

10 NYCRR § 405.4

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New York Codes, Rules, and Regulations > TITLE 10. DEPARTMENT OF HEALTH > CHAPTER V. MEDICAL FACILITIES > SUBCHAPTER A. MEDICAL FACILITIES--MINIMUM STANDARDS > ARTICLE 2. HOSPITALS > PART 405. HOSPITALS--MINIMUM STANDARDS

§ 405.4 Medical staff

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.

(4) The medical staff shall adopt, implement, periodically update and submit to the Department evidence-based protocols for the early recognition and treatment of patients with severe sepsis and septic shock (sepsis protocols) that are based on generally accepted standards of care. Sepsis protocols must include components specific to the identification, care and treatment of adults, and of children, and must clearly identify where and when components will differ for adults, and for children. These protocols must include the following components:

(i) a process for the screening and early recognition of patients with sepsis, severe sepsis and septic shock;

(ii) a process to rapidly identify and document individuals appropriate for treatment through severe sepsis and septic shock protocols, including explicit criteria defining

those patients who should be excluded from the protocols, such as patients with certain clinical conditions or who have elected palliative care;

(iii) guidelines for hemodynamic support, including monitoring, therapeutic endpoints and timeframe goals;

(iv) for infants and children, guidelines for fluid resuscitation with explicit timeframes for vascular access and fluid delivery consistent with current, evidence-based guidelines for severe sepsis and septic shock with defined therapeutic goals for children; and

(v) a procedure for identification of infectious source and delivery of early antibiotics with timeframe goals.

(5) The medical staff shall ensure that professional staff with direct patient care responsibilities and, as appropriate, staff with indirect patient care responsibilities, including, but not limited to laboratory and pharmacy staff, are periodically trained to implement sepsis protocols required pursuant to paragraph (4) of this subdivision. Medical staff shall ensure updated training when the hospital initiates substantive changes to the protocols.

(6) Hospitals must update sepsis protocols required pursuant to paragraph (4) of this section based on newly emerging evidence-based standards. Protocols are to be submitted to the department at the request of the department.

(7) Collection and reporting of sepsis measures.

(i) The medical staff shall be responsible for the collection, use, and reporting of quality measures related to the recognition and treatment of severe sepsis for purposes of internal quality improvement and hospital reporting to the department. Such measures shall include, but not be limited to, data sufficient to evaluate each hospital's adherence to timeframes and implementation of all protocol components for adults and children.

(ii) Hospitals shall submit data specified by the department to permit the department to develop risk-adjusted severe sepsis and septic shock mortality rates in consultation with appropriate national, hospital and expert stakeholders. Hospitals shall submit data to the department or the department's designee in the form and format, and according to such specifications as may be required by the department.

(iii) Such data shall be reported annually, or more frequently at the request of the department, and shall be subject to audit at the discretion of the department.

(8) Definitions. Sepsis is a life threatening medical emergency that requires early recognition and intervention. For the purposes of hospital data collection, the following terms shall have the following meanings:

(i) sepsis shall mean a confirmed or suspected infection accompanied by two systemic inflammatory response syndrome (SIRS) criteria;

(ii) severe sepsis shall mean sepsis complicated by organ dysfunction; and

(iii)for adults, septic shock shall mean sepsis-induced hypotension persisting despite adequate IV fluid resuscitation and/or evidence of tissue hypoperfusion; for pediatrics, septic shock shall mean sepsis and cardiovascular organ dysfunction.

(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; and

(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;

(d)"on call" duty in the hospital during the night shift hours by trainees in surgery shall not be included in the 24-hour 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 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.
- (2) 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 on 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.

(3) 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.

(e) 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.

(f) Postgraduate trainees. Patient care services may be provided by physicians in post graduate 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 post-graduate 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; and

(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 physicians' working hour limits set forth in subparagraph (iv) of paragraph (6) of subdivision (b) 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.

Statutory Authority

Section statutory authority:

Education Law, § A131. Section statutory authority: Education Law, § 6526. Section statutory authority: Education Law, § 6525. Section statutory authority: Education Law, § 6528

Statutory authority:

Public Health Law, §§ 2803, 2805-k, 2805-l, 2805-m, 4351

History

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