulations (42 CFR part 482).
(b) All patients admitted to units having an operating certificate granted by the New York State Division of Alcoholism and Alcohol Abuse for the operation of an acute care alcoholism program or inpatient rehabilitation program shall be subject to the admission, continuation of stay, care plan, staffing, services and discharge requirements of applicable State regulations. Such regulations include requirements of 14 NYCRR Parts 374 and 381.

Section 405.27.* Information, policy and other reporting requirements.

(a) Hospitals shall comply with the requirements of section 400.18 of this Title regarding the provision to the commissioner of the following data and reports:
   (1) uniform bill;
   (2) uniform discharge abstract;
   (3) data from hospital-based ambulatory surgery services;
   (4) uniform financial report and uniform statistical reports; and
   (5) emergency service data.
(b) Access to and disclosure of data contained in the uniform bill, uniform discharge abstract, emergency service data and ambulatory surgery data abstract shall be governed by the provisions of section 400.18(e) of this Title.

Section 405.28.* Social services.

The hospital shall provide appropriate supportive services to meet the psychosocial needs of its patients. The services shall be oriented to assist patients and their families with personal and environmental difficulties which predispose illness or interfere with obtaining maximum benefits from hospital care.

(a) Each patient shall be screened prior to or upon admission to determine the need for social services. All patients and families identified through such screening, and all patients and families subsequently identified as needing social services by medical, nursing or other clinical staff, shall be provided with the support they require.
(b) Social services shall be provided under the direction of a qualified medical social worker or other person with appropriate training and experience.
(c) Personnel providing social services shall be qualified by training and experience to:
   (1) recognize the psychosocial needs of patients and their families;
   (2) evaluate crisis situations and disability resulting from the emotional, social and economic stresses of illness;
   (3) counsel patients and families to deal with the particular stresses affecting them;
   (4) participate in hospital care planning and assist patients and families to understand, accept and follow medical and other professional recommendations to restore patients to optimum social and health adjustments; and
   (5) arrange for specialized assistance from other sources within the hospital from community resources for patients and families who need such assistance. Such arrangements shall include, but not be limited to, educational and tutorial services with the patient's school district in accordance with section 3202(6) of the Education Law for inpatients between the ages of 5 and 21 who:
      (i) are physically and mentally capable of benefitting from such services;
(ii) are expected to be hospitalized for a period of time sufficient to interrupt their normal educational program; and
(iii) if over age 16, are still enrolled in school.

(d) All hospitals except rural hospitals and hospitals outside an urban area shall have an organized social work department, which shall be directed by a qualified social worker. The department shall be integrated with other departments of the hospital, and shall participate in appropriate education, training and orientation programs for medical, nursing and other clinical staff, and for administrative personnel.

(e) The hospital shall implement, in conjunction with the quality assurance committee, a systematic process for the monitoring and evaluation of the quality and appropriateness of social services provided to patients and families and for the resolution of identified problems.

(f) The hospital shall develop and implement written policies and procedures relating to the long term care ombudsman program as provided for in section 545 of the Executive Law and section 2803-c of the Public Health Law which provide the following:

(1) The hospital shall permit and not restrict or prohibit access to the hospital by duly designated ombudsman who are performing their official duties on behalf of hospital inpatients who have been admitted from, or who are awaiting readmission to, a residential health care facility licensed under article 28 of the Public Health Law, or an adult care facility licensed under section 461-b of the Social Services Law.

(2) The hospital and the hospital staff shall permit and not interfere with confidential visits and communications between such inpatients and such ombudsman except in the case of in-person visits which are medically contraindicated. Such medical contraindication shall be documented for that patient by the attending practitioner in the patient's medical record.

(3) The hospital and the hospital staff shall not retaliate or take reprisals against any patient, employee or other person, who has filed a complaint with, or provided information to, such ombudsmen.

10 NY ADC 405.28
10 NY ADC 405.28
2008 WL 75295890
10 NY ADC 405.28

* Section 405.29.* Cardiac services.

(a) Definitions. For the purposes of this section, the following terms shall have the following meanings:

(1) adult patient means a patient 18 years of age or older at the time of admission;

(2) pediatric patient means a patient who has not reached their 18th birthday at the time of admission to the hospital;

(3) cardiac surgery center means a general hospital that is approved through the certificate of need process to perform surgery on the heart and great vessels, and is approved for and provides cardiac diagnostic and interventional services including, but not limited to percutaneous coronary interventions (PCI) and diagnostic cardiac angiography procedures. Heart transplant procedures may only be performed at cardiac surgery centers that are also approved as heart transplant centers in accordance with standards at section 709.9 of this Title and approved for organ sharing by the United Network for Organ Sharing (UNOS). Cardiac surgery centers must operate in compliance with standards at section 709.9 of this Title and approved for organ sharing by the United Network for Organ Sharing (UNOS). Cardiac surgery centers must operate in compliance with this section, and must meet the construction provisions of Part 711 and Part 712 of this Title. Cardiac surgery centers may be approved to serve adult patients (adult cardiac surgery centers) and or pediatric cardiac patients (pediatric cardiac surgery centers). However, separate certificate of need approvals are required for adult and pediatric cardiac surgery centers in accordance with standards at section 709.14 of this Title.

(4) cardiac catheterization laboratory center means a general hospital approved through the certificate of need process to perform catheter based procedures in specially equipped laboratories. Such laboratories are rooms with specialized radiological equipment and supplies used primarily to perform cardiac based angiographic or electrophysiological (EP) procedures on the heart or great vessels. Cardiac catheterization laboratory centers may be approved to serve adult and or pediatric cardiac patients, but separate certificate of need approvals are required in accordance with standards at section 709.14 of this Title for each service. Cardiac catheterization laboratory centers must operate in compliance with standards set forth in this section. Cardiac catheterization laboratory centers are further categorized by the procedures performed as defined below:
(i) a PCI capable cardiac catheterization laboratory center performs percutaneous coronary and other percutaneous procedures to diagnose and treat abnormalities of the heart or great vessels in adult patients. Such PCI capable cardiac catheterization laboratory centers may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at subparagraph (c)(8)(i) of this section;

(ii) a diagnostic cardiac catheterization service performs catheter based angiographic procedures on the heart or great vessels and is strictly limited to the diagnosis of abnormalities in adult patients. Such hospitals must maintain an affiliation with a cardiac surgery center as specified in subparagraph (c)(8)(i) of this section, and are subject to annual review by DOH to determine the continuing operation of the center. Catheter based interventional procedures, such as percutaneous coronary intervention, are prohibited at diagnostic cardiac catheterization service hospitals;

(iii) a cardiac EP laboratory program shall be located in a cardiac catheterization laboratory center and is approved through the certificate of need process to perform catheter based cardiac electrophysiology (EP) procedures. Such programs may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at paragraph (e)(5) of this section;

(iv) a pediatric cardiac catheterization laboratory center shall be located at a cardiac surgery center approved through the certificate of need process to provide cardiac surgery to pediatric patients and is approved to perform catheter based diagnostic and interventional procedures on pediatric patients; and

(5) cardiac reporting system is a New York State reporting system that gathers demographic, clinical, procedural and outcomes information from cardiac surgery centers and cardiac catheterization laboratory centers on every patient who has undergone a surgical procedure or a percutaneous interventional procedure on the heart or great vessels. The cardiac reporting system includes separate reporting modules to capture procedure specific data elements for the procedure (cardiac surgery or percutaneous interventions) and age group (adult or pediatric) involved.

(b) State cardiac advisory committee. There shall be a State cardiac advisory committee consisting of physicians and other professionals with expertise in cardiac care appointed by the Commissioner of Health. The State cardiac advisory committee shall, at the request of the commissioner, consider any matter relating to cardiac services including, but not limited to review of existing and prospective services, and shall advise the commissioner thereon.

(c) General provisions.

(1) Cardiac catheterization laboratory center services shall be limited to general hospitals.

(2) Hospitals shall not admit patients for cardiac surgery or cardiac catheterization laboratory procedures unless the hospital is approved to provide such services.

(3) Hospitals that provide cardiac surgery, diagnostic cardiac catheterization service, interventional cardiac laboratory services including percutaneous coronary intervention (PCI) and other percutaneous cardiac interventions, or cardiac electrophysiology (EP) must comply with section 405.22(a) of this Part.

(4) Review and approval. Site visits to and or data and record reviews from existing and prospective new centers by the department, members of the cardiac advisory committee or other designees of the commissioner shall be made as indicated, as an adjunct to initial approval and or for consideration of continued approval. Such site visits and reviews shall include, but not be limited to, evaluation of data, review of service specific quality of care, and compliance with minimum workload standards as set forth in this section.

(5) Closure.

(i) Failure to meet one or more statutory or regulatory requirements or inactivity in a program for a period of six months may result in actions to include: probationary status, withdrawal of approval as a cardiac surgery center and or cardiac catheterization laboratory center.

(ii) Voluntary closure. The hospital must give written notification, including a closure plan to the department at least 60 days prior to planned discontinuance of cardiac surgery or cardiac catheterization laboratory center services. No cardiac surgery center and no cardiac catheterization laboratory center shall discontinue operation without first obtaining written approval from the department.

(6) Notification of significant changes. A hospital must notify the Department of Health in writing within seven days of any significant changes in its cardiac surgery center or cardiac catheterization laboratory center services including, but not limited to, any temporary or permanent suspension of services; departure of or change in the physician program director; if the program is without a
physician credentialed to perform one or more of the procedures or services of the cardiac surgery center or cardiac catheterization laboratory center; or inability to meet workload requirements.

(7) Data collection and reporting. Data as deemed necessary by the commissioner shall be maintained for cardiac patients treated by the hospital and submitted upon request to the Department of Health in a format specified by the department. Such data shall include, but not be limited to data documenting appropriate case selection and or appropriate access to care and, cardiac reporting system data for cardiac surgery centers and cardiac catheterization laboratory centers.

(8) Quality assurance. There shall be an organized quality assurance program for cardiac surgery and cardiology that requires participation by all clinical members of the cardiac surgery team and or cardiac laboratory team and includes: monitoring of volume and outcomes; morbidity and all case mortality review; regular multidisciplinary conferences including all health professionals involved in the care of cardiac patients; medical/nursing audit; utilization review, pre hospital and post hospital care review, and a system that assesses pre-operative risk and evaluates outcome trends. Quality improvement efforts must recognize that patients move through multiple systems of care (EMS, emergency department, catheterization laboratory etc.) and optimum quality improvement efforts must include participation from as many systems as possible to address those issues at the juncture of systems of care.

(i) In addition, cardiac catheterization laboratory centers located in hospitals with no cardiac surgery on-site must enter into and comply with a fully executed written agreement with a New York State cardiac surgery center. The agreement will include provisions that address, at a minimum:

(a) cardiac surgery center representatives shall participate in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and other reviews of the quality of cardiac care provided by the affiliated cardiac catheterization laboratory center and in the provision of recommendations for quality improvement of cardiac services. Each cardiac surgery center and each affiliated cardiac catheterization laboratory center hospital shall take actions necessary, including but not limited to entering into a written agreement to authorize such participation by the cardiac surgery center representatives in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and for purposes of such participation, the cardiac surgery center representative or representatives shall be deemed members of the affiliated cardiac catheterization laboratory center hospital's quality assurance committee. Cardiac surgery center representatives may only access confidential patient information for quality assurance committees as set forth in the affiliation agreements and these regulations. Members of hospitals' quality assurance committees must maintain the confidentiality of patient information and are subject to the confidentiality restrictions of Public Health Law section 2805-m and other applicable confidentiality restrictions as provided by law. The cardiac surgery center representative(s) shall participate in the review of information and data for quality improvement purposes as described in the agreement which may include:

(1) statistical data and reports used in quality improvement activities;
(2) the affiliated cardiac catheterization laboratory center hospital's quality improvement program, policies, and procedures;
(3) care provided by medical, nursing, and other health care practitioners associated with the cardiac services;
(4) appropriateness and timeliness of patient referrals and of patients retained at the affiliated cardiac catheterization laboratory center hospital who met criteria for transfer to the cardiac surgery center hospital; and
(5) adverse events or occurrences including death and major complications for patients receiving cardiac care at the affiliated cardiac catheterization laboratory center hospital;
(b) joint cardiology/cardiac surgery conferences to be held at least quarterly, with a focus on continuous quality improvement to include review of: all cardiac laboratory related morbidity and mortality, review of a random selection of uncomplicated routine cases, patient selection, rates of normal outcomes for diagnostic studies performed, rates of studies needed to be repeated prior to intervention, quality of the studies conducted, rates of patients referred for and receiving interventional procedures subsequent to the diagnostic cardiac catheterization procedure, and the number and duration of cardiac catheterization laboratory system failures;
(c) a mechanism for a telemedicine link between the cardiac catheterization laboratory center and the cardiac surgery center that provides the capability for off-site review of digital studies, and a commitment on the part of each hospital to provide timely treatment consultation by appropriate physicians on an as needed basis;
(d) the cardiac surgery center's involvement in developing privileging criteria for physicians performing cardiac catheterization procedures at the hospital with no cardiac surgery on-site;
(e) development and ongoing review of patient selection criteria and review of implementation of those criteria. The process shall include a comprehensive review of the appropriateness of treatment for a random selection of cases;

(f) consultation on equipment, staffing, ancillary services, and policies and procedures for the provision of cardiac catheterization laboratory procedures;

(g) a pre-procedure risk stratification tool which ensures that high risk and or complex cases are treated at a cardiac surgery center;

(h) procedures to provide for appropriate patient transfers between facilities;

(i) an agreement to notify the department of any proposed changes to the initial agreement and to obtain department approval prior to the change; and

(j) an agreement to jointly sponsor and conduct annual studies of the impact that the cardiac catheterization laboratory center service has on costs and access to cardiac services in the hospital’s service area.

(ii) The department’s cardiac surgery center reviews, as specified at paragraph (4) of this subdivision, shall include review of the quality of the services the cardiac surgery center has provided to each of the cardiac catheterization laboratory centers with which it has a written agreement as specified at subparagraph (i) of this paragraph; and

(iii) cardiac surgery centers with one or more affiliated cardiac catheterization laboratory centers shall provide professional education and training for physicians, nurses and other staff of the affiliated centers for which it provides quality of care review. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures and technological advances.

(9) The hospital must have written policies and procedures clearly delineating medical equipment vendor activities in the hospital including restrictions on vendor participation in clinical services.

(10) Cardiac surgery centers shall be approved to operate as PCI capable cardiac catheterization laboratory centers without a separate certificate of need (CON) approval, but must operate in compliance with standards at paragraphs (e)(1) and (2) of this section.

(11) Hospitals with approved cardiac catheterization laboratories approved prior to July 1, 2009 to perform PCI with no cardiac surgery on site shall be approved to operate as PCI capable cardiac catheterization laboratory centers without a certificate of need approval but must operate in compliance with standards at paragraphs (e)(1) and (2) of this section.

(12) Hospitals with approved cardiac catheterization laboratories approved prior to July 1, 2009 to perform cardiac electrophysiology procedures shall be approved to operate as cardiac EP laboratory programs without a certificate of need approval but must operate in compliance with standards at paragraphs (e)(1) and (5) of this section.

(d) Cardiac surgery center criteria. The following criteria apply to cardiac surgery centers approved to perform adult and or pediatric cardiac surgery. The cardiac surgery services must be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice:

(1) Direction. The physician director is responsible for the overall quality of the cardiac surgical program and carries out this responsibility through the administrative structure of the institution, including but not limited to the governing body. The hospital must notify the Department of Health within seven days of any change in the cardiac surgery program director, together with the name and curriculum vitae of the new director. The director shall be a qualified physician board certified in thoracic surgery or meet accepted equivalent training and experience.

(i) The director shall:

(a) Continuously monitor the performance of all surgeons working in the cardiac surgical program, including each individual surgeon’s annual case load and level of competence. The director shall advise the chief of service, hospital medical director and credentials committee on requirements for credentialing and privileging within the cardiac surgery department and will provide assessments of compliance with standards of care, policies and guidelines as part of the credentialing and privileging process;

(b) in conjunction with the medical staff, monitor the quality and appropriateness of cardiac related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved; and

(c) assure the timely and accurate reporting of the cardiac surgery component of cardiac reporting system data to the department.

(2) Structure and service requirements. Hospitals providing cardiac surgery services shall be adequately staffed and equipped for cardiac diagnostic and therapeutic services including, but not
limited to cardiac surgery, percutaneous coronary interventions (PCI) and diagnostic cardiac catheterization and, in addition, provide the following:

(i) for adult cardiac surgery centers:
   (a) cardiac surgical intensive care, organized, staffed and available on a 24 hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required by adult cardiac surgery patients;
   (b) coronary care organized, staffed and available - on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions; and
   (c) PCI capable cardiac catheterization laboratory center services meeting standards at paragraphs (e)(1) and (2) of this section.

(ii) for pediatric cardiac surgery centers: age appropriate intensive care, organized, staffed and available on a 24-hour basis by clinical personnel trained and equipped to meet the needs of pediatric patients undergoing cardiac surgery, and pediatric cardiac catheterization laboratory center services meeting standards at paragraphs (e)(1) and (4) of this section.

(iii) for all cardiac surgery centers:
   (a) operating rooms adequately staffed and equipped for the needs of the cardiac surgery patient;
   (b) preoperative and post operative care areas to serve the needs of the surgery patient;
   (c) a qualified cardiac surgeon must be immediately available for consultation. The surgeon must remain available (arrive on-site within 20 minutes of being called) after each cardiac surgery procedure. The surgeon must remain available until at least such time that the patient is evaluated on post operative day one and for a clinically appropriate period of time thereafter to handle cardiac surgery emergencies;
   (d) the hospital must assure that a cardiac surgery team is immediately mobilized for handling cardiac surgery emergencies. In the event that a patient must return on an emergency basis to the operating room, appropriate resources shall be immediately available in order to have the patient in the operating room and the team ready within 20 minutes of an identified surgical emergency. There shall be written documentation of a triage protocol including identification of specific responsibilities;
   (e) non-invasive cardiac diagnostic equipment and capabilities;
   (f) in addition, the hospital shall provide clinical support services in keeping with generally accepted standards. Such services shall be integrated and available on an inpatient basis, but there shall also be adequately and appropriately organized outpatient services to preclude unnecessary hospitalization and ensure continuity of care;
   (g) cardiac surgery conferences shall be held no less than 10 times per year at which the staff reviews the studies of a statistically significant number of cases. Records of these conferences indicating attendance, cases reviewed and decisions on patient management shall be maintained; and
   (h) the hospital shall attempt to determine and document the status of the patient at 30 days post surgery for those who are no longer inpatient and throughout the hospital stay for those who are discharged from the cardiac surgery service to another service within the hospital. Status shall include living or deceased and other pertinent criteria as determined by the commissioner.

(3) staffing. All personnel shall be qualified for their responsibilities through appropriate training and educational programs.

(i) Physicians shall all be residency trained and board certified, or meet accepted equivalent training and experience for physicians in their respective specialty and shall be appropriately credentialed and privileged as part of the medical staff, and shall be available in sufficient numbers and on a 24 hour basis to meet the needs of the cardiac surgery patients. Such specialists shall, at a minimum include:
   (a) cardiothoracic surgeons in sufficient numbers to meet the ongoing needs of the patients, and each of whom performs a minimum of 50 cardiac surgeries per year. Review by the physician director shall be conducted and provided to the chief of service, hospital medical director and medical staff credentials committee for all physicians whose annual volume is below 50 cardiac surgeries to determine what actions are deemed necessary. In addition, for programs approved to perform pediatric cardiac surgery, cardiac surgeons with advanced training and or with significant experience in pediatric cardiac surgery to meet the needs of the pediatric patients;
   (b) anesthesiologist(s), who have acceptable minimum experience with cardiac surgical procedures;
   (c) specialists with expertise in critical care and the care of post cardiac surgery patients;
   (d) cardiologists to care for adults and, for programs approved to care for pediatric patients, pediatric cardiologists, with expertise in children’s cardiovascular diseases, each of whom meet qualifications in accordance with generally accepted standards from recognized specialty organizations; and
(e) complement of additional physicians shall be in keeping with generally accepted standards to meet the needs of cardiac surgery patients and shall include, but not be limited to practitioners, readily available for consultation in additional specialties, including hematology, pulmonology, neurology, nephrology and clinical pharmacology.

(ii) Nurses. Nursing personnel shall be certified in advanced cardiac life support (ACLS) or meet acceptable equivalent training and experience and shall include:
   (a) a registered professional nurse, with 24-hour accountability, in charge of coordinating the care of post cardiac surgery patients and in charge of staffing levels for the unit;
   (b) registered professional nurses, licensed practical nurses and nursing assistants in such ratios that are commensurate with the type and amount of nursing needs of the patients.

(iii) Nurse practitioners, advanced practice nurses and or registered physician assistants may be utilized when these specialists are appropriately credentialed and privileged on the medical staff.

(iv) The cardiac surgery center shall have perfusionists who have special training and experience in an active program of open heart surgery, including a thorough background in sterile techniques, perfusion physiology, and the use of monitoring equipment and must demonstrate, through a formal review process, competencies in these areas. The operator may be a specially trained physician, nurse, or technician, at the discretion of the director of the center.

(v) The cardiac surgery center shall have a data manager who has special training in the clinical criteria used in the cardiac surgery module of the cardiac reporting system as provided by the department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of cardiac reporting system data to the department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the cardiac reporting system and the specific data element definitions involved.

(4) patient selection criteria and limitations. Criteria shall be adopted by the cardiac surgery center to be used as indications of appropriate case selection. Such criteria shall be in keeping with generally accepted standards and, at a minimum, shall provide the following limitations:
   (i) the hospital shall not perform heart transplantation unless the hospital is a cardiac surgery center approved for heart transplantation and approved for organ sharing by UNOS;
   (ii) the hospital shall not electively admit patients for implantable ventricular assist devices unless the hospital is a cardiac surgery center approved for heart transplantation or has an agreement with at least one New York State heart transplantation center that provides for appropriate consultation and expertise for such cases;
   (iii) the hospital shall not admit patients under the age of 18 for cardiac surgery unless the hospital is a cardiac surgery center approved for pediatric cardiac surgery or unless the patient's diagnosis indicates a condition, such as acquired heart disease, that can be most appropriately treated in an adult program with pediatric trained personnel and pediatric consultative services. Such exceptions must be supported by written documentation of consultation with a pediatric cardiologist; and
   (iv) cardiac surgery centers approved to perform pediatric cardiac surgery that are not also approved as adult cardiac surgery centers shall not admit patients over the age of 18 for cardiac surgery unless the procedure will be performed to treat a congenital anomaly and the hospital can meet the additional clinical needs of the patient.

(5) minimum workload standards. There shall be sufficient utilization of a cardiac surgery center to insure both quality and economy of services, as determined by the commissioner. An institution seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved and maintained. The following annual minimum workload standards must be achieved within two years following initiation of the service to ensure both quality and economy of services:
   (i) adult cardiac surgery centers shall maintain an annual minimum of 100 procedures on adult patients; and
   (ii) pediatric cardiac surgery centers shall maintain an annual minimum of 75 pediatric cardiac surgery procedures excluding the number of isolated patent ductus arteriosus (PDA) repairs. The annual minimum volume shall be deemed to be met when two or more pediatric cardiac surgery centers, at least one of which must perform a minimum of 75 pediatric cardiac surgery procedures a year (excluding isolated PDA repairs), join in a coordinated program based on a fully executed written agreement, approved by the commissioner, and the combined volume of the collaborating pediatric cardiac surgery centers (excluding the number of PDA repairs) is greater than 100 procedures a year. The agreement between the collaborating hospitals must include, at a minimum, information on: quality improvement, peer review and coordination of care of patients between the coordinated
pediatric cardiac surgery centers. The agreement must specify that the department will be provided 60 day prior written notice of any proposed change, termination or expiration of the agreement. Changes must be found acceptable to the department prior to implementation and any proposed termination or expiration of the agreement will result in termination of the coordinated pediatric cardiac surgery center program.

(6) waiver of minimum workload standards. The commissioner may waive the workload requirements upon a satisfactory showing by a cardiac surgery center as determined by the commissioner upon seeking advice from cardiac advisory committee representatives that the quality of care provided is adequate as supported, at a minimum, by a review of cases and outcome trends conducted by the department, and:

(i) there are extenuating circumstances precluding compliance with the workload requirements; and
or

(ii) there is documented evidence that need for cardiac surgery in the hospital's geographical service area would be substantially unmet if the program were closed.

(e) Cardiac catheterization laboratory center criteria.

(1) The following criteria apply to all cardiac catheterization laboratory centers. Cardiac catheterization laboratory center services must be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice.

(i) Direction. The physician director is responsible for the overall quality of the cardiac catheterization laboratory center and must have the appropriate authority to carry out those responsibilities through the support of the chief of cardiology, the medical director of the hospital and the hospital administration. The hospital must notify the department within seven days of a change in the directorship of the cardiac catheterization laboratory center, together with the name and curriculum vitae of the new director.

(ii) Qualifications of the director. The director must be board certified in internal medicine and the subspecialty of cardiac disease or meet equivalent standards, be experienced in the performance of procedures specific to type of cardiac catheterization laboratory center services provided, have good management skills and must be appropriately credentialed and privileged as a member of the medical staff.

(iii) The director shall:

(a) continuously monitor the performance of all cardiologists working in the cardiac catheterization laboratory center, including but not limited to, each cardiologist's annual case load requirement and level of competence. The director shall advise the chief of service, the hospital medical director and the credentials committee on requirements for credentialing and privileging in the cardiac catheterization laboratory center and shall provide assessments of compliance with standards of care, policies and guidelines as part of the credentialing and privileging process;

(b) in conjunction with the medical staff, monitor the quality and appropriateness of cardiac related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved; and

(c) for centers approved as PCI capable cardiac catheterization laboratory centers, assurance of the timely and accurate reporting the cardiac catheterization laboratory center module of the cardiac reporting system data to the department.

(iv) Structure and service requirements:

(a) all cardiac catheterization laboratory centers must provide diagnostic services, including but not limited to diagnostic radiology, clinical laboratory, and invasive and noninvasive cardiac diagnostic procedures. Such services shall be available on an inpatient and outpatient basis;

(b) all cardiac catheterization laboratory centers must have a process in place that allows for appropriate transfer of cases to a higher level of care to handle cardiac emergencies;

(c) cardiac catheterization laboratory centers approved to provide care to adult patients must provide coronary care organized, staffed and available on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions;

(d) cardiac catheterization laboratory centers approved to perform pediatric procedures must provide age appropriate intensive care, organized, staffed and available on a 24-hour basis by clinical personnel trained and equipped to meet the needs of pediatric patients undergoing cardiac laboratory procedures;

(e) cardiology conferences shall be held no less than 10 times per year at which the staff reviews the studies of a statistically significant number of cases. Records of these conferences indicating attendance, cases reviewed and decisions on patient management shall be maintained;
(f) records of the disposition of the cases shall be maintained in compliance with standards set forth in section 405.10 of this Part;

(g) the number of patients referred annually for surgery and the center(s) to which they are referred shall be maintained and readily available upon request from the Department of Health;

(h) statistics shall be kept on the number of normal invasive cardiac diagnostic studies performed, and written criteria shall be adopted and used for determining when a study is to be considered abnormal. Such criteria shall be in keeping with generally accepted standards of medical practice; and

(i) the hospital shall ensure high quality imaging and radiation protection for patients and personnel in accordance with section 405.15 of this Part.

(j) in addition to standards at subparagraph (c)(8)(i) of this section, for cardiac catheterization laboratory centers approved under a co-operator agreement as set forth in section 709.14(d)(1)(ii)(n) of this Title, the written and signed co-operator agreement between a cardiac surgery center and the cardiac catheterization laboratory center without cardiac surgery on site must be maintained and must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or expiration of the agreement, any changes must be found acceptable to the department prior to implementation and any proposed termination or expiration shall require prior submission of a plan of closure to the department. The agreement shall provide for an integration of expertise and resources from the cardiac surgery center that would support a high quality program at the hospital without cardiac surgery on site, and shall delineate responsibilities of each institution. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated cardiac catheterization laboratory center.

(v) Staffing. All personnel shall be qualified for their responsibilities through appropriate training and educational programs.

(a) physicians shall all be board certified, or meet accepted equivalent training and experience for physicians in their respective specialty, and shall be appropriately credentialed and privileged as part of the medical staff. Such specialists shall, at a minimum, include a cardiologist and or pediatric cardiologist depending upon the age group(s) served; a cardiac angiographer whose basic medical training is in keeping with generally accepted standards;

(b) nurses with appropriate education and training shall be regularly assigned to the center; and

(c) additional healthcare personnel as needed, each of whom is qualified through appropriate training and education to serve the needs of cardiac catheterization laboratory center patients.

(vi) Patient selection criteria.

(a) the hospital shall not admit patients under the age of 18 for a cardiac laboratory procedure unless the hospital is an approved pediatric cardiac catheterization laboratory center or unless the patient's diagnosis indicates a condition, such as acquired heart disease, that can be most appropriately treated in an adult program with pediatric trained personnel and pediatric consultative services, or except as provided in clause (5)(iii)(c) of this subdivision. Such exceptions must be supported by written documentation of consultation with a pediatric cardiologist;

(b) pediatric cardiac catheterization laboratory centers that are not also approved as adult cardiac services programs shall not admit patients over the age of 18 for a cardiac laboratory procedure unless the procedure will be performed to diagnose or treat a congenital anomaly and the hospital can meet the additional needs of the patient;

(c) the hospital shall not admit adult patients for percutaneous coronary intervention or other percutaneous cardiac interventions unless it is an approved PCI capable cardiac catheterization laboratory center; and

(d) the hospital shall not provide cardiac EP laboratory program services unless it is an approved cardiac catheterization laboratory center with an approved cardiac EP laboratory program.

(2) PCI capable cardiac catheterization laboratory centers. PCI capable cardiac catheterization laboratory centers must meet the following standards:

(i) structure and service requirements:

(a) PCI capable cardiac catheterization laboratory centers must be appropriately staffed and equipped for diagnostic and therapeutic services including but not limited to diagnostic cardiac catheterization and percutaneous coronary and other percutaneous interventions;

(b) PCI capable cardiac catheterization laboratory centers must maintain capabilities to perform emergency percutaneous coronary interventions including, but not limited to percutaneous coronary intervention for the treatment of ST elevation Myocardial Infarction (STEMI) on a 24 hour a day, 365 days a year basis and must be capable of assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year. Exception to this standard shall be made only for temporary and extenuating circumstances and when:
(1) local emergency medical services have been notified and documentation is in place for triaging patients in need of emergency PCI; and

(2) the Department of Health has been provided with a specific description of the circumstances, documentation of the revised triage arrangements and a timeline for return to the 24 hour provision of services, and has approved the arrangement.

(c) the hospital must insure that once an ambulance calls to indicate transport of an emergency cardiac patient, the PCI team is immediately mobilized;

(d) the hospital must effectively and efficiently identify patients in need of an emergency percutaneous coronary intervention and must transfer those patients rapidly (within 30 minutes) from the emergency department to the cardiac laboratory; and

(e) the hospital must have a system documented and in place to ensure effective and efficient identification and transfer of a patient from the cardiac laboratory to a cardiac surgical program either in the hospital or at another hospital.

(ii) staffing.

(a) physicians shall all be board certified, or meet accepted equivalent training and experience for physicians in their respective specialty and shall be appropriately credentialed and privileged as members of the medical staff and in sufficient numbers to meet the care needs of the patients;

(b) a minimum of three interventional cardiologists, at least one of whom dedicates the majority of his or her professional time at the facility, must be credentialed and privileged on the medical staff to perform percutaneous coronary interventions. Each interventional cardiologist shall maintain sufficient volume on-site to maintain familiarity with the laboratory and shall perform a minimum of 75 total percutaneous coronary intervention cases per year of which 11 are emergency percutaneous coronary intervention cases, and not all 75 minimum cases or 11 minimum emergency cases must be performed at one site. Review by the physician director shall be conducted and provided to the chief of service, hospital medical director and medical staff credentials committee for all physicians whose volume falls below these minimum volumes to determine actions deemed necessary; and

(c) the PCI capable cardiac catheterization laboratory center shall have a data manager who has special training in the clinical criteria used in the PCI module of the cardiac reporting system as provided by the department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of cardiac reporting system data to the department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the cardiac reporting system and the specific data element definitions involved.

(iii) patient selection criteria. PCI capable cardiac catheterization laboratory centers shall adopt criteria for appropriate coronary artery diagnostic and interventional procedures in accordance with generally accepted standards for cardiac patients. For centers with no cardiac surgery on site, patient selection criteria shall be reviewed and approved annually by the affiliated cardiac surgery center in accordance with subparagraph (c)(8)(i) of this section.

(iv) minimum workload standards. There shall be sufficient utilization of a center to ensure both quality and economy of services, as determined by the commissioner. For hospitals that are part of an article 28 network and multi-site facilities with more than one approved PCI capable cardiac catheterization laboratory center, and for PCI capable cardiac catheterization laboratory centers operating under a co-operator agreement pursuant to section 709.14(d)(1)(ii)(c)(3)(viii) of this Title, minimum volume standards are site specific and may not be combined for purposes of achieving minimum workload standards. Any hospital seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved by the second full year following initiation of the service and maintained thereafter. Each PCI capable cardiac catheterization laboratory center must maintain a minimum volume of 150 percutaneous coronary intervention cases per year including at least 36 emergency percutaneous coronary intervention cases per year. Hospitals with volumes below 400 percutaneous coronary intervention cases per year must comply with the following:

(a) PCI capable cardiac catheterization laboratory centers with an annual volume between 300 and 400 percutaneous coronary intervention cases shall undergo a review of cases and outcomes trends conducted by the department to evaluate the appropriateness and quality of care provided by the center;

(b) PCI capable cardiac catheterization laboratory centers with a volume between 150 and 300 percutaneous coronary intervention cases a year must procure the services of an independent physician consultant, acceptable to the department, who shall conduct an annual review of the appropriateness and quality of percutaneous coronary intervention cases performed at the facility and
shall provide a copy of the findings directly to the department. Findings will be used by the department to determine whether continued approval or withdrawal of approval best meets the needs of the patients in the region; and

(c) PCI capable cardiac catheterization laboratory centers with an annual volume below 150 percutaneous coronary intervention cases a year for two consecutive calendar years, or a volume below 36 emergency percutaneous coronary intervention cases a year for two consecutive calendar years, shall surrender approval to perform percutaneous coronary interventions or have approval to perform the procedure revoked.

(v) PCI capable cardiac catheterization laboratory centers with no cardiac surgery on-site must enter into a formal relationship documented by a fully executed written agreement with a cardiac surgery center meeting standards at subparagraph (c)(8)(i) of this section.

(3) Diagnostic cardiac catheterization services. As of the effective date of these regulations, no additional diagnostic cardiac catheterization services shall be approved. Diagnostic cardiac catheterization services hospitals are not approved to perform percutaneous coronary intervention or cardiac surgery, are subject to annual reviews of volume, appropriateness of cases and other quality indicators for diagnostic cardiac catheterization, and must meet the following standards:

(i) affiliation agreement. The hospital must enter into and maintain a fully executed written agreement with a cardiac surgery center with demonstrated high volume and high quality interventional cardiac services (cardiac surgery and percutaneous coronary interventions). The agreement, must be approved by the commissioner, and must provide, at a minimum, for the standards at subparagraph (c)(8)(i) of this section.

(ii) Patient selection criteria. Written criteria shall be adopted by the diagnostic cardiac catheterization service hospital to be used as indications for coronary angiography and or other cardiac invasive diagnostic procedures and shall be available for review during site visits.

(iii) minimum workload standards. There shall be sufficient utilization of a diagnostic cardiac catheterization service to ensure both quality and economy of services, as determined by the commissioner. For hospitals that are part of an article 28 network and for multi-site facilities with more than one approved cardiac catheterization laboratory center, minimum volume standards are site specific and may not be combined for purposes of achieving minimum workload standards. Any institution seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved and maintained. Diagnostic cardiac catheterization services shall achieve and maintain an annual minimum volume of 200 angiographic diagnostic cardiac catheterization procedures within two years of initial approval. Such procedures include left and or right heart catheterization with or without the use of contrast visualization and with or without coronary arteriograms, and such procedures exclude:

(a) placement of permanent or temporary pacemaker or automatic implantable cardioverter defibrillator (AICD);
(b) any floating type catheter;
(c) bundle of his study;
(d) balloon septostomy;
(e) radionuclide study;
(f) right heart catheterization without contrast visualization in adults;
(g) placement of intra-aortic balloon pump; and
(h) non-coronary studies.

(iv) Waiver of minimum workload standards. The commissioner may temporarily waive the workload requirements upon a satisfactory showing by the hospital that the quality of care provided is adequate as supported, at a minimum, by a review conducted by the department of cases, outcome trends and appropriateness of care, and that:

(a) there are extenuating circumstances temporarily precluding compliance with the workload requirements; and

(b) there is a documented unmet need in the center's geographical service area that cannot be met by existing PCI capable cardiac catheterization laboratory center laboratory centers.

(4) Pediatric cardiac catheterization laboratory centers. In addition to the standards at paragraph (1) of this subdivision, pediatric cardiac catheterization; laboratory centers must meet the following standards:

(i) pediatric cardiac catheterization laboratory centers are limited to hospitals approved to perform pediatric cardiac surgery and that meet standards at subdivision (d) of this section; and

(ii) during any interventional pediatric cardiac catheterization procedure and for a clinically appropriate period of time following such a procedure, a qualified pediatric cardiac surgeon must be
immediately available for consultation and available on-site within 30 minutes, when requested, to perform procedures as needed to meet the patient’s needs.

(5) Cardiac EP laboratory programs. In addition to the standards at paragraph (1) of this subdivision, cardiac EP laboratory programs must meet the following standards:

(i) structure and service requirements:
(a) cardiac electrophysiology laboratories must be adequately staffed and equipped for providing intracardiac electrophysiology procedures;
(b) an ultrasound (echocardiographic) machine must be readily available to the laboratory during all electrophysiology procedures;
(c) the cardiac EP laboratory program must have written protocols utilized for addressing complications including tamponade; and
(d) cardiac EP laboratory programs serving patients between the ages of 12 and 18 with adult cardiac surgery on site, but no pediatric cardiac surgery on site, must maintain pediatric trained personnel.

(ii) staffing. Staffing for cardiac EP laboratory programs shall include:
(a) electrophysiologists, board certified or with separate equivalent training and experience each of whom shall maintain an average annual volume of 50 adult cardiac electrophysiology procedures based on review of two years of cases, or 20 pediatric cardiac electrophysiology procedures per year depending on the population served. Review by the physician director shall be conducted and provided to the chief of service, hospital medical director and medical staff credentials committee for all physicians whose volume falls below these minimum workload standards to determine what actions are deemed necessary;
(b) physicians, on staff and immediately available to the laboratory with the expertise to perform local exploration and diagnose and treat tamponade; and
(c) registered nurses specifically trained in electrophysiology.

(iii) patient selection criteria.
(a) Written criteria shall be adopted to be used as indications and contraindications for cardiac electrophysiology procedures in accordance with generally accepted standards of medical care for cardiac patients.
(b) Notwithstanding clause (1)(vi)(a) of this subdivision, a hospital with a cardiac EP laboratory program and no cardiac surgery on-site shall not admit patients under the age of 18, patients in need of chronic lead extractions, patients being treated for ventricular tachycardia ablations, and patients being treated for atrial fibrillation ablations for cardiac EP laboratory program services. Additional patient selection criteria for cardiac EP laboratory programs with no cardiac surgery on-site shall be developed in collaboration with a cardiac surgery center with an active cardiac EP laboratory program and the agreed upon criteria shall be documented in writing.
(c) Notwithstanding clause (a) of this subdivision, a hospital with a cardiac EP laboratory program and with adult cardiac surgery on-site, but no pediatric cardiac surgery on-site may perform cardiac electrophysiology procedures on patients between the age of 12 and 18 when the patient’s diagnosis and condition can be most appropriately treated in an adult program and when pediatric trained personnel are available to meet the additional needs of the patient and when consultation with a pediatric cardiologist is documented in writing for each pediatric patient.

Section 405.43.* Orders not to resuscitate.

(a) The hospital shall adopt and implement written policies and procedures governing orders not to attempt cardiopulmonary resuscitation of a patient where consent has been obtained and which ensure the clarification of the rights and obligations of patients, their families, and health care providers regarding cardiopulmonary resuscitation and the issuance of orders not to resuscitate. Such policies shall assure that:
(1) each patient who consents to an order not to resuscitate is informed of the range of available resuscitation measures, consistent with the hospital’s equipment and facilities; and
(2) all staff involved in the care of any person for whom an order not to resuscitate has been issued are promptly informed of the order, including any limitations or other instructions.
(b) Definitions. The following words or phrases, as used in this section, shall have the following meanings unless the context otherwise requires:

1. Adult means any person who is 18 years of age or older, or is the parent of a child, or has married.

2. Attending physician means the physician selected by or assigned to a patient in a hospital or, for the purpose of provisions herein governing nonhospital orders not to resuscitate, a patient not in a hospital, who has primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such physician may act as the attending physician pursuant to this section.

3. Capacity means the ability to understand and appreciate the nature and consequences of an order not to resuscitate, including the benefits and disadvantages of such an order, and to reach an informed decision regarding the order.

4. Cardiopulmonary resuscitation means measures to restore cardiac function or to support ventilation in the event of a cardiac or respiratory arrest, such as manual chest compression, mouth-to-mouth rescue breathing, intubation, direct cardiac injection, intravenous medications, electrical defibrillation and open-chest cardiac massage. Cardiopulmonary resuscitation shall also include the transfer of a patient to another facility if solely for the purpose of providing cardiopulmonary resuscitation. Cardiopulmonary resuscitation shall not include measures to improve ventilation and cardiac function in the absence of an arrest.

5. Close friend means any person, 18 years of age or older, who presents an affidavit to an attending physician stating that he is a close friend of the patient and that he has maintained such regular contact with the patient as to be familiar with the patient's activities, health, and religious or moral beliefs and stating the facts and circumstances that demonstrate such familiarity.

6. Developmental disability means a developmental disability as defined in section 1.03(22) of the Mental Hygiene Law.

7. Emergency medical services personnel means the personnel of a service engaged in providing initial emergency medical assistance, including but not limited to first responders, emergency medical technicians, and advanced emergency medical technicians.

8. Health care agent means a health care agent of the patient designated pursuant to article 29-c of the Public Health Law.

9. Hospital means a general hospital as defined in Public Health Law, section 2801(10), a nursing home as defined in section 414.1(a)(3) of this Title, and a health-related facility as defined in section 414.1(a)(1).

10. Hospitalization means the period during which a person is a patient in, or a resident of, a hospital.

11. Hospital emergency service personnel means the personnel of the emergency service of a general hospital, as defined in subdivision 10 of section 2801 of the Public Health Law, including but not limited to emergency services attending physicians, nurse practitioners, emergency services registered professional nurses, and registered professional nurses, nursing staff and registered physicians assistance assigned to the general hospital's emergency service.

12. Medically futile means that cardiopulmonary resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs.

13. Mental hygiene facility means a residential facility operated or licensed by the Office of Mental Health or the Office of Mental Retardation and Developmental Disabilities.

14. Mental illness means a mental illness as defined in section 1.03(20) of the Mental Hygiene Law, provided, however, that mental illness shall not include dementia, such as Alzheimer's disease or other disorders related to dementia.

15. Minor means any person who is not an adult.

16. Nonhospital order not to resuscitate means an order, issued in accordance with section 2977 of the Public Health Law, that directs emergency medical services personnel and hospital emergency service personnel not to attempt cardiopulmonary resuscitation in the event a patient suffers cardiac or respiratory arrest.

17. Order not to resuscitate means an order not to attempt cardiopulmonary resuscitation in the event a patient suffers cardiac or respiratory arrest. Such order may cover all cardiopulmonary resuscitation measures or may be limited to specific procedures or equipment, depending on the scope of the consent.

18. Parent means a parent who has custody of a minor.

19. Patient means a person admitted to a hospital.
(20) Reasonably available means that a person to be contacted can be contacted with diligent efforts by an attending physician or another person acting on behalf of the attending physician or the hospital.

(21) Surrogate means the person selected to make a decision regarding resuscitation on behalf of another person.

(22) Surrogate list means the list set forth in subparagraph (f)(2)(i) of this section.

(23) Terminal condition means an illness or injury from which there is no recovery, and which reasonably can be expected to cause death within one year.

(c) Presumption in favor of a patient's consent to resuscitation; lawfulness of order; effectiveness of order; duty to provide information; no duty to expand equipment.

(1) Every person admitted to a hospital shall be presumed to consent to the administration of cardiopulmonary resuscitation in the event of cardiac or respiratory arrest, unless there is consent to the issuance of an order not to resuscitate as provided in this section.

(2) It shall be lawful for the attending physician to issue an order not to resuscitate a patient, provided that the order has been issued pursuant to the requirements of this section. The order shall be included in writing in the patient's chart. An order not to resuscitate shall be effective upon issuance.

(3) Before obtaining, pursuant to this section, the consent of the patient, or of the surrogate of the patient, or parent or legal guardian of the minor patient, to an order not to resuscitate, the attending physician shall provide to the person giving consent information about the patient's diagnosis and prognosis, the reasonably foreseeable risks and benefits of cardiopulmonary resuscitation for the patient, and the consequences of an order not to resuscitate.

(4) Nothing in this section shall require a hospital to expand its existing personnel, training, equipment and facilities to provide cardiopulmonary resuscitation.

(5) With regard to the provisions of article 29-C of the Public Health Law governing health care proxies:

(i) the provisions of that article shall take precedence over conflicting provisions of this section; and

(ii) when a patient who has a health care agent lacks capacity, the agent shall have the rights and authority that a patient with capacity would have under this section, subject to the terms of the health care proxy and that article.

(d) Determination of capacity to make a decision regarding cardiopulmonary resuscitation.

(1) Every adult shall be presumed to have the capacity to make a decision regarding cardiopulmonary resuscitation unless determined otherwise pursuant to this section or pursuant to a court order. A lack of capacity shall not be presumed from the fact that a committee of the property or conservator has been appointed for the adult pursuant to article 77 or 78 of the Mental Hygiene Law, or that a guardian has been appointed pursuant to article 17-A of the Surrogate's Court Procedure Act.

(2) A determination that an adult patient lacks capacity shall be made by the attending physician to a reasonable degree of medical certainty. The determination shall be made in writing and shall contain such attending physician's opinion regarding the cause and nature of the patient's incapacity as well as its extent and probable duration. The determination shall be included in the patient's medical chart.

(i) At least one other physician, selected by a person authorized by the hospital to make such selection, must concur in the determination that an adult lacks capacity. The concurring determination shall be made in writing after personal examination of the patient and shall contain the physician's opinion regarding the cause and nature of the patient's incapacity as well as its extent and probable duration. Each concurring determination shall be included in the patient's medical chart.

(ii) If the attending physician of a patient in a general hospital determines that a patient lacks capacity because of mental illness, the concurring determination required by subparagraph (i) of this paragraph shall be provided by a physician certified or eligible to be certified by the American Board of Psychiatry and Neurology.

(iii) If the attending physician determines that a patient lacks capacity because of a developmental disability, the concurring determination required by subparagraph (i) of this paragraph shall be provided by a physician or psychologist employed by a school named in section 13.17 of the Mental Hygiene Law, or who has been employed for a minimum of two years to render care and service in a facility operated or licensed by the Office of Mental Retardation and Developmental Disabilities, or who has been approved by the Commissioner of Mental Retardation Developmental Disabilities, in accordance with regulations promulgated by such commissioner.

(4) Notice of a determination that the patient lacks capacity shall promptly be given:

(i) to the patient, where there is any indication of the patient's ability to comprehend such notice, together with a copy of a statement summarizing the rights, duties and requirements of this section;
(ii) to the person on the surrogate list highest in order of priority listed, when persons in prior clauses are not reasonably available; and

(iii) if the patient is in or is transferred from a mental hygiene facility, to the facility director.

Nothing in this paragraph shall preclude or require notice to more than one person on a surrogate list.

(5) A determination that a patient lacks capacity to make a decision regarding an order not to resuscitate pursuant to this section shall not be construed as a finding that the patient lacks capacity for any other purpose.

(e) Decisionmaking by an adult with capacity.

(i) The consent of an adult with capacity must be obtained prior to issuing an order not to resuscitate, except as provided in paragraph (3) of this subdivision.

(ii) If the adult has capacity at the time the order is to be issued, the consent must be obtained at or about such time, notwithstanding any prior oral or written consent.

(iii) During hospitalization, an adult with capacity may express a decision consenting to an order not to resuscitate orally in the presence of at least two witnesses 18 years of age or older, one of whom is a physician affiliated with the hospital in which the patient is being treated. Any such decision shall be recorded in the patient's medical chart.

(iv) Prior to or during hospitalization, an adult with capacity may express a decision consenting to an order not to resuscitate in writing, dated and signed in the presence of at least two witnesses 18 years of age or older who shall sign the decision.

(v) An attending physician who is provided with or informed of a decision pursuant to this subdivision shall record or include the decision in the patient's medical chart if the decision has not been recorded or included, and either:

(a) promptly issue an order not to resuscitate the patient or issue an order at such time as the conditions, if any, specified in the decision are met, and inform the hospital staff responsible for the patient's care of the order; or

(b) promptly make his or her objection to the issuance of such an order and the reasons therefor known to the patient, and either make all reasonable efforts to arrange for the transfer of the patient to another physician, if necessary, or promptly submit the matter to the dispute mediation system.

(vi) Prior to issuing an order not to resuscitate a patient who has expressed a decision consenting to an order not to resuscitate under specified medical conditions, the attending physician must make a determination, to a reasonable degree of medical certainty, that such conditions exist, and include the determination in the patient's medical chart.

(v) If a member of the hospital staff responsible for the care of a patient for whom an order not to resuscitate has been issued objects to providing care in accordance with the order, the hospital shall take reasonable steps, such as adjustments in staff assignments, consistent with the care needs of the patient, to accommodate the staff member's objections.

(i) In the event that the attending physician determines, in writing, that to a reasonable degree of medical certainty, an adult patient who has capacity would suffer immediate and severe injury from a discussion of cardiopulmonary resuscitation, the attending physician may issue an order not to resuscitate without obtaining the patient's consent, but only after:

(a) consulting with and obtaining the written concurrence of another physician selected by a person authorized by the hospital to make such selection, given after personal examination of the patient, concerning the assessment of immediate and severe injury to the patient from a discussion of cardiopulmonary resuscitation;

(b) ascertaining the wishes of the patient to the extent possible without subjecting the patient to a risk of immediate and severe injury;

(c) including the reasons for not consulting the patient in the patient's chart; and

(d) obtaining the consent of a health care agent who is available and would be authorized to make a decision regarding cardiopulmonary resuscitation if the patient lacked capacity or, if there is no such agent, a surrogate pursuant to subdivision (f) of this section; provided, however, that the consent of an agent or surrogate shall not be required if the patient has previously consented to an order not to resuscitate pursuant to paragraph (2) of this subdivision.

(ii) Where the provisions of this paragraph have been invoked, the attending physician shall reassess the patient's risk of injury from a discussion of cardiopulmonary resuscitation on a regular basis and shall consult the patient regarding resuscitation as soon as the medical basis for not consulting the patient no longer exists.

(4) If the patient is in or is transferred from a mental hygiene facility, notice of the patient's consent to an order not to resuscitate shall be given to the facility director prior to the issuance pursuant to this subdivision of an order not to resuscitate. Notification to the facility director shall not delay
issuance of an order not to resuscitate. If the facility director concludes that the patient lacks capacity or that issuance of an order not to resuscitate may be inconsistent with the patient's wishes, the facility director shall submit the matter to the dispute mediation system.

(f) Surrogate decisionmaking.

(i) The consent of a surrogate or health care agent acting on behalf of an adult patient who lacks capacity, or on behalf of an adult patient for whom consent by a surrogate or health care agent is authorized by paragraph (e)(3) of this section, must be obtained prior to issuing an order not to resuscitate the patient, except as provided in subparagraph (ii) of this paragraph or subdivision (g) of this section.

(ii) The consent of a surrogate or health care agent shall not be required where the adult had, prior to losing capacity, consented to an order not to resuscitate pursuant to paragraph (e)(2) of this section.

(iii) A decision regarding cardiopulmonary resuscitation by a health care agent on a principal's behalf is governed by article 29-C of the Public Health Law and shall have priority over decisions by any other person except the patient or as otherwise provided in the health care proxy.

(i) One person from the following list, to be chosen in order of priority listed, when persons in the prior clauses are not reasonably available, willing to make a decision regarding issuance of an order not to resuscitate, and competent to make a decision regarding issuance of an order not to resuscitate, shall have the authority to act as surrogate on behalf of the patient:

(a) a committee of the person or a guardian appointed pursuant to article 17-A of the Surrogate's Court Procedure Act, provided that this clause shall not be construed to require the appointment of a committee of the person or guardian for the purpose of making the resuscitation decision;
(b) the spouse;
(c) a son or daughter 18 years of age or older;
(d) a parent;
(e) a brother or sister 18 years of age or older; or
(f) a close friend.

(ii) After the surrogate has been identified, the name of such person shall be included in the patient's medical chart.

(iii) A determination that a surrogate is not competent to act as surrogate shall be made in the same manner as a determination that a patient lacks capacity pursuant to subdivision (d) of this section, and may be the subject of an appeal to the dispute mediation system by the surrogate.

(i) The surrogate shall make a decision regarding cardiopulmonary resuscitation on the basis of the adult patient's wishes, including a consideration of the patient's religious and moral beliefs, or, if the patient's wishes are unknown and cannot be ascertained, on the basis of the patient's best interests.

(ii) Notwithstanding any law to the contrary, the surrogate shall have the same right as the patient to receive medical information and medical records.

(iii) A surrogate may consent to an order not to resuscitate on behalf of an adult patient only if there has been a determination by an attending physician, with the concurrence of another physician selected by a person authorized by the hospital to make such selection, given after personal examination of the patient, that, to a reasonable degree of medical certainty:

(a) the patient has a terminal condition; or
(b) the patient is permanently unconscious; or
(c) resuscitation would be medically futile; or
(d) resuscitation would impose an extraordinary burden on the patient in light of the patient's medical condition and the expected outcome of resuscitation for the patient.

Each determination shall be included in the patient's medical chart.

(i) A surrogate shall express a decision consenting to an order not to resuscitate either:

(a) in writing, dated, and signed in the presence of one witness 18 years of age or older who shall sign the decision; or

(b) orally, to two persons 18 years of age or older, one of whom is a physician affiliated with the hospital in which the patient is being treated. Any such decision shall be recorded in the patient's medical record.

(ii) The attending physician who is provided with the decision of a surrogate shall include the decision in the patient's medical chart and, if the surrogate has consented to the issuance of an order not to resuscitate, shall either:

(a) promptly issue an order not to resuscitate the patient and inform the hospital staff responsible for the patient's care of the order; or
(b) promptly make the attending physician's objection to the issuance of such an order known to the
surrogate, and either make all reasonable efforts to arrange for the transfer of the patient to another
physician, if necessary, or promptly refer the matter to the dispute mediation system.

(iii) If the patient is in or is transferred from a mental hygiene facility, notice of a surrogate's
consent to an order not to resuscitate shall be given to the facility director prior to the issuance
pursuant to this section of an order not to resuscitate. Notification to the facility director shall not
delay issuance of an order not to resuscitate. If the facility director concludes that the patient has
capacity or that issuance of an order not to resuscitate is otherwise inconsistent with this section, the
facility director shall submit the matter to the dispute mediation system.

(iv) If the attending physician has actual notice of opposition to a surrogate's consent to an order
not to resuscitate by any person on the surrogate list, or, if the patient is in or is transferred from a
mental hygiene facility, by the facility director, the physician shall notify the facility director of the
matter to the dispute mediation system and such order shall be issued or shall be revoked in accordance with the
provisions of paragraph (m)(3) of this section.

(v) If a member of the hospital staff responsible for the care of a patient for whom an order not to
resuscitate has been issued objects to providing care in accordance with the order, the hospital shall
take reasonable steps, such as adjustments in staff assignments, consistent with the care needs of the
patient, to accommodate the staff member's objections.

(5) If a surrogate has consented to an order not to resuscitate, notice of the surrogate's decision
shall be given to the patient where there is any indication of the patient's ability to comprehend such
notice, except if determination has been made pursuant to paragraph (e)(3) of this section. If the
patient objects, an order not to resuscitate shall not be issued.

(g) Decisionmaking on behalf of an adult patient without capacity for whom no surrogate is
available.

(1) If no surrogate is reasonably available, willing to make a decision regarding issuance of an order
not to resuscitate, and competent to make a decision regarding issuance of an order not to resuscitate
on behalf of an adult patient who lacks capacity and who had not previously expressed a decision
regarding cardiopulmonary resuscitation, an attending physician:

(i) may issue an order not to resuscitate the patient, provided that the attending physician
determines, in writing, that, to a reasonable degree of medical certainty, resuscitation would be
medically futile, and another physician selected by a person authorized by the hospital to make such
selection, after personal examination of the patient, reviews and concurs in writing with such
determination; or

(ii) shall issue an order not to resuscitate the patient, provided that a court has granted a judgment
directing the issuance of such an order.

(2) If the patient is in or is transferred from a mental hygiene facility, prior to issuance of an order
not to resuscitate pursuant to paragraph (1) of this subdivision, notice of such order shall be given to
the facility director. Notification to the facility director shall not delay issuance of an order not to
resuscitate. If the facility director concludes that the patient has capacity or that issuance of an order
not to resuscitate is otherwise inconsistent with this section, the facility director shall submit the
matter to the dispute mediation system.

(3) Notwithstanding any other provision of this subdivision, where a decision to consent to an order
not to resuscitate has been made, notice of the decision shall be given to the patient where there is
any indication of the patient's ability to comprehend such notice, except where a determination has
been made pursuant to paragraph (e)(3) of this section. If the patient objects, an order not to
resuscitate shall not be issued.

(h) Decisionmaking on behalf of a minor patient.

(1) An attending physician, in consultation with a minor's parent or legal guardian, shall determine
whether a minor has the capacity to make a decision regarding resuscitation.

(i) The consent of a minor's parent or legal guardian and the consent of the minor, if the minor has
capacity, must be obtained prior to issuing an order not to resuscitate the minor.

(ii) Where the attending physician has reason to believe that there is another parent or a
noncustodial parent who has not been informed of a decision to issue an order not to resuscitate the
minor, the attending physician, or someone acting on behalf of the attending physician, shall make
reasonable efforts to determine if the uninformed parent or noncustodial parent has maintained
substantial and continuous contact with the minor, and, if so, shall make diligent efforts to notify that
parent or noncustodial parent of the decision prior to issuing the order.

(iii) If the minor is in or is transferred from a mental hygiene facility, notice of a decision to issue an
order not to resuscitate the minor shall be given to the facility director prior to issuance of an order
not to resuscitate. Notification to the facility director shall not delay issuance of an order not to resuscitate. If the facility director concludes that issuance of an order not to resuscitate is inconsistent with this section, the facility director shall submit the matter to the dispute mediation system.

(3) A parent or legal guardian may consent to an order not to resuscitate on behalf of a minor only if there has been a written determination by the attending physician, with the written concurrence of another physician selected by a person authorized by the hospital to make such selections, given after personal examination of the patient, that, to a reasonable degree of medical certainty, the minor suffers from one of the medical conditions set forth in subparagraph (f)(3)(iii) of this section. Each determination shall be included in the patient's medical record.

(i) A parent or legal guardian of a minor, in making a decision regarding cardiopulmonary resuscitation, shall consider the minor patient's wishes, including a consideration of the minor patient's religious and moral beliefs, and shall express a decision consenting to issuance of an order not to resuscitate either:

(a) in writing, dated and signed in the presence of one witness 18 years of age or older who shall sign the decision; or

(b) orally, to two persons 18 years of age or older, one of whom is a physician affiliated with the hospital in which the patient is being treated. Any such decision shall be recorded in the patient's medical record.

(ii) The attending physician who is provided with the decision of a minor's parent or legal guardian, expressed pursuant to this paragraph, and of the minor if the minor has capacity, shall include such decision or decisions in the minor's medical chart and shall comply with the provisions of subparagraph (f)(4)(ii) of this section.

(iii) If the attending physician has actual notice of the opposition of a parent or noncustodial parent to consent by another parent to an order not to resuscitate a minor, the physician shall submit the matter to the dispute mediation system and such order shall not be issued or shall be revoked in accordance with the provisions of paragraph (m)(3) of this section.

(i) Effect of order not to resuscitate on other treatment. Consent to the issuance of an order not to resuscitate shall not constitute consent to withhold or withdraw medical treatment other than cardiopulmonary resuscitation.

(j) Revocation of consent to order not to resuscitate.

(1) A person may, at any time, revoke his or her consent to an order not to resuscitate himself or herself by making either a written or an oral declaration to a physician or member of the nursing staff at the hospital where he or she is being treated, or by any other act evidencing a specific intent to revoke such consent.

(2) Any surrogate, parent or legal guardian may at any time revoke his or her consent to an order not to resuscitate a patient by:

(i) notifying a physician or member of the nursing staff of the revocation of consent in writing, dated and signed; or

(ii) orally notifying the attending physician in the presence of a witness 18 years of age or older.

(3) Any physician who is informed of or provided with a revocation of consent pursuant to this subdivision shall immediately include the revocation in the patient's chart, cancel the order, and notify the hospital staff responsible for the patient's care of the revocation and cancellation. Any member of the nursing staff who is informed of or provided with a revocation of consent pursuant to this subdivision shall immediately notify a physician of such revocation.

(k) Physician review of the order not to resuscitate.

(1) For each patient for whom an order not to resuscitate has been issued, the attending physician shall review the patient's chart to determine if the order is still appropriate in light of the patient's condition and shall indicate on the patient's chart that the order has been reviewed:

(i) for a patient, excluding outpatients described in subparagraph (ii) of this paragraph and alternate level of care patients, in a hospital, other than a residential health-care facility, at least every seven days;

(ii) for an outpatient whose order not to resuscitate is effective while the patient receives care in a hospital, each time the attending physician examines the patient, whether in the hospital or elsewhere, provided that the review need not occur more than once every seven days; and

(iii) for a patient in a residential health-care facility or an alternate level of care patient in a hospital, each time the patient is required to be seen by a physician, but at least every 60 days. Failure to comply with this paragraph shall not render an order not to resuscitate ineffective.

(i) If the attending physician determines at any time that an order not to resuscitate is no longer appropriate because the patient's medical condition has improved, the physician shall immediately
notify the person who consented to the order. Except as provided in subparagraph (ii) of this paragraph, if such person declines to revoke consent to the order, the physician shall promptly (a) make reasonable efforts to arrange for the transfer of the patient to another physician, or (b) submit the matter to the dispute mediation system.

(ii) If the order not to resuscitate was entered upon the consent of a surrogate, parent or legal guardian, and the attending physician who issued the order or, if unavailable, another attending physician, at any time determines that the patient does not suffer from one of the medical conditions set forth in subparagraph (f)(3)(iii) of this section, the attending physician shall immediately include such determination in the patient's medical record, cancel the order, and notify the person who consented to the order and all hospital staff responsible for the patient's care of cancellation.

(iii) If an order not to resuscitate was entered upon the consent of a surrogate and the patient at any time gains or regains capacity, the attending physician who issued the order, or, if unavailable, another attending physician, shall immediately cancel the order and notify the person who consented to the order and all hospital staff directly responsible for the patient's care of the cancellation.

(i) Interinstitutional transfer.

(1) If a patient for whom an order not to resuscitate has been issued is transferred from a hospital to a different hospital:

(i) the transferring hospital shall notify the ambulance personnel and the transferee hospital of the order; and

(ii) the order shall be binding upon ambulance personnel during the transfer and shall remain effective for the transferee hospital unless revoked pursuant to this section, until the attending physician first examines the transferred patient, whereupon the attending physician must either:

(a) issue an order continuing the prior order not to resuscitate. Such order may be issued without obtaining further consent from the patient, surrogate or parent pursuant to this section; or

(b) cancel the order not to resuscitate, provided the attending physician immediately notifies the person who consented to the order and the hospital staff directly responsible for the patient's care of the cancellation. Such cancellation does not preclude the entry of a new order pursuant to this section.

(2) If the attending physician at the transferee hospital disagrees with the person who consented to the order regarding the appropriateness of issuing a new order, the attending physician shall promptly make his or her objection to the issuance of an order known to the person who consented and either make all reasonable efforts to arrange for the transfer of the patient to another physician, if necessary, or promptly submit the matter to the dispute mediation system.

(m) Dispute mediation system.

(i) Each hospital shall establish a mediation system for the purpose of mediating disputes regarding the issuance of orders not to resuscitate.

(ii) The dispute mediation system shall be described in writing and adopted by the hospital's governing authority. It may utilize existing hospital resources, such as a patient advocate's office or hospital chaplain's office, or it may utilize a body created specifically for this purpose, which may include the State Ombudsman representative, but, in the event a dispute involves a patient deemed to lack capacity pursuant to:

(a) subparagraph (d)(3)(ii) of this section, the system must include a physician eligible to provide a concurring determination, or a family member or guardian of a person with a mental illness of the same or similar nature; or

(b) subparagraph (d)(3)(iii) of this section, the system must include a physician eligible to provide a concurring determination, or a family member or guardian of a person with a developmental disability of the same or similar nature.

(2) The dispute mediation system shall be authorized to mediate any dispute including disputes regarding the determination of the patient's capacity, arising under this section between the patient and an attending physician or the hospital that is caring for the patient and, if the patient is a minor, the patient's parent, or among an attending physician, a parent, noncustodial parent, or legal guardian of a minor patient, any person on the surrogate list, the hospital that is caring for the patient, the Commissioner of Health and, where the dispute involves a patient who is in or is transferred from a mental hygiene facility, the facility director.

(3) After a dispute regarding the issuance of an order not to resuscitate has been submitted to the dispute mediation system, an order not to resuscitate shall not be issued, or shall be revoked and may not be reissued, until (i) the dispute has been resolved or the system has concluded its effort to resolve the dispute, or (ii) 72 hours have elapsed from the time of the submission of the dispute, whichever shall occur first. Persons participating in the dispute mediation system shall be informed of their right to judicial review.
(4) If a dispute between a patient who expressed a decision rejecting cardiopulmonary resuscitation and an attending physician or the hospital that is caring for the patient is submitted to the dispute mediation system, and either:
   (i) the dispute mediation system has concluded its efforts to resolve the dispute; or
   (ii) 72 hours have elapsed from the time of submission without resolution of the dispute, whichever shall occur first;
the attending physician shall either: promptly issue an order not to resuscitate the patient or issue the order at such time as the conditions, if any, specified in the decision are met, and inform the hospital staff responsible for the patient's care of the order; or promptly arrange for the transfer of the patient to another physician or hospital.

(5) Persons appointed pursuant to this subdivision to participate in the dispute mediation system shall not have authority to determine whether a do not resuscitate order shall be issued.

(n) Judicial review.
   (1) The patient, an attending physician, a parent, noncustodial parent, or legal guardian of a minor patient, any person on the surrogate list, the hospital that is caring for the patient and, in disputes involving a patient who is in or is transferred from a mental hygiene facility, the facility director, may commence a special proceeding pursuant to article 4 of the Civil Practice Law and Rules, in a court of competent jurisdiction, with respect to any dispute arising under this article, except that the decision of any patient not to consent to issuance of an order not to resuscitate may not be subjected to judicial review. In any proceeding brought pursuant to this paragraph challenging a decision regarding issuance of an order not to resuscitate on the ground that the decision is contrary to the patient's wishes or best interests, the person or entity challenging the decision must show, by clear and convincing evidence, that the decision is contrary to the patient's wishes, including consideration of the patient's religious and moral beliefs, or, in the absence of evidence of the patient's wishes, the decision is contrary to the patient's best interests. In any other proceeding brought pursuant to this paragraph, the court shall make its determination based upon the applicable substantive standards and procedures set forth in this section.
   (2) In any proceeding brought pursuant to this subdivision, the court may issue an order, pursuant to the standards applicable to the issuance of a temporary restraining order according to section 6313 of the Civil Practice Law and Rules, which shall suspend the order not to resuscitate to permit review of the matter by the court.
   (3) Where a person or entity may invoke the dispute mediation system, no such proceeding shall be commenced until the dispute mediation system has concluded its efforts to resolve the dispute or 72 hours have elapsed from the submission of the dispute to the dispute mediation system, whichever shall occur first; provided, however, that the patient may commence an action for relief with respect to any dispute under this section at any time and provided further that the Department of Health or any other duly authorized State agency may commence an action or proceeding to enjoin a violation of this section at any time.

(o) Immunity.
   (1) No physician, health-care professional, nurse's aide, hospital or person employed by or under contract with the hospital shall be subject to criminal prosecution, civil liability, or be deemed to have engaged in unprofessional conduct for carrying out in good faith pursuant to this section a decision regarding cardiopulmonary resuscitation by or on behalf of a patient or for those actions taken in compliance with the standards and procedures set forth in this section.
   (2) No physician, health-care professional, nurse's aide, hospital, or person employed by or under contract with the hospital shall be subjected to criminal prosecution, civil liability, or be deemed to have engaged in unprofessional conduct for providing cardiopulmonary resuscitation to a patient for whom an order not to resuscitate has been issued, provided such physician or person:
      (i) reasonably and in good faith was unaware of the issuance of an order not to resuscitate; or
      (ii) reasonably and in good faith believed that consent to the order not to resuscitate had been revoked or cancelled.
   (3) No person shall be subjected to criminal prosecution or civil liability for consenting or declining to consent in good faith, on behalf of the patient, to the issuance of an order not to resuscitate pursuant to this section.
   (4) No person shall be subjected to criminal prosecution or civil liability or be deemed to have engaged in unprofessional conduct for acts performed in good faith as a mediator in the dispute mediation system established by this section.

(p) Effect of order not to resuscitate on insurance and health-care services.
(1) No policy of life insurance shall be legally impaired, modified or invalidated in any manner by the issuance of an order not to resuscitate, notwithstanding any term of the policy to the contrary.

(2) A person may not prohibit or require the issuance of an order not to resuscitate for an individual as a condition for such individual's being insured or for receiving health-care services.

(q) Judicially approved order not to resuscitate.

(1) If no surrogate is reasonably available, willing to make a decision regarding issuance of an order not to resuscitate, and competent to make a decision regarding issuance of an order not to resuscitate on behalf of an adult patient who lacks capacity and who had not previously expressed a decision regarding cardiopulmonary resuscitation pursuant to this section, an attending physician or hospital may commence a special proceeding pursuant to article 4 of the Civil Practice Law and Rules, in a court of competent jurisdiction, for a judgment directing the physician to issue an order not to resuscitate where the patient has a terminal condition, is permanently unconscious, resuscitation would impose an extraordinary burden on the patient in light of the patient's medical condition and the expected outcome of resuscitation for the patient, and issuance of an order not to resuscitate is consistent with the patient's wishes including a consideration of the patient's religious and moral beliefs or, in the absence of evidence of the patient's wishes, the patient's best interests.

(2) Nothing in this section shall be construed to preclude a court of competent jurisdiction from approving the issuance of an order not to resuscitate under circumstances other than those under which such an order may be issued pursuant to this section.

(r) The hospital shall:

(1) ensure that each member of the hospital's staff involved in the provision of care is trained in the requirements governing orders not to resuscitate;

(2) ensure that all hospital emergency service personnel honor nonhospital orders not to resuscitate in accordance with section 2977 of the Public Health Law and that all hospital personnel otherwise comply with the provisions of such section as they relate to in-hospital activities affected by such nonhospital orders not to resuscitate;

(3) post in a public place in the hospital a summary of the rights, duties and requirements of this section as prepared by the commissioner; and

(4) furnish a copy of such summary to patients or to persons on the surrogate list known to the hospital at the time of the first decision made pursuant to subdivisions (e) through (h) of this section.

10 NY ADC 405.43
10 NY ADC 405.43
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10 NY ADC 405.43

* Section 405.44.* Validity.

If any clause, sentence, paragraph or section of this Part shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph or section thereof directly involved in the controversy in which such judgment shall have been rendered.

10 NY ADC 405.44
10 NY ADC 405.44
2008 WL 75295906
10 NY ADC 405.44