

Hospital Pediatric Care

Effective: 12/31/13

SUMMARY OF EXPRESS TERMS

This proposal will amend Part 405 (Hospitals – Minimum Standards), primarily with respect to pediatric provisions and also to update various provisions to reflect current practice. Hospitals, for the purposes of Part 405, pertain to general hospitals.

Proposed amendments to Section 405.1 (Introduction) specify that the requirements of Part 405 relating to patient care and services will apply to patients of all ages, including newborns, pediatric and geriatric patients.

Proposed amendments to Section 405.3 (Administration), which currently requires hospitals to provide to the State Education Department (“SED”) a written report whenever enumerated professionals licensed by SED lose hospital employment or privileges for certain reasons, will require similar reporting to the Department of Health for certain individuals licensed by such Department.

Proposed amendments to Section 405.6 (Quality Assurance Program) will require hospital quality assurance processes to include a determination that the hospital is admitting only those patients for whom it has appropriate staff, resources and equipment and transferring those patients for whom the hospital does not have the capability to

provide care, except under conditions of disasters or emergency surge that may require admissions to provide care to those patients.

A new subdivision (d) is added to Section 405.7 to require hospitals to post and provide a copy of a Parent's Bill of Rights, setting forth the rights of patients, parents of minors, legal guardians or other persons with decision-making authority to certain minimum protections required under other provisions of these regulations. In particular, the Parent's Bill of Rights would advise that patients may not be discharged from the hospital or the emergency room until any tests that could reasonably be expected to yield "critical value" results – results that suggest a life-threatening or otherwise significant condition such that it requires immediate medical attention – are reviewed by a physician, physician assistant (PA), and/or nurse practitioner (NP) and are communicated to the patient, his or her parents or other decision-makers as appropriate.

Proposed amendments to Section 405.9 (Admission/Discharge) specify that a hospital will be required to admit pediatric patients consistent with its ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients. If the hospital cannot meet these requirements, it will be required to develop criteria and policies and procedures for transfer of pediatric patients. This section also requires hospitals to develop policies and procedures permitting at least one parent/guardian to remain with a pediatric patient at all times, to the extent possible given the patient's health and safety. Proposed amendments will also require hospitals to develop and implement written policies and procedures pertaining to review and

communication of laboratory and diagnostic test/service results to the patient and, if the patient is not legally capable of making decisions, the patient's parent, legal guardian, health care agent or health care surrogate, as appropriate and subject to all applicable confidentiality laws and regulations. Such policies and procedures must ensure that no discharge will occur while the results of a test that reasonably could be expected to yield a "critical value" are pending so as to assure appropriate care is provided to the patient. Further, all communication with the patient, parent, legal guardian, etc. must be clear and understandable to the recipient. In addition, the hospital must ask the patient or the patient's representative for the name of the patient's primary care provider, if known, and forward lab results to such provider.

This proposal also updates Section 405.12 (Surgical Services), which currently requires hospitals to develop and implement effective written policies and procedures, to provide that such policies and procedures include the performance of surgical procedures, 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. The amendments will also require hospitals to assure that the privileges of each practitioner performing surgery are commensurate with his or her training and experience. Precautions must be clearly identified in written policies and procedures specific to the surgical service and post anesthesia care unit ("PACU") including appropriate resuscitation, airway and monitoring equipment including a resuscitation cart with age and size appropriate medications, equipment and supplies.

Updates to Section 405.13 (Anesthesia Services), which currently require hospitals to develop and implement effective written policies and procedures on matters such as the administration of anesthetics, the maintenance of safety controls and the integration of such services with other related services of the hospital. Under the amendments, such policies and procedures will have to be reviewed and updated at least biennially. In addition, hospitals will have to establish clinical competencies that are relevant to the care provided and, 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. The amendments further provide that all equipment and services provided must be age and size appropriate.

Updates to Section 405.14 (Respiratory Care Services) will provide that orders for respiratory care services, in addition to specifying the type, frequency and duration of treatment, and as appropriate, the type and dose of medication, the type of diluent, and the oxygen concentration, must be consistent with generally accepted standards of care. The amendments further provide that all equipment and services provided must be age and size appropriate.

Updates to Section 405.15 (Radiologic and Nuclear Medicine Services) will specify that care must be provided in accordance with generally accepted standards of practice. The amendments will also require that policies and procedures regarding imaging studies for newborns and pediatric patients must include standards for clinical

appropriateness, appropriate radiation dose and beam collimation, image quality and patient shielding. In addition, a policy and procedure must be developed to ensure that the practitioner's order for an imaging study is specific to the body part(s) that are to be imaged. Quality improvement audits must verify that these policies and procedures are being followed and must include a review of the adequacy of diagnostic images and interpretations. Radiation safety principles must be adequate to ensure compliance with all generally accepted standards of practice as well as pertinent laws, rules and regulations. The amendments also provide that the chief of radiology, in conjunction with the radiation safety officer, must ensure that all practitioners who utilize ionizing radiation equipment within the hospital are properly trained in radiation safety procedures for patients of all ages.

The amendments to Section 405.15 also will update the megavoltage ("MEV") requirements for therapeutic radiology or radiation oncology services to provide that they utilize six or more MEV unit with a source-axis distance of 100 or more centimeters as the primary unit in a multi-unit radiation oncology service. In addition, as amended, the regulations will require each therapeutic radiology service to have full time New York State licensed radiation therapists sufficient to meet the needs of the service and also a New York State licensed radiation therapy physicist who will be involved in treatment, planning and dosimetry as well as calibrating the equipment. The amendments will also change a reference to an MEV unit so that it instead refers to a linear accelerator. A computed tomography ("CT") scanner must be available within the radiation therapy program that is equipped for radiation oncology treatment planning or arrangements must

be made for access to a CT scanner on an as needed basis. Provisions must be made for access to a magnetic resonance imaging (“MRI”) scanner for treatment planning purposes on an as needed basis.

Updates to Section 405.17 (Pharmaceutical Services) will require hospital pharmacy directors, in conjunction with designated members of the medical staff, to ensure that for patients of all ages, weight must be measured in kilograms and that resources relating to drug interactions, drug therapies, side effects, toxicology, dosage, indications for use, and routes of administration are available to the professional staff. Pediatric dosing resources must include age and size appropriate fluid and medication administration and dosing. Dosing must be weight based and not exceed adult maximum dosage, or in emergencies, length based, with appropriate references for pediatric dosing available. The amendments will further require the director to ensure that the pharmacy quality assurance program include monitoring and improvement activities to identify, measure, prevent and/or mitigate adverse drug events, adverse drug reactions and medication errors in accordance with generally accepted standards and practices in the field of medication safety and quality improvement. All drugs and biologicals must be controlled and distributed in accordance with written policies and procedures to maximize patient safety and quality of care.

Updates to Section 405.19 (Emergency Services) provisions will require at least one clinician on every shift to have the skills to assess and manage a critically ill or injured pediatric patient and be able to resuscitate a child. The director of the hospital’s

emergency service, attending physicians, supervising nurses, registered professional nurses (“RNs”), physician assistants (“PAs”) and nurse practitioners (“NPs”) must satisfactorily complete and be current in Pediatric Advanced Life Support (“PALS”) or have current training equivalent to PALS. Hospitals with less than 15,000 unscheduled emergency visits per year do not need to have the supervising or attending physician present, but such supervising or attending physician must be available within 30 minutes of “patient presentation” provided that at least one physician, NP, or PA is on duty in the emergency service 24 hours a day, seven days a week.

In addition, the amendments will require hospitals to develop and implement protocols specifying when supervising or attending physicians must be present. In no event shall a patient be discharged or transferred to another hospital, unless evaluated, initially managed, and treated as necessary by an appropriately privileged physician, PA or NP. Specifically, no discharge should occur while the results of a test that reasonably could be expected to yield a “critical value” are pending so as to assure appropriate care is provided. The amendments will also require hospitals to develop and implement written policies and procedures pertaining to review and communication of laboratory and diagnostic test/service results ordered for a patient receiving emergency services to the patient and, if the patient is not legally capable of making decisions, the patient’s parent, legal guardian, health care agent or health care surrogate, as appropriate and subject to all applicable confidentiality laws and regulations. Further, policies and procedures must ensure that all communication with the patient, parent of a minor, legal guardian, etc. must be clear and understandable to the recipient. In addition, the

hospital must ask the patient or the patient's representative for the name of the patient's primary care provider, if known, and lab results must be forwarded to such provider.

Section 405.20 (Outpatient Services) requires outpatient services, including ambulatory care services and extension clinics to be provided in a manner which safely and effectively meets the needs of all patients. Written policies must be in place for admission of patients whose postoperative status prevents discharge and necessitates inpatient admission to a hospital capable of providing the appropriate level of care.

Section 405.22 (Critical Care and Special Care Services) adds new provisions regarding Pediatric Intensive Care Unit (PICU) Services. A "PICU" is defined as a physically separate unit that provides intensive care to pediatric patients (infants, children and adolescents) who are critically ill or injured. It must be staffed by qualified practitioners competent to care for critically ill or injured pediatric patients. "Qualified practitioners" are practitioners functioning within his or her scope of practice according to State Education Law and who meets the hospital's criteria for competence, credentialing and privileging practitioners in the management of critically ill or injured pediatric patients. PICUs must be approved by the Department and the governing body must develop written policies and procedures for operation of the PICU in accordance with generally accepted standards of medical care for critically ill or injured pediatric patients. The PICU must have a minimum average annual pediatric patient number of 200/year. It must provide medical oversight for interhospital transfers of critically ill or injured patients during transfer to the receiving PICU.

The PICU must be directed by a board certified pediatric medical, surgical, anesthesiology or critical care/intensivist physician who must be responsible for the organization and delivery of PICU care and has specialized training and demonstrated competence in pediatric critical care. Such physician in conjunction with the nursing leadership responsible for the PICU must participate in administrative aspects of the PICU. All hospitals with PICUs must have a physician, notwithstanding emergency department staffing, in-house 24 hours per day who is available to provide bedside care to patients in the PICU. PICU physician and nursing staff must successfully complete and be current in pediatric advanced life support (PALS) or have current training equivalent to PALS.

The hospital must have an organized quality performance improvement program for PICU services and include monitoring of volume and outcomes, morbidity and all case mortality review, regular multidisciplinary conferences including all health professionals involved in the care of PICU patients. Failure to meet one or more regulatory requirements or inactivity in a program for a period of 12 months or more may result in actions, including, but not limited to, withdrawal of approval to serve as a PICU. No PICU can discontinue operation without first obtaining written approval from the department and must give written notification, including a closure plan acceptable to other department at least 90 days prior to planned discontinuance of PICU services. A hospital must notify the department in writing within 7 days of any significant changes in

its PICU services, including, but not limited to: (a) any temporary or permanent suspension of services or (b) difficulty meeting staffing or workload requirements.

Section 405.28 (Social Services) is updated to current standards that care be provided under the direction of a qualified social worker who is licensed and registered by the New York State Education Department to practice as a licensed master social worker (LMSW) or licensed clinical social worker (LCSW), with the scope of practice defined in Article 154 of the Education Law.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval of the Commissioner of Health by paragraph (2) of section 2803 of the Public Health Law, Part 405 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended to be effective upon publication of a Notice of Adoption in the New York State Register to read as follows:

Section 405.1 is amended to read as follows:

405.1 Introduction.

* * *

(e) The requirements of this Part relating to patient care and services shall apply to patients of all ages, including newborns, pediatric and geriatric patients.

Subdivision (e) of Section 405.3 is amended to read as follows:

405.3 Administration.

(e) Other reporting requirements.

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(2) The hospital shall furnish to the Department of Education or the Department of Health for individuals licensed by the Department 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,] licensed master social worker (LMSW), licensed clinical social worker (LCSW), dental hygienist, dentist, medical laboratory technologist, nurse, occupational therapist, ophthalmic dispenser, optometrist, pharmacist, physical therapist, podiatrist, psychologist, radiologic technologist, radiologist assistant, respiratory therapist, respiratory therapy technician 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 measure; and
- (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.

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Section 405.6 is amended to read as follows:

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.

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(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[;]. Such review shall include a

determination that the hospital is admitting only those patients for whom it has appropriate staff, resources and equipment and transferring those patients for whom the hospital does not have the capability to provide care, except under conditions of disasters and/or emergency surge that may require admissions to provide care to those patients;

* * *

A new subdivision (d) is added to Section 405.7 to read as follows:

(d) Each hospital shall be required to post in a conspicuous place and provide a pediatric patient's parent or other medical decision maker with a copy of a Parent's Bill of Rights advising that, at a minimum and subject to laws and regulations governing confidentiality, that in connection with every hospital admission or emergency room visit:

(i) The hospital must ask each patient or the patient's representative for the name of his or her primary care provider, if known, and shall document such information in the patient's medical record.

(ii) The hospital may admit pediatric patients only to the extent consistent with their ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients.

(iii) To the extent possible given the patient's health and safety, the hospital shall allow at least one parent/guardian to remain with the patient at all times.

(iv) All test results completed during the patient's admission or emergency room visit will be reviewed by a physician, physician assistant or nurse practitioner who is familiar

with the patient's presenting condition.

(v) Patients may not be discharged from the hospital or the emergency room until any tests that could reasonably be expected to yield "critical value" results – results that suggest a life-threatening or otherwise significant condition such that it requires immediate medical attention – are reviewed by a physician, physician assistant (PA) and/or nurse practitioner (NP) and are communicated to the patient, his or her parents or other decision-makers, as appropriate.

(vi) Patients may not be discharged until they receive a written discharge plan, which will also be verbally communicated to patients, their parents or other medical decision-makers, which will identify critical value results of laboratory or other diagnostic tests ordered during the patient's stay and identify any other tests that have not yet been concluded.

(vii) The communication of critical value results and the discussion of the discharge plan must be accomplished in a manner that reasonably assures that the patient, their parents or other medical decision makers understand the health information provided in order to make appropriate health decisions.

(viii) Hospitals shall provide all lab results to the patient's primary care provider, if known.

(ix) A patient, his or her parent or other medical decision maker has the right to request information about the diagnosis, possible diagnoses that were considered and complications that could develop as well as information about any contact that was made with the patient's primary care provider.

(x) On discharge, the hospital must provide a patient, his or her parent or other

medical decision maker a phone number that the patient, his or her parent or other medical decision maker could call for advice in the event that complications or questions arise.

Subdivision (b) of Section 405.9 is amended to read as follows:

405.9 Admission/discharge.

(b) Admission.

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(7) Pediatrics. (i) The hospital shall admit pediatric patients consistent with its ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients. The [facility] hospital shall establish a separate pediatric unit if the hospital regularly has 16 or more pediatric patients at one time or if pediatric patients cannot be adequately and safely cared for in other than separately certified pediatric beds. If a hospital cannot meet these requirements the hospital must develop criteria and policies and procedures for transfer of pediatric patients.

(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.]

(iv) [(v)] In the event a separate pediatric 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.

(v) The hospital shall develop policies and procedures enabling parents/guardians to stay with pediatric patients. To the extent possible given the patient's health and safety, the hospital shall allow at least one parent/guardian to remain with the patient at all times.

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(16) The hospital shall ask each patient for the name of his or her primary care provider,

if known, on admission and shall document such information in the patient's medical record.

* * *

(f) Discharge.

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(10) The hospital shall develop and implement written policies and procedures pertaining to the review and communication of laboratory and diagnostic test/service results ordered for a patient while admitted or receiving emergency services to the patient. If the patient lacks medical decision-making capacity, the communication shall be to the patient's medical decision-maker. The results shall also be provided to the patient's primary care provider, if known. Such policies and procedures shall be reviewed and updated as necessary and at a minimum shall include:

- (i) a requirement that all laboratory and other diagnostic tests/service results be reviewed upon completion by a physician, physician assistant or nurse practitioner familiar with the patient's presenting condition;
- (ii) a requirement that all laboratory and other diagnostic test services results be forwarded to the patient's primary provider, if known, after review by a physician, physician assistant or nurse practitioner;
- (iii) provisions to include in the discharge plan information regarding the patient's completed and pending laboratory and other diagnostic test/service results, medications, diagnoses, and follow-up care and to

review such information with the patient or, if the patient is not legally capable of making decisions, the patient’s parent, legal guardian or health care agent, or surrogate, as appropriate, subject to all applicable confidentiality laws and regulations;

- (iv) a requirement that patients may not be discharged from the hospital or the emergency room until any tests that could reasonably be expected to yield “critical value” results – results that suggest a life-threatening or otherwise significant condition such that it requires immediate medical attention – are reviewed by a physician, physician assistant (PA) and/or nurse practitioner (NP);

- (v) a requirement that before a patient is discharged, any critical laboratory test results are communicated to the patient or, if the patient is not legally capable of making decisions, the patient’s parent, legal guardian or health care agent, or surrogate, as appropriate, subject to all applicable confidentiality laws and regulations;

- (vi) a requirement that all information be presented to the patient or if the patient is not legally capable of making decisions, the patient’s parent, legal guardian or health care agent, or surrogate, as appropriate, subject to all applicable confidentiality laws and regulations, in a manner that reasonably assures that the patient, their parents or other medical decision

makers understand the health information provided in order to make appropriate health decisions.

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Section 405.12 is amended to read as follows:

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.]

If surgical services are provided, the hospital shall develop and keep current and implement effective written policies and procedures regarding staff privileges consistent with provisions set forth in section 405.4 of this Part, the performance of surgical procedures, 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. Such policies and procedures shall be reviewed and updated as necessary, but at a minimum biennially.

- (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) A registered professional nurse qualified by the hospital and by training and experience in operating room nursing shall be present as the circulating nurse in any and each separate operating room where surgery is being performed for the duration of the operative procedure. Nothing in this section precludes a circulating nurse from leaving the operating room as part of the operative procedure, leaving the operating room for short periods; or, in accordance with employee rules or regulations, being relieved during an operative procedure by another circulating nurse assigned to continue the operative procedure.

(iii) Licensed practical nurses and surgical technologists may perform scrub functions and may assist in circulating duties under the supervision of the circulating nurse who is present in the operating room for the duration of the procedure, 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. The hospital shall assure that the privileges of the practitioner are commensurate with his or her training and experience.

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(6) Precautions shall be clearly identified in written policies and procedures specific to the department and the post anesthesia care unit (PACU) 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 and PACU of [a] appropriate resuscitation, airway and monitoring equipment [call-in system, cardiac monitor, resuscitator, defibrillator, aspirator,] including a resuscitation cart with age and size appropriate medications, equipment and supplies, [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. The policies shall assure that service and equipment routinely available in the operating suite and PACU are age and size appropriate.

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Section 405.13 is amended to read as follows:

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 consistent with provisions set forth in section 405.4 of this Part, 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. Such policies and procedures shall be reviewed and updated as necessary, but at a minimum biennially.

(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 services.

(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, competencies 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, clinical competencies 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 generally 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 services 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 that is age and size appropriate. 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) All equipment and services provided shall be age and size appropriate.

[(iv)] (v) 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)] (vi) With respect to inpatients a post-anesthetic follow-up evaluation and report by the individual who administered the anesthesia or by an individual qualified to 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)] (vii) 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.

Section 405.14 is amended to read as follows:

405.14 Respiratory care services.

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(b) *Operation and service delivery.* Respiratory care services shall be provided in 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 order 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, consistent with generally accepted standards of care.

(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.

(5) All equipment and services provided shall be age and size appropriate.

Section 405.15 is amended to read as follows:

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 in accordance with generally accepted standards of practice 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. A practitioner's order for an imaging study shall be specific as to the body part(s) to be imaged.

(3) Safety for patients and personnel. [The radiologic services shall be free from hazards for patients and personnel.] Written policies and procedures shall be developed and implemented and available for review [inspection.] The policies and procedures regarding imaging studies for newborns and pediatric patients shall include standards for clinical appropriateness, appropriate radiation dosage and beam collimation, image quality and patient shielding. A policy and a procedure shall be developed to ensure that the practitioner's order for an imaging study is specific as to the body part(s) that are to be imaged.

Quality improvement audits shall verify that these policies and procedures are being followed. Quality improvement activities shall include a review of the adequacy of diagnostic images and interpretations.

(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. The radiation safety principles shall be adequate to ensure compliance with all [regulatory requirements] generally accepted standards of practice as well as pertinent laws, rules and regulations. Policies and procedures shall be developed to minimize the radiation exposure that is necessary to produce high quality imaging studies on patients of all ages.

(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 a 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 test 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.

(v) The chief of radiology, in conjunction with the radiation safety officer, shall ensure that all practitioners who utilize ionizing radiation equipment within the hospital are properly trained in radiation safety procedures for patients of all ages.

(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. All electronic images shall have a duplicate storage either offsite or in another area of the hospital separate from the primary storage devices.

(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] hospital providing the service shall refuse treatment of a patient on the basis of the referring practitioner or practitioner's hospital affiliation, if [any]known;

(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] six or more megavoltage (MEV) [or cobalt teletherapy] units with a source-axis distance of [80] 100 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;] radiation oncology service.

(4) a therapeutic radiology service shall be headed by a board admissible or board certified radiation [therapist] oncologist 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] a full time New York State licensed radiation therapists sufficient to meet the needs of the service; and

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

(6) a [facility] hospital 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 New York State licensed radiation therapy [a radiological] physicist who will be involved in treatment, planning and dosimetry as well as calibrating the equipment. The hospital shall provide for the services of a licensed radiation therapy physicist(s) in sufficient quantity to adequately meet the needs of its patients of all ages. [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]

(iii) A physicist in training must be supervised by a licensed radiation therapy physicist.

[(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 hospital;

(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 hospital, to a full range of diagnostic services, including [ultrasound,] hematology, pathology, [CT scanners, nuclear medicine and diagnostic radiology] and medical imaging procedures;

(10) each hospital 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] a linear accelerator 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, medical imaging and nuclear medicine. 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.] a CT scanner shall be available within the radiation therapy program that is equipped for radiation oncology treatment planning or arrangements shall be made for access to a CT scanner on an as needed basis.

Provisions shall be made for access to an MRI scanner for treatment planning purposes on an as needed basis.

(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 hospital'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 hospital'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 hospital'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.

Section 405.17 is amended to read as follows:

405.17 Pharmaceutical services.

The hospital shall provide pharmaceutical services that are available at all times on the premises to meet the needs of 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 generally 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) for patients of all ages weight shall be measured in metric units. [information] Up-to-date drug information reference systems relating to drug interactions, drug therapies, side effects, toxicology, dosage, indications for use, and routes of administration [is] are available to the professional staff. Pediatric dosing resources shall include age and size appropriate fluid and medication administration and dosing. Pediatric dosing must be weight based, should include the calculated dose, the dosing determination, such as the dose per weight (e.g., milligrams per kilogram) or body surface area, to facilitate an independent double-check of the calculation, and should not exceed adult maximum dosage, or in emergencies, length based,

(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.

* * *

(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 and monitoring and improvement activities to identify, measure, prevent, [to] minimize and/or mitigate adverse drug [errors] events, adverse drug reactions and medication errors in accordance with generally accepted standards and practices in the field of medication safety and quality improvement.

(iii) The director in conjunction with the medical and nursing 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 to maximize patient safety and quality of care.

(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, rules and regulations.

* * *

Section 405.19 is amended to read as follows:

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 with 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) At least one clinician on every shift must have the skills to assess and manage a critically ill or injured pediatric patient and be able to resuscitate an infant or a child. 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 current training and experience equivalent to ATLS. Such

physician shall also have successfully completed a current course in advanced cardiac life support (ACLS) and pediatric advanced life support (PALS) or have had current training and experience equivalent to ACLS and PALS. 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, ACLS and PALS or have current training and experience equivalent to ATLS, ACLS and PALS.

(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 of 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] develop and implement written policies and procedures, including written patient criteria and guidelines, for transfer of those patients for whom the hospital does not have the capability to care. Such policies and procedures shall [specifying]specify 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. On arrival to emergency services, a patient shall be asked for the name of his or her primary care provider, if known, which shall be documented in the patient's medical record.

(8) The hospital shall develop and implement written policies and procedures pertaining to the review and communication of laboratory and diagnostic test/service results ordered for a patient while admitted or receiving emergency services to the patient. If the patient

lacks medical decision-making capacity, the communication shall be to the patient's medical decision-maker, if known. The results shall also be provided to the patient's primary care provider, if known. Such policies and procedures shall be reviewed and updated as necessary and at a minimum shall include:

(i) a requirement that all laboratory and other diagnostic tests/service results be reviewed upon completion by a physician, physician assistant or nurse practitioner familiar with the patient's presenting condition;

(ii) a requirement that all laboratory and other diagnostic test services results be forwarded to the patient's primary provider, if known, after review by a physician, physician assistant or nurse practitioner;

(iii) provisions to include in the discharge plan information regarding the patient's completed and pending laboratory and other diagnostic test/service results, medications, diagnoses, and follow-up care and to review such information with the patient or, if the patient is not legally capable of making decisions, the patient's parent, legal guardian or health care agent, or surrogate, as appropriate, subject to all applicable confidentiality laws and regulations;

(iv) a requirement that patients may not be discharged from the hospital or the emergency room until any tests that could reasonably be expected to yield "critical value" results – results that suggest a life-threatening or

otherwise significant condition such that it requires immediate medical attention– are reviewed by a physician, physician assistant (PA) and/or nurse practitioner (NP) and are communicated to the patient, his or her parents or other decision makers, as appropriate.

(v) a requirement that all information be presented to the patient or if the patient is not legally capable of making decisions, the patient’s parent, legal guardian or health care agent, or surrogate, as appropriate, subject to all applicable confidentiality laws and regulations, in a manner that reasonably assures that the patient, their parents or other medical decision makers understand the health information provided in order to make appropriate health decisions.

[(8)](9) Review of the hospital emergency service shall be conducted at least four times a year as 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 hospitals’ 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:

(i) The emergency services attending physician shall meet the minimum qualifications set forth in either clauses (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 current training and experience equivalent to ATLS. Such physician shall also have successfully completed a course and be current in advanced cardiac life support (ACLS) and pediatric advanced life support (PALS) or have had current training and experience equivalent to ACLS and PALS. 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-admissible in one of these specialty areas and is currently certified in ATLS or who has current training and experience equivalent to ATLS and has successfully completed a course and is current in ACLS and PALS or has had current training and experience equivalent to ACLS and PALS, 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] The requirement to be qualified to perform ATLS, [and] ACLS and PALS 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 current training and experience equivalent to ATLS; and

(6) has successfully completed a course and is current in advanced cardiac life support

(ACLS) and pediatric advanced life support (PALS) or has had current training and experience equivalent to ACLS and PALS.

(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 30 minutes of patient presentation, provided that at least one physician, nurse practitioner, or [registered] licensed physician assistant shall be on duty in the emergency service 24 hours a day, seven days a week. The hospital shall develop and implement protocols specifying when physicians must be present.

(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] and be current in ACLS and PALS or have [had] current training and experience equivalent to ACLS and PALS;

(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] be current in ACLS and PALS

or have [had] current training and experience equivalent to ACLS and PALS [and shall maintain current competence in ACLS as determined by the hospital].

(iv) 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] licensed [physician's] physician assistants and nurse practitioners.

(i) Patient care services provided by [registered] licensed [physician's] physician 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] licensed physician assistants and the nurse practitioners shall meet the following standards:

(a) the [registered] licensed physician assistants and the nurse practitioners in the emergency service shall [have successfully completed a course] be current in ACLS and PALS or have had current training and experience equivalent to ACLS and PALS 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] licensed physician assistants and nurse practitioners in the emergency service shall be current in ATLS or have had current 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 label[ing] 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] presenting for emergency services [for treatment] receive emergency health care that meets generally accepted standards of practice [medical care].

(2) Every person [arriving at the] presenting for emergency services [for care] shall be promptly examined, diagnosed and appropriately treated in accordance with triage and transfer policies, procedures and protocols adopted by the emergency service and approved by the [hospital] governing body. Such policies, procedures and 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 or transferred to another [facility] hospital, unless evaluated, initially managed, and treated as necessary by an appropriately privileged physician, physician assistant, or nurse practitioner. No later than eight hours after presenting in the emergency service, every person shall be admitted to the hospital, or assigned to an observation unit in accordance with subdivision (g) of this section, or transferred to another hospital in accordance with paragraph (6) of this subdivision, or discharged to self-care or the care of a physician or other appropriate follow-up service. Hospitals which elect to use physician assistants or nurse practitioners shall develop and implement written policies, procedures and treatment protocols subject to approval by the governing body that specify patient conditions that may be treated by a [registered] licensed physician 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 including consultation 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]higher level 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) Reserved.

(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 pre-hospital 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 pre-hospital care providers, emergency services personnel and emergency service physicians; and

(iv) adequacy of staff training and continuing education to meet the needs of patients of all ages presenting for emergency services.

* * *

Section 405.20 is amended to read as follows:

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 Part 751, sections 752.1 and 753.1 and Parts 756, 757 and 758 of Subchapter C of this Title.

* * *

(d) *Hospital-based ambulatory 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 that have privileges in the hospital-based ambulatory surgery service, and are appropriate in the facilities and consistent with the equipment [available] necessary to meet the needs of all patients. 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 post-operative status prevents discharge and necessitates inpatient admission to a hospital capable of providing the appropriate level of care.

(6) Detailed verbal instructions understandable to the patient, or the patient's parent, legal guardian, or health care agent, confirmed by written instructions, and approved by the medical staff of the hospital-based ambulatory surgery service shall be provided to each patient, or the patient's parent, legal guardian, or health care agent, 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 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] body 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 405.22 is amended to read as follows:

405.22 Critical care and special care services.

(a) General provisions.

* * *

(b) Pediatric Intensive Care Unit (PICU) Services.

(1) Definitions.

(1) PICU. A PICU is a physically separate unit that provides intensive care to pediatric patients (infants, children and adolescents) who are critically ill or

injured. A PICU must be staffed by qualified practitioners competent to care for critically ill or injured pediatric patients.

(2) *Qualified practitioner.* 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 competence, credentialing and privileging practitioners in the management of critically ill or injured pediatric patients.

(2) *General.* (i) A PICU must be approved by the Department. The governing body of a hospital that provides PICU services must develop written policies and procedures for operation of the PICU in accordance with generally accepted standards of medical care for critically ill or injured pediatric patients. The PICU shall:

(a) Provide multidisciplinary definitive care for a wide range of complex, progressive, and rapidly changing medical, surgical, and traumatic disorders occurring in pediatric patients;

(b) Have a minimum average annual pediatric patient number of 200/year;

(c) Have age and size appropriate equipment available in the unit; and

(d) Provide medical oversight for interhospital transfers of critically ill or injured patients during transfer to the receiving PICU.

(ii) Organization and Direction. The PICU shall be directed by a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician who shall be responsible for the organization and delivery of PICU care and has specialized training and demonstrated competence in pediatric critical care. Such physician in conjunction with the nursing leadership responsible for the PICU shall participate in administrative aspects of the PICU. Such responsibilities shall include development and annual review of PICU policies and procedures, oversight of patient care, quality improvement activities, and staff training and development.

(a) All hospitals with PICUs must have a physician, notwithstanding emergency department staffing, in-house 24 hours per day who is available to provide bedside care to patients in the PICU. Such physician shall be at least a post graduate year three in pediatrics or anesthesiology. This physician must be skilled in and be credentialed by the hospital to provide emergency care to critically ill or injured children.

(b) The PICU shall have, at a minimum, a physician at the level of post graduate year two or above and/or physician assistant and/or nurse practitioner with specialized training in pediatric critical/intensive care assigned to the unit 24

hours/day, 7 days/week with an attending pediatric, medical, surgical or anesthesiology critical care/intensivist available within 60 minutes.

(c) An attending pediatric medical, surgical, or anesthesiology critical care/intensivist physician shall be responsible for the oversight of patient care at all times.

(d) The PICU shall provide registered professional nursing staffing sufficient to meet critically ill or injured pediatric patient needs, ensure patient safety and provide quality care.

(e) PICU physician and nursing staff shall have successfully completed a course and be current in pediatric advanced life support (PALS) or have current equivalent training and/or experience to PALS.

(iii) Quality Performance. The hospital shall have an organized quality assessment performance improvement (QAPI) program for PICU services. Such program shall require participation by all clinical members of the PICU team and include: monitoring of volume and outcomes, morbidity and all case mortality review, regular multidisciplinary conferences including all health professionals involved in the care of PICU patients.

(iv) Closure. Failure to meet one or more regulatory requirements or inactivity in a program for a period of 12 months or more may result in actions, including, but not limited to, the Department's withdrawal of approval for the hospital to serve as a PICU.

(v) Voluntary closure. The hospital must give written notification, including a closure plan acceptable to the department, at least 90 days prior to planned discontinuance of PICU services. No PICU shall discontinue operation without first obtaining written approval from the department.

(vi) Notification of significant changes. A hospital must notify the department in writing within 7 days of any significant changes in its PICU services, including, but not limited to: (a) any temporary or permanent suspension of services or (b) difficulty meeting staffing or workload requirements.

(c) [(b)] Organ transplant center.

* * *

(d) [(c)] Burn unit/center.

* * *

(e) [(d)] Alternate level of care.

* * *

(f) [(e)] Acquired immune deficiency syndrome (AIDS) centers.

* * *

(g) [(f)] Comprehensive and extended screening and monitoring services for epilepsy.

* * *

(h) [(g)] Pediatric and maternal human immunodeficiency virus (HIV) services.

* * *

(i) [(h)] Secure units for tuberculosis patients including detainees.

* * *

(j) [(i)] Tuberculosis treatment center - for legally detained tuberculosis patients.

* * *

(k) [(j)] Live Adult Liver Transplantation Services.

* * *

Section 405.28 is amended to read as follows:

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 to 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.]

Social services shall be provided under the direction of a qualified social worker who is licensed and registered by the New York State Education Department to practice as a licensed master social worker (LMSW) or licensed clinical social worker (LCSW), with the scope of practice defined in Article 154 of the Education Law.

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (“PHL”) Sections 2800 and 2803 (2). PHL Article 28 (Hospitals), Section 2800 specifies that “Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state . . . , the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services”

PHL Section 2803(2) authorizes the Public Health and Health Planning Council (“PHHPC”) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

These amendments are promulgated to update various Part 405 pediatric and general hospital provisions including surgical, anesthesia, radiology and pharmacy and emergency services. Pediatrics is a unique, distinct part of medicine which is very different than adult medicine. Historically, children have often been seen as small adults. This has changed over time and it is now recognized that certain areas of pediatric care such as emergency, critical care and medication dosing require specialized knowledge, skills and equipment.

Part 405 of Title 10 NYCRR sets forth general hospital minimum standards. In 2010, the New York State Emergency Medical Services for Children (“EMS-C”) Advisory Committee recommended and the Department determined that Part 405 needed to be updated to address the unique needs of children. A comprehensive approach was necessary to make sure that hospitals are admitting children for whom it has appropriate staff, resources and equipment and that policies and procedures are in place for

transferring those patients for whom the hospital does not have the capability to provide care, except under conditions of disasters and emergency surge situations. Many facilities that once had dedicated pediatric units have closed or reduced their units, resulting in a reduced focus on pediatric care. Currently, the pediatric provisions need strengthening as they do not specifically address minimum standards for pediatric critical or emergency care. Pediatric care has become much more sophisticated and requires highly trained staff with expertise in the particular requirements for caring for children. In addition, various Part 405 subdivisions have been updated for all patients including surgical, anesthesia, radiologic and nuclear medicine, pharmaceutical and emergency services to reflect current practice.

The Department, in conjunction with the EMS-C Advisory Committee, carefully reviewed Part 405 of Title 10 and proposes numerous updates and amendments. In particular, significant changes have been made to the Emergency, Radiology and Pharmacy provisions and new provisions are added regarding standards for Pediatric Intensive Care Units (PICUs). New provisions will require age appropriate equipment and supplies. The new provisions assure that personnel in the emergency department and pediatric intensive care unit have the skills to access and manage a critically ill or injured pediatric patient, including resuscitation. Changes in technology and equipment for diagnostic medical imaging and appropriate use of such equipment are addressed. Policies and procedures regarding imaging studies for newborns and pediatric patients are updated to include standards for clinical appropriateness, appropriate radiation dosage and beam collimation, image quality and patient shielding. Pharmacy and equipment

requirements for pediatric patients are revised to assure age and size appropriate dosing. The regulations clarify that pediatric dosing must be weight based and all patients must be weighed in kilograms. Current regulations require Advanced Cardiac Life Support (“ACLS”) training or current training equivalent to ACLS for adults but do not require Pediatric Advanced Life Support (“PALS”) or current training equivalent to PALS for appropriate staff that will be caring for children within the hospital. These regulations address this inequity. This regulatory proposal attempts to strengthen minimum standards for the care of children that are flexible enough to fit the large tertiary care facilities as well as rural and community hospitals. This measure also requires that if laboratory and other diagnostic tests/services are ordered for a patient while receiving emergency services, the hospital must develop and implement written policies and procedures pertaining to the review and communication of the laboratory and diagnostic test/service results to the patient, the patient’s parent, legal guardian or health care agent, or surrogate, if known, and the patient’s primary provider, if known.

These regulations, requiring hospitals provide patients and their parents or other medical decision makers with critical information about the patient’s care and to provide and post a Parent’s Bill of Rights, and another set of regulations requiring hospitals to adopt protocols to identify and treat sepsis, were inspired by the case of Rory Staunton, a 12-year old boy who died of sepsis in April of 2012. Both sets of regulations, together known as “Rory’s Regulations,” will help New York State set a “gold standard” for patient care.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Costs that may be incurred by the regulated parties could include PALS training, accommodations for parent(s) to stay with their child at all times, review and update of various policies and procedures, pharmacy requirements regarding weight based dosing and the requirement of a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician who has demonstrated competence in pediatric critical care to direct PICU services. The cost of providing and posting the Parent's Bill of Rights should be minimal. Regulated parties must also ensure that their equipment is age and size appropriate.

PALS certification costs can range from \$0-\$300. Currently there are grant funded opportunities for PALS certification. Accommodations for parents may be able to be arranged with existing resources, but could also require additional furnishings. What accommodation costs would be incurred depends on the hospital involved. Review and update of the various policies and procedures and the pharmacy requirements could be accomplished with existing staff imposing little or no additional cost to the regulated parties. The "average" salary of a board certified medical, surgical, pediatric, or anesthesia intensivist to direct the PICU would be approximately \$187,192. Hospitals will need to inventory their equipment and supplies to ensure that they are size and age appropriate and provide accordingly. Pediatric dosing resources must include age and

size appropriate fluid and medication administration dosing information if not already currently provided.

Cost to State and Local Government:

There is no anticipated fiscal impact to State or local government as a result of these regulations, except that hospitals operated by the State or local governments will incur minimal costs as discussed above.

Cost to the Department of Health:

There will be no additional costs to the Department associated with the implementation of this regulation. Existing staff will be utilized to conduct surveillance of the regulated parties and monitor compliance with these provisions.

Local Government Mandates:

Hospitals operated by State or local governments will be affected and be subject to the same requirements as any other hospital licensed under PHL Article 28.

Paperwork:

This measure will require facilities to develop various written policies and procedures with respect to: transfers of pediatric patients when unable to appropriately and safely care for them, enabling parents/guardians to stay with pediatric patients, assurance that staff privileges are commensurate with training and experience, assurance that various equipment is age and size appropriate, imaging studies and orders. In addition, monitoring and improvement activities to identify, measure, prevent or mitigate adverse drug events, and for a hospital that provides PICU services policies and procedures for the operation of the PICU in accordance with generally accepted standards of medical care for critically ill or injured pediatric patients.

For hospitals with less than 15,000 unscheduled emergency visits per year, the hospital must develop and implement protocols specifying when supervising or attending physicians must be present. (Such facilities must have at least one physician, nurse practitioner, or licensed physician assistant on duty in the emergency service 24 hours a day, seven days a week).

Duplication:

These regulations will not conflict with any state or federal rules.

Alternative Approaches:

There are no viable alternatives to this regulatory proposal. All general hospitals must be able to admit pediatric patients consistent with its ability to provide qualified staff, size and age appropriate equipment necessary for the unique needs of pediatric patients. If the hospital cannot meet these requirements, it will be required to develop criteria and policies and procedures for transfer of pediatric patients.

Consideration was made when developing the Pharmaceutical Services provisions in Section 405.17, that for pediatric patients only weight must be measured in kilograms. Upon further consideration it was determined that it was more appropriate to require that weight be measured in kilograms for patients of all ages.

When developing the Critical Care and Special Care Services for provisions for Pediatric Intensive Care Unit (PICU) services in Section 405.22 the Department initially considered a minimum bed standard of six beds. Upon further consideration it was determined that a minimum standard would not be a bed standard but instead require that a PICU must have a minimum average annual pediatric patient number of 200/per year.

Federal Requirements:

These regulations will not conflict with any state or federal rules.

Compliance Schedule:

These regulations will take effect upon publication of a Notice of Adoption in the New York State Register, but general hospitals will have 90 days from such date to comply with these provisions.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations will apply to the 228 general hospitals in New York State. A recent survey conducted by the Department determined that 32 hospitals in New York State currently have a pediatric intensive care unit (“PICU”). The proposed amendments will apply Statewide, including 18 general hospitals operated by local governments. These hospitals will not be affected in any way different from any other hospital. The operation of a PICU is not mandated by the State but is at the option of the hospital.

Compliance Requirements:

The literature supports the regulatory changes made to general hospital minimum standards with respect to pediatric care. These provisions specify that general hospitals in New York State must ensure that at least one clinician on every shift in the emergency department has the skills to assess and manage a critically ill or injured pediatric patient and be able to resuscitate a child. This standard is supported by the American Academy of Pediatrics (*see Pediatrics* 1995; 96:526). This measure also states that policies and procedures regarding imaging studies for newborns and pediatric patients must include standards for clinical appropriateness, appropriate radiation dosage and beam collimation, image quality and patient shielding. Medical imaging policies must provide age and

weight-appropriate dosing for children receiving studies involving ionizing radiation as supported by the American Academy of Pediatrics and the American College of Emergency Physicians (*Pediatrics* 2009; 124:1223). Pediatric pharmacy resources must include age and size appropriate fluid and medication administration and dosing. Dosing must be weight based and weight must be measured in kilograms as recommended by the American Academy of Pediatrics; (*Pediatrics* 2003;111:1120). Pediatric Advanced Life Support (PALS) or equivalent training will be required for appropriate staff that will be caring for children in the hospital, a practice supported by the American Academy of (*Pediatrics* 1995;96:526).

The PICU shall have a medical director who has received special training and has demonstrated competence in pediatric critical care as recommended by the American Academy of Pediatrics and Society of Critical Care Medicine (*Pediatrics* 2004; 114: 1114). PICU medical and nursing directors shall be responsible for promoting and verifying pediatric qualifications of staff, overseeing pediatric quality assurance and developing and reviewing PICU care policies consistent with recommendations of the American Academy of Pediatrics, Society of Critical Care Medicine, *Pediatrics* 2004; 114: 1114. PICUs must have a minimum average annual patient number of 200/year. This is consistent with the recommendation made in the American College of Surgeons' *Resources for Optimal Care of the Injured Patient, 2006*.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Professional Services:

The majority of facilities have in-house staff that could make any required changes to the policies and procedures. Small facilities may contract with outside professional staff from the various disciplines to assist them.

Compliance Costs:

A hospital that wants to provide PICU services must have an intensivist who has received special training and has demonstrated competence in pediatric care to direct the PICU. Currently, the majority of PICUs in New York State already have an intensivist in their employ. According to Jobs-Salary.com, the average pediatric intensivist salary is \$187,712, with a range from \$100,651 to \$280,000. PALS training ranges from \$0-300.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

General hospitals will have 90 days from the effective date of these regulations to implement these provisions. In addition, at present, grant funding is available for PALS certification.

Small Business and Local Government Participation:

This proposal has been discussed and reviewed by the EMS-C Advisory Committee, the Greater New York Hospital Association (“GNYHA”), the Healthcare Association of New York State (“HANY”), the Iroquois Hospitals Association and the State Hospital Pharmacy Association.

RURAL AREA FLEXIBILITY ANALYSIS

Effect of Rule:

The provisions of these regulations will apply to general hospitals in New York State, including the 47 general hospitals located in rural areas of the State. These hospitals will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those hospitals located in rural areas.

Compliance will require the admission of pediatric patients only if qualified staff and appropriate equipment are available. Further, compliance will require the adoption and implementation of policies and procedures tailored to the pediatric patient related to surgery, anesthesia, respiratory care, radiologic and nuclear medicine, pharmacy, emergency medicine, etc. ensuring the pediatric patient is appropriately cared for by skilled staff with the appropriate equipment in the appropriate location.

Professional Services:

Professional services for hospitals in rural areas are not expected to be impacted as a result of these regulations differently than other hospitals.

Compliance Costs:

Costs for general hospitals in rural areas will be the same as for general hospitals in nonrural areas. Cost that may be incurred by the regulated parties could include PALS training, accommodations for parent(s) to stay with their child at all times, review and update of various policies and procedures, pharmacy requirements regarding weight based dosing and the requirement of a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician who has demonstrated competence in pediatric critical care to direct PICU services. Regulated parties must also ensure that their equipment is age and size appropriate.

PALS certification costs can range from \$0-\$300. Currently there are grant funded opportunities for PALS certification. Accommodations for parents may be able to be arranged with existing resources, but could also require additional furnishings. What accommodation costs would be incurred depends on the hospital involved. Review and update of the various policies and procedures and the pharmacy requirements could be accomplished with existing staff imposing little or no additional cost to the regulated parties. The “average” salary of a board certified medical, surgical, pediatric, or anesthesia intensivist to direct the PICU would be approximately \$187,192. Hospitals will need to inventory their equipment and supplies to ensure that they are size and age appropriate and provide accordingly. Pediatric dosing resources must include age and size appropriate fluid and medication administration dosing information if not already currently provided.

Minimizing Adverse Impact:

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. Hospitals will have a minimum of 90 days following adoption of these regulations to adopt and implement sepsis protocols and at least six months before information to inform risk adjusted mortality measures will have to be reported to the Department.

Rural Area Participation:

These regulations have been discussed with hospital associations that represent hospitals throughout the state, including those that are located in rural areas. The associations are supportive of this initiative.

JOB IMPACT STATEMENT

Nature of Impact:

These provisions will not have a significant impact on jobs. A PICU in any New York State general hospital must be directed by a board certified pediatric medical, surgical, anesthesiology or critical care/intensivist physician who must be responsible for the organization and delivery of PICU care. Such intensivist must have specialized training and demonstrated competence in critical care. Hospitals that want to provide PICU services may already have an intensivist to direct their unit.

Categories and Numbers Affected:

There are 32 hospitals in New York State the report that they have a PICU.

Regions of Adverse Impact:

There are no regions of adverse impact.

Minimizing Adverse Impact:

Hospitals will have 90 days from the effective date of these regulations to implement the provisions. In addition, at present, there is grant funding available for PALS certification.

ASSESSMENT OF PUBLIC COMMENT

The Department received one comment. This comment period was in response to a revised rule proposal.

COMMENT

The comment was received by the Healthcare Association of New York State (HANYS). HANYS indicated that it supports the intent of the regulatory changes and appreciates that many of the prior comments received by the Department during the initial comment period were considered and incorporated into this revised proposal. HANYS stated, however, that one area of concern that remains relates to the language surrounding “critical value results.” It believes that the requirement to not discharge inpatient or emergency room patients until critical value test results are reviewed and communicated is not well defined. Further, HANYS states that there are a number of tests that take hours, even days to complete. HANYS states that some tests are appropriately done to inform the patient’s future plan of care, and may not necessarily need to be complete before the patient can be safely discharged.

RESPONSE

It is the expectation that hospitals will each develop an appropriate policy and procedure to determine the process to guide the review of critical value results as defined in Sections 405.7 and 405.19 in order to implement these provisions in their facilities. The definition requires the results to be reviewed by a physician, physician assistant and/or

nurse practitioner and communicated to the patient, his or her parents or other decision makers as appropriate. It is also the expectation that the clinician's professional judgment and interpretation within the context of each patient's presenting clinical condition and treatment plan will be reflected in this process to determine whether discharge should be delayed pending completion of certain test results.