Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting
Agenda and Informational Announcements

Wednesday, October 11, 2017
10:15 AM

MAIN MEETING SITE: Empire State Plaza, Concourse Level, Meeting Room 6, Albany

VIDEO CONFERENCE SITE: 90 Church Street 4th Floor, Room 4A & 4B, New York City

A.

For Adoption	Program Area	Unit Representative
Amendment to Subpart 34-2 of Title 10 NYCRR – Laboratory Business Practices	Wadsworth Division of Laboratory Quality Certification	Dr. Michael Ryan

For Information	Program Area	Unit Representative
Amendment to Parts 405 and 708 of Title 10 NYCRR – Trauma Centers	Bureau of Emergency Medical Services and Trauma Systems	Lee Burns

B. Information Announcements

1. Anyone wishing to make oral comments at this meeting should contact the Bureau of Policy and Standards Development by 11:00 A.M. on Tuesday, October 10, at 518-402-5914 to arrange for placement on the speakers' list. Please give your name, affiliation, if any and the agenda item(s) you wish to address. To ensure that all commenters have an opportunity to address the Committee, speakers should limit their comments to 3-4 minutes maximum.

2. All meeting attendees including Committee members are requested to sign the Attendance Sheet, which will be circulated in the meeting room.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 586 and 587 of the Public Health Law, Section 34-2.11(b) 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 State Register, to read as follows:

§ 34-2.11 Recall letters and reporting of test results.

(b) A clinical laboratory shall not communicate to a patient of a referring health services purveyor the results of a clinical laboratory test, including, but not limited to, a Pap smear. A clinical laboratory shall not prepare such communication for the health services purveyor to send, or otherwise facilitate the preparation or sending of such communication by the health services purveyor. Such communication or its facilitation shall be deemed consideration given for referral of specimens for performance of clinical laboratory services and is prohibited, except that:

* * *

(2) nothing in this subdivision shall prohibit a licensed physician from communicating with a patient:

(i) when requested by the referring health services purveyor;

(ii) when requested by the patient; or

(iii) when the referring health services purveyor, or other health services purveyor responsible for using the test results, cannot be reached and a critical value needs to be communicated to the patient.

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) sections 586 and 587 set forth the duties and powers of the department related to clinical laboratory business practices. PHL sections 586(3) and 587(6) specifically authorize the Department to adopt regulations pertaining to clinical laboratory business practices.

Legislative Objectives:

The legislature enacted PHL sections 586 and 587 to prevent health services purveyors from splitting fees with clinical laboratories and to prevent payment for referrals. The Public Health and Health Planning Council and the Commissioner of Health are authorized to adopt and amend regulations necessary to effectuate the provisions and purpose of PHL sections 586 and 587. This proposed regulation is consistent with the legislative objective, as it will clarify for physicians and clinical laboratories allowable business practices.

Needs and Benefits:

Subpart 34-2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) regulates the business practices of clinical laboratories. These regulations prohibit certain practices by clinical laboratories and health services purveyors. The intent of these regulations is to mitigate improper business practices that could, among other things, result in kickbacks to laboratories from hospitals, physicians, and other health services purveyors for the referral of patients or specimens.

Section 34-2.11 prohibits certain communications between a clinical laboratory and a patient of a referring health services purveyor to prevent kickbacks or other payments from being given for the referral of laboratory services. To prevent such kickbacks, section 34-2.11(b)(1)(iv) requires clinical laboratories to direct a patient's inquiries regarding the meaning or interpretation of test results to the referring health services purveyor.

Direct communication between pathologists and patients regarding test results is not always needed but in some instances, direct communication is crucial to providing safe, high quality, patient centered care. Traditionally, pathologists communicate with health care providers to help interpret test results or to guide further management of a patient. However, there are instances when patients may wish to obtain information from a pathologist concerning their test results. Pathologists may also need to communicate test results to a patient when a critical value is obtained by the testing laboratory, especially if the pathologist cannot reach the ordering physician, or other health services purveyor responsible for using the test results. Under these circumstances, a licensed physician working at the laboratory should be able to reach out to the patient to ensure that a critical value is communicated. The proposed regulation will add affirmative language to Section 34-2.11 to provide that, under specific circumstances, a licensed physician employed by a clinical laboratory may discuss the meaning and interpretation of test results directly with patients.

Costs:

Costs to Regulated Parties:

The new language allows, but does not require, licensed physicians to discuss the meaning and interpretation of test results with patients. The proposed regulation will not impose costs on regulated parties.

Costs to the Agency, State and Local Governments:

The proposed regulation will not impose additional costs on the New York State Department of Health or local governments.

Local Government Mandates:

The proposed regulation imposes no new mandates on any county, city, town or village government.

Paperwork:

The proposed regulation does not mandate new paperwork requirements. However, laboratory physicians should document all communications with patients.

Duplication:

These rules do not duplicate any other law, rule or regulation.

Alternative Approaches:

One alternative is to not amend the regulation. However, this would prevent clinical laboratory physicians from communicating with their patients the meaning or interpretation of test results. The Department recognizes the importance of a pathologist-patient relationship as part of the spectrum of physician-patient relationships and its role in ensuring the delivery of safe, high quality, patient centered health care. Therefore, the Department rejected this alternative.

Federal Standards:

The proposed regulation does not exceed any minimum standards of the federal government.

Compliance Schedule:

The proposed regulation is permissive. Accordingly, regulated parties do not need to take any action to come into compliance.

Contact Person:

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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.

Rural Area Flexibility Analysis

No Rural Area Flexibility Analysis is required pursuant to section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

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 regulation, that it will not have an adverse impact on jobs and employment opportunities.

SUMMARY OF EXPRESS TERMS

These regulations establish a new regulatory framework for the operation of trauma centers at hospitals in New York State, by adding a new 10 NYCRR section 405.45. Subdivision (a) defines terms relating to trauma centers, including but not limited to trauma patient, trauma care, Levels I-IV trauma centers, pediatric trauma center, and Regional Trauma Center. Subdivision (a) also defines the transfer agreements that must exist between hospitals, and the trauma affiliation agreement that each hospital must have with the Regional Trauma Center.

Subdivision (b) establishes certain general provisions relating to trauma care. More specifically, the regulation states that the Department has authority to determine whether a hospital meets the legal requirements for designation by the Department as a trauma center. Only trauma centers designated by the Department may admit and provide care to trauma patients, except in certain emergency situations. Any hospital not designated as a trauma center must transfer a trauma patient to the most appropriate trauma center pursuant to a transfer agreement. A hospital may not state that it has trauma center status unless it is designated by the Department.

Subdivision (c) establishes the process for obtaining trauma center designation. 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. The regulation provides details on what must occur during consultation and verification site visits.

Subdivision (d) establishes certain requirements for operating a trauma center, including but not limited to complying with ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* (2014), maintaining appropriate equipment, maintaining transfer agreements, participating in a performance improvement process, submitting notices of noncompliance to the Department, and notifying the Department immediately of any inability to meet trauma care capabilities.

Subdivision (e) sets forth the conditions under which the Department may withdraw trauma center designation. Subdivision (f) requires trauma centers to submit information to the New York State Trauma Registry. Subdivision (g) requires trauma centers to participate with the coordinating Regional Trauma Center and other hospitals and healthcare facilities, EMS agencies and governmental disaster preparedness programs in regional trauma performance improvement activities. The regulation provides additional details concerning the trauma performance improvement program.

Two provisions in existing regulation relating to trauma centers are repealed as no longer needed, in light of the proposed regulations.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval of the Commissioner of Health by sections 2800, 2803, 3063, 3064, 3066, 3074 and 3075 of the Public Health Law, Part 405 and Part 708 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

Paragraph (8) of subdivision (b) of section 708.2 is hereby repealed.

Subdivision (i) of section 708.5 is hereby repealed.

A new section 405.45 is proposed to read as follows:

405.45 Trauma Centers

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

(1) "Trauma patient" means a patient at high risk of death or disability from multiple and severe injuries.

(2) "Trauma care" means health care provided to a trauma patient.

(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). The standards set forth in the ACS-COT's publication entitled *Resources*

for Optimal Care of the Injured Patient (2014) 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) 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.

(4) "Level II trauma center" means a facility verified by the ACS-COT, or other entity determined by the Department, and designated by the Department as a facility that is capable of providing comprehensive trauma care. A Level II trauma center shall have a transfer agreement with at least one Level I trauma center and, unless otherwise designated, at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

(5) "Level III trauma center" means a facility verified by the ACS-COT, or other entity determined by the Department, and designated by the Department to serve communities that do not have immediate access to a Level I or II trauma center that is capable of providing prompt assessment, resuscitation, emergency operations and stabilization of trauma patients. A Level III trauma center shall have a transfer agreement with at least one Level I or Level II trauma center, whichever is the most appropriate trauma center, and at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

(6) "Level IV trauma center" means a facility located in a rural area verified by the ACS-COT, or other entity determined by the Department, and designated by the Department as a

facility that is capable of providing initial evaluation and stabilization of trauma patients prior to transfer to a higher level trauma center. A Level IV trauma center shall have a transfer agreement with at least one Level I, Level II, or Level III trauma center, whichever is the most appropriate trauma center, and at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

(7) “Pediatric trauma center” means a facility verified by the ACS-COT, or other entity determined by the Department, and designated by the Department as a level I or level II trauma center and as a facility that is capable of providing comprehensive pediatric trauma care to pediatric trauma patients. A pediatric trauma center shall have a transfer agreement with at least one Level I or Level II trauma center, whichever is the most appropriate trauma center.

(8) “Region” means a defined geographic area of the state where a regional trauma advisory committee has been established pursuant to PHL § 3065.

(9) “Regional Trauma Center” means a Level I or Level II trauma center selected by the Department to coordinate regional trauma performance improvement activities in its region. The Regional Trauma Center will be selected from facilities in a region that have been successfully verified by ACS-COT, or other entity determined by the Department, and designated as a trauma center by the Department, with a history of leadership and commitment to the region.

(10) “Transfer agreement” means a written and fully executed agreement between a hospital that has limited capability to receive and treat trauma patients in need of specialized emergency care and a designated trauma center that is capable of providing such care, for the transfer of such patients, that is consistent with the criteria, policies and procedures set forth in the hospitals’ trauma affiliation agreement with the Regional Trauma Center.

(11) “Trauma affiliation agreement” means a written and fully executed agreement between the Regional Trauma Center and each of the Level I, Level II, Level III, and Level IV trauma centers and non-designated hospitals in the Regional Trauma Center’s region. A trauma affiliation agreement shall include provisions for:

(i) criteria, policies and procedures for the transfer of trauma patients to trauma centers and between levels of trauma center;

(ii) participation in the New York State Trauma Registry including the maintenance of confidentiality and protection of all data provided to the Registry;

(iii) cooperation in outreach, education, training and data collection activities; and

(iv) authority for a representative or representatives of the Regional Trauma Center to participate in and receive information from the affiliate hospital’s quality assurance committee, participate in other reviews of the quality of trauma care provided by the affiliate, and provide recommendations for quality improvement of trauma care.

(b) *General Provisions*.

(1) The Department may designate a hospital as a designated trauma center if the hospital demonstrates that it has met the requirements of section 3066 of the Public Health Law and this Part, to the Department’s satisfaction.

(2) Only those hospitals designated as trauma centers by the Department shall admit and provide trauma care to trauma patients; provided, however, that if the existing designated trauma centers have exceeded their capacity during a state-declared disaster or an emergency surge, an

undesignated hospital, upon approval by the commissioner, may temporarily provide trauma care.

(3) Any hospital not designated as a trauma center that receives a trauma patient shall transfer such patient to the most appropriate trauma center pursuant to a transfer agreement as required under section 405.19 of this Part. Trauma centers shall be consulted prior to transfer. Trauma patients requiring trauma care shall be transported to the most appropriate trauma centers in accordance with State Emergency Medical Advisory Committee (SEMAC) approved Emergency Medical Services (EMS) protocols developed and adopted pursuant to subdivision two of section 3002-a of the Public Health Law.

(4) No hospital shall state that it has trauma center status unless so designated by the Department.

(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).

(i) Consultation site visits.

A hospital seeking designation as a trauma center shall request a consultation site visit by the ACS-COT, or other entity determined by the Department, for the purpose of providing recommendations and assistance in preparation for verification.

(a) The cost of the consultation site visit shall be at the facility's own expense.

(b) A hospital shall provide 30 days' notice to the Department prior to any and all consultation site visits.

(c) The Department may participate in any consultation site visits.

(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).

(a) The cost of any verification site visit shall be at the hospital's own expense.

(b) A hospital shall provide 30 days' notice to the Department prior to any and all verification site visits.

(c) The Department may participate in any verification site visits.

(d) A hospital seeking Level I, Level II, or Level III trauma center designation shall require that any verification review team, as provided by ACS-COT, or other entity determined by the Department, include a nurse reviewer. The hospital shall submit to the

Department documentation confirming that a nurse reviewer was a member of the verification review team.

(e) A hospital shall submit to the Department a copy of all verification site visit reports and verification certificates issued by the ACS-COT, or other entity determined by the Department, within ten business days of receipt.

(f) A hospital shall submit to the Department immediately upon receipt any statement of deficiencies found or interim reports of focused surveys issued by the ACS-COT, or other entity determined by the Department, during a verification review.

(g) A hospital shall notify the Department immediately upon receipt of notice of failure to be verified by the ACS-COT, or other entity determined by the Department. Such notification must be made in writing to the Department by the hospital's chief administrative official.

(2) A hospital seeking designation as a trauma center must provide to the Department any additional materials received by the hospital from the ACS-COT, or other entity determined by the Department, upon the Department's request.

(3) A verified trauma center must be re-verified every three years by the ACS-COT, or other entity determined by the Department, and in accordance with subparagraph (ii) of paragraph (1) of subdivision (c) this section.

(d) *Requirements for Operating a Trauma Center.*

(1) Upon designation, a hospital operating a trauma center shall:

(i) remain subject to the provisions of this Part and all other applicable requirements of this Title and of the Public Health Law related to general hospitals;

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

(iii) have age and size appropriate resuscitation equipment consistent with section 405.19(b) and this Part;

(iv) participate and submit information to the New York State Trauma Registry as set forth in subdivision (f) of this section;

(v) maintain transfer agreements with non-designated hospitals and the nearest designated Level I, Level II, Level III and pediatric trauma center, as appropriate for the region, to assure the timely transfer of trauma patients to the appropriate level of trauma care;

(vi) participate in the performance improvement process as set forth in subdivision (g) of this section;

(vii) submit to the Department any notices of noncompliance issued by the ACS-COT, or other entity determined by the Department, within one business day of receipt;

(viii) provide to the Department any additional materials received by the hospital from the ACS-COT, or other entity determine by the Department, upon the Department's request; and

(ix) notify the Department immediately of any inability to meet the capabilities required by its current designation. Such notification must be made in writing to the Department by the hospital's chief administrative official.

(e) *Withdrawal of Designation*

(1) The Department may withdraw designation from a hospital if:

(i) the hospital's trauma center verification certificate lapses;

(ii) the hospital is not issued a certificate of trauma center verification after a reverification site visit; or

(iii) the hospital fails to comply with paragraph (1) of subdivision (d) of this section.

(2) Upon withdrawal of a trauma care designation, the hospital shall immediately take measures to notify affected parties and divert trauma patients to designated trauma centers, and within 30 days, provide to the Department a written plan describing the specific measures it has taken to notify affected parties and its process for diversion of trauma patients to designated trauma centers. In addition, the hospital shall ensure that it has a transfer agreement with at least one designated Level I, Level II or Level III trauma center, whichever is the most appropriate trauma center available, and at least one pediatric trauma center to assure the timely transfer of trauma patients in need of specialized emergency care, consistent with section 405.19 of this Part.

(f) *New York State Trauma Registry*.

Each designated trauma center, and every hospital that treats trauma patients prior to transferring them to a designated trauma center, shall submit information to the New York State Trauma Registry. The data elements that are required to be reported to the New York State Trauma Registry are set forth in the New York State Trauma Registry's data dictionary. Hospitals must submit data to the New York State Trauma Registry at least quarterly and at such other times as the Department may require. The hospital shall have in place appropriate measures to ensure the confidentiality of all information provided to the Registry.

(g) *Performance improvement.*

(1) Each designated trauma center shall participate with the coordinating Regional Trauma Center and other hospitals and healthcare facilities, EMS agencies and governmental disaster preparedness programs in regional trauma performance improvement activities that shall include:

(i) evaluation of the quality and appropriateness of care provided, including providing referring hospitals with information on trauma patient outcome;

(ii) analysis of data from the New York State Trauma Registry, Patient Care Report database and other sources to identify opportunities for improvement. The Regional Trauma Center shall have in place appropriate measures to ensure the confidentiality of all data utilized to conduct this analysis;

(iii) development of trauma protocols, procedures, guidelines and policies;

(iv) assessment of the regional trauma system;

(v) utilization of trauma and EMS data sources to guide public education and injury prevention efforts;

(vi) provision of trauma-related/injury prevention education to allied healthcare providers; and

(vii) participation in emergency and disaster planning including incorporation of resources and capabilities into plans to address mass casualty and other disaster events.

(2) The Regional Trauma Center in each region will coordinate with each hospital within its region to participate in regional trauma performance improvement activities.

(i) Each Regional Trauma Center shall enter into and comply with a trauma affiliation agreement with each hospital in its region. A representative of the Regional Trauma Center may participate in and receive information from the affiliate hospital's quality assurance committee, and may review other reviews of the quality of trauma care provided by the affiliate hospital, in order to make informed recommendations about improving trauma care and about the performance improvement process. Each Regional Trauma Center and each affiliate hospital shall take actions necessary, including but not limited to, incorporating necessary provisions in the trauma affiliation agreement, to authorize such participation. For purposes of such participation, the Regional Trauma Center's representative(s) shall be deemed a member(s) of the affiliate hospital's quality assurance committee. The Regional Trauma Center's representative(s) shall only access confidential patient information for purposes of quality improvement of trauma care. Members of an affiliate hospital's quality assurance committee shall maintain the confidentiality of patient information and are subject to all applicable

confidentiality laws and regulations, including subdivision three of section 3006 of the Public Health Law.

(ii) The Regional Trauma Center shall participate in the review of information and data for quality improvement purposes as described in the affiliation agreement, which shall include:

(*a*) a quarterly review of all pediatric trauma deaths, delays of three hours or more in transferring trauma patients to a higher level of trauma care, and any transport and/or admission of trauma patients to a non-trauma center;

(*b*) making quality improvement recommendations for trauma care for the hospitals in its region; and

(*c*) periodic review, at the Department's request, of potential issues with trauma care in its region identified by the Department during routine analysis of regional data in the New York State Trauma Registry; and

(d) any other activities required by the Department for quality improvement purposes.

(iii) The Regional Trauma Center shall submit to the Department on a quarterly basis a report, in a format determined by the Department, describing its quality improvement reviews of all pediatric trauma deaths, delays of three hours or more in transferring trauma patients to a higher level of trauma care, any transport and/or admission of trauma patients to a non-trauma center and any additional information requested by the Department, and a report, in a

format determined by the Department, describing any quality improvement recommendations made to the hospitals in its region.

(iv) The Regional Trauma Center shall cooperate with the Department in regular reviews by the Department of the Regional Trauma Center's quality improvement activities, including providing medical records and other relevant documents and information on a timely basis when requested.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 2800, 2803(2), 3063, 3064, 3066, 3074 and 3075. Section 2800 provides that "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 § 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.

PHL §§ 3063 and 3064 establish the State Emergency Medical Advisory Committee (SEMAC) and the State Trauma Advisory Committee (STAC), respectively, to advise the Commissioner and the Department on emergency medical care and trauma care within the state. PHL § 3066 authorizes the Department to develop standards for trauma care and to categorize hospitals as trauma centers appropriate for providing trauma care. PHL § 3074 establishes the State Emergency Medical Services for Children Advisory Committee to advise the Commissioner and the Department on all aspects of emergency medical services for children, including trauma care. PHL § 3075 authorizes the Department to develop and maintain, with the advice of the State Emergency Medical Services for Children Advisory Committee, the State Emergency Medical Advisory Committee and the State Trauma Advisory Committee, a statewide system for recognition of facilities able to provide pediatric trauma care.

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. The legislative objective of PHL Articles 30-B and 30-C includes the protection of public health and safety through the development of systems for adult and pediatric trauma care.

Needs and Benefits:

After a traumatic event, the complexity of injuries sustained, the health of the patient at the time of the event, and the trauma care available to that patient will determine the risk of death, loss of limb, disability and/or other permanent harm. Because hospitals vary in the scope of resources they can provide to treat trauma patients, the state's network of healthcare providers works to ensure that trauma patients receive high quality care at those hospitals that have the resources to maximize chances for good outcomes. Since 1984, several research studies, including more than 15 published articles, have concluded that a patient's chances of survival following significant trauma improve when he or she is cared for in a specialized trauma center.

These proposed regulations repeal certain provisions of Part 708 that define trauma care and trauma centers. These provisions were originally promulgated in 1990 and were modeled after the national trauma care standards at that time. The proposed regulations update and modernize these standards.

The State Trauma Advisory Committee (STAC), as established by PHL Article 30-B, advises the Department and Commissioner regarding trauma and disaster care. In collaboration with STAC, the Department determined that, to strengthen the provision of trauma care in New

York State, and to improve access to trauma care and improve patient care, the Department should require hospitals seeking trauma center designation to comply with the current national trauma care standards published by the American College of Surgeons Committee on Trauma (ACS-COT) in *Resources for Optimal Care of the Injured Patient* (2014).

Consistent with STAC's recommendation, the Department advised the 40 hospitals designated as trauma centers that the Department intended to make compliance with ACS-COT standards a requirement of designation, and the Department advised those hospitals to contact the ACS-COT to schedule a consultation site visit. To date, twenty-nine (29) hospitals have received verification from the American College of Surgeons, and the remaining hospitals are in the process of scheduling their verification survey visits. While completing the ACS-COT verification site visit process, all currently designated trauma centers retain their designation and continue to receive trauma patients.

In March 2013, the Department advised that those hospitals seeking trauma center designation for the *first* time should contact the ACS-COT by May 2015 to schedule a consultation site visit, and that within two years of a final consultation site visit, request a verification site visit. This initial timeline was established to facilitate advance compliance with the regulations now being proposed. The Department advised those facilities seeking trauma care designation for the first time that, prior to their consultation site visit, the facility must have in place: a trauma service, a trauma medical director, a trauma program manager, a hospital-based trauma registry, 9-12 months of trauma data, and a performance improvement process of some kind. To date, four (4) hospitals have been provisionally designated in anticipation of receiving verification. One of the provisional hospitals completed the verification survey and has been verified as a Level III trauma center and has received its designation from the

Commissioner. Trauma care requires significant resources and highly trained staff with expertise in caring for severely injured patients. The ACS-COT has set the standard for caring for trauma patients since 1922 when the ACS-COT was created. The ACS-COT standards are national standards which are updated regularly to reflect current trends and evidence-based practice. The current ACS-COT publication entitled *Resources for the Optimal Care of the Injured Patient* was published in 2014 and is the edition which is being incorporated by reference in these regulations. The ACS-COT conducts surveillance of trauma centers in three-year cycles to verify that a facility is still capable of providing its verified level of trauma care.

The Department's current regulations allow for only two levels of trauma center: Regional and Area trauma centers. In keeping with the ACS-COT standards, the proposed regulations would allow the Department to designate four levels of trauma centers. The addition of two more levels of trauma centers will strengthen the state's trauma system and include facilities in underserved area of the state.

These regulations will not preclude non-designated hospitals from caring for patients with minor trauma. It is expected, however, that those hospitals will transfer all seriously injured trauma patients – those patients at high risk of death or disability from multiple and severe injuries – to designated trauma centers. Emergency Medical Services (EMS) protocols already dictate that trauma patients be transported to the highest level of care within a region's trauma system.

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

Costs incurred by those hospitals voluntarily seeking trauma center designation would include the cost of a consultation site visit and verification site visit. The cost for a consultation site visit is approximately $15,000, while the cost for a verification site visit, including a nurse reviewer, is approximately $16,000. Verification must be completed every three years. Hospitals may also incur costs associated with the hiring of additional trauma surgeons, trauma registrars and an injury prevention coordinator. The average salary of a board-certified trauma surgeon is approximately $304,500. The average salary of a nurse manager is $62,840. The average salary for an injury prevention coordinator (or "health educator") is $47,812.

The total costs per institution will vary depending on the resources already at hand. For current trauma hospitals, review and update of a hospital's trauma policies and procedures could be accomplished with existing staff, imposing little or no additional cost. Those hospitals seeking trauma designation for the first time may need to create a full-time position for a trauma program manager. For those facilities seeking a new Level II designation, this new trauma program manager may also co-ordinate injury prevention activities. This position may be filled by someone currently employed by the hospital, or the hospital could choose to hire a new employee. Level I facilities must also have an injury prevention coordinator.

Designated trauma centers are already required to maintain a hospital-based trauma registry which captures information pertaining to the patient's injury, pre-hospital care, Emergency Department care, hospital care and outcome information so that the hospital can submit information to the New York State Trauma Registry. ACS-COT standards require trauma data submission to the National Trauma Data Bank (NTDB) (a minimum of 80% of cases

entered within 60 days of discharge) and the periodic monitoring of data validity. The New York State Trauma Registry "data dictionary" already incorporates the ACS-COT National Trauma Data Bank (NTDB) data elements along with 22 data elements specific to New York. At the state level, each record receives a unique identifier to protect patient confidentiality. Registry information is stored on a protected server with highly limited access.

The ACS-COT currently recommends one registrar for every 750-1,000 patients entered into the registry. Currently designated trauma centers, which already maintain a hospital-based trauma registry, may need to hire an additional registrar to meet these registry standards. The "average" salary for a "registrar" is $37,828. According to one of the vendors currently supporting the New York State Trauma Registry, for those facilities pursuing designation as a trauma center for the first time, the average cost of purchasing the software necessary to begin a hospital-based trauma registry is approximately $5,000 - 10,000, and the annual cost for maintaining such registry is approximately $2,000 - 3,000.

The goal of the New York State Trauma Registry is to capture all data for trauma patients cared for in the state. For those non-designated hospitals that occasionally receive trauma patients, there will be a mechanism for capturing an abbreviated set of data elements. The mechanism for submitting an abbreviated subset of trauma data is expected to be offered free of charge. For the small numbers of trauma patients expected at these facilities, entry of trauma data can be accomplished by existing staff and should not require additional hiring.

Those hospitals that will be caring for pediatric trauma patients must also ensure that their equipment is age and size appropriate.

Cost to State and Local Government:

There are no additional costs to State and local governments to implement this regulation. Existing staff will be utilized to conduct surveillance of the regulated parties and monitor compliance with these provisions.

Cost to the Department of Health:

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

Local Government Mandates:

There are no additional programs, services, duties or responsibilities imposed by this rule upon any county, city, town, village, school district, fire district or any other special district.

Paperwork:

Hospitals may need to develop or revise written trauma policies and procedures, including trauma activation criteria and procedures, a massive transfusion protocol, a difficult airway management policy, trauma diversion policy, performance improvement processes and activities, transfer agreements and trauma data analysis. Hospitals seeking trauma center designation will need to complete an application for their consultation and verification site visits, along with a pre-review questionnaire.

Duplication:

This regulation will not duplicate any state or federal rules.

Alternative Approaches:

ACS-COT sets the national standard of care for trauma patients. Adopting any other standards would be contrary to good medical practice. Moreover, leaving the regulations unchanged would subject trauma centers, and their patients, to outdated standards that would also be contrary to good medical practice. These regulatory changes ensure that trauma centers are subject to the most up-to-date standards.

Federal Requirements:

This regulation will not conflict with any federal rules.

Compliance Schedule:

This proposal will go into effect upon a Notice of Adoption in the New York *State Register*.

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REGULATORY FLEXIBILITY ANALYSIS

FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

This regulation will apply to the 228 general hospitals in New York State that either have or would seek trauma center designation. Currently, there are 40 designated trauma centers in New York State, four of which are operated by local government.

Compliance Requirements:

There are no additional programs, services, duties or responsibilities imposed by this rule upon any county, city, town, village, school district, fire district or any other special district. Hospitals would only need to comply with these regulations if they choose to become trauma centers.

Professional Services:

Most currently designated trauma centers already employ an adequate number of trauma surgeons, a trauma program manager and a registrar, and several hospitals already employ an injury prevention coordinator. Some currently designated trauma centers may need to hire additional trauma registrars to comply with the ACS-COT standards regarding data submission. Some facilities may need to hire additional surgeons. Newly designated trauma centers will likely need to hire a trauma program manager and trauma registrar.

Compliance Costs:

Costs incurred by those hospitals voluntarily seeking trauma center designation would include the cost of a consultation site visit and verification site visit. The cost for a consultation site visit is approximately $15,000, while the cost for a verification site visit, including a nurse reviewer, is approximately $16,000. Verification must be completed every three years. Hospitals may also incur costs associated with the hiring of additional trauma surgeons, trauma registrars and an injury prevention coordinator.

The total costs per institution will vary depending on the resources already at hand. For current trauma hospitals, review and update of a hospital's trauma policies and procedures could be accomplished with existing staff, imposing little or no additional cost. Those hospitals seeking trauma designation for the first time may need to create a full-time position for a trauma program manager. For those facilities seeking a new Level II designation, this new trauma program manager may also co-ordinate injury prevention activities. This position may be filled by someone currently employed by the hospital, or the hospital could choose to hire a new employee. Level I facilities must also have an injury prevention coordinator.

Designated trauma centers are already required to maintain a hospital-based trauma registry which captures information pertaining to the patient's injury, pre-hospital care, Emergency Department care, hospital care and outcome information so that the hospital can submit information to the New York State Trauma Registry. ACS-COT standards require trauma data submission to the National Trauma Data Bank (NTDB) (a minimum of 80% of cases entered within 60 days of discharge) and the periodic monitoring of data validity. The New York State Trauma Registry "data dictionary" already incorporates the ACS-COT National Trauma Data Bank (NTDB) data elements along with 22 data elements specific to New York.

At the state level, each record receives a unique identifier to protect patient confidentiality. Registry information is stored on a protected server with highly limited access.

The ACS-COT currently recommends one registrar for every 750-1,000 patients entered into the registry. Currently designated trauma centers, which already maintain a hospital-based trauma registry, may need to hire an additional registrar to meet these registry standards. According to one of the vendors currently supporting the New York State Trauma Registry, for those facilities pursuing designation as a trauma center for the first time, the average cost of purchasing the software necessary to begin a hospital-based trauma registry is approximately $5,000 - 10,000, and the annual cost for maintaining such registry is approximately $2,000 - 3,000.

The goal of the New York State Trauma Registry is to capture all data for trauma patients cared for in the state. For those non-designated hospitals that occasionally receive trauma patients, there will be a mechanism for capturing an abbreviated set of data elements. The mechanism for submitting an abbreviated subset of trauma data is expected to be offered free of charge. For the small numbers of trauma patients expected at these facilities, entry of trauma data can be accomplished by existing staff and should not require additional hiring.

Those hospitals that will be caring for pediatric trauma patients must also ensure that their equipment is age and size appropriate.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

Trauma center designation is voluntary. Those hospitals that do not wish to care for trauma patients will not need to comply with this regulation.

In May 2012, the Department advised currently designated trauma centers that it intended to make compliance with ACS-COT standards a requirement of designation and advised those hospitals to contact the ACS-COT to schedule a consultation site visit by May 2013. Following receipt of their final consultation site visit report, those centers have two years in which to schedule a verification site visit. In March 2013, the Department advised those hospitals seeking trauma center designation for the first time that they should contact the ACS-COT by May 2015 to schedule a consultation site visit and within two years following receipt of their final consultation site visit report to request a verification site visit. The Department has also advised these hospitals that, prior to having a consultation site visit, they should have in place: a trauma service, a trauma medical director, a trauma program manager, a hospital-based trauma registry, 9-12 months of trauma data and a performance improvement process of some kind. In this way, the Department has sought to facilitate compliance with these regulations in advance of their proposal.

Small Business and Local Government Participation:

The Department has conducted outreach to the affected parties. The State Trauma Advisory Committee (STAC) has discussed and reviewed this proposal during open, webcast meetings, and the Department has shared this proposal with the Greater New York Hospital

Association (GNYHA) and the Healthcare Association of New York State (HANYS). Organizations that represent the affected parties are also given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

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.

RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment that it will not impose any adverse impact on rural areas, and the rule does not impose any reporting, recordkeeping or other compliance requirements on public or private entities specific to rural areas as participation in the trauma system is voluntary

JOB IMPACT STATEMENT

These provisions will not have a significant impact on jobs. Currently designated trauma centers have been required to have a trauma program director, trauma program manager, trauma registrar and an injury prevention coordinator. Many may be required to hire an additional trauma registrar to maintain ACS-COT standards regarding data abstraction and submission, and some will need to hire additional trauma surgeons to manage their current trauma census and performance improvement responsibilities.