

Controlled Substances for EMS Agency Agent and Requirements for an Advanced Life Support System

Effective date: 7/20/16

Pursuant to the authority vested in the New York State Emergency Medical Services Council and subject to the approval of the Commissioner of Health pursuant to section 3002 of the Public Health Law, sections 80.136 and 800.5 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, to read as follows:

Paragraph (2) of subdivision (e) of section 80.136 of Part 80 is amended to read as follows:

(2) The Department shall issue such registration unless the Department finds that the application should be denied by reason of false statements in the application, [conviction of a felony,] failure to provide adequate safeguards against diversion of the controlled substances, [any conviction related to controlled substances, or] other good and sufficient reason such as an administrative determination that article 30 or 33 of the Public Health Law [or any provision within Part 800 of this Title or any provision within this Part] was violated, or conviction of one or more criminal offenses, as defined in section 800.3(ak), unless the applicant is found eligible after a balancing of the factors set out in Article 23-A of the Correction Law. In accordance with that Article, no application for registration shall be denied by reason of the applicant having been previously convicted of one or more criminal offenses unless (i) there is a direct relationship between one or more of the previous criminal offenses and duties required of the registration or (ii) registering the applicant would involve an unreasonable risk to property or the safety or welfare of a specific

individual or the general public. In determining these questions, the department will look at all factors listed under New York State Correction Law section 753.

Section 800.5 of Part 800 is amended to read as follows:

800.5 Requirements For An Advanced Life Support System

(a) An advanced life support system must meet the following requirements:

- (1) designation of a qualified physician to provide medical supervision and direction; and
- (2) integration with a hospital emergency service, or intensive care, coronary care, or other appropriate hospital unit.

(b) An ambulance or advanced life support first response service, when providing advanced life support services, must meet the requirements of Sections 800.23 and 800.24 of this Part and utilize a treatment record provided by or approved by the department, including submission of such record for use in quality assurance programs.

(c) An advanced life support system providing prehospital [intermediate] Advanced EMT care must include the following:

- (1) voice communications to receive medical direction;
- (2) equipment and supplies to provide prehospital [intermediate] advanced care; and

(3) staffing by a certified advanced emergency medical technician [technician-intermediate], emergency medical technician-critical care, or emergency medical technician-paramedic, as appropriate.

(d) An advanced life support system providing prehospital EMT- critical care and/or EMT-paramedic services must include the following:

(1) voice communications to receive medical direction;

(2) biomedical telemetry;

(3) equipment and supplies to provide pre-hospital critical care and/or EMT-paramedic services; [and]

(4) a current class 3(c) institutional dispenser limited license, in accordance with Article 33 of the Public Health Law and section 80.136 of this Title, unless exempt as an ALS agency owned and operated by a hospital, to purchase, possess, deliver and administer controlled substance medications to treat patients, in accordance with applicable State-approved regional protocols developed pursuant to sections 3002-a and 3004-a of the Public Health Law; and

[(4)] (5) staffing by a certified emergency medical technician-critical care or emergency medical technician-paramedic, as appropriate.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of this regulation is contained in Public Health Law (PHL) Article 30 (Emergency Medical Services), Section 3002, as well as Article 33 (Controlled Substances), Sections 3308 and 3390. Section 3002 sets forth the provisions creating the New York State Emergency Medical Services Council (SEMSCO) and specifies that it shall have the power, by an affirmative vote of a majority of those present, subject to approval by the Commissioner, to enact, and from time to time, amend and repeal, rules and regulations establishing minimum standards for ambulance services, ambulance service certification, advanced life support first response services, the provision of prehospital emergency medical care, public education, the development of a statewide emergency medical services system, the provision of ambulance services outside of the primary territory specified in the ambulance services' certificate and the training, examination, and certification of certified first responders, emergency medical technicians, and advanced emergency medical technicians; provided, however that such minimum standards must be consistent with the staffing standards established by the ambulance services and advanced life support first response services provisions outlined in PHL Section 3005-a.

PHL 3308 authorizes the Commissioner to promulgate regulations which are necessary and proper to supplement the provisions of Article 33 to effectuate its purposes and intent.

Additionally, PHL 3390 authorizes the Commissioner to revoke a license or certificate issued under Article 33 in whole or in part upon a finding that the licensee or certificate holder has been convicted in any jurisdiction relating to a substance listed as a controlled substance in Article 33.

Legislative Objectives:

The purpose of PHL Article 30 is to promote the public health, safety and welfare by providing certification for pre-hospital care providers and all advanced life support first response and ambulance services. The purpose of PHL Article 33 is to prevent the illegal use of and trade in controlled substances and to provide for the legitimate use of controlled substances in health care.

Needs and Benefits:

The revisions to Section 800.5 add a requirement that Advanced Life Support (ALS) agencies providing Critical Care and/or Paramedic level service must be licensed, in accordance with PHL Article 33 and Title 10 NYCRR Part 80.136, to purchase, possess, deliver and administer controlled substance medications as per state approved regional protocols. The State Emergency Medical Advisory Committee (SEMAC), the advisory board to the Commissioner of Health, and the SEMSCO have recognized that the ability to provide a patient with controlled substance medications when indicated is the national standard for ALS prehospital emergency medical care. At present, there are 675 ALS EMS agencies in New York State. Of the 675 ALS EMS agencies, 522 already hold current controlled substances licenses under PHL Article 33. This

revision will currently affect the remaining 153 agencies and any newly established advanced life support level EMS agency. Agencies that do not seek licensure to purchase, possess, deliver and administer controlled substances in accordance with PHL Article 33 Section 800.5 would be authorized to apply for and provide care only at the Advanced EMT level. Agencies that operate at the Advanced EMT level are allowed to perform advanced airway management and some medication for emergency treatment for diabetics and allergies, but does not allow advanced medication therapy.

An ALS EMS agency's ability to administer controlled substance medication to patients during prehospital emergency care is of significant benefit to the patient. Controlled substance medications may be used to treat seizures, medical anxiety, profound agitation and excited delirium, as well as pain prior to arrival at a hospital.

For example, prehospital medical protocols to allow ALS providers to use benzodiazepines for seizure management have been a mainstay of EMS care in much of the State for many years. Indeed, when the National Association of EMS Physicians first examined prehospital care standards in 2008, they carefully considered the ability to provide timely treatment of seizures. (Evidence Based Performance Measures for EMS Systems, Prehospital Emergency Care, 2008;12:141-51.) Patients experiencing prolonged or continuous seizures -- seizures that do not stop rapidly on their own -- can develop subtle brain damage; brain damage that may have been prevented by administration of a benzodiazepine such as midazolam or diazepam. In addition, management of seizures in the field makes transportation safer for both the patient and the EMS providers.

Furthermore, on January 14, 2015, the SEMAC and SEMSCO authorized an update to the EMS protocols for the City of New York to recommend access to the benzodiazepine (midazolam) for the treatment of patients with excited delirium. Excited delirium is a condition that manifests as a combination of delirium, psychomotor agitation, anxiety, hallucinations, speech disturbances, disorientation, violent and bizarre behavior, insensitivity to pain, elevated body temperature, and superhuman strength. Excited delirium can result in sudden death (usually via cardiac or respiratory arrest) when the patient is subjected to physical control measures, including police restraint. ("White Paper Report on Excited Delirium Syndrome", ACEP Excited Delirium Task Force, American College of Emergency Physicians, September 10, 2009). Rapid chemical sedation of patients with excited delirium may prevent such outcomes and would allow EMS to assist law enforcement effectively in the care of people in crisis.

Pain management is the standard of care for patients suffering acute traumatic injury. (ATLS 9th Ed.) Early treatment of pain improves care in the emergency department and reduces the need for higher doses of medication. The Joint Commission: Accreditation, Healthcare, Certification (Joint Commission) has made early administration of pain medication a goal of its hospital surveys and prehospital pain management reduces the time to emergency department analgesia significantly. Also, for patients suffering heart attacks, early pain management reduces the oxygen demand on the heart and may reduce long-term damage and morbidity. (Circulation 12/13/05, vol 112, no 24, p IV-98 for reduction of oxygen demand.)

Critical care technicians and paramedics train to use complex medications as a part of the delivery of care. The agencies and the medical directors authorizing these providers to afford

patient care must have access to controlled substances to provide necessary medical therapy to best protect the health of their patients.

The proposed regulation also amends section 80.136 of Part 80 related to the issuance of certifications to agents of advanced life support agencies. Section 80.136 is updated to incorporate Correction Law Article 23-A's balancing test when reviewing applications to register an agent to purchase, possess, and deliver controlled substances, and specifies that the factors set forth in Correction Law § 753 will be utilized when making a determination whether to grant the application to an applicant who has a criminal conviction.

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

There is a fee of \$100 for the original application and each renewal thereafter. Municipally owned EMS agencies are exempt from the application fee. Affected EMS agencies will be required to purchase the controlled substance medications and develop a method of securing them in the vehicles and the base of operations as required by Title 10 NYCRR Part 80.136. This cost will vary depending on the cost of the medications and the locking system chosen by the EMS agency.

Cost to State and Local Government:

There will be no costs to the general public, state and local government. These regulations are directed at the advanced life support level EMS agency. An EMS agency that is part of state or local municipal government is exempted by regulation from the application fee.

Cost to the Department of Health:

The Department of Health will not incur any additional costs.

Local Government Mandates:

These regulations are directed at the advanced life support level EMS agency. An EMS agency that is part of state or local municipal government is exempted by regulation from the application fee. To obtain and maintain an ALS license, local municipal government agencies will have to hold a current class 3(c) institutional dispenser limited license.

Paperwork:

Affected EMS agencies will need to apply for a Controlled Substance license through the Department of Health.

Duplication:

This measure does not duplicate, overlap or conflict with a State or federal statute or rule.

Alternative Approaches:

There are no other viable alternative approaches. Current provisions must be updated to reflect appropriate EMS standards and practice.

Federal Requirements:

This regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas. This proposal is intended to update Part 800 provisions with language appropriate and applicable to the modern EMS system.

Compliance Schedule:

This proposal will go into effect upon publication of the 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:

With respect to small businesses, the amendment will affect only those that are also certified advanced life support (ALS) ambulance or advanced life support first response emergency medical service agencies as defined by Article 30 of the New York State Public Health Law. With respect to local governments, the amendment will only affect those that are also certified ambulance or advanced life support first response emergency medical service agencies as defined by Article 30 of the New York State Public Health Law.

Compliance Requirements:

Small businesses and local governments must comply if they are certified advanced life support (ALS) ambulance or advanced life support first response emergency medical service agencies as defined by Article 30 of the New York State Public Health Law.

In order to comply with Title 10 NYCRR Part 80.136, these agencies must apply to the Department of Health to obtain a Controlled Substance License for EMS Agencies. This includes completing specific forms provided by the Department and developing policies and procedures that detail the medical direction, service management, personnel responsibilities, purchase, inventory storage and security, and patient administration and the quality assurance process. In order to maintain the license, the EMS agency must renew every two years using an abbreviated process.

Professional Services:

Small businesses and local governments that are certified advanced life support (ALS) ambulance or advanced life support first response emergency medical service agencies will need no additional professional services to comply.

Compliance Costs:**Costs to Private Regulated Parties:**

The regulation will present a cost for the application process (\$100, however this may be waived for municipal entities), medication and security system. This is dependent upon how the EMS agency chooses implement its own controlled substance program. At present, none of the controlled substance medications commonly carried by currently licensed EMS agencies exceeds \$6.00 per single unit. Securing these medications both on vehicles and in EMS stations may range from a small amount of money to several thousand dollars, depending on the EMS service and medical director's preference.

Costs to State Government and Local Government:

There will be no additional cost to State government.

Economic and Technological Feasibility:

There will be a minimal impact on small businesses that are currently certified advanced life support (ALS) ambulance or advanced life support first response emergency medical service agencies that have yet to obtain a controlled substance license. The regulation will present a cost for the application process (\$100, however this may be waived for municipal entities),

medication and security system used to secure medications. The cost and impact are dependent upon how each EMS agency chooses to implement its own controlled substance program.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing consultation, coordination and information and updates on its website.

Small Business and Local Government Participation:

The Department received comments during the notice and comment period, and took those comments into consideration when developing this regulation.

Cure Period:

The intent of this regulatory amendment is to ensure that patients whose prehospital injury or illness is best treated with controlled substances may receive such lifesaving medications. The ability for an advanced life support EMS agency to administer this class of medication is a standard of care for the ALS level of service, and the Department is satisfied that the benefits to the public outweigh any cost. Violations of such standards would pose a threat to public health, safety and well-being of the patients served. For those EMS agencies not willing to obtain a license, it is expected that they would remain an active part of the EMS response system, as basic life support ambulance services.

RURAL AREA FLEXIBILITY ANALYSIS

Pursuant to section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.

JOB IMPACT STATEMENT

Nature of Impact:

The proposed rule will have minimal or no impact on jobs. Some current ambulance agencies employ part time staff to provide ALS level of care without a controlled substance license. These agencies would have to continue to employ EMS staff regardless of the level of care they provide. The ambulance services that employ larger numbers of EMS providers are unaffected as they already hold controlled substance licenses.

ASSESSMENT OF PUBLIC COMMENT

Public comments were submitted to the NYS Department of Health (DOH) in response to the proposed changes to Title 10 NYCRR Part 800.5 requiring EMS agencies to obtain a license issued by the Department of Health to possess and administer controlled substance medication per approved regional protocols. The Department received comments from four groups representing the EMS community in Nassau County and the American College of Emergency Physicians. Many of the comments were the same or similar. These comments and the Department of Health's responses are summarized below:

A letter was received via email from a paramedic with the following comments:

COMMENT: The paramedic expressed concern that 45 days would not be enough time for the unlicensed EMS agencies to come into compliance.

RESPONSE: In January 2013, the State Emergency Medical Advisory Committee (SEMAC) resolved that EMS agencies providing advanced life support obtain a controlled substance license. Since that time, the affected advanced life support (ALS) EMS agencies have been working towards compliance with the SEMAC decision as well as this anticipated regulatory amendment. At present, there are a total of 1,150 certified EMS agencies in New York State, of which 582 EMS agencies will be affected by this regulatory amendment. Currently, 456 agencies are already in compliance, leaving 126 services that will have to obtain controlled substance licenses if they choose to continue to provide ALS level of care. The Department

believes that, given this background, 45 days provides sufficient additional time to come into compliance.

COMMENT: The paramedic also suggested that the regulation should clearly indicate that EMS agencies obtain the controlled substance license, not individual providers.

RESPONSE: The Department agrees that, under Article 33 of the NYS Public Health Law, a Controlled Substance License is issued to an EMS agency, not an individual certified EMS provider. The Regulatory Flexibility Analysis was revised to clarify this.

Multiple commenters submitted the following comments:

COMMENT: The section concerning the Cure Period in the Regulatory Flexibility Analysis for Small Business and Local Governments states “Violations of such standards would pose a threat to public health, safety and well-being of the patients served.” Commenters asserted that requiring Controlled Substance licensure actually creates a larger risk to public safety because ambulance services that refuse or cannot comply will no longer be available to provide ALS level care.

RESPONSE: The intent of this regulatory amendment is to ensure that patients whose prehospital injury or illness is best treated with controlled substances may receive such lifesaving medications. The ability for an advanced life support EMS agency to administer this class of medication is a standard of care for the ALS level of service, and the Department is satisfied that the benefits to the public outweigh any cost. For those EMS agencies not willing to obtain a

license, it is expected that they would remain an active part of the EMS response system, as basic life support ambulance services.

COMMENT: Multiple commenters raised concerns that the application process and record keeping burden are not adequately articulated in the Paperwork section the Regulatory Impact Statement.

RESPONSE: It appears that many commenters misinterpreted the Regulatory Impact Statement. Many of the forms listed in the commenters' letters were provided for convenience by the Department, as samples of what could be required in different applications. The actual number of forms required for each particular application will generally be far less.

COMMENT: Multiple commenters stated that, contrary to the Regulatory Flexibility Analysis, the regulation will have an effect on small business and local government, specifically commercial and volunteer ambulances.

RESPONSE: At present, there are at total of 1,150 certified EMS agencies in New York State, of that 582 EMS agencies will be affected by this regulatory amendment. Currently, 456 agencies are already in compliance, leaving only 126 services that will have to obtain controlled substance licenses if they choose to continue to provide ALS level of care. The Regulatory Flexibility Analysis has been revised accordingly.

COMMENT: Multiple commenters expressed concern that the Job Impact Statement does not reflect the possibility that, if an agency does not obtain a license and downgrades the level of care provided, providers may have to lay off advanced certified staff.

RESPONSE: The Department agrees that the regulations may affect a small number of individuals if their EMS agency chooses not to obtain a controlled substance license. However, many of the unlicensed agencies are volunteer fire department-based ambulance services, which would not be affected. The Job Impact Statement has been revised accordingly.

COMMENT: Multiple commenters asked for an explanation as to why, for regions that do not have protocols to obtain, stock and administer controlled substance medications, EMS agencies should be required to hold controlled substance licenses. They further commented that Regional Emergency Medical Advisory Committees (REMACs) are authorized to develop protocols that address specific local conditions. Commenters asserted that the proposed regulation would conflict with the authority of REMACs to develop such protocols.

RESPONSE: The State Emergency Medical Advisory Committee (SEMACE) sets statewide minimum standards for treatment, transportation and triage protocols for the provision of prehospital EMS care by certified providers and agencies. The SEMACE reviews and approves regional EMS protocols, which must be consistent with the SEMACE's standards. This regulatory amendment was submitted at the request of the SEMACE membership. Additionally, these regulations are well within the regulatory authority of the State Emergency Medical Services Council.

COMMENT: Multiple commenters raised concerns regarding the initial cost for implementation and the cost to remain in continuing compliance with these regulations. The commenters asserted that the evaluation of costs in the Regulatory Impact Statement is misleading and that there will be significant expense to the EMS agencies affected by this amendment.

RESPONSE: While there will be cost for the medication and security system, these depend on how each EMS agency chooses to implement its own controlled substance program. At present, none of the controlled substance medications commonly carried by currently licensed EMS agencies exceeds \$6.00 per single unit. Securing these medications both on vehicles and in EMS stations may range from a small amount of money to several thousand dollars, depending on the EMS service and medical director's preference. The Regulatory Impact Statement was revised accordingly.

The Nassau County Regional EMS Council (REMSCO) submitted written comments as follows:

COMMENT: The REMSCO stated a concern that having controlled substance medications on the ambulance in their county "will inevitably lead to break-ins of parked ambulances."

RESPONSE: The Department has not received any reports of ambulances being broken into for their controlled substance medications. The Department will continue to monitor this concern but, at present, it is satisfied that the benefit of EMS ALS agencies possessing these medications outweighs the costs.

COMMENT: The REMSCO disputes the section in the Regulatory Impact Statement entitled Local Government Mandate, which states: "These provisions do not add any additional mandates to local government."

RESPONSE: If the EMS agency is owned by a local government, the Department agrees that these provisions add minimal cost to maintain an ALS license. However, the Department is

satisfied that the benefit of EMS agencies possessing these medications outweighs the costs. The Local Government Mandate section was revised accordingly.

The Association of Fire Districts of Nassau County, the Nassau County Fireman’s Association, the Fire Chief’s Council of Nassau County, the Nassau County Fire Commission, Vocational Education and Extension Board of EMS Nassau County and the Executive Council of Firematic Association of Nassau County collectively submitted the following comments:

COMMENT: The commenters generally comment that they “agree with the essence of the proposed regulation, which is the ability to provide patients with controlled substance medications when indicated; however, the practicality of providing the narcotics, under this manner, will immediately and severely impact the 1.4 million residents of Nassau County.”

RESPONSE: The Department respectfully disagrees. This regulatory amendment will improve the level of prehospital emergency medical care available to the 1.4 million residents of Nassau County, and across the State of New York.

COMMENT: The commenters generally recommend that the regulation be amended to allow controlled substances to be provided by alternative means such as “Mutual Aid / Dual Response / ALS Intercept”. The commenters requested that ALS agencies not be downgraded to BLS if they do not get a controlled substances license.

RESPONSE: The State Emergency Medical Advisory Committee (SEMAC) reviewed this issue and determined that such alternatives means were based on the service being provided by

neighboring agencies. The SEMAC's physicians were concerned that there would be a delayed response or the neighboring agency would be unavailable. The Department agrees with the SEMAC that these alternatives are not sufficiently reliable.

COMMENT: The Nassau County Executive wrote a letter on behalf of the Association of Fire Districts of Nassau County and the Nassau County Fire Commission, requesting that the Department of Health amend its 2013 policy statement requiring ALS EMS agencies to obtain a Controlled Substance License and be able to administer controlled substance medication to patient's requiring these medications.

RESPONSE: The Department suspended the policy statement at the end of 2014.

COMMENT: The Department received a letter from the New York – American College of Emergency Physicians (ACEP), located in Webster, NY (Monroe County), in support of the proposed changes to the Part 800 regulations.

RESPONSE: The Department acknowledges that the letter states that the ability to control seizures and manage pain is an essential component of advanced prehospital care. The Department concurs with the ACEP's opinion that the use of controlled substances for these purposes have been proven both safe and highly effective and should be considered the standard of care for paramedic and critical care technicians practicing in New York State.