Hospital Observation Services

Effective date: 11/4/15

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval by the Commissioner of Health pursuant to Sections 2803, 2805-v and 2805-w of the Public Health Law, paragraph (2) of subdivision (e) of Part 405.19 is amended, subdivision (g) of Section 405.19 is repealed and a new Section 405.32 is added to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York to be effective upon publication of a Notice of Adoption in the New York State Register to read as follows:

Paragraph (2) of subdivision (e) of Section 405.19 is amended to read as follows:

(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]services in accordance with [subdivision (g) of this] section 405.32 of this part, 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.]

Subdivision (g) of section 405.19 is repealed.

A new Section 405.32 is added to read as follows:

405.32 Observation services.

(a) General.

(1) Observation services are post-stabilization services appropriate for short-term treatments, assessment, and re-assessment of those patients for whom diagnosis and a determination concerning inpatient admission, discharge, or transfer can reasonably be expected within forty-eight hours.

(2) If observation services are provided, the services shall be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice.

(3) Direct referral is defined as a patient referred to the hospital for observation services by a nursing home, hospital outpatient clinic, diagnostic and treatment center, private practice physician or appropriately licensed practitioner, without receiving emergency room or critical care services on the day observation care begins. The referring practitioner must be a licensed physician or appropriately licensed practitioner and must have conducted a physical assessment of the patient within the previous eight hours from the referral.

(4) Patients may be assigned to observation services only by order of a physician or appropriately licensed practitioner.

(5) Patients may be assigned to observation services only through the emergency department or by direct referral in accordance with hospital policies, procedures and bylaws, in conformance with applicable statutes and regulations.

(b) Organization and Notice.

(1) The medical staff shall develop and implement written policies and procedures, approved by the governing body, that are based on the clinical needs of the patient, that shall specify:

(i) the organizational structure for providing observation services, including the specification of authority and accountability of the services,

(ii) the proper clinical location for the care of a patient requiring observation services,

(iii) the appropriate medical and administrative oversight of observation services

(iv) clinical criteria for observation assignment and discharge,

(v) assignment of a physician, nurse practitioner, or physician assistant who will be responsible for the care of the patient and timely discharge from observation services, and

(vi) integration with related services and quality assurance activities of the hospital.

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

(3) Patients in observation shall be cared for by staff appropriately trained and in sufficient numbers to meet the needs of the patients.

(4) Patients being assigned to the observation services, or the patient representative, shall be provided with an oral and written notice within twenty-four hours of such placement that the patient is not admitted to the hospital and is under observation status. The hospital shall make a good faith effort to obtain written acknowledgment of receipt of the notice by the patient or the patient representative, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained. Such written notice shall include, but not be limited to the following information:

(i) a statement that observation status may affect the patient's Medicare, Medicaid and/or private insurance coverage for the current hospital services, including medications and other pharmaceutical supplies, as well as coverage for any subsequent discharge to a skilled nursing facility or home and community based care; and

(ii) that the patient should contact his or her insurance plan to better understand the implications of being placed in observation status.

(c) Locations. Hospitals may provide observation services in the following locations:

(1) Inpatient beds;

(2) Distinct Observation Units; or

(3) 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, observation services may be provided in the emergency department.

(d) Distinct Observation Units.

(1) Physical Standards

(i) 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, except that the unit need not be adjacent to the emergency department.

(ii) 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 of this Title.

(iii) The observation unit shall be marked with a clear and conspicuous sign that states: "This is an observation unit for visits of up to 48 hours. Patients in this unit are not admitted for inpatient services."

(2) Any hospital seeking to establish a distinct observation unit shall, not less than 90 days prior:

(i) if no construction, as defined in subdivision 5 of section 2801 of the Public Health Law, will be needed, no construction waivers are being requested, and no service will be eliminated, notify the Department in writing of the general location of the unit and the number of beds; and 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

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

(a) submit a request for limited review under 710.1(c)(5) 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 section 710.1(c)(2) or (3)

of this Title, unless the total project cost exceeds $15 million or $6 million respectively; and

(b) 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.

(3) Any 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 12 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 and section 2805-v of the PHL, which authorizes PHHPC and the Commissioner to adopt regulations with respect to observation services in general hospitals. In addition, Section 2805-w of the Public Health Law requires patient notice of observation services.

**Legislative Objectives:**

While observation services have been widely used, it wasn't until 2011 a Medicaid rate was implemented and 2012 that regulations were adopted creating operational standards for observation units, pursuant to a recommendation adopted by Governor Cuomo's Medicaid Redesign Team. In January 2013 Governor Cuomo signed legislation (L. 2013, ch. 5) creating section 2805-v of the Public Health Law in relation to hospital observation services which differ from the type of observation services provided for in the current regulations. In addition, Chapter 397 of the Laws of 2013 added a new Section 2805-w to the Public Health Law specific to patient notice of observation services.

The proposed changes are designed to make the regulations consistent with sections 2805-v and 2805-w, as well as make modifications based on the experiences of hospitals and the desire to bring the regulations more in line with Medicare rules, while still assuring patient safety and quality of care.

**Current Requirements:**

Current regulations require that observation services be rendered in a discrete unit, under the direction and control of the emergency services. Additionally, observation services are currently limited to twenty-four hours, at which time the hospital must either discharge or admit the patient. Observation services have been identified as a means of improving patient care and relieving overcrowding in emergency departments by increasing efficiency and patient through-put. However, the current regulations differ significantly from sections 2805-v and 2805-w and from Medicare rules.

**Needs and Benefits:**

The proposed regulations repeal 405.19(g) and create a new section 405.32. In response to the recent legislation, the new regulations will allow observation services to be rendered in a distinct unit or in inpatient beds, with no limit on the number of observation beds. The facility will be able to determine the appropriate oversight, and the maximum observation stay will increase to

forty-eight hours. Many of the provisions in the current section 405.19(g) are retained in the new 405.32(d).

Additionally, proposed changes would allow hospitals to accept direct referrals to observation by community providers, following appropriately adopted policies and procedures. The new regulations will also require both verbal and written notice be given to patients explaining that observation services are considered outpatient services with all concurrent applicable insurance rules.

These regulatory changes incorporate the statutory changes and take into account the desire for appropriate consistency with Medicare rules and operational experiences over the past year, while maintaining proper safeguards and attention to patient safety and quality of care.

## COSTS

### Costs to Private Regulated Parties:

This regulation creates no additional burdens or costs to regulated parties. It will eliminate the requirement for discrete units which may have required construction costs to be in compliance with construction standards.

### 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 requires no additional paperwork other than written notice to patients about their assignment to observation services and signage at the entrance to the observation area.

**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 clear and consistent operating standards for observation services. The regulations do not conflict with Medicare payment rules.

**Alternatives:**

The Department believes that Chapter 5 of the Laws of 2013 requires the Department to promulgate these regulations. The Department considered not requiring verbal and written notice to patients regarding their assignment to observation services. Based on the literature and recent newspaper articles, the Department determined that such information was important for patients to know.

**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 amendments will be effective 90 days after 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 12 months to comply with these regulations.

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## STATEMENT IN LIEU OF

## 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 for critical access hospitals and sole community hospitals, allowing them to utilize emergency room beds.

## 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.

## ASSESSMENT OF PUBLIC COMMENT

**COMMENT:** A hospital association expressed general support for the regulations but wanted the Department to make it clear that referrals for observation services from nursing homes and community providers, such as physicians, nurse practitioners and physician assistants are permissible, and that the referring practitioner does not have to be a member of the medical staff of the receiving hospital.

**RESPONSE:** The Department agrees with this commenter. The Regulatory Impact Statement published along with the Notice of Proposed Rule Making (*State Register*, October 29, 2014, p. 5), states that this regulation allows direct referrals by "properly privileged and credentialed" community providers. The Department now wishes to make clear that this regulation also allows these direct referrals by community providers who are not members of the medical staff of the receiving hospital.

In the final rule, paragraph (3) of subdivision (a) of section 405.32 is amended to read as follows:

(3) Direct referral is defined as a patient referred to the hospital for observation services by a nursing home, hospital outpatient clinic, diagnostic and treatment center [or], private practice physician or appropriately licensed practitioner, [practicing in the community,] without receiving emergency room or critical care services on the day observation care begins. The referring practitioner must be a licensed physician or appropriately licensed practitioner and must have conducted a physical assessment of the patient within the previous eight hours from the referral.

The Department believes that this non-substantive change provides greater clarity regarding the community providers who may make direct referrals for observation services. A referring practitioner must be a licensed physician or appropriately licensed practitioner and must have conducted a physical assessment of the patient within the previous eight hours from the referral, but the referring practitioner does not have to be privileged and credentialed at the hospital where the patient is being referred for observation services.

**COMMENT:** One commenter believed that the Department of Health should revisit discharge planning regulations to assure that the needs of observation status patients and families are handled timely and appropriately.

**RESPONSE:** Section 405.32(b)(2) creates a new requirement that discharge planning policies and procedures be developed and implemented specifically for observation status.

**COMMENT:** One commenter thought that the Department should amend the language to state that a decision whether to admit or discharge a person can be expected to be within twenty-four hours and most rarely in forty-eight hours. The commenter also indicated the value of identifying a hospital representative that the patent may speak with regarding questions about observation status, in particular the insurance aspects of this.

**RESPONSE:** The Department does not believe these suggestions are consistent with the enabling statute that is being implemented, Public Health Law §§ 2805-v and 2805-w.

**COMMENT:** One commenter believed that the requirement that hospitals develop "clinical criteria" for observation status should be amended to clarify that inpatient admissions should be provided in instances where patients demonstrate signs and symptoms significant enough to indicate the need for medical care that would more safely and effectively be furnished on an inpatient basis.

**RESPONSE:** The amendments in 405.32(b)(1) will require the hospital to develop policies and procedures that specify the clinical criteria for observation status assignment and discharge; the organizational structure, proper location and medical oversight for observation services; and their integration with existing quality assurance services. The Department determined this suggestion would add unneeded complexity to the regulations with little added benefit.

**COMMENT:** A comment was received recommending that "conspicuous signage" be used in observation areas.

**RESPONSE:** Section 404.32(d)(1)(iii) does require signage for observation units. It is impractical to expand this for scattered observation services those beyond designated units, and the Department does not believe this suggestion is consistent with the enabling statute that is being implemented, Public Health Law §§ 2805-v and 2805-w.

**COMMENT:** One commenter did not agree that observation units should be exempt from 10 NYCRR Part 709, concerning public need determinations.

**RESPONSE:** The Department believes that adding a public need review would add additional cost and delay implementation without any clear added benefit.