

Observation Unit Operating Standards

Effective date: 1/11/12

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by 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 amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

405.19 Emergency services

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

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

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

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(g) Observation units. Observation units shall be a under the direction and control of the emergency service and, unless a contrary requirement is specified in this subdivision, observation units shall be subject to all requirements of this section applicable to emergency services.

- (1) Patient Care: An observation unit shall be used only for observation, diagnosis and stabilization of those patients for whom diagnosis and a determination concerning admission, discharge, or transfer cannot be accomplished within eight hours, but can reasonably be expected within twenty-four hours. Patients shall be assigned to the observation unit by physician order and within twenty-four hours of the issuance of an order assigning the patient to an observation unit, the patient must be admitted to the inpatient service, be transferred in accordance with paragraph (6) of subdivision (e) of this section, or be discharged to self-care or the care of a physician or other appropriate follow-up service.
- (2) Physical Space:
- (i) The total number of dedicated observation unit beds in a hospital shall be limited to five percent of the hospital's certified bed capacity, and shall not exceed forty, provided that in a hospital with less than 100 certified beds, an observation unit may have up to five beds.
- (ii) The observation unit shall be located within a distinct physical space, except in a hospital designated as a critical access hospital pursuant to subpart F of part 485 of Title 42 of the Code of Federal Regulations or a sole community hospital pursuant to section 412.92 of Title 42 of the Code of Federal Regulations or any successor provisions.
- (iii) The observation unit shall comply with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011.

- (iv) Observation unit beds shall not be counted within the state certified bed capacity of the hospital and shall be exempt from the public need provisions of Part 709.
- (v) The observation unit shall be marked with a clear and conspicuous sign that states: “This is an observation unit for visits of up to 24 hours. Patients in this unit are not admitted for inpatient services.”

(3) Staffing.

- (i) Patients in an observation unit shall be cared for, pursuant to a defined staffing plan, by staff, appropriately trained and in sufficient numbers to meet the needs of patients in the observation unit.
- (ii) At a minimum, a physician, nurse practitioner, or physician assistant shall be responsible for oversight of the medical care of the patients assigned to the observation unit. Such physician, nurse practitioner, or physician assistant assigned to oversee the observation unit shall be immediately available to meet the needs of patients in the observation unit and shall not be assigned concurrent duties that will interfere with such availability.

(4) Organization. The medical staff shall develop and implement written policies and procedures approved by the governing body for the observation unit that shall include, but not be limited to:

- (i) the integration of the observation unit and its services with the emergency service and other related services of the hospital; and

(ii) appropriate use of the observation unit, including documentation of the clinical reasons and indications that warrant the period of observation, rather than admission or discharge, consistent with section 405.10 of this Part.

(5) Opening and Closure.

(i) Any hospital seeking to establish an observation unit shall:

(A) if no construction, as defined in subdivision 5 of section 2801 of the Public Health Law, will be needed, and no service will be eliminated:

(I) submit a written notice to the Department on a form developed by the Department, not less than 90 days prior to opening the unit, indicating the hospital's intent to establish such a unit; the number of beds to be located in the unit; the location of the unit within the facility, and such other information as the Department may require; and

(II) submit a certification from a licensed architect or engineer, in the form specified by the Department, that the space complies with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011; or

(B), if construction, as defined in subdivision 5 of section 2801 of the Public Health Law, will be needed or a service will be eliminated:

(I) comply with Part 710 of this Title, provided that for purposes of Part 710, a construction project involving only the creation of an observation unit and the addition of observation unit beds shall not be subject to review under paragraph (2) or (3) of subdivision (c)

of section 710.1 of this title, unless the total project cost exceeds \$15 million or \$6 million respectively; and

- (II) comply with the applicable provisions of Parts 711 and 712-2 and section 712-2.4 of this Title for construction projects approved or completed after January 1, 2011.

(ii) No hospital may discontinue operation of an observation unit without providing written notification to the Department of the impending closure not less than 90 days prior to the closure.

(6) Transition. A hospital operating an observation unit pursuant to a waiver granted by the Department shall be required to comply with the provisions of this subdivision within 24 months of its effective date.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the proposed revision to Title 10 NYCRR Part 405 is section 2803 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health, to effectuate the provisions and purposes of Article 28 of the PHL with respect to minimum standards for hospitals.

Legislative Objectives:

In March 2011, Governor Cuomo's Medicaid Re-Design Team (MRT) voted to approve certain regulatory reforms to support improvements in the quality of care and assist health care facilities to operate more efficiently. The creation of a regulatory framework for observation units and a Medicaid rate for observation services was one of several reforms adopted by the MRT.

The Department proposes to allow hospitals to create observation units to be used for patient assessment, including diagnostic testing, and stabilization for a period of up to twenty-four hours from the time the patient is assigned to the observation unit, after which time, the patient will either be admitted, transferred, or discharged. Observation unit beds in a facility will be limited to a total of five percent of the hospital's certified bed capacity, and up to a maximum of forty beds, provided that in a hospital with less than 100 certified beds, an observation unit may have up to five beds.

It is important for state regulations governing hospitals to safeguard and promote patient safety, while also allowing hospitals to operate efficiently. The Department's goal is to keep pace with the health care environment, while assuring patient safety and quality of care. The intent of this regulation is to avoid unnecessary inpatient admissions, premature discharges from the emergency department, and repeated emergency department visits, and to improve the quality and experience of care received by patients seeking emergency services. Observation units can also help to improve the efficiency of emergency services and relieve emergency service overcrowding.

Current Requirements:

Current regulations require that after eight hours in the emergency department, hospitals must either discharge or admit the patient. In some circumstances, eight hours may not be enough time to stabilize a patient and complete the diagnostic tests required to assess the patient properly. Even patients who have been stabilized may remain in the emergency department while they await test results, occupying emergency service space that could be used by other patients who may require more immediate services. Hospitals have identified observation services as a means of improving patient care and relieving overcrowding in emergency departments by increasing efficiency and patient throughput.

The Department has granted waivers for the use of observation services to approximately 22 hospitals. Observations services in a unit under the auspices of the emergency service, allow hospitals to provide focused assessment and treatment as

needed, beyond the 8 hours permitted for emergency services. When properly utilized, observation services can prevent inappropriate admissions and premature discharges from the emergency service.

Needs and Benefits:

State regulations governing hospitals should safeguard and promote high-quality care and patient safety, while also allowing hospitals to operate efficiently and maintain access to services. Regulations should also keep pace with the advances in health care technology, best practices, and models of care.

This proposed regulation creates operating standards for observation units under the auspices of the emergency service. Patients will be permitted to stay in observation units for up to twenty-four hours from assignment to the observation unit from the emergency service. After this time patients must be discharged, admitted as an inpatient or transferred to another hospital. Observation services provided in these units will be eligible for Medicaid reimbursement, provided that payment requirements are met. This regulatory change will support improvements in emergency service efficiency and reductions in unnecessary inpatient admissions and in premature discharges from the emergency service that can lead to poor outcomes. These provisions will also improve the patient's experience of care by preventing prolonged stays in crowded emergency departments and relieve emergency department overcrowding.

COSTS

Costs to Private Regulated Parties:

As the creation of an observation unit is optional, this regulation creates no additional burdens or costs to regulated parties. It will eliminate the need for the cumbersome waiver process that is currently used to authorize the operation of observation units. A few providers that are currently operating observation units pursuant to waivers approved by the Department may have to make modifications to the observation unit space. Costs associated with these modifications should be minimal, and those providers will, for the first time, be able to bill Medicaid for services provided in the unit.

Costs to Local Government:

There are no costs to local government.

Costs to the Department of Health:

The proposed amendment would impose no new costs on the Department.

Costs to Other State Agencies:

There are no costs to other State agencies or offices of State government.

Local Government Mandates:

The proposed amendment does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

This regulation will eliminate the paperwork associated with a cumbersome waiver application process. The regulation does not require a certificate of need or other application in order to establish an observation unit unless construction is necessary or a service is to be eliminated. Instead, it imposes a notice requirement.

Duplication:

There are no relevant State regulations which duplicate, overlap or conflict with the proposed amendment. Federal Medicare payment rules set forth standards for reimbursement of observation services. These proposed regulations provide a clear and consistent process for creating observation units and operating standards for such units. The regulations do not conflict with Medicare payment rules.

Alternatives:

The Department considered allowing providers to use undesignated emergency service beds as observation beds, instead of creating a distinct unit. Based on the literature, the Department determined that this arrangement would not achieve the goals of the regulation. It would merely prolong emergency service visits without altering the

model of care, relieving overcrowding, or improving quality and the patient experience of care.

Federal Standards:

The proposed amendment does not exceed any minimum operating standards for health care facilities imposed by the Federal government.

Compliance Schedule:

The proposed amendment will be effective upon publication of a Notice of Adoption in the New York State Register. Facilities operating observation units pursuant to a waiver approved by the Department will have 24 months to comply with these regulations.

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REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas. The regulation includes an exemption from the requirement of a discrete physical space for critical access hospitals and sole community hospitals.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.