SUMMARY OF EXPRESS TERMS

The proposed rulemaking would repeal and replace sections 800.24, 800.25 and 800.26 of Title 10 of the New York Codes, Rules and Regulations (10 NYCRR) pertaining to Emergency Medical Services equipment requirements for certified ambulance and emergency ambulance service vehicles.

Section 800.24, pertaining to equipment requirements for certified ambulance services, is repealed and replaced to consolidate minimum equipment requirements contained in current sections 800.24 and 800.26. It also expands minimum equipment standards to current industry best practices, defines the requirements for advanced life support equipment on a basic life support vehicle, clarifies how advanced life support equipment must be stored and addresses the required proficiency of all providers operating or using equipment and provides the guidance for basic life support (BLS) providers who are operating on a vehicle with advanced life support (ALS) equipment standards.

Section 800.25, pertaining to special use vehicles, is repealed and replaced. The new section sets forth the process for emergency medical service agencies to obtain a regulatory waiver from the Department for special circumstances that render compliance with the regulations unreasonable, burdensome, or impractical, or where compliance would result in impediment of emergency medical services. The section sets forth the limited nature of such waivers and the criteria the Department will use to determine whether to grant a waiver.

Section 800.26, pertaining to equipment requirements for emergency ambulance service vehicles other than an ambulance, is repealed and replaced. The new section sets forth build standards for emergency ambulance service vehicles that reflect current industry standards. It also includes

newly required safety equipment such as camera systems that record certain driving events, guidance for securing all equipment in the patient compartment, reverse driving safety mechanisms, and anti-theft devices for when the vehicle is idling.

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, Part 800 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 800.24 is hereby REPEALED and replaced to read as follows:

§ 800.24 Equipment requirements for certified ambulance services and emergency ambulance service vehicles.

(a) All vehicles in a certified ambulance service, basic life support first response service, basic life support emergency ambulance service vehicles, and advanced life support first response service, shall be equipped with the following, unless otherwise exempted or pursuant to a waiver obtained in accordance with section 800.25 of this Part. Table 1 outlines the equipment standard for Basic Life Support First Response vehicles (BLS FR), Ambulance vehicles (Ambulance), Basic Life Support – Emergency Ambulance Service Vehicles (BLS EASV) and Advanced Life Support – First Response vehicles (ALS FR):

Table 1

	Item(s)	**Minimum Quantity**			
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(a)	**Patient Transfer Equipment:**				
	(1) Wheeled ambulance cot capable of supporting patients in the Fowlers position.	N/A	1	N/A	N/A
	(2) A second rigid device capable of carrying a recumbent patient. Examples include a scoop	N/A	1	N/A	N/A

	stretcher, a backboard, and flexible stretchers with integrated support.				
	(3) A device enabling ambulance personnel to carry a sitting patient over stairways and through narrow spaces where a rigid device (referenced in paragraph (2), above) cannot be used. The requirements of paragraphs (2) and (3) of this subdivision may be satisfied by use of one combination device capable of both operations.	N/A	1	N/A	N/A
	(4) All devices used to move or transport patients shall be secured using crash resistant fasteners.	N/A	1	N/A	N/A
	(5) All devices used to move or carry patients shall be equipped with safety restraints as recommended by the device manufacturer. In the absence of manufacturer guidance, any device used to move or carry a patient shall at least be equipped with three, two-inch wide web straps with fasteners to secure the patient to the device.	N/A	1	N/A	N/A
	(6) Age and / or size-appropriate restraint systems for patients 10lbs to 400lbs transported in ground ambulances. For children, this should be according to the National Association of State EMS Officials "Pediatric Transport Products for Ground Ambulances" Version 2.2 (October, 2020).This document is incorporated by reference in section 800.24 (b) of this Part.	N/A	1	N/A	N/A
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(b)	**<u>Airway and Oxygen Equipment/ Sudden Cardiac Arrest Resuscitation Equipment:</u>**				
	(1) A manually operated self-refilling adult-size bag valve mask ventilation device capable of operating with oxygen enrichment and clear adult-size mask with air cushion.	1	1	1	1
	(2) Oropharyngeal Airways in Size 0 (50mm), Size 1 (60mm), Size 2 (70mm), Size 3 (80mm), Size 4 (90mm), Size 5 (100mm), and Size 6 (110mm).	1 of each	1 of each	1 of each	1 of each
	(3) Nasopharyngeal Airways in sizes 20 fr, 24 fr, 28 fr, and 32 fr.	1 of each	1 of each	1 of each	1 of each
	(4) FDA Approved Pulse Oximetry device with pediatric and adult sensors.	1	1	1	1

	(5) Portable oxygen with a minimum 350-liter capacity (medical "D" size) with pressure gauge, regulator and flow meter and one spare cylinder, medical "D" size or larger. The oxygen cylinders must contain a minimum of 1000 PSI pressure.	1 of each	1 of each	1 of each	1 of each
	(6) An in-ambulance oxygen system with a minimum 1200-liter capacity (two medical "E" size) with yoke(s), or CDC fitting, pressure gauges, regulators, and flow meters capable of delivering oxygen to two patients at two different flow rates of up to 15 liters per minute simultaneously. If a liquid oxygen system is used, manufacturer documentation must be provided that the system has at least a 1,200-liter capacity.	N/A	1	N/A	N/A
	(7) Adult partial non-rebreather oxygen masks and adult nasal cannulas.	1 of each	4 of each	1 of each	1 of each
	(8) Battery operated, portable suction equipment capable, according to the manufacturer's specifications, of producing a vacuum of over 300 millimeters of mercury when the suction tube is clamped. This will meet the requirement of paragraph (10), below, of this section if equipped to operate off the ambulance electrical system.	1 -BLS FR may use FDA approved manual device	1	1	1
	(9) Installed adjustable suction capable of producing a vacuum of over 300 millimeters of mercury when tube is clamped. A Powered Portable suction unit may serve as an installed unit if it operates on vehicle power, the unit can serve as a portable suction unit as long as it operates on battery power.	N/A	R	N/A	N/A
	(10) Rigid plastic wide bore pharyngeal tips individually wrapped. Examples include, but not limited to, Yankauer, DuCanto, and Hi-D.	Optional	2	2	2
	(11) Soft sterile suction catheters in at least two adult sizes.	1 each	1 each	1 each	1 each
	(12) Automated External Defibrillator with equipment (multiple sets of pads, attenuator, key, etc.) necessary to provide defibrillation for both adult and pediatric patients.	1	1	1	1
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(c)	**Immobilization and Trauma Patient Management Equipment**				

	(1) Full size (at least 72 inches long and 16 inches wide) fluid impermeable backboard with necessary straps, as noted in Patient Transfer Equipment paragraph (5), capable of restricting spinal motion of a recumbent patient; may substitute any acceptable device that satisfies the requirements of Patient Transfer Equipment paragraph (2).	N/A	1	N/A	N/A
	(2) Half-length fluid impermeable spinal immobilization device with necessary straps capable of restricting spinal motion of a sitting patient.	Optional	1	1	1
	(3) Traction splinting device for the lower extremity.	Optional	1	Optional	Optional
	(4) Devices in at least two sizes capable of securing injured joints or extremities in fixed position. Examples include: padded board splint, cardboard splint, vacuum splint, and commercial immobilizers.	2	2	2	2
	(5) Rigid extrication collars capable of limiting movement of the cervical spine of various size adult and pediatric patients. The devices must permit access to the patient's anterior neck when in place.	1 adult / 1 pediatric	2 adult 2 pediatric	1 adult / 1 pediatric	1 adult / 1 pediatric
	(6) A device or devices capable of immobilizing the head of a patient who is secured to a long backboard.	N/A	1	N/A	N/A
	(7) Flexible litter. Examples include, but are not limited to: MegaMover and poleless litters.	N/A	1	1	1
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(d)	**<u>Infant and Pediatric Airway, Oxygen and resuscitation equipment and other Infant and Pediatric related equipment:</u>**				
	(1) Pediatric bag valve mask, equipped with oxygen reservoir system.	1	1	1	1
	(2) Clear face masks in newborn, infant and child sizes, inflatable rim (or mask with minimal under-mask volume) to fit pediatric bag valve mask, equipped with oxygen reservoir system.	1	1	1	1
	(3) Pediatric nasal cannula and pediatric partial non-rebreather oxygen mask.	1 of each	2 of each	1 of each	1 of each
	(4) Sterile suction catheters in at least two pediatric sizes.	N/A	2 of each	2 of each	2 of each
	(5) Sterile or modified suction trap, or small bulb syringe.	1	2	2	2
	(6) Child size blood pressure cuffs with gauge.	1	1	1	1

	(7) Pediatric stethoscope (interchangeable type acceptable). May be satisfied by any stethoscope with pediatric adapter diaphragm.	1	1	1	1
	(8) One commercially prepared infant swaddler.	1	1	1	1
	(9) Emergency childbirth (OB) supplies in a kit, consisting of the following sterile supplies: disposable gloves; scissors or scalpel; umbilical clamps or tape; bulb syringe; drapes; and an individually wrapped sanitary napkin.	1	1	1	1
	(10) A length-based resuscitation tape OR a reference material that provides appropriate guidance for pediatric drug dosing and equipment sizing based on patient length.	Optional	1	Optional	1
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(e)	**Bleeding and Hemorrhage Control Equipment**				
	(1) Sterile gauze pads 4 inches by 4 inches.	6	12	6	6
	(2) Rolls of adhesive tape in at least 1" and 3" size.	1 of each	1 of each	1 of each	1 of each
	(3) Rolls of conforming gauze bandages in two or more sizes.	1 of each	3 of each	1 of each	1 of each
	(4) Sterile universal dressings approximately 10 inches by 30 inches.	2	2	2	2
	(5) Sterile gauze pads, minimum size 5 inches by 9 inches.	3	6	3	3
	(6) Trauma shears.	1	1	1	1
	(7) Sterile bed-size burn sheet.	1	2	1	1
	(8) Triangular bandages.	3	6	3	3
	(9) One liter of sterile normal saline in plastic container(s) within the manufacturer's expiration date.	Optional	1	1	1
	(10) Commercial chest seal.	2	2	2	2
	(11) Commercial windlass tourniquet at least 1-inch in width. Examples include, but are not limited to: CAT, SOFT-T, SOFT-T Wide, and SAM XT.	2	4	2	2
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(f)	**Miscellaneous and Special EMS Equipment in clean and sanitary condition:**				

	(1) Linen on wheeled ambulance cot.	N/A	R	N/A	N/A
	(2) Cloth towels.	N/R	4	N/R	N/R
	(3) Pillow (covered or disposable).	N/R	1	N/R	N/R
	(4) Cloth or disposable pillow case.	N/R	2	N/R	N/R
	(5) Cloth or disposable sheet.	N/R	4	N/R	N/R
	(6) Cloth or disposable blanket.	N/R	2	N/R	N/R
	(7) Facial tissues.	N/R	1 box	N/R	N/R
	(8) Emesis containers.	1	2	1	1
	(9) Adult and large adult size blood pressure cuff with gauge.	1 each	1 each	1 each	1 each
	(10) Adult stethoscope.	1	1	1	1
	(11) A thermometer capable of measuring a reasonable temperature range of non-hypothermic patients.	1	1	1	1
	(12) Carrying case or bag for essential emergency care equipment and supplies.	1	1	1	1
	(13) Chemical cold pack and chemical hot pack.	1 of each	2 of each	1 of each	1 of each
	(14) Single-use, water based lubricating jelly.	2	4	2	2
	(15) Eye protections for droplet / splash exposure. Examples include goggles and face shields.	1 pair	2 pairs	1 pair	1 pair
	(16) Latex-free, disposable exam gloves in sizes small, medium, and large.	4 pairs each	10 pairs each	4 pairs each	4 pairs each
	(17) Blanket (disposable or other).	1	1	1	1
	(18) Flashlight with batteries.	1	1	1	1
	(19) Triage tags, or equivalent, for at least 20 patients.	R	R	R	R
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(g)	**<u>Safety Equipment</u>**				
	(1) Six flares or three U.S. Department of Transportation approved reflective road triangles or equivalent.	R	R	R	R
	(2) One Underwriters' Laboratory rated five-pound U.L.-rated ABC chemical fire extinguisher or any extinguisher having a U.L. rating of 10BC.	N/A	1	1	1
	(3) Portable, passive monitoring CO detector with real-time visual and audible alerts for the presence of high level CO.	1	1	1	1

	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(h)	**Required BLS Medications and adjuncts:**				
	(1) Adult Epi Pen or Syringe Epinephrine.	1 dose	2 doses	1 dose	1 dose
	(2) Pediatric Epi Pen or Syringe Epinephrine.	1 dose	2 doses	1 dose	1 dose
	(3) Aspirin.	2 doses	2 doses	2 doses	2 doses
	(4) Naloxone (or equivalent).	1 dose	2 doses	1 dose	1 dose
	(5) Albuterol.	Optional	4 doses	2 doses	2 doses
	(6) Nebulizer capable of delivering medication to adult and pediatric patients.	Optional	2 doses	1 dose	1 dose
	(7) CPAP and at least two different adult size masks.	Optional	Optional BLS	Optional	1
	(8) Blood Glucose monitoring equipment.	R	R	R	R
	(9) Liquid Glucose or equivalent.	1 dose	1 dose	1 dose	1 dose
	"R" = required equipment "N/A" = not applicable "N/R" = not required	**BLS FR**	**Ambulance**	**BLS EASV**	**ALS FR**
(i)	**Required ALS Medications and adjuncts if vehicle is operating as ALS vehicle:**				
	(1) Direct and / or video laryngoscopy equipment.	N/A	R	N/A	R
	(2) Adult and pediatric endotracheal tubes.	N/A	R	N/A	R
	(3) Magill forceps, adult and pediatric.	N/A	R	N/A	R
	(4) Supraglottic airways, adult and pediatric.	N/A	R	N/A	R
	(5) Adult chest decompression needle - minimum size 14ga x 3.25 inch.	N/A	R	N/A	R
	(6) Pediatric chest decompression needle - minimum size 14ga x 1.5 inch.	N/A	R	N/A	R
	(7) A device capable of performing automatic or manual defibrillation, cardiac rhythm monitoring (at least three leads), 12-lead ECG acquisition, and transcutaneous pacing.	N/A	R	N/A	R
	(8) A device capable of continuous waveform capnography.	N/A	R	N/A	R
	(9) Medications required to perform care as directed by approved protocols.	N/A	R	N/A	R
	(10) All devices and supplies necessary to administer medications required by protocol in sizes to fit neonate, infant, child, and adult patients.	N/A	R	N/A	R

	(11) Isotonic crystalloid fluids and administration tubing capable of adjustable fluid delivery rate.	N/A	R	N/A	R
	(12) A device to provide pressure infusion of IV fluids.	N/A	R	N/A	R
	(13) A device that limits risk of inadvertent fluid over-administration for pediatric patients.	N/A	R	N/A	R

(b) Table 1 (a) (6) references the National State EMS Officials "Pediatric Transport Products for Ground Ambulances" Version 2.2 (October 2020) which provides guidelines for the selection of pediatric restraint systems. The guidelines set forth in National State EMS Officials "Pediatric Transport Products for Ground Ambulances" Version 2.2 (October 2020) are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of National State EMS Officials "Pediatric Transport Products for Ground Ambulances" Version 2.2 (October 2020) 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.

(c) An ambulance operating at the Basic Life Support (BLS) level is not required to carry the items listed under "required ALS Medications and adjuncts" in Table 1 of this section. Any BLS ambulance that has Advance Life Support (ALS) equipment onboard must have the ALS equipment stored away in such a manner that BLS providers are not able to access any of the ALS equipment when not in service as an ALS vehicle.

(d) All certified first responders, emergency medical technicians, and advanced emergency medical technicians operating on a certified vehicle shall have appropriate training of all equipment on the vehicle for their level of certification and must be able to demonstrate competency of equipment at any time to ensure the appropriate care and treatment of a patient.

(e) All certified vehicles are required to be fully secured when not in use to prevent theft or unauthorized use of the vehicle or equipment.

(f) The equipment standards set forth in this section shall go into effect six months after the regulations are adopted. All current equipment standards shall remain in effect until such time as this section shall become effective.

Section 800.25 is hereby REPEALED and replaced to read as follows:

§ 800.25 General regulatory waivers.

(a) The department may waive regulatory requirements of this Part if the department finds that compliance with the requirement or requirements is:

(1) unreasonable, impractical, or burdensome, because of special circumstances that exist; or

(2) compliance would result in impediment of emergency medical services delivery in operations, education, or other circumstance as determined by the department.

(b) Waivers granted under this section may be limited in time or may be conditioned as the department considers necessary to protect the public welfare.

(c) In determining whether a waiver may be granted, the department shall weigh the equities involved and the advantages and disadvantages to the welfare of patients and emergency medical services system.

(d) Applications for a waiver must be submitted in writing to the department and must include, at minimum, the following:

(1) the specific regulation for which a waiver is sought;

(2) the reason the waiver is necessary; and

(3) a description of what steps will be taken to achieve or maintain the purpose of the regulation to be waived and to protect the health, safety, and well-being of the public.

(e) Approvals for waivers under this Part must be kept in any locations specified by the department and be available upon request by the department during any scheduled or unscheduled inspection or review until they are expired or no longer apply.

(f) Waivers that have been granted by the department will be applicable for a specific period determined by the department and their effect shall not exceed the period beyond any regular renewal or recertification period.

(g) Failure to adhere to the terms of the approved waiver will result in rescission of the waiver and may result in a regulatory citation and imposition of penalties for violation of the applicable regulation.

Section 800.26 is hereby REPEALED and replaced to read as follows:

§ 800.26 Equipment requirements for emergency ambulance service vehicles other than an ambulance.

(a) The governing authority of any ambulance service which, as a part of its response system, utilizes emergency ambulance service vehicles other than an ambulance must have policies in effect for equipment, staffing, individual authorization, dispatch, and response criteria, and must

maintain appropriate insurance coverage. The department may define additional policies or requirements as deemed necessary.

(b) For the purposes of this section, an emergency ambulance service vehicle is defined as a primary response vehicle that provides prehospital care to a patient by bringing personnel and equipment to the scene and is equipped with basic life support medications and adjuncts required in Table 1 of section 800.24 of this Part.

(c) An emergency ambulance service vehicle operating at the Basic Life Support (BLS) level is not required to carry the items listed under "required ALS Medications and adjuncts" in Table 1 of section 800.24 of this Part.

(d) Any emergency ambulance service vehicle that has Advance Life Support (ALS) equipment onboard must have the ALS equipment stored away in such a manner that BLS providers are not able to access any of the ALS equipment when not in service as an ALS vehicle.

(e) All emergency ambulance service vehicles in a certified ambulance service shall be equipped pursuant to section 800.24 of this Part, unless otherwise exempted or pursuant a waiver obtained pursuant to section 800.25 of this Part.

(f) All certified providers operating on the vehicle shall have appropriate training of all equipment on the vehicle and must be able to demonstrate competency of equipment for their level of certification at any time to ensure the appropriate care and treatment of a patient.

(g) Any emergency ambulance service vehicle other than an ambulance shall be equipped and supplied with emergency care and safety equipment, including the following:

(1) have seat belts on all seats and seating areas in the driver and all passenger seating that meets or exceeds the standards set forth in chapter 301 of title 49 of the United States Code, "Motor

Vehicle Safety" (May 2008) and the Society of Automotive Engineers Standard J3026_201611 (November 1, 2016): Ambulance Patient Compartment Seating Integrity and Occupant Restraint. The standards set forth in chapter 301 of title 49 of the United States Code, "Motor Vehicle Safety" (May 2008) are hereby incorporated by reference with the same force and effect as if fully set forth herein. The standards set forth in the Society of Automotive Engineers Standard J3026_201611 (November 1, 2016): Ambulance Patient Compartment Seating Integrity and Occupant Restraint are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of chapter 301 of title 49 of the United States Code, "Motor Vehicle Safety" (May 2008) and a copy of Society of Automotive Engineers Standard J3026_201611 (November 1, 2016): Ambulance Patient Compartment Seating Integrity and Occupant Restraint are 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;

(2) have two-way voice communications capability to provide communication with dispatch and medical control at all times. Alternative communication systems are subject to approval of the department as being equivalent in capability;

(3) have a system in place to provide visual and audible alerts when the vehicle is in reverse motion, and a camera system capable of providing the vehicle operator with view to the rear of the vehicle in reverse motion;

(4) at a minimum, a camera or camera system which records from the driver's perspective at least towards the front of the vehicle, recording sound and video, activated by "g" force change and recording pre and post activation, capable of retaining such recording for a period no less than 10 days;

(5) have any equipment or materials over three pounds mounted or secured to the vehicle using standards established by Society of Automotive Engineers Ground Vehicle Standard J3043_201407: Ambulance Equipment Mount Device or Systems (July 14, 2014), unless secured in a cabinet. The standards set forth in the Society of Automotive Engineers Ground Vehicle Standard J3043_201407: Ambulance Equipment Mount Device or Systems (July 14, 2014) are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of Society of Automotive Engineers Standard J3043_201407: Ambulance Equipment Mount Device or Systems (July 14, 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; and

(6) have an anti-theft device, other than the ignition key or keyless ignition fob, that disables the vehicle from being operated by anyone other than an authorized user.

(h) Vehicle construction standards shall go into effect 12 months after the regulations are adopted and shall apply to new and used emergency ambulance service vehicles acquired after such date. Any emergency ambulance service vehicle in service at the time this regulation takes effect will be exempted from this section until such time as existing vehicles are replaced and after the 12-month period before the regulations take full force and effect.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 3002 authorizes the State Emergency Medical Services Council (SEMSCO), subject to approval by the Commissioner of Health, 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 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.

Legislative Objectives:

The legislative objective of PHL § 3005 is, in part, to protect the public health, safety and welfare by establishing rules and regulations relative to the standardized equipment and construction of ambulance vehicles.

Needs and Benefits:

The current regulations regarding equipment requirements for certified ambulance services are outdated and fail to address industry advances with available equipment and supplies in the commercial market. The industry has been requesting these changes due to changing equipment standards and current regulations are outdated. This includes the technology developments for in-vehicle camera systems that record and store videos and the restraint systems that are available for equipment and stretchers. Recent protocol updates also include new equipment and

medications which affect the standard of care for EMS providers and should be encompassed in regulation.

In addition, the applicable regulations are located in multiple sections of regulation, making it difficult for regulated entities to utilize. The proposed regulations set forth a list of required vehicle equipment for emergency medical services vehicles based on the type of vehicle and level of service and place these requirements in an easy to use table for ease of compliance. In addition, the regulations update the equipment standards to reflect more current equipment, which includes automatic external defibrillators, child safety restraint systems, and the standardization of certain medical equipment that must be carried on a vehicle. The required equipment list was developed by the SEMSCO Safety Committee and approved by SEMSCO and the Commissioner of Health.

Current regulatory language for requesting a waiver of regulation from the department is vague and does not provide clear guidance on the types of waivers that may be requested, the length of time a waiver may be in effect, and where an agency is required to maintain any waiver(s) received from the department. Additionally, the requirement that an agency re-apply for an existing waiver upon its expiration ensures that waivers are in line with current regulatory requirements and best practices. The new general waiver section will provide clear guidance for any agency requesting any type of waiver from the department.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

Initial capital costs associated with the proposed rule change related to equipment requirements for certified ambulance agencies will be minimal. The only piece of equipment that may be

considered a significant cost is the addition of an automated external defibrillator and the required accessories. These devices are approximately $2,000 per unit; however, in keeping with best practice, most ambulance services affected by this rule already possess these devices.

Additional capital costs associated with the proposed rule change to section 800.26 – Equipment Requirements for emergency ambulance service vehicles other than an ambulance vehicle – are estimated to be as high as $4,000.00 for the addition of the equipment outlined in the proposed rule and will be incorporated into the initial build or re-fit of an emergency ambulance service vehicle. There may be additional cost for the installation of the proposed equipment, but those costs are difficult to estimate as emergency ambulance service vehicle manufacturers bid on vehicle specifications and costs will vary from vendor to vendor. Additionally, as emergency ambulance service vehicles differ from manufacturer to manufacturer, some equipment may be installed either at the manufacturer factory or by the vendor prior to delivery, which could impact the cost of the vehicle.

The required equipment in many instances is already incorporated into new vehicles and is included in estimated vehicle replacement costs. All equipment will be available through approved vendors utilizing pricing set forth in the State Contract System. The proposed equipment may be re-installed on a new ambulance or re-chassis of an existing emergency ambulance service vehicle in accordance with manufacturer recommendations.

There may be funding opportunities in the form of grants at either the State or Federal level to offset the purchase and implementation of the required items. Additionally, there is no specific manufacturer required and agencies can use bulk purchasing, state contract vendors, and put out requests for proposals and bids from vendors and manufacturers to obtain the best pricing.

Costs to State and Local Governments:

The costs to local governments that operate certified ambulance services or advanced life support first response agencies will be significant when new ambulances or other response vehicles are purchased. The costs are outlined above under the cost for implementing and complying with these proposed regulations. There are approximately 1,770 certified ambulance agencies and advanced life support first response agencies in New York State, of those approximately 376 of those are municipal at either the village, town, city, or county level.

Costs to the Department of Health:

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

Local Government Mandates:

These regulations will impose new mandates on local governments that operate ambulance services in the form of new equipment requirements for ambulances and emergency response vehicles. The new safety requirements will bring regulations of vehicle construction in line with national safety standards and will ensure the greatest protection of the life and safety of the public.

Paperwork:

These regulatory changes will impose new paperwork and record keeping requirements on agencies. They will need to follow the provisions contained within the proposed section 800.25 to obtain a waiver for equipment or vehicle construction requirements. Additionally, any waivers will need to be reissued at the time of an agency's recertification. Waivers will need to be accessible during both agency recertifications and during any unannounced inspections by bureau staff. Agencies will need to ensure that all vehicle equipment is maintained and

recalibrated according to manufacturer's instructions to ensure it is functioning properly and that records of same are kept on file.

Duplication:

This regulation does not duplicate, overlap, or conflict with any existing State or Federal rules or other legal requirements.

Alternatives:

The alternative to the proposed new regulation would be to keep the current regulation as-is. However, this alternative is not viable because it is necessary to update the regulations to keep with current industry standards and to provide a more accessible and comprehensive point of reference in regulation for required equipment. The compliance schedule that is contained within the regulation for equipment included the consideration for implementation of any training programs and the acquisition of the equipment and supplies. The compliance schedule contained within section 800.26 considered the vehicles that an agency may have ordered but not yet delivered and the burden of adding equipment that was not included in the original specifications or bid package. The equipment requirements were the product of SEMSCO and represents the industry's request.

Federal Standards:

The regulations are consistent with applicable Federal requirements and national standards.

Compliance Schedule:

The equipment standards set forth in section 800.24 will go into effect six (6) months after the regulatory amendments are adopted.

The vehicle standards set forth in section 800.26 will not go into effect for twelve (12) months after adoption.

The new regulations contained within section 800.25 will become effective upon publication of a Notice of Adoption in the New York State Register.

Contact Person:

Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed rule changes will affect all the 1,780 active emergency medical services certified by the department, approximately 376 of those are municipal at either the village, town, city, or county level. 988 of these are certified ambulance agencies, 81 are advanced life support services, 711 are basic life support services.

Compliance Requirements:

Section 800.24 of the proposed rule, concerning equipment requirements of ambulances and emergency ambulance services vehicles, condenses the required equipment standards from several locations within the current regulations. Much of the equipment that will be required in the new regulations is already being carried by certified agencies on their vehicles and so this will not impose a significant burden on these entities. The proposed regulation also includes required medications for basic life support and advanced life support vehicles, which is not contained in current equipment regulations. However, most certified agencies already carry these medications and therefore the regulatory amendments are not expected to create an undue burden. All emergency medical services agencies will be required to have policies and procedures in place for the maintenance of equipment, and for the tracking of medications and other equipment that has an expiration date.

Section 800.25 of the proposed rule sets forth the requirements and process for requesting a regulatory waiver. Applicants will be required to maintain records of approved waivers and be able to produce them for inspection by the department.

Section 800.26 of the proposed rule relates to emergency ambulance services vehicles and will require agencies to ensure that when they purchase new vehicles, they include the required safety equipment, which will impact the bidding process as they will contain specifications for equipment that they may not currently have in place on agency vehicles. Emergency medical services agencies will be required to provide any paperwork relative to the periodic recalibration of equipment or in service policies and procedures during a certification inspection.

Professional Services:

In order to comply with the proposed rules, regulated entities may be required to engage with professionals to install and maintain the video and audio equipment they will be required to have installed. Additionally, regulated entities will need to contract with these same professionals to install this equipment when purchasing vehicles. Lastly, equipment should be installed by a professional so as not to void any manufacturer warranty and to ensure proper and safe installation.

Compliance Costs:

The estimated capital costs for the proposed equipment required by section 800.24 is approximately $2,000, with the bulk of the cost being applied to the purchase of automated external defibrillators. The ongoing cost of compliance for the proposed equipment regulations will involve the purchase of defibrillator pads and medication replacement for expired stock. It is difficult to estimate this cost as regulated entities are free to purchase from any vendor for these items and they are also free to purchase medications and other supplies in bulk with other emergency medical services agencies for cost savings.

Section 800.25 does impose new requirements on regulated entities in that a more formal process for applying for and maintaining waivers is set forth. However, it is not anticipated to impose any significant compliance costs. Instead, section 800.25 would allow regulated entities to request regulatory waivers, so it may in fact help to reduce compliance costs on regulated entities.

The estimated capital costs for the proposed vehicle specifications in section 800.26 of the proposed regulation is approximately $4,000 for the equipment that is required. This cost would be factored into the purchase of a new or used vehicle. It should be noted that many agencies currently incorporate these requirements voluntarily into vehicle purchases. Additionally, it is difficult to estimate the cost of compliance as there are many manufacturers of the required safety items in this proposed regulation and their pricing can vary greatly in terms of maintenance or replacement equipment. Agencies will be able to take advantage of bulk purchasing with other agencies, State contract pricing, or put out a request for proposals for the required equipment, including installation, to attempt to contain costs.

Certified Ambulance Agencies will need to provide proof of compliance during periodic vehicle inspections and when agency certifications are renewed every two (2) years. Additionally, waivers will need to be requested to continue at the end of an agency certification period. This will impose some additional time for an agency in preparing for an inspection however, it is not anticipated to cause any additional significant costs to the agency.

Economic and Technological Feasibility:

Since many of the regulated entities already have the equipment that will be required by the proposed rule changes in sections 800.24 and 800.26, the economic feasibility of compliance should already be factored into their budget. For agencies that will need to incorporate the new

equipment requirements, there is a six-month grace period for the requirements contained in section 800.24 and a twelve-month grace period for the requirements contained in the proposed 800.26. These grace periods will allow agencies to plan for the estimated costs of compliance.

Technology for the proposed regulations should not be difficult for agencies to implement. The vehicle equipment contained in section 800.26 is usually installed by the manufacturer and tested prior to the delivery of the vehicle and for vehicles that are retrofitted there are ambulance service companies that are qualified to install the technology contained in the proposed regulations.

Minimizing Adverse Impact:

The adverse impact on small businesses and local governments of the proposed rule can be mitigated in several ways. Agencies are not restricted from ordering their equipment in bulk to obtain the greatest savings, they are allowed to seek out State contract pricing wherever applicable, and they are not required to use certain manufacturers or suppliers of equipment. They are also allowed to create bid specification packages and request as many bids as they wish to ensure they are receiving the best service for the least amount of cost.

In addition, section 800.25 will allow regulated entities to apply to the department for a regulatory waiver, which could minimize the cost of compliance. In addition, delaying implementation of sections 800.24 and 800.26 will provide regulated entities with additional time to come into compliance, further minimizing any adverse impact the regulations may have.

Small Business and Local Government Participation:

The proposed rules for sections 800.24, 800.25, and 800.26 were a result of the collaboration of the SEMSCO which has representatives from a wide swath of EMS agencies, including

municipal entities and agencies that are small in size and budget. The department created these proposed regulations based on their recommendations and input.

The department will share information with the regional EMS Program Agencies and the State Emergency Medical Services Council which has representation from each regional EMS council and several State EMS trade organizations, including but not limited to, FASNY, NYSVARA and UNYAN members to ensure that the new regulatory requirements are widely circulated among those affected.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

The proposed equipment regulations contained in section 800.24 allow for a six-month grace period to comply which would prevent the imposition of any fines or other action for noncompliance.

The proposed vehicle construction regulations contained in section 800.26 allow for a twelve-month grace period to avoid the imposition of unbudgeted for equipment on vehicles that have already been ordered by an agency. Additionally, the existing agency vehicles will be grandfathered and not required to comply on existing vehicles until they are replaced by another vehicle. This allows for agencies to budget the capital and maintenance costs.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

Rural areas as defined by Executive Law § 418(7) are counties with a population less than 200,000 and towns with a population density less than 150 people per square mile. There are 654 certified agencies that qualify as rural who may be impacted by the proposed changes.

Reporting, Recordkeeping, and Other Compliance Requirements; and Professional Services:

Section 800.24 of the proposed rule, concerning equipment requirements of ambulances and emergency ambulance services vehicles, condenses the required equipment standards from several locations within the current regulations. Much of the equipment that will be required in the new regulations is already being carried by certified agencies on their vehicles and so this will not impose a significant burden on these entities. The proposed regulation also includes required medications for basic life support and advanced life support vehicles, which is not contained in current equipment regulations. However, the majority of certified agencies already carry these medications and therefore the regulatory amendments are not expected to create an undue burden. All emergency medical services agencies will be required to have policies and procedures in place for the maintenance of equipment, and for the tracking of medications and other equipment that has an expiration date.

Section 800.25 of the proposed rule sets forth the requirements and process for requesting a regulatory waiver. Applicants will be required to maintain records of approved waivers and be able to produce them for inspection by the department.

Section 800.26 of the proposed rule relates to emergency ambulance services vehicles and will require agencies to ensure that when they purchase new vehicles, they include the required safety equipment, which will impact the bidding process as they will contain specifications for equipment that they may not currently have in place on agency vehicles.

In order to comply with the proposed rules, regulated entities may be required to engage with professionals to install and maintain the video and audio equipment they will be required to have installed. Additionally, regulated entities will need to contract with these same professionals to install this equipment when purchasing vehicles. Lastly, equipment should be installed by a professional so as not to void any manufacturer warranty and to ensure proper and safe installation.

Certified Ambulance Agencies will need to provide proof of compliance during periodic vehicle inspections and when agency certifications are renewed every two (2) years. They will also be required to maintain any manufacturer related calibration and maintenance recommendations to ensure the equipment remains in good working order.

Costs:

The estimated capital costs for the proposed equipment required by section 800.24 is approximately $2,000, with the bulk of the cost being applied to the purchase of automated external defibrillators. The ongoing cost of compliance for the proposed equipment regulations will involve the purchase of defibrillator pads and medication replacement for expired stock. It is difficult to estimate this cost as regulated entities are free to purchase from a particular vendor for these items and they are also free to purchase medications and other supplies in bulk with other emergency medical services agencies for cost savings.

Section 800.25 does not impose any new requirements on regulated entities and therefore it is not anticipated to impose any compliance costs. Instead, section 800.25 would allow regulated entities to request regulatory waivers, so it may in fact help to reduce compliance costs on regulated entities.

The estimated capital costs for the proposed vehicle specifications in the section 800.26 of the proposed regulation are approximately $4,000 for the equipment that is required. This cost would be factored into the purchase of a new vehicle. It should be noted that many agencies currently incorporate these requirements voluntarily into vehicle purchases. Additionally, it is difficult to estimate the cost of compliance as there are many manufacturers of the required safety items in this proposed regulation and their pricing can vary greatly in terms of maintenance or replacement equipment. Agencies will be able to take advantage of bulk purchasing with other agencies or State contract pricing to attempt to contain costs.

Certified Ambulance Agencies will need to provide proof of compliance during periodic vehicle inspections and when agency certifications are renewed every two (2) years.

Minimizing Adverse Impact:

The adverse impact of the proposed regulation on those emergency medical services agencies classified as rural can be mitigated in several ways. Agencies are not restricted from ordering their equipment in bulk to obtain the greatest savings, they are allowed to seek out State contract pricing wherever applicable, and they are not required to use certain manufacturers or suppliers of equipment. They are also allowed to create bid specification packages and request as many bids as they wish to ensure they are receiving the best service for the least amount of cost.

In addition, section 800.25 will allow regulated entities to apply to the department for a regulatory waiver, which could minimize the cost of compliance. In addition, delaying implementation of sections 800.24 for six (6) months after enactment and 800.26 for twelve (12) months after enactment will provide regulated entities with additional time to come into compliance, further minimizing any adverse impact the regulations may have.

Rural Area Participation:

These proposed regulations will be subject to a 60-day public comment period, and subject to review and approval by a subcommittee of the State Emergency Medical Services Council, as well as the approval of the full State Emergency Medical Services Council. All certified ambulance agencies, including those from rural areas within the state, will have an opportunity to comment during the public comment period and through their representatives on their respective Regional Emergency Services Medical Committee, Regional Emergency Medical Services Council and the State Emergency Medical Services Council.

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.