Adverse Event Reporting Via NYPORTS System

Effective date for Section 405.8: 5/29/13

Effective date for Section 751.10: 10/26/13

Pursuant to the authority vested in the Commissioner of Health by section 2805-l of the Public Health Law, sections 405.8 and 751.10 of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York are hereby repealed and new sections 405.8 and 751.10 are hereby added; section 405.8 to be effective upon the publication of a Notice of Adoption in the New York State Register and section 751.10 to be effective 150 days after the publication of a Notice of Adoption in the New York State Register, to read, as follows:

Section 405.8 is repealed.

A new section 405.8 is added to read as follows:

405.8 Adverse Event Reporting

(a) Any adverse event required to be reported pursuant to subdivision (b) of this section shall be reported to the department. Hospitals shall report such adverse events, as defined in subdivision (b) of this section, within 24 hours or one business day of when the adverse event occurred or when the hospital has reasonable cause to believe that such an adverse event has occurred. This report to the department shall be submitted in a format
specified by the department and shall at a minimum include: the date, the nature, classification and location of the adverse event; and medical record numbers of all patients directly affected by the adverse event.

(b) Adverse events to be reported are:

(1) patients' deaths in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards;

(2) injuries and impairments of bodily functions, in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards that necessitate additional or more complicated treatment regimens or that result in a significant change in patient status;

(3) equipment malfunction or equipment user error during treatment or diagnosis of a patient which results in death or serious injury of a patient;

(4) patient elopements resulting in death or serious injury;

(5) abduction of a patient of any age;
(6) sexual abuse/sexual assault on a patient or staff member within or on the grounds of a general hospital;

(7) physical assault of a patient or staff member within or on the grounds of a general hospital;

(8) discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;

(9) patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process;

(10) patient suicide, attempted suicide or self harm resulting in serious injury;

(11) poisoning occurring within the hospital;

(12) fires or other internal disasters in the hospital which disrupt the provision of patient care services or cause harm to patients or staff members;
(13) disasters or other emergency situations external to the hospital environment which affect hospital operations;

(14) termination of any services vital to the continued safe operation of the hospital or to the health and safety of its patients and staff members, including but not limited to the termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food, or contract services; and

(15) strikes by staff members.

(c) The hospital shall conduct an investigation of adverse events described in paragraphs (1-10) of subdivision (b) of this section. Such investigations shall be thorough and credible and occur within thirty days of when the adverse event occurred or when the hospital has reasonable cause to believe that such an adverse event occurred or upon determination by the department that an investigation is warranted in order to protect patient health and safety. If the hospital reasonably expects such investigation to extend beyond the thirty day period, the hospital shall notify the department electronically of such expectation and the reason(s) and shall inform the department of the expected date of completion, not to exceed sixty days. For adverse events described in paragraphs (1-10) of subdivision (b) of this section, the hospital shall submit its investigative report electronically, in a format prescribed by the department. The investigative report shall document all hospital efforts to identify and analyze the circumstances surrounding the
adverse event and to develop and implement appropriate measures to prevent recurrence and improve the overall quality of patient care. This report shall be credible and thorough and contain all information in a format specified by the department.

(d) The requirements of this section shall be in addition to and shall not replace other reporting required by this Part.

(e) Nothing in this section shall prohibit the department from investigating any adverse event occurring in general hospitals.

Section 751.10 is repealed.

A new section 751.10 is added to read as follows:

751.10 Adverse Event Reporting

(a) Any adverse event required to be reported pursuant to subdivision (b) of this section shall be reported to the department within 24 hours or one business day of when the adverse event occurred or when the center has reasonable cause to believe that such an adverse event has occurred. This notification shall be submitted in a format specified by the department and shall at least include: the date, the nature, classification, and location
of the adverse event and medical record numbers of all patients directly affected by the adverse event.

(b) Adverse events to be reported are:

(1) patients’ deaths in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards;

(2) injuries and impairments of bodily functions, in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards that necessitate additional or more complicated treatment regimens or that result in a significant change in patient status;

(3) equipment malfunction or equipment user error during treatment or diagnosis of a patient which results in death or serious injury of a patient;

(4) patient elopements resulting in death or serious injury;

(5) abduction of a patient of any age;
(6) sexual abuse/sexual assault on a patient or staff member within or on the grounds of a center;

(7) physical assault of a patient or staff member within or on the grounds of a center;

(8) discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person;

(9) patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process;

(10) patient suicide, attempted suicide or self harm resulting in serious injury;

(11) poisoning occurring within the center;

(12) fires or other internal disasters in the center which disrupt the provision of patient care services or cause harm to patients or staff members;

(13) disasters or other emergency situations external to the center environment which affect center operations;
(14) termination of any services vital to the continued safe operation of the center or to the health and safety of its patients and staff members, including but not limited to the termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food, or contract services; and

(15) strikes by staff members.

(c) The center shall conduct an investigation of any adverse events described in paragraphs (1 - 10) of subdivision (b) of this section. Such investigation shall be thorough and credible and occur within thirty days of when the adverse event occurred or when the center has reasonable cause to believe that such an adverse event occurred or upon determination by the department that an investigation is warranted in order to protect patient health and safety. If the center reasonably expects such investigation to extend beyond the thirty day period, the center shall notify the department electronically of such expectation and the reason(s) and shall inform the department of the expected date of completion, not to exceed sixty days. This investigative report shall be thorough and credible and the center shall submit its report electronically, in a format prescribed by the department.

(d) Nothing in this section shall prohibit the department from investigating any adverse event included in subdivision (b) of this section occurring in such centers.
(e) The requirements of this section shall be in addition to and shall not replace other reporting required by this Chapter.
REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of this regulation is contained in Section 2805-l of the Public Health Law (PHL). PHL Section 2805-l outlines the adverse event reporting requirements for hospitals and diagnostic and treatment centers and directs the Commissioner to make, adopt, promulgate and enforce such rules and regulations as he deems appropriate to effectuate the purposes of PHL Section 2805-l. PHL Section 2805-l also authorizes the Commissioner, after consultation with experts, to add, modify or eliminate by regulation one or more of the adverse events at PHL Section 2805-l consistent with the standards of a consensus based entity selected by the U.S. Department of Health and Human Services pursuant to the Medicare Improvement for Patients and Providers Act. That entity is currently the National Quality Forum (NQF).

Legislative Objectives:

The legislative intent of PHL Article 28 is to provide for the protection and promotion of the health of the inhabitants of the State of New York by delivering high quality hospital and related services in a safe and efficient manner at a reasonable cost. PHL Section 2805-l is intended to strengthen New York State’s hospital and diagnostic and treatment center system by enhancing safeguards and protocols to ensure patient safety with its adverse event reporting requirements. Its aim is to ensure that facility staff become promptly aware of problems, take necessary corrective action and minimize the potential for recurrence. The Department has over time developed and implemented a
state of the art and nationally recognized adverse event reporting system, the New York Patient Reporting System (NYPORTS), with a strong reliance on each facility’s statutory reporting obligation.

**Needs and Benefits:**

Current adverse event reporting practice includes the reporting of defined occurrences, adverse events and unexpected deaths to the Department’s Office of Health Systems Management’s New York Patient Reporting System (NYPORTS). NYPORTS has been in place since 1998 and serves as a nationally recognized adverse event reporting system. NYPORTS is an internet-based system with all required security measures in place. Facilities can query the database to compare their experience with reported events statewide, regionally or within their peer group. While the identity of individual facilities in the comparative groups is not disclosed, the comparative database is a useful tool in support of facility quality improvement activities.

Chapter 542 of the Laws of 2000 created Article 29-D of the Public Health Law, known as the Patient Health Information and Quality Improvement Act of 2000. This law included provisions that established a patient safety center to maximize patient safety, reduce medical errors, and improve the quality of health care. This was to be accomplished by improving systems of data reporting, collection, analysis and dissemination, and to improve public access to health care information not otherwise restricted. The Department’s NYPORTS activities support the mission of the patient safety center through its efforts to collect adverse event report data, analyses of the data and dissemination of such analyses to the hospital community.
A collaborative effort between the Department and stakeholders to align the NYPORTS system with national reporting trends resulted in statutory changes made by the Legislature in 2011. PHL Section 2805-l was revised to allow the Department to modify the reporting requirements so they align with the standards of a consensus based entity selected by the U.S. Department of Health and Human Services pursuant to the Medicare Improvement for Patients and Providers Act. That entity is currently the National Quality Forum (NQF). The amendments to PHL 2805-l also allow the Department to release, in a format that does not identify patients, analyses and findings derived from adverse event data to hospitals or the public and adverse event data to researchers for patient safety research projects approved by the Commissioner. These regulatory amendments: update the adverse reporting requirements to more closely align with NQF standards; update the process for reporting; and change the term “incident reporting” to conform with the terminology now used in PHL 2805-l which is “adverse event reporting”.

Costs:

This proposal will not increase costs to the Department or to the facilities required to report adverse events to the Department via the NYPORTS system. These amendments update the regulations to: more closely align with NQF standards for reporting; update the process for reporting to reflect current practice; and conform terminology to statutory changes.
Local Government Mandates:

This regulation does not impose any new programs, services, duties, or responsibilities upon any county, city, town, village, school district, fire district or other special district including local government run general hospitals and diagnostic and treatment centers.

Paperwork:

There will be no additional paperwork as these amendments merely update the regulation to more closely align with NQF standards for reporting; update the process for reporting to reflect current practice; and conform terminology to statutory changes.

Duplication:

This regulation does not duplicate any other state or federal law or regulation.

Alternatives:

There are no other alternatives. The current regulation is out of date. This proposal updates the regulation to reflect current practice and to implement and conform with statutory changes.
Federal Standards:

This regulatory amendment does not exceed any minimum standards of the federal government.

Compliance Schedule:

The proposed rule will become effective upon publication of a Notice of Adoption in the State Register for Section 405.8 and 150 days after publication of a Notice of Adoption in the State Register for section 751.10.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Pursuant to section 202-b of the State Administrative Procedure Act, a regulatory flexibility analysis is not required. This regulatory action simply updates already existing adverse event reporting requirements in sections 405.8 and 751.10 of 10 NYCRR to reflect current practice regarding the process for reporting and to implement and conform with statutory changes.

The proposed rule will not impose an adverse economic impact on any of the facilities required to report adverse events to the Department, and will not impose a negative impact on local governments. These provisions will not impose additional recordkeeping, reporting and other compliance requirements since the proposal simply updates already existing adverse event reporting and investigative requirements.

The proposed regulation is not subject to the requirement at State Administrative Procedure Act section 202-b(1-a) to provide for a cure period or other opportunity for ameliorative action because such provisions are required for only regulations that both require a regulatory flexibility analysis and involve violations or penalties associated with violations. This regulation does not require a regulatory flexibility analysis for the reasons noted above. Nor is this proposed regulation one that involves the establishment or modification of a violation or of penalties associated with violations. Rather, the regulation clarifies the process for adverse event reporting and provides the occurrences to report.
RURAL AREA FLEXIBILITY ANALYSIS

Pursuant to section 202-bb of the State Administrative Procedure Act, a rural area flexibility analysis is not required. This regulatory action simply updates already existing adverse event reporting requirements in sections 405.8 and 751.10 of 10 NYCRR to reflect current practice regarding the reporting process and to implement and conform with statutory changes.

The proposed rule will not impose an adverse economic impact on hospitals and diagnostic treatment centers located in rural areas in New York State and will not impose any additional recordkeeping, reporting and other compliance requirements since the proposal simply updates already existing adverse event reporting and investigative requirements.
JOB IMPACT STATEMENT

A Job Impact Statement is not included because it is apparent from the nature and purpose of these amendments that they will not have a substantial adverse impact on jobs and employment opportunities. This proposal merely updates the adverse event reporting and investigative provisions in sections 405.8 and 751.10 of 10 NYCRR to reflect current practice regarding reporting process and to implement and conform to statutory changes.