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, section 405.45 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon publication of a Notice of Adoption in the New York State Register to read as follows:

#### 405.45 Trauma Centers

(a) *Definitions*. The following terms when used in this section shall have the following meanings:

\* \* \*

(3) "Level I trauma center" means a facility verified by the American College of Surgeons

Committee on Trauma (ACS-COT), or other entity determined by the Department, and
designated by the Department as a facility that is capable of providing the full range of services
required of trauma patients; conducts trauma research; and provides training to surgical residents
that comports with the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022). The standards set forth in the ACS-COT's publication
entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) are hereby
incorporated by reference with the same force and effect as if fully set forth herein. A copy
of *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) is available for inspection
and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning
Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the
American College of Surgeons Committee on Trauma, 633 North Saint Clair Street, Chicago,

Illinois 60611. A Level I trauma center shall have a transfer agreement with at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

\* \* \*

# (c) Trauma Center Designation

(1) A hospital seeking designation as a trauma center must receive verification by the American College of Surgeons, Committee on Trauma (ACS-COT), or other entity determined by the Department. To receive verification, the hospital must undergo a consultation site visit and verification site visit by the ACS-COT, or other entity determined by the Department. During the verification site visit, the hospital must exhibit that it is capable of providing Level I, Level II, Level III, Level IV or pediatric trauma care in accordance with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

\* \* \*

## (ii) Verification site visit.

A hospital seeking designation as a trauma center shall request an official verification site visit by the ACS-COT, or other entity determined by the Department, no later than two years following a hospital's receipt of its consultation site visit report. The hospital must receive confirmation from the ACS-COT, or other entity determined by the Department, that the hospital meets the criteria for trauma center verification in accordance with the criteria outlined in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

\* \* \*

- (d) Requirements for Operating a Trauma Center.
- (1) Upon designation, a hospital operating a trauma center shall:

\* \* \*

(ii) comply with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022);

\* \* \*

#### REGULATORY IMPACT STATEMENT

## **Statutory Authority:**

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) section 2803. Pursuant to PHL § 2803(2), the Public Health and Health Planning Council (PHHPC) is authorized 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 objectives of PHL Article 28 include the protection and promotion of the health of the residents of the State by requiring the efficient provision and proper utilization of health services.

### **Needs and Benefits:**

The criteria and standards in the Resources for the Optimal Care of the Injured Patient are used to ensure that trauma center applications are compliant with the most current standards and the ACS uses these standards to issue the verification of trauma center status. The current edition of the Resources for Optimal Care of the Sick and Injured Patient (2014) is out-of-date and the proposed rule change would update the edition of Resources for Optimal Care of the Sick and Injured Patient to the most current version dated 2022. This change is necessary because the American College of Surgeons (ACS) will be using the updated edition to perform hospital trauma center verifications and re-verifications starting on September 1, 2023.

## **COSTS:**

## **Costs to Regulated Parties:**

The proposed rule change may impose additional costs on trauma center hospitals due to new education requirements, expansion of available surgical and medical experts, the addition of a performance improvement coordinator, and the number of trauma registrars required in the updated 2022 standards set forth in *Resources for Optimal Care of the Sick and Injured* compared to the 2014 standards. The Department cannot provide an accurate estimate of these costs because they will vary significantly depending on what actions each trauma center hospital will need to take, or may have already taken, to meet the updated 2022 standards.

### **Costs to State and Local Governments:**

This regulation imposes no new costs or fees to state and local governments. General hospitals operated by local governments may be affected as regulated entities if they are also designated as trauma centers pursuant to 10 NYCRR section 405.45.

## **Costs to the Department of Health:**

This regulation imposes no new costs or fees to the Department of Health.

### **Local Government Mandates:**

This regulation imposes no new government mandates.

## Paperwork:

This regulation imposes no additional paperwork.

## **Duplication:**

This regulation does not duplicate any State or federal rules.

## **Alternatives:**

No alternatives to the proposed rule change were considered viable. The regulation needs to be updated since the ACS will be using the updated edition of *Resources for Optimal Care of the Injured Patient* to perform hospital trauma center verifications and re-verifications starting on September 1, 2023.

### **Federal Standards:**

There are no federal standards.

# **Compliance Schedule:**

Beginning September 1, 2023, designated trauma center hospitals will need to use the new 2022 edition of *Resources for Optimal Care of the Sick and Injured*.

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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**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

# STATEMENT IN LIEU OF

# JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.