

TABLE 1-INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PROPOSED RULE ON REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS DOCKET

Activity	Date	Electronic address	Other information
First public meeting	November 6, 2020; 8:30 a.m.-3:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by October 28, 2020 ..	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements .	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 9, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements .	
Notice confirming opportunity to make oral presentation.	by October 16, 2020 ..		An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	https://www.regulations.gov	See ADDRESSES for additional information on submitting comments.
Second public meeting	November 18, 2020; 9:30 a.m.-4:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 6, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements .	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 16, 2020 ..	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements .	
Notice confirming opportunity to make oral presentation.	by October 23, 2020 ..		An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	https://www.regulations.gov	See ADDRESSES for additional information on submitting comments.
Third public meeting	December 2, 2020; 11:30 a.m.-6:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 18, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements .	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 26, 2020 ..	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements .	
Notice confirming opportunity to make oral presentation.	by November 9, 2020		An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	https://www.regulations.gov	See ADDRESSES for additional information on submitting comments.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at: <https://www.regulations.gov>. You may also view the transcript at the Dockets Management Staff (see **ADDRESSES**).

Dated: September 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-21935 Filed 10-2-20; 8:45 am]

BILLING CODE 4164--01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1306, and 1307

[Docket No. DEA-377]

RIN 1117-AB37

Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of proposed rulemaking.

SUMMARY: The "Protecting Patient Access to Emergency Medications Act of 2017," (hereafter the "Act") which became law on November 17, 2017, amended the Controlled Substances Act to allow for a new registration category for emergency medical services agencies that handle controlled substances. It also established standards for registering emergency medical services agencies, and set forth new requirements for delivery, storage, and recordkeeping related to their handling of controlled substances. In addition, the Act allows emergency medical services professionals to administer controlled substances outside the physical

presence of a medical director or authorizing medical professional pursuant to a valid standing or verbal order. The Drug Enforcement Administration proposes to amend its regulations to make them consistent with the Act and to otherwise implement its requirements.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before December 4, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before December 4, 2020.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-377" on all correspondence, including any attachments.

- *Electronic Comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

- *Paper Comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152-2639.

- *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention:

Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB37/Docket No. DEA-377.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA or "the Administration") for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic

submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

Outline

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I. Background and Purpose

A. Legal Authority

On November 17, 2017, the "Protecting Patient Access to Emergency Medications Act of 2017," Public Law 115-83 (131 Stat. 1267) ("the Act"), became law.

The Act amended a section of the CSA, 21 U.S.C. 823, by adding a new subsection, 21 U.S.C. 823(j). This new subsection alters a number of CSA requirements "[f]or the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services." 21 U.S.C. 823(j)(1). The Act also specifically authorizes the Attorney General (and thus the Administrator of DEA by delegation) to issue certain regulations to implement the Act. *Id.* 823(j)(11).

B. Purpose

The purposes of this proposed rule are twofold. First, this proposed rule is to codify in DEA regulations the statutory amendments made by the Act. Such proposed changes are merely conforming DEA's implementing regulations to statutory amendments of the CSA that have already taken effect. Second, this proposed rule amends DEA

regulations in some ways that do not directly codify the Act's amendments. These limited changes are authorized by the CSA, as amended by the Act, and seek to implement the Act and effectuate its purposes.

C. Background

When an individual experiences a medical emergency, his or her entry into the healthcare system may not start with the care of a physician within a traditional clinical setting, but instead with the intervention of emergency medical services (EMS) personnel affiliated with a local EMS agency at the incident site. EMS personnel, who provide emergency medical services by ground, air, or otherwise, respond to 37 million calls annually.¹ EMS involves the evaluation and management of patients with acute traumatic and medical conditions in a prehospital environment,² and is an important component of medical care, as early medical intervention saves lives and often reduces the severity of injury.³ The nature of medical intervention at the incident site and during transport to the hospital can vary widely depending on the severity and type of injury or impairment, and may include the administering of controlled substances.⁴

The delivery of emergency medical care is primarily a local function; and, accordingly, a wide variety of organizational structures are utilized across the nation. EMS programs may be a part of the local municipal government, hospital, or independent government agency, or may be contracted by local government with a private entity. Each state has a State EMS licensing office that is responsible for the overall planning, coordination, and regulation of the State EMS system, as well as licensing or certifying EMS

providers and ambulances.⁵ These agencies are often located within the State health department, but may also be found as part of the public safety department or as independent agencies.⁶

D. Summary of the Act and Changes to the CSA

The Act established uniform EMS agency requirements for the administration of controlled substances while ensuring adequate safeguards against theft and diversion. The Act added a new subsection to the CSA, 21 U.S.C. 823(j), and in the process redesignated the previous subsection (j) as subsection (k). The new 21 U.S.C. 823(j) makes a number of notable changes to the CSA. The Act makes five key changes.

First, the Act creates a new registration category under the CSA for EMS agencies, directing the Attorney General (and thus the Administrator of DEA by delegation) to register such an agency under the CSA if the agency submits an application demonstrating that it is authorized to conduct emergency medical services under the laws of each State in which the agency practices. 21 U.S.C. 823(j)(1)(A). Pursuant to 21 U.S.C. 823(j)(1)(B), the Act authorizes the Attorney General to deny the application of an EMS agency if registering it would be inconsistent with other requirements of 21 U.S.C. 823(j) or with the public interest based on the factors of 21 U.S.C. 823(f).

Second, the Act directs the Attorney General (and thus the Administrator) to allow a registered EMS agency to obtain a single registration for each State in which the agency administers controlled substances, rather than requiring the agency to obtain a separate registration for each location at which it operates within that State. 21 U.S.C. 823(j)(2). The Act also provides that a hospital-based emergency medical services agency registered under 21 U.S.C. 823(f) may use the registration of the hospital to administer controlled substances under 21 U.S.C. 823(j), without requiring the agency to acquire a separate registration. 21 U.S.C. 823(j)(3).

Third, subject to certain restrictions, the Act authorizes EMS professionals of a registered EMS agency to administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services. 21 U.S.C. 823(j)(4). EMS professionals

are only allowed to make such administrations if authorized by State law and pursuant to standing or verbal orders that satisfy a number of statutory conditions. *Id.*

Fourth, the Act provides a variety of requirements for how registered EMS agencies must deliver controlled substances from registered to unregistered locations, store controlled substances, restock EMS vehicles at a hospital, maintain records, and otherwise conduct their operations. 21 U.S.C. 823(j)(5)-(10).

Fifth, the Act specifically authorizes the Attorney General (and thus the Administrator) to issue regulations regarding the delivery and storage of controlled substances by EMS agencies. *Id.* 823(j)(11).

II. Summary of Proposed Changes

The Act amended the CSA to add regulatory provisions pertaining to the handling of controlled substances by EMS professionals, and the majority of this proposed rule merely reiterates those statutory requirements. The portion of this proposed rule that goes beyond those statutory requirements includes proposed changes to the registration, security, recordkeeping, inventory, and administering requirements for EMS agencies, which are discussed below.

Consistent with the Act, DEA is proposing regulations to explicitly include EMS agencies handling controlled substances as registrants under the CSA,⁷ and to delineate the security, and recordkeeping requirements for EMS registrants who store, transport, and administer controlled substances. DEA is also proposing regulations that would codify, in DEA regulations, the Act's provisions that allow EMS personnel to administer controlled substances in schedules II-V outside of the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if authorized in the State in which the medical service occurs and pursuant to a standing order or verbal order. In addition, DEA is proposing

⁷Consistent with 21 U.S.C. 823(j)(3), DEA is proposing regulations that would continue to allow an EMS agency based in a hospital that is registered under § 1301.13 to use the hospital's registration to administer controlled substances, without being separately registered as an EMS agency.

⁸ 21 U.S.C. 823(j)(13)(M) defines *standing order* as a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services. 21 U.S.C. 823(j)(13)(N) defines *verbal order* as an oral directive that is given through any method of communication including

¹ National EMS Assessment, 2011. The National EMS Assessment, led by researchers at the University of North Carolina at Chapel Hill, incorporated data from the National Association of State EMS Officials 2011 EMS Industry Snapshot: Emergency Medical Services for Children Program 2010-2011 report, the 2007 Indian Health Services Tribal EMS Pediatric Assessment, and the National EMS Database.

² FICEMS 2011 National EMS Assessment.

³ Kuehl, Alexander. "25." Prehospital Systems and Medical Oversight. Dubuque, IA: Kendall/Hunt Pub., 2002. ["For most prehospital medical conditions, patient outcome is assumed to be beneficially influenced by early medical intervention, and contemporary prehospital care systems are a well-defined practice of medicine in the United States."].

⁴ Anon-exhaustive list of common controlled substance pharmaceuticals utilized by EMS include the benzodiazepine class of drugs for seizures and sedation as well as morphine [schedule II], fentanyl [schedule II], and meperidine [schedule II] for pain management.

⁵ <http://www.ems.gov>.
6/d.

regulations that codify the Act's amendments allowing EMS agencies to receive controlled substances from hospitals for the purpose of restocking EMS vehicles, and allowing EMS agencies and hospitals to deliver controlled substances to each other in the event of shortages of such substances, public health emergencies, or mass casualty events.

In this manner, DEA will bring its regulations into conformity with the Act's amendments to the CSA. In particular, DEA's proposed 21 CFR 1300.06 would add 21 U.S.C. 823(j)(13)'s new definitions of relevant terms to DEA regulations. Section 1301.12 would be amended to reflect the statutory amendments of 823(j)(2) and 823(j)(5), and § 1301.13 would be amended to bring it into conformity with 823(j)(1). Proposed § 1301.20(a) is adapted directly from the statutory amendment, specifically from 823(j)(1)-(3). The proposed provisions of § 1301.B0(a) would add provisions from 823(j)(6). Proposed § 1304.03(j) is taken from 823(j)(9)(A). Proposed § 1306.07(e) would add the provisions of 823(j)(4) and 823(j)(10)(D) to DEA regulations, while proposed § 1307.14 would add those of 823(j)(8).

Not all of the proposed amendments to DEA regulations, however, directly codify the Act's statutory amendments in DEA regulations. Some of the proposed changes—specifically, §§ 1301.20(b), 1301.B0(b), 1304.03(i), 1304.04, 1304.27, 1306.07(), and 1307.15—implement the purposes of the Act more broadly, consistent with the Administrator's authority to promulgate regulations under 21 U.S.C. 821, 21 U.S.C. 823(j)(11), and 21 U.S.C. 871(b).

A. Definitions

The Act contains a provision, 21 U.S.C. 823(j)(13), defining the terms used throughout its other provisions. In order to conform to the Act, DEA is proposing to add these new definitions to its regulations as part of a new section, 21 CFR 1300.06. This includes defining the terms "authorizing medical professional," "designated location," "emergency medical services," "emergency medical services agency," "emergency medical services professional," "emergency medical services vehicle," "hospital-based," "medical director," "medical oversight," "registered emergency

by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

medical services agency," "registered location," "specific state authority," "standing order," and "verbal order."

Additionally, the Act contains provisions that allows DEA to issue regulations specifying, with regard to the delivery of controlled substances under 21 U.S.C. 823(j)(5), the types of locations that may be designated. 21 U.S.C. 823(j)(11)(A)(i). In order to conform with the Act, DEA has identified this type of location as a "stationhouse" and is proposing to add the definition of a "stationhouse" to its regulations as part of 21 CFR 1300.06.

B. Registration for Emergency Medical Services Agencies

1. Current Regulations for EMS Registration

Pursuant to 21 CFR 1301.12(a), controlled substances may only be delivered to, and distributed or dispensed from, a DEA registered location. In addition, under the CSA and DEA regulations, a separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person. 21 U.S.C. 822(e); 21 CFR 1301.12(a).

Until the passage of the Act, the CSA and its implementing regulations did not directly mention EMS. Historically, DEA has not specifically registered EMS agencies to procure or dispense controlled substances. Instead, generally, EMS vehicles have obtained controlled substances for dispensing pursuant to a physician's instructions by operating under the registration of a hospital through one of two options.

Under the first option, an EMS vehicle owned and operated by a hospital handles controlled substances under the hospital's registration.⁹ The EMS vehicle obtains controlled substances from the hospital's pharmacy or emergency room, as an extension of the hospital pharmacy. Under the second option, an EMS agency is registered under a hospital registration by agreement—that is, a private EMS agency enters into a formal agreement with a specified hospital to act as the hospital's agent. The hospital supplies each EMS vehicle with a prepared kit containing controlled substances needed by the EMS agency and replenishes the kit as necessary. Many EMS agencies are currently using

⁹EMS agencies' use of this option is now explicitly authorized by the Act, 21 U.S.C. 823(j)(3), and DEA is proposing to add this option to its regulations as 21 CFR 1301.20(a)(2).

hospital registrations to stock and operate their EMS vehicles at those hospitals in this manner.

2. Proposed Regulations for EMS Registration

The Act authorized the Attorney General (and thus, by delegation, the Administrator) to register EMS agencies, which allowed for a new registration category for EMS professionals to administer controlled substances in schedule 11-V to patients receiving emergency medical services. 21 U.S.C. 823(j)(1). The Act thereby effectively amends the CSA to add a new category of registrant—an EMS agency—and to require DEA to grant registrations to those agencies if certain conditions are met. Thus, in conformity with the Act, DEA proposes to amend 21 CFR 1301.13 and to add 21 CFR 1301.20 to provide for the registration of EMS agencies.

As part of this regulatory change, DEA is proposing to add § 1301.20(a) to its regulations, which will describe the registration requirements for EMS agencies registered under § 1301.13. The proposed registration requirements of § 1301.20(a) are taken directly from the Act, 21 U.S.C. 823(j)(1)-(3).

DEA recommends three options to allow EMS agencies to transition their registrations, in accordance with the Act. The three options for EMS agencies to transition are: (1) Transition immediately on the effective date established by DEA; (2) transition at the expiration of their current registration; or (3) transition three to six months prior to their renewal date. DEA recommends that registrants contact their local DEA field office to complete this transition.

C. Designated Location of an Emergency Medical Services Agency

Many EMS agencies currently utilize what is sometimes termed the "hub-and-spoke" model where the agency has a main or central location and several stationhouses managed by the main location. The stationhouses are strategically placed throughout a geographical area to provide timely responses to emergency medical needs of the residents of the area. Under DEA's current registration regulations, if only the main location is registered with DEA, the employees of each of the individual (unregistered) stationhouses are not allowed to acquire or store controlled substances at the unregistered stationhouse.

To lessen the burden for EMS agencies with several stationhouses in a single state, the Act allows EMS agencies to choose the option of a single registration in each state where the EMS

agency operates, 21 U.S.C. 823(j)(2), and DEA proposes to amend its regulations accordingly through proposed § 1301.20(a)(1). The Act and the proposed regulation still require EMS agencies that operate EMS facilities in multiple states to have a separate registration in each state where the agency operates, however. In addition, under the Act and § 1301.20(a)(2) of these proposed regulations, hospital-based EMS agencies are allowed to operate under the registration of a hospital to administer controlled substances without being separately registered pursuant to 21 U.S.C. 823(j)(3).

Additionally, the Act amended the CSA to specifically authorize EMS agencies to designate specific unregistered locations where controlled substances would be delivered and stored, but requires registered EMS agencies to provide notice of these locations to the Attorney General at least 30 days before delivery. 21 U.S.C. 823(j)(5). DEA proposes to bring its regulations into conformity with the Act by adding 21 CFR 1301.20(b). Consistent with the Attorney General's authority under 21 U.S.C. 823(j)(11)(A)(ii) to prescribe how EMS agencies provide notice of designated locations, that regulation proposes to require notification of the name and physical address of the designated location through DEA's website, www.DEAdiversion.usdoj.gov. Pursuant to proposed § 1301.20(b), an EMS agency still must obtain a DEA registration for the registered location at which it receives controlled substances from distributors. After an EMS agency has been approved for a DEA registration, the EMS agency may identify designated locations through DEA's website, www.DEAdiversion.usdoj.gov. An EMS agency that has thus identified designated locations may deliver controlled substances to that designated location 30 days after notification to DEA.

The Act also authorizes the Attorney General to issue regulations specifying the types of locations that may be designated by an EMS agency. 21 U.S.C. 823(j)(11)(A)(i). Pursuant to this authority, DEA is proposing to include a provision in § 1301.20(b) that would allow an EMS agency to label stationhouses as the types of location that would be considered a "designated location" of the EMS agency. Additionally, only agency locations that satisfy the proposed regulation's definition of stationhouse (*i.e.*, enclosed structures housing EMS agency vehicles within the state of the emergency

medical services agency's registration, and which are actively and primarily being used for emergency response) may be selected as "designated locations" by EMS agencies that are registered with DEA. Thus, for example, a location that serves primarily as a residence (such as a house or apartment building) does not meet the proposed definition of a stationhouse and may not be selected as a "designated location" by an EMS agency that is registered with DEA. In contrast, a building that is actively serving primarily to house the equipment of a county fire and rescue department, for example, is a stationhouse under the proposed rule (and thus may be selected as a "designated location" by an EMS agency that is registered with DEA) regardless of whether such building is also used for overnight accommodation by EMS personnel.

As discussed above, the provisions of proposed § 1301.20(b) outline the process by which a stationhouse is "designated" under an existing EMS agency registration. This notification must occur at least 30 days prior to the first delivery of controlled substances to the unregistered designated location of the agency. Unless an objection is raised by DEA, an unregistered location automatically becomes a designated location of the agency 30 days after notification of the designated location is made to DEA.

Additionally, parts of proposed § 1301.80 would codify in DEA regulations the Act's list of the locations where a registered EMS agency may store controlled substances. *See* 21 U.S.C. 823(j)(6). The permissible locations include both the registered and designated location(s) of the agency, and inside an EMS vehicle situated at a registered location or designated location of the agency. Furthermore, the controlled substances may be stored inside any EMS vehicle used by the agency that is traveling from or returning to a registered or designated location of the agency. *Id.* These provisions directly incorporate the Act and make it clear to registrants that under the specified conditions, DEA is allowing the transportation of controlled substances between both registered and designated locations of the agency.

D. Emergency Medical Services Vehicles

Both the Act and the proposed definition of emergency services vehicles in § 1300.06 define EMS vehicles as ambulances, fire apparatus, supervisor trucks, or other vehicles used by an EMS agency for the purpose of providing or facilitating emergency medical care and transport or

transporting controlled substances to and from the registered and designated locations. *See* 21 U.S.C. 823(j)(13)(F). Under the control of the consultant practitioner registration or hospital registration, controlled substances can be supplied to and stored in an EMS vehicle. Proposed § 1301.80 allows a registered EMS agency to store controlled substances in an EMS vehicle located at a registered location, a designated location, or in an EMS vehicle used by the agency that is traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency, or otherwise actively in use by the agency.

E. Proposed Changes to Recordkeeping Requirements

1. Records and Inventories

The transportation of controlled substances for administration to EMS patients presents unique recordkeeping concerns. With regard to non-practitioners that transport controlled substances (e.g., manufacturers, distributors, exporters, importers), DEA can track the movement of the controlled substances through recordkeeping and reporting requirements within the two-registrant integrity system. Generally, the registrant that transports controlled substances maintains a record of, and would report delivery of the controlled substances, while the registrant that receives the controlled substances must account for the received controlled substances. Every registrant is required to maintain complete and accurate records of each substance manufactured, imported, received, sold, delivered, exported, or disposed of. 21 CFR 1304.21(a). This two-registrant integrity system provides an effective means of protection against diversion in that the transfer of the controlled substances shall be verified by two separate registrants, thus helping to ensure that controlled substances are not diverted for illicit use.

EMS agencies are typically the last registrants to possess controlled substances prior to administering to a patient at the scene of an emergency. As such, the two-registrant integrity system does not exist beyond the transfer to an EMS agency, in the traditional sense of registrant recordkeeping. Therefore, DEA is proposing recordkeeping regulations for EMS agencies to incorporate the Act's CSA amendments regarding recordkeeping, and to ensure an accurate accounting of the controlled substances outside the two-registrant integrity system.

DEA proposes § 1304.03(i) to require EMS agencies to maintain records of the EMS personnel whose State license or certification gives them the ability to administer controlled substances, in compliance with their State laws. Because states have differing requirements for the ability to handle controlled substances, maintaining records of employees authorized to handle controlled substances will help DEA identify the source of any diversion occurring at EMS agencies.

Proposed § 1304.03(i) is not based directly on the text of the Act, but instead on DEA's general authority under the CSA to prevent diversion of controlled substances by requiring registrants to maintain records. *See* 21 U.S.C. 823(j)(12)(B) (nothing in the Act is to be construed to limit the authority of the Attorney General to take measures to prevent diversion).

a. Restocking

Following an emergency response where controlled substances were administered, EMS personnel may not have enough time to return to their stationhouse to restock their EMS vehicle with controlled substances. Depending on the circumstances, the stationhouse may be a considerable distance from the hospital where the EMS personnel brought a patient, or the volume of emergencies may be so great that the ambulance does not have time to return to the stationhouse. Rural EMS systems in the United States may face transport distances of 20 to 100 miles to the nearest hospital.¹⁰ Thus, the Act allows non hospital-based EMS agencies to receive controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. 21 U.S.C. 823(j)(8). DEA's proposed § 1307.14(a) codifies this allowance in DEA regulations.

b. Maintenance of Records

Under § 1304.04(a), controlled substance records for all DEA registrants are required to be maintained for at least two years from the date of such inventory or records. Under this proposed rule, DEA would require maintenance of records of deliveries of controlled substances between all locations of the agency. Following the Act, 21 U.S.C. 823(j)(9)(B)(ii), DEA also proposes in § 1304.04(a)(5) to require that records be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances

involved are received, administered, or otherwise disposed of.

Because EMS agencies have a unique registration that differs from other types of registrants, DEA is also proposing to add a new section to its regulations that describes the additional recordkeeping requirements applicable to EMS agencies. Consistent with the Act's amendments to the CSA, 21 U.S.C. 823(j)(9), proposed § 1304.27(a) would require an EMS agency to maintain records for each controlled substance administered or disposed of in the course of providing emergency medical services. Under proposed § 1304.27(a), any EMS personnel who disposes of or administers controlled substances to a patient in the course of providing emergency medical care must record the name of the controlled substance(s) and detailed information about the circumstances surrounding the administration of the controlled substance(s) (e.g., name of the substance, date dispensed, identification of the patient). EMS personnel do not have independent authority to administer controlled substances; therefore, more stringent recordkeeping requirements are necessary when allowing administration of controlled substances without direct oversight.

DEA proposes in § 1304.27(b)(3) that an EMS agency must maintain records of controlled substances delivered between registered and designated locations of the agency (except agencies restocking at the hospital under which the EMS agency is operating, because the hospital is required to keep records of such restocking). These records, for example, should include the name of the controlled substance(s), finished form, number of units in the commercial container, date delivered, and the address of the EMS agency location where the controlled substances were delivered. In the event of theft or loss of controlled substances, registrants must report such occurrence in accordance with the theft and loss reporting requirements of 21 CFR part 1304.

Finally, under 21 U.S.C. 823(j)(8)(c) of the Act, designated locations of an EMS agency must notify the registered location of their EMS agency within 72 hours of receiving controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. DEA's proposed § 1304.27(c) would codify this requirement in DEA regulations. However, EMS agencies that operate under a hospital-based registration and receive restock of controlled substances from the hospital under which the agency is operating would be exempt

from these requirements. In this specific instance, under proposed § 1307.14(a)(2), hospitals would already have a record of the controlled substances that the hospital delivered to the EMS agency operating under that hospital's registration. As such, it would be duplicative to require that EMS agency to obtain a receipt of those controlled substances because the EMS agency would be reporting receipt of the controlled substances back to the hospital that issued the controlled substances in the first place.

F. Proposed Changes for Security Requirements

1. Security Controls

Every DEA registrant must follow certain security requirements to prevent the theft or loss of controlled substances, and the Act authorizes the Attorney General to issue regulations specifying the manner in which controlled substances must be stored by EMS agencies. 21 U.S.C. 823(j)(11)(B). Pursuant to this authorization, DEA proposes to implement physical security requirements for EMS agencies similar to those already established for practitioners in § 1301.75. Although § 1301.75 addresses general physical security controls for practitioners, EMS agencies have some unique security concerns that require additional security controls as discussed below.

a. Storage of Controlled Substances

Pursuant to its authorization under the Act to issue regulations regarding EMS agencies' storage of controlled substances, DEA proposes to add § 1301.80 to address additional security concerns for EMS agencies. First, although designated locations of EMS agencies are not individually registered, they are allowed to store controlled substances in certain secured locations. Proposed § 1301.80(a)(1) through (4) specifies the locations within an EMS agency where controlled substances may be stored, and implements the Act's allowance in 21 U.S.C. 823(j)(6) of storage at EMS registered locations, at designated locations, inside of EMS vehicles stationed at registered or designated locations, and inside of EMS vehicles that are actively in use by the agency.

In addition, DEA proposes to add § 1301.80(b) to allow two options for storage components in which EMS agencies may store controlled substances. This change is not taken directly from the Act's statutory amendments to the CSA, but instead implements the Act's authorization to the Attorney General to "specify ...

¹⁰Williamson, H.A., Jr. (2001). Emergency Care. In J.P. Geyman, T.E. Norris & L.G. Hart (Eds.), *Textbook of Rural Medicine* (pp. 93-102). New York: The McGraw-Hill Companies, Inc.

the manner in which [controlled] substances must be stored at registered and designated locations, including in EMS vehicles." 21 U.S.C. 823(j)(11)(B).

The first option in proposed § 1301.B0(b)(1) would allow for an EMS agency to store controlled substances in a securely locked, substantially constructed cabinet or safe that cannot be readily removed. This storage component must be located at a secured location, as stated in proposed § 1301.B0(i).

The second option in proposed § 1301.80(b)(2) would allow an EMS agency to store controlled substances in an automated dispensing system (ADS) machine, under specific conditions. An ADS is "a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transactions in information." 21 CFR 1300.01. Currently, DEA regulations permit retail pharmacies to install and operate ADS machines at long-term care facilities as a way of preventing the accumulation of surplus controlled substances at those facilities. *See id.* § 1301.27. At an EMS agency registered or designated location, an ADS machine effectively would serve as a controlled substance storage locker with advanced capabilities and would provide a mechanism for storing stocks of controlled substances before they are secured in emergency vehicles as well as for monitoring the dissemination of those substances.

The proposed conditions in § 1301.80(b)(2) under which an EMS agency could use an ADS machine to store controlled substances include the following: (1) The ADS machine must be located at an EMS agency registered location or designated location; (2) the EMS agency cannot permit any entity other than the registered EMS agency to install and operate the ADS machine; (3) the ADS machine cannot be used to directly dispense controlled substances to an ultimate user; and (4) EMS agency must operate the ADS machine in

compliance with requirements of State law. It is necessary that access to the ADS machine be limited to employees of the EMS agency in order to account for and monitor dissemination of controlled substances.

In sum, proposed § 1301.B0(b) would provide alternative options for short-term or long-term storage of controlled substances that are actively being transported or stored in a fixed location.

b. Delivery

As discussed in Section C, the Act allows for controlled substances to be delivered between a registered location and a designated location of an EMS agency. 21 U.S.C. 823(j)(5). Also, pursuant to its authorization to issue regulations regarding the delivery of controlled substances under 21 U.S.C. 823(j)(11), DEA proposes that medical directors determine who accepts deliveries of controlled substances because medical directors provide oversight for EMS agencies. Specifically, proposed § 1301.B0(c) would require that the delivery of controlled substances at a registered or designated location be accepted by a medical director of the agency or a person designated in writing by the medical director. For record keeping purposes of the delivery of controlled substances, proposed § 1304.27(b)(3) would require the medical director of the agency or designated person accepting the controlled substances to provide their signature, title, date received, quantity, and any additional information required. The proposed regulations specify the requirements that would be set forth regarding the delivery of controlled substances for emergency medical services.

G. Proposed Administration Requirements

DEA proposes to add § 1306.07(e), which implements 21 U.S.C. 823(j)(4) in DEA regulations, allowing EMS professionals of registered EMS agencies to administer controlled substances outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services.¹¹ Medical directors and EMS professionals authorized to administer controlled substances under their State license may administer controlled substances in the course of providing emergency medical services. However, under 21 U.S.C. 823(j)(4) and proposed § 1306.07(e), an EMS professional who is outside the physical presence of a medical director or authorizing medical professional must not only have authority from their EMS agency to administer controlled

substances, but such administration must also be pursuant to a proper standing or verbal order issued and adopted by one or more medical directors of the agency, as discussed below.

1. Standing Orders

Many agencies have given their EMS personnel the autonomy to administer controlled substances in the event of an emergency by establishing what is commonly known as a standing order. The Act defines a standing order as a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services. 21 U.S.C. 823(j)(13)(M). DEA's proposed § 1300.06 incorporates this definition into DEA regulations.

The Act and proposed § 1306.07(e) would allow standing orders to be used by EMS professionals. Under both the Act and the proposed regulation, such EMS professionals must be authorized by their individual State to administer controlled substances. *See* 21 U.S.C. 823(j)(4). Standing orders that are developed by a state authority may be issued and adopted by the medical director of an EMS agency. Under the Act and proposed § 1306.07(e), only the medical director of an EMS agency is given the authority to issue and adopt a standing order. *See* 21 U.S.C. 823(j)(4). Also, under both the Act and proposed § 1306.07(e), the EMS agency is required to maintain a record of the standing orders issued and adopted by a medical director at the registered location of the agency. 21 U.S.C. 823(j)(10)(D).

2. Verbal Orders

In the absence of standing orders, EMS personnel may receive a verbal order. Under the Act and proposed § 1300.06, a verbal order is an oral directive through any method of communication including by radio or telephone, directly to an EMS professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or

authorizing medical professional. *See* 21 U.S.C. 823(j)(13)(N). The Act and proposed § 1300.06 define "authorizing medical professional" as an emergency or other physician, or other medical professional (including an advanced practice registered nurse or physician assistant) who is registered under 21 U.S.C. 823, who is acting within the scope of the registration, and whose scope of practice under a State license

¹¹ Currently, the regulations in 21 CFR part 1306 relate primarily to prescriptions, and thus 21 CFR 1306.01 states part 1306's scope as generally consisting of "[r]ules governing the issuance, filling and filing of prescriptions pursuant to ... 21 U.S.C. 829." Because DEA is proposing to add provisions related to the administration of controlled substances by EMS agencies to part 1306, DEA is also proposing to amend § 1306.01 to broaden part 1306's stated scope to "the process and procedures for dispensing, by way of prescribing and administering controlled substances to ultimate users."

or certification includes the ability to provide verbal orders. *See* 21 U.S.C. 823(j)(13)(A).

Under the Act and proposed § 1306.07(e), an EMS professional may administer directly a controlled substance in schedules 11-V outside of the presence of a practitioner in the course of providing emergency medical services if the administration is authorized by State law and is pursuant to a verbal order that is issued in accordance with the policy of the agency. Such authorization must be provided by a medical director or authorizing medical professional in response to a request by the EMS professional with respect to a specific patient, either in the case of a mass casualty incident, or to ensure the proper care and treatment of a specific patient. Under proposed § 1307.15 and consistent with the Act under 21 U.S.C. 823(j)(4)(B), EMS agencies must contact the Special Agent in Charge (SAC) for the area or DEA Headquarters Diversion Control Division for approval of shortages, public health emergencies, or mass casualty events.

III. Regulatory Analyses

As explained above, DEA is issuing this proposed rule to amend its regulations in order to make them consistent with the changes made to the CSA by the "Protecting Patient Access to Emergency Medications Act of 2017," and to otherwise implement the Act's requirements. DEA conducted an analysis of the statutory and regulatory changes of this proposed rule, the results of which are discussed below.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 13771. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result

in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

DEA expects that the annual economic impact of this proposed rule, in the form of changes in transfers, to range from a decrease of \$302,885 to an increase of \$550,612 at a 7 percent discount rate; or from a decrease of \$379,584 to an increase of \$690,043 at a 3 percent discount rate. Fees paid to DEA are considered transfer payments and not costs.¹² Annual changes in labor burden costs as a result of this proposed rule are expected to range from a decrease of \$12,696 to an increase of \$42,782 at a 7 percent discount rate; or from decrease of \$16,253 to an increase of \$49,879 at a 3 percent discount rate. Therefore, this proposed rule is not an economically significant regulatory action. The analysis of transfers, cost savings, and benefits is below. The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and while the proposed rule is not economically significant, it has been determined that it is a significant regulatory action under E.O. 12866. Accordingly, this rule has been submitted to OMB for review.

E.O. 13771, titled "Reducing Regulation and Controlling Regulatory Costs," was issued on January 30, 2017, and published in the **Federal Register** on February 3, 2017. 82 FR 9339. Section 2(a) of E.O. 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of E.O. 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Guidance from OMB, issued on April 5, 2017, explains that the above

requirements only apply to each new "significant regulatory action that ... imposes costs." Additionally, this guidance states that "Generally, 'one-time' regulatory actions (*i.e.*, those actions that are not periodic in nature) that expand consumption and/or production options would qualify as E.O. 13771 deregulatory actions." While DEA has determined that this proposed rulemaking is a "significant regulatory action," DEA anticipates that it will be classified as an enabling rule by OMB because it allows EMS agencies to consolidate many registrations in the same State under a single registration, and EMS personnel to administer controlled substances in schedules 11-V pursuant to a standing or verbal order, which was previously not authorized. Therefore, this proposed rule is not expected to be an E.O. 13771 regulatory action.

Analysis of the Proposed Rule's Economic Impact

DEA analyzed the impact of the following provisions of the proposed rule: Allowing EMS agencies to register under the CSA with a single registration for each State in which an agency operates, along with the proposed security and recordkeeping requirements for such a registrant; allowing EMS personnel to administer controlled substances in schedules 11-V outside the presence of a medical director or authorizing medical professional when authorized in the State and pursuant to a standing or verbal order; and allowing EMS agencies and hospitals to transfer controlled substances between each other in order to restock EMS vehicles or to deliver controlled substances in the event of shortages, public health emergencies, or mass casualty events. Additionally, this proposed rule is incorporating into regulation several new terms defined in the Act.

Benefits of the proposed rule are expected to be generated by reducing regulatory uncertainty among EMS agencies and personnel regarding the administration, transfer, and disposal of controlled substances, and these benefits will be discussed qualitatively. By allowing EMS registrants to consolidate multiple registrations into a single registration for each State in which they currently operate, there will be a resulting reduction in transfer payments for current registrants. The proposed rule may also result in an increase in transfer payments for EMS agencies that are currently not separately registered. The expected net change in transfer payments is quantified below. There are also labor

¹² OMB Circular A-4.

burden costs associated with obtaining a DEA registration for any EMS agencies that must become separately registered after this rule is promulgated. These costs or cost savings are discussed and quantified below. DEA expects the recordkeeping and security requirements of this proposed rule to have no impact, as they are codifications of existing practice among EMS agencies. Finally, the newly defined terms being incorporated into regulation by this proposed rule will have no impact on regulated entities.

Registrations for Emergency Medical Services Agencies

While this proposed rule is allowing for a new registration category for EMS agencies that handle controlled substances, many EMS agencies have already obtained separate DEA registrations as "Mid-level Practitioner-Ambulance Service" (MLP-AS).¹³ As of November 2019, there were 3,521 MLP-AS registrants, 1,413 of which are private sector entities that pay a registration fee of \$731 every three years. The remaining 2,108 are governmental entities that are fee-exempt. DEA reviewed its registration database and determined that 395 of the 1,413 fee-paying registrations are held by EMS agencies with other existing registrations in the same State. Because the proposed rule allows EMS agencies to obtain a single registration for each State in which they operate, these 395 registrations can be consolidated under other existing registrations, reducing the total amount of registration fees collected by DEA. The resulting annual reduction in transfer payments from registrants to DEA amounts to \$96,248.¹⁴

Similarly, of the 2,108 fee-exempt registrations, 411 can be consolidated into an agency's existing registration in the same State, reducing the labor-related paperwork burden for these agencies, as they no longer need to complete multiple registration renewal applications for the same State every three years. Combining the 411 fee-exempt registrations with the 395 fee-paying registrations results in a total of 806 registration renewal applications that are eliminated. The resulting annual cost savings generated from this reduction in labor burden is \$3,026.¹⁵

¹³ These existing registrations will be transitioned to the new "Emergency Medical Services Agency" registration category created by this proposed rule.

¹⁴ $395 \times \$731 = \$288,745$. Dividing this figure by three to account for the three-year registration cycle, and rounding to the nearest whole dollar gives \$96,248.

¹⁵ See approved burden estimates for DEA form 224A within the 1117-0014 Supporting Statement

DEA assumes that all other EMS agencies not registered as MLP-AS currently operate under the registration of another DEA registrant in one of two ways: A DEA registered practitioner, typically a licensed physician, serves as the medical director of the EMS agency; or for EMS agencies operated by hospitals, the agency will utilize that hospital's registration. In the latter case, hospital-based EMS agencies can continue to operate under the registration of their hospital after promulgation of this proposed rule. In the former case, practitioners who serve as the medical director of an EMS agency may utilize a single registration for their personal place of business and EMS agency locations,¹⁶ or they may hold practitioner registrations separate from their personal place of business registration for each EMS agency location that they oversee. Because this proposed rule allows a medical director holding multiple registrations to transfer those existing registrations directly to one EMS agency, EMS agencies operating under this arrangement will not need a new registration. However, for EMS agencies currently operating under their medical director's registered personal place of business, a new EMS agency registration for each state in which they operate will be required. Additionally, affected non-governmental EMS agencies must pay the \$731 registration fee.

Accurately measuring how many EMS agencies fall into the two aforementioned categories is not possible using DEA registration data, because DEA has not historically collected data on how many practitioners hold multiple registrations for the purposes of serving as the medical director of an EMS agency.

¹⁶ https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians (\$140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (806). The product (\$9,078.14) is then divided by three in order to account for the three-year registration renewal period, and rounded to the nearest whole dollar. The loaded hourly wage of \$140.79 is based on the median hourly wages for Occupation Code 29-1069 Physicians and Surgeons, All Other (\$96.58). May 2018 National Occupational Employment and Wage Estimates, United States, Bureau of Labor Statistics, https://www.bls.gov/oes/current/oes_nat.htm#29-1069 (last visited November, 2019). Average benefits for employees are 31.4 percent of total compensation. Employer Costs for Employee Compensation-June, 2019, Bureau of Labor Statistics, <https://www.bls.gov/news.release/pdf/ecec.pdf> (last visited November, 2019). The 31.4 percent of total compensation equates to a 45.77 percent (31.4/68.6) load on wages and salaries. $\$96.58 \times (1 + 0.4577) = \140.79 .

¹⁷ Under this scenario, the EMS agency must pick up controlled substances from the practitioner's personal place of business.

Therefore, DEA chose to estimate how many new registrations will be required by considering the entire range of possible scenarios, and calculated the outcome if either 0 percent, 50 percent, or 100 percent of EMS agencies will receive a transferred practitioner registration from their medical director. While DEA cannot accurately assess the likelihood of each of these scenarios given the lack of available data, DEA considers the 50 percent scenario to be the most plausible of the three estimates because it is the mid-point of the upper and lower bounds.

In order to calculate the range of impacted entities, DEA must first estimate the total population of EMS agencies active in the United States. Because DEA registration data are insufficient for these purposes, DEA used the latest data available from the National Highway Traffic Safety Administration's (NHTSA) Office of EMS. According to an NHTSA research note published in 2014,¹⁷ there are an estimated 21,283 governmental and non-governmental EMS agency locations throughout the United States. The 21,283 figure is NHTSA's estimation of the total population using data gathered from 49 of 50 States.¹⁸

DEA then analyzed its registration database to match current MLP-AS registrants with the corresponding EMS organizational types defined in the NHTSA research note.¹⁹ Because the survey data used by NHTSA to develop these organizational types did not include California (CA), Illinois (IL), Washington (WA), or Virginia (VA), the total number of EMS agency locations categorized by type amounts to 15,516 instead of the total 21,283 estimated EMS agency locations throughout the United States. DEA assumes that the distribution of EMS agencies by

¹⁷ https://www.ems.gov/pdf/812041-Natl_EMS_Assessment_2011.pdf. The comprehensive national assessment that this research note is based on, the first of its kind, has not been updated since 2011. Prior to this national assessment, data on the number and type of EMS agencies operating throughout the United States was fragmented and considered to be inaccurate. Therefore, DEA considers this is the most accurate data regarding EMS agency demographics available.

¹⁸ CA data were not available.

¹⁹ The NHTSA research note breaks down the demographics of EMS agencies into the following organizational types: "Fire-Department-Based," "Governmental Non-Fire-Based," "Hospital-Based," "Private Non-Hospital," "Tribal," "Other EMS Agency," and "Emergency Medical Dispatch." The "Other EMS Agency" organizational type is not defined in the research note or national assessment survey on which the research note is based; however, for the purposes of this analysis, DEA considers this category to be made up of private sector entities. The "Emergency Medical Dispatch" category is excluded from this analysis because dispatch agencies will not be required to obtain a DEA registration.

organizational type in CA, IL, WA, and VA broadly matches the national distribution. Therefore, DEA adjusted for this missing data by calculating the percent of the total for each organizational type for the 46 reporting States and applied those percentages to the estimated 21,283 EMS agencies in the entire United States.²⁰ DEA was then able to categorize current MLP-AS registrants as Fire-Department-Based, Governmental Non-Fire-Based, Private Non-Hospital, or Tribal, according to their registration name.²¹

It is reasonable to assume that a portion of these estimated EMS agencies not separately registered operate multiple locations in the same State. The NHTSA research note states that EMS agencies are "licensed in each State to provide service to a specific location or service area. EMS service areas can be very large, as in a geopolitical boundary, such as a county, city or municipality, or as small as the local service area of a single EMS agency station." This definition suggests

that the 21,283 total EMS agencies estimated by NHTSA includes EMS agencies operating multiple stations in the same State. Because only one registration is required for multiple "agencies," as defined by NHTSA, DEA must adjust its calculation of the number of EMS agencies not separately registered to account for this.

In order to estimate how many EMS agencies not separately registered operate more than one location in a State, DEA used the existing MLP-AS registrant category as a model. It is reasonable to assume that the characteristics of the population of EMS agencies registered as MLP-AS are broadly representative of the characteristics of the population of EMS agencies that are not separately registered. As discussed previously, the fee-paying MLP-AS registrant category contains 1,413 registrations that can be consolidated into 1,018 registrations. Similarly, the fee-exempt category contains 2,108 registrations that can be consolidated into 1,697 registrations.

DEA used these figures to calculate a State-level "agency-to-location" ratio of 0.72 for fee-paying registrants,²² and 0.81 for fee-exempt registrants.²³ These ratios are then applied to the estimated 6,705 private-sector and 13,342 governmental EMS agency locations not separately registered with DEA, respectively, to determine the expected total number of EMS agencies that require separate registrations as a result of this proposed rule.²⁴ This calculation yields an estimated total of 15,634 EMS agencies that will be separately registered, 4,827 of which are fee-paying, and 10,807 of which are fee-exempt. Removing the 1,018 fee-paying and 1,697 fee-exempt MLP-AS registrants from these respective totals yields an estimated 3,809 fee-paying and 9,110 fee-exempt EMS agencies that must obtain a separate registration after this rule is promulgated. These calculations are summarized in table 1 below.

TABLE 1

EMS agency org type	Reported pop	%of reported pop	Est. pop	Est. number of reg*	Current MLP-AS	MLP-AS reg eliminated	Post-rule MLP-AS	Non-MLP-AS reg eliminated	Total reg eliminated	Fee status
Fire-Dep't-Based	6,388	41.17	8,762	7,097	1,145	251	894	1,414	1,665	Exempt.
Gov't Non-Fire	3,255	20.98	4,465	3,617	960	160	800	688	848	Exempt.
Hospital-Based	901	5.81	1,236	N/A	N/A	N/A	N/A	N/A	N/A	N/A.
Private Non-Hospital	3,910	25.20	5,363	3,861	1,413	395	1,018	1,107	1,502	Paying.
Tribal	84	0.54	115	93	3	0	3	22	22	Exempt.
Other EMS.. ..	978	6.30	1,342	966	0	N/A	0	376	376	Paying.
Total.	15,516	100	21,283	15,634	3,521	806	2,715	3,607	4,413	

* Figures in this column are calculated by multiplying the corresponding row of the Est. Pop column by either the fee-paying "Agency-to-Location" ratio of 0.72 or the fee-exempt "Agency-to-Location" ratio of 0.81, depending on each registrant's fee status reported in the Fee Status column.
 .. Category not defined in the 2011 National Assessment; assumed to be private-sector entities.

As discussed previously, DEA's methodology for estimating the number of new EMS agency registrations must account for situations in which a practitioner is currently using a single DEA registration to serve as the medical director of multiple EMS agency locations. Because DEA does not have the ability to identify how many EMS agencies are currently operating in this manner, DEA chose to calculate a range of between 0 percent and 100 percent of EMS agencies that may have a DEA registration transferred from a practitioner. If 100 percent of the

estimated 3,809 fee-paying EMS agencies not separately registered are currently operating under a practitioner registration that will be transferred from their medical director, there will be no increase in fees (transfer payments) from these future registrants to DEA. If 0 percent of these 3,809 fee-paying EMS agencies operate under a practitioner registration that can be transferred from their medical director, there will be an increase in fees (transfer payments) of \$928,126 to DEA on an annual basis.²⁵ Likewise, calculations for the 50 percent

scenario yield an estimated increase in fees (transfer payments) of \$464,185.²⁶

Similarly, if 100 percent of the estimated 1,483²⁷ fee-paying registrations able to be consolidated currently operate under a practitioner that is using a single DEA registration to serve as the medical director of an EMS, there will be an annual reduction in transfer payments of \$361,358.²⁸ This transfer payment reduction is combined with the previously calculated reduction in transfers of \$96,248 from the 806 MLP-AS registrations that will be consolidated, resulting in a total

²⁰For example, of the 15,516 EMS agency locations reported to NHTSA by organizational type, 6,388 were Fire-Department-Based. 6,388 is 41.17 percent of 15,516. 41.17 percent of 21,283 is 8,762. This calculation is repeated for each organizational type and the results are reported in the "Est. Pop" column of Table 1.

²¹In order to classify EMS agencies currently registered as MLP-AS as either "Fire-Department-Based" or "Governmental Non-Fire-Based," DEA filtered all fee-exempt MLP-AS registrants into two

groups based on whether their registration name contained the word "fire."

²² 1,018/1,413 = 0.72.

²³ 1,697/2,108 = 0.81.

²⁴An "agency-to-location" ratio is not applied to the estimated 1,236 hospital-based EMS agencies, because this proposed rule does not impact their registration status.

²⁵3,809 x \$731 = 2,784,379. This figure is divided by three in order to account for the three-year

registration cycle, resulting in \$928,126 (figure is rounded).

²⁶3,809 x .5 = 1,905 (rounded). (1,905 x \$731)/3 = \$464,185.

²⁷Sum of the "Private Non-Hospital" and "Other EMS" rows of the Non-MLP-AS Registrations Eliminated column of Table 1. 1,107 + 376 = 1,483.

²⁸1,483 x \$731 = \$1,084,037. This figure is divided by three in order to account for the three-year registration cycle, resulting in \$361,358.

reduction in transfers of \$457,606. However, if 0 percent of agencies are operating in this manner, only the 806 MLP-AS consolidated registrations are relevant, resulting in a net increase in transfer payments of \$831,878.²⁹ Calculations for the 50 percent scenario yield an estimated reduction in fees (transfer payments) of \$277,049.³⁰ This results in a net increase of \$187,136 for

the midpoint scenario.³¹ Therefore, DEA estimates the annual net change in transfer payments as a result of this proposed rule will range between a decrease of \$457,606 and an increase of \$831,878, with the midpoint of these estimates resulting in an increase of \$187,136.

For the respective 0 percent, 50 percent, and 100 percent scenarios, DEA

converted the estimated annual change in transfer payments calculated above into annualized present values at a 7 percent discount rate and a 3 percent discount rate over 12 years, or three registration cycles.³² The results of this analysis are summarized below in Table 2.

TABLE 2

	100% of registrations Are transferred	50% of registrations are transferred	0% of registrations are transferred
Annual Change in Transfer Payments-MLP-AS (Consolidated)	\$(96,248)	\$(96,248)	\$(96,248)
Annual Change in Transfer Payments-EMS not Separately Registered	0	464,185	928,126
Annual Change in Transfer Payments-EMS Not Separately Registered (Consolidated)	(361,358)	(180,801)	0
Net Annual Change in Transfer Payments	(457,606)	187,163	831,878
Annualized Net Change in Transfer Payments Over 12 Years (Discounted 7%)	(302,885)	123,864	550,612
Annualized Net Change in Transfer Payments Over 12 Years (Discounted 3%)	(379,584)	155,229	690,043

All figures are rounded.

Labor Burden of Applications for DEA Registrations and Renewals

As detailed previously, of the estimated 4,827 fee-paying EMS agency locations and 10,807 fee-exempt EMS agency locations not separately registered, only 3,809 and 9,110 (a total of 12,919) will require separate registrations after the promulgation of this proposed rule, respectively. If 100 percent of these 12,919 EMS agencies will have an existing practitioner registration transferred from their medical director, there will be a decrease in labor burden of \$16,568,³³ due to the estimated 4,413³⁴ unnecessary registration renewal applications that can be consolidated

under one registration in a state. The previously calculated annual cost savings of \$3,026 (see note 15) from the consolidation of existing MLP-AS registrants is added to this total, resulting in an annual total labor burden reduction of \$19,594. DEA converted the \$19,594 decrease in labor burden into an annualized present value of \$12,969 at a 7 percent discount rate and \$16,253 at a 3 percent discount rate over three registration cycles, or 12 years.³⁵

However, if 0 percent of these 12,919 EMS agencies will have an existing practitioner registration transferred from their medical director, there will be a one-time increase in labor burden of \$272,830³⁶ due to the initial registration application paperwork for 12,919

registrants, and a triennial labor burden increase of \$136,431,³⁷ due to 12,919 registration renewals every three years. DEA converted the one-time burden of \$272,830 and the triennial burden of \$136,431 into an annualized present value of \$42,782 at a 7 percent discount rate and \$49,879 at a 3 percent discount rate over three registrations cycles, or 12 years.³⁸

Finally, under the 50 percent scenario, there will be a one-time increase in labor burden of \$136,426³⁹ due to the initial registration application paperwork for 6,460 registrants, and a triennial labor burden increase of \$38,824,⁴⁰ due to 4,253 registration renewals every three years. DEA converted the one-time burden of

²⁹ \$928,126 (calculated in note 25)-\$96,248 = \$831,878.

³⁰ $1,483 \times .5 = 742$ (rounded). $((742 \times \$731)/3) + \$96,248 = \$277,049$.

³¹ $\$464,185$ (calculated in note 26) $-\$277,049 = \$187,136$.

³² The present value of \$(457,606) over 12 years equals \$(3,634,620.91) at 7 percent and \$(4,555,011.95) at 3 percent. The present value of \$831,878 over 12 years equals \$6,607,305.99 at 7 percent and \$8,280,516.93 at 3 percent. The present value of \$187,136 over 12 years equals \$1,486,362.54 at 7 percent and \$1,862,752.49 at 3 percent. Dividing these respective results by 12 to account for three registration cycles yields the annualized net change in transfer payments found in Table 2.

³³ See approved burden estimates for DEA form 224A within the 1117-0014 Supporting Statement https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians (\$140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (4,413). The product (\$49,704.50) is then divided by three in

order to account for the three-year registration renewal period.

³⁴ As calculated previously, there are 395 fee-paying and 411 fee-exempt MLP-AS registrations that will be consolidated under a single registration in a State. Of the EMS agencies that are not separately registered, an estimated 3,607 can be consolidated under a single registration in a State. Combining 806 with 3,607 results in 4,413.

³⁵ The present value of \$19,594 over 12 years equals \$195,038.75 at 3 percent and \$155,629 at 7 percent. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

³⁶ See approved burden estimates for DEA form 224 within the 1117-0014 Supporting Statement https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians (\$140.79) by the hour burden per electronic DEA form 224 (0.15), by the estimated number of forms (12,919). The result is rounded.

³⁷ See approved burden estimates for DEA form 224A within the 1117-0014 Supporting Statement <https://www.reginfo.gov/public/do/>

[PRAViewDocument?ref_nbr=201903-1117-005](https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005). This labor burden estimate is derived by multiplying the loaded hourly wage for physicians (\$140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (12,919), resulting in \$145,509.28. This figure is reduced by \$9,078 to account for the triennial cost savings from the consolidation of existing MLP-AS registrants calculated in note 15, resulting in \$136,431.

³⁸ The present value of \$272,830 in year 1 and \$136,431 in years 4, 7, and 10 equal \$598,549.04 at 3 percent and \$513,380.84 at 7 percent discount rates. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

³⁹ $12,919 \times 0.5 = 6,460$ registrants. $\$140.79 \times 0.15 \times 6,460 = \$136,426$. The result is rounded.

⁴⁰ $(12,919 \times 0.5) - (4,413 \times 0.5) = 4,253$. $\$140.79 \times 0.08 \times 4,253 = \$47,902$ (rounded). This figure is reduced by \$9,078 to account for the triennial cost savings from the consolidation of existing MLP-AS registrants calculated in note 15, resulting in \$38,824.

\$136,426 and the triennial burden of \$38,824 into an annualized present value of \$16,753 at a 7 percent discount rate and \$18,950 at a 3 percent discount

rate over three registration cycles, or 12 years.⁴¹ Table 3 summarizes the estimated net change in labor burden cost for both

scenarios as a result of this proposed rule.

TABLE 3

	100% of registrations are transferred	50% of registrations are transferred	0% of registrations are transferred
Annualized Net Change in Labor Burden Over 12 Years (Discounted 7%)..... ¹	\$(12,969)	\$16,7531	\$42,782
Annualized Net Change in Labor Burden Over 12 Years (Discounted 3%)	(16,253)	18,950	49,879

Security and Recordkeeping Requirements

Because some EMS agencies are currently registered under the practitioner business activity as MLP-AS, this proposed rule adopts similar physical security controls for EMS agencies as practitioners. EMS agencies will be authorized to store controlled substances at EMS registered locations and designated locations inside of a securely locked, substantially constructed cabinet or safe that cannot be readily removed or an automated dispensing system; inside EMS vehicles stationed at registered or designated locations; and inside EMS vehicles that are actively in use by the agency. DEA expects currently unregistered EMS agencies to be operating in a similar manner as registered MLP-AS, and such EMS agencies are already in compliance with the minimum physical security requirements outlined above. Therefore, DEA expects the physical security requirements of this proposed rule to be a codification of existing practice that will impose no costs.

The recordkeeping provisions of this proposed rule require EMS agencies to record the details of any administration, disposal, acquisition, distribution, or delivery of controlled substances and make these records readily retrievable. DEA believes that EMS agencies are already collecting and storing these records as a normal course of their business operations, and therefore these recordkeeping requirements will have no economic impact on EMS registrants. Designated EMS locations with vehicles that restock controlled substances at a hospital after an emergency event or receive controlled substances from another designated location must also notify the registered location of the EMS agency within 72 hours. Because designated EMS locations have 72 hours to notify registered locations, and because designated and registered locations are likely to communicate on

a more frequent basis during their normal course of business, DEA does not expect these events to require any additional communication between designated and registered locations. Therefore, this provision will also have no economic impact on EMS registrants. DEA requests comment on the impact of this proposed rule's recordkeeping requirements.

Reducing Regulatory Uncertainty

Prior to the CSA amendments of the "Protecting Patient Access to Emergency Medications Act of 2017," the CSA did not explicitly explain exactly how its rules governing the administration, disposal, delivery, acquisition, and distribution of controlled substances applied to EMS agencies. Most adhered to rules governing mid-level practitioners in the absence of regulation that addressed the unique circumstances of EMS operations, and advocacy groups frequently highlighted their concerns regarding the need for regulations to specifically address EMS operations.

With the Act, and this proposed rule codifying the resulting CSA amendments into DEA regulation, EMS registrants have clear rules that direct their behavior regarding controlled substances. DEA expects there to be benefits resulting from this reduction in regulatory uncertainty, especially the explicit authorization of standing and verbal orders, by allowing EMS vehicles to restock their supply of controlled substances at hospitals following an emergency, and by allowing EMS vehicles and hospitals to transfer controlled substances between each other in the event of a shortage, public health emergency, or mass casualty event. DEA does not have a method to quantify the impact of these reductions in regulatory uncertainty; however, DEA believes the regulatory clarity provided by this proposed rule will result in a benefit to EMS agencies, EMS

professionals, and the public. Furthermore, due to the Act and proposed rule's authorization of standing and verbal orders afforded to EMS personnel which was previously not authorized, DEA considers this rule to be an enabling rule for the purposes of E.O. 13771.

Executive Order 12988, Civil Justice Reform

The proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have direct effects on one or more Indian tribes via Indian Health Services.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612) (RFA), has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. This proposed rule will have no bearing in reference to costs associated with registration fees.

⁴¹ The present value of \$136,426 in year 1 and \$38,824 in years 4, 7, and 10 equal \$227,403.22 at

3 percent and \$201,033.37 at 7 percent discount rates. Dividing these results by 12 to account for

three registration cycles yields the annualized present values.

All fees will be substantially the same irrespective of status, as there is no distinction in fee, when an applicant requests registration or modification for an EMS agency.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities, and discussions of its findings are below.

As discussed in the above economic analysis of the proposed rule, because DEA is not able to identify how many EMS agencies currently operate under the practitioner registration of their medical director, DEA chose to assess the impact of this proposed rule by considering the full range of possible scenarios. Thus, DEA considered the impact of the proposed rule if 0 percent, 50 percent, or 100 percent of EMS agencies receive an existing DEA registration from a practitioner. For the purposes of this analysis, DEA conservatively assumes that 0 percent of EMS agencies will have a DEA

registration transferred from a practitioner because this is the scenario with the largest possible economic impact on affected entities, including small entities.

There are three types of EMS agencies that are affected by this proposed rule: hospital-based, private, and governmental. Of these types, some agencies currently hold their own DEA registrations while others operate under the registration of another DEA registrant. As detailed previously, DEA estimated that 3,809 private EMS agencies and 9,110 governmental EMS agencies are currently not separately registered with DEA, while 1,018 private EMS agencies and 1,697 governmental EMS agencies are currently registered with DEA. Additionally there are an estimated total of 1,236 hospital entities⁴² that are affected by this proposed rule. DEA assumes all EMS agencies are affected in some way by this proposed rule, therefore, this proposed rule is expected to affect a substantial number of small entities.

These three types of entities are affected by at least one of the following four quantifiable impacts of the proposed rule: registration fees,

recordkeeping and security requirements, the labor burden of obtaining a DEA registration, and the labor burden of renewing a DEA registration. Only the 4,827 private EMS agencies are affected by registration fees. Governmental EMS agencies are fee-exempt and hospital-based agencies can continue to operate under their hospital's registration. All three types of entities, whether separately registered or not, are affected by the security and recordkeeping requirements of the proposed rule. However, there is no impact because these entities are expected to already be in compliance with these requirements. Both the estimated 3,809 private agencies and 9,110 governmental agencies not separately registered must incur the labor burden of registering and renewing their registration with DEA every three years. Hospital-based agencies already incur this labor burden, and this proposed rule will have no further impact on these entities. The following table summarizes the estimated impact of the provisions of the proposed rule for each type of EMS agency.

TABLE 4-PROVISIONS OF PROPOSED RULE

	Registration fees		Records & Security		DEA form 224		DEA form 224A	
	Affected entities	Impact per entity ⁴³	Affected entities	Impact per entity	Affected entities	Impact per entity ⁴⁴	Affected entities	Impact per entity ⁴⁵
Hospital-based EMS	N/A	N/A	1,236	\$0	N/A	N/A	N/A	N/A
Private EMS	3,809	218	4,827	0	3,809	21	3,809	4
Governmental EMS ..	N/A	N/A	10,807	0	9,110	21	9,110	4

DEA compared the combined annual economic impact per entity of the proposed rule with the annual revenue of the smallest of small entities in each

affected industry sector. For each of the affected industry sectors, the annual increase was not more than 0.6 percent of average annual revenue for the

smallest entities. The table below summarizes the results.

TABLE 5

NAICS code	NAICS code description	Number of affected entities	Number of smallest affected entities	Average revenue per smallest entity	Annual impact per entity (\$)	Impact %of revenue
622110	Offices of physical, occupational, speech, and hearing therapists (except audiologists)	1,236	20	\$190,600	\$0	0.00%
621910	Offices of all other health practitioners	16,239	373	44,150	243	0.55%

⁴² DEA does not have the ability to identify how many hospital registrants operate an EMS agency under the hospital's registration. However, DEA used NHTSA's national EMS assessment data to estimate the total number of hospital-based EMS agencies to be 1,236 [see Table 1]. Therefore, DEA considers 1,236 hospital entities to be affected by this proposed rule.

⁴³ The impact per entity of registration fees is calculated by dividing the net annual change in

transfer payments for the 0 percent range in Table 2 [\$831,878] by the number of affected private entities [3,809]. The final figure is rounded to the nearest whole dollar.

⁴⁴ The impact per entity of the labor burden for DEA form 224 is found by dividing the total labor burden for DEA form 224 calculated in note 36 [\$272,830] by the number of affected entities [12,919]. The final figure is rounded to the nearest whole dollar.

⁴⁵ The impact per entity of the labor burden for DEA form 224A is found by first dividing the triennial labor burden for DEA form 224A calculated in note 37 [\$145,509] by three to account for the three year registration cycle. This annualized labor burden [\$48,503] is then divided by the number of affected entities [12,919]. The final figure is rounded to the nearest whole dollar.

While this rule affects a substantial number of small entities, because the economic impact for the smallest entities is not significant, the proposed rule will not have a significant impact on small entities as a whole. In summary, DEA's evaluation of economic impact by size category indicates that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action would not result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year." Therefore, neither a Small Government Agency Plan nor any other action is required under URMA of 1995.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), DEA has identified the following collections of information related to this proposed rule and has submitted this collection request to the OMB for review and approval. This proposed rule would update DEA's regulations to provide for registration of EMS agencies and to require EMS agencies to maintain certain records and provide notice to DEA in certain circumstances. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/publicdoIPRAMain>.

A. Collections of Information Associated With the Proposed Rule

1. *Title:* Emergency Medical Services Recordkeeping and Notice Requirements.

OMB Control Number: 1117-New.

Form Number: N/A.

DEA is proposing to create a new collection of information by establishing new recordkeeping and notice requirements for EMS agencies.

For each EMS professional employed by a registered EMS agency, the agency would be required to maintain those documents, as required by the State in which the professional practices, which describe the conditions and extent of the professional's authorization to dispense or administer controlled substances, and must make such documents available for inspection and

copying by authorized employees of the Administration.

EMS agencies would also be required to maintain records of all controlled substances received, administered, or otherwise disposed of. Such records would be maintained, whether electronically or otherwise, at each registered and designated location of the agency where such controlled substances are received, administered, or otherwise disposed of.

For each dose of controlled substances administered or disposed of in the course of providing emergency medical services, these records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the date the substance was administered or disposed of; (4) identification of the patient, if applicable; (5) amount administered; (6) the initials of the person who administered the substance; (7) the initials of the medical director or authorizing medical professional issuing the standing or verbal order; (8) the amount disposed of, if applicable; (9) the manner disposed of; and (10) the initials of the person who disposed of the substance and of one witness to the disposal.

For controlled substances acquired from or distributed to another registrant, the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers transferred; (5) the date of the transfer; (6) name, address, and registration number of the person to or from whom the substance was transferred; and (7) the name and title of the person in receipt of the transferred substance.

For deliveries of controlled substances between a designated location and a registered location—except hospital-based agencies restocking at the hospital under which the agency is operating—the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers transferred; (5) the date of the transfer; (6) the name and address of the designated location to which the substance is delivered; and (7) the name and title of the person in receipt of the transferred substance.

For destruction of a controlled substance (*e.g.*, expired inventory), the records must include: (1) The name of the substance; (2) the finished form of

the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers destroyed; (5) the date of the destruction; (6) the name, address, and registration number of the person to whom the substance was distributed, if applicable; and (7) the name and title of the person destroying the substance.

Additionally, designated locations of EMS agencies would be required to notify their registered locations within 72 hours of any receipt of controlled substances in the following circumstances: (1) An EMS vehicle primarily situated at the designated location acquires controlled substances from a hospital while restocking following an emergency response; or (2) a designated location receives controlled substances from another designated location of the same EMS agency.

DEA does not have a good basis to estimate the number of respondents and burden related to this collection of information, because there is no available data regarding the administration, receipt, delivery, acquisition or distribution, and disposal of controlled substances specific to the operation of EMS agencies. Therefore, DEA submits the following estimated number of respondents and burden associated with this collection of information and will update this estimate with data when the collection is renewed:

Number of respondents: 21,283.

Frequency of response: average of 52 per year.

Number of responses: average of 1,106,716 per year.

Burden per response: .0833 hour.

Total annual hour burden: 92,226 hours.

Figures are rounded.

2. *Title:* Application for Registration-DEA 224, Application for Registration Renewal-DEA 224A.

OMB Control Number: 1117-0014.

Form Numbers: DEA-224, DEA-224A.

DEA is proposing to modify an existing collection of information by establishing new registration rules for EMS agencies.

Under proposed § 1301.13, EMS agencies, if authorized by state law, may register as a new type of business activity. A new "EMS Agency" business activity will be added to the application for registration and application for registration renewal forms to allow EMS agencies to obtain a DEA registration that will permit EMS agencies to deliver controlled substances to their

designated locations without obtaining a separate registration as a Distributor. This registration will allow EMS personnel to administer controlled substances outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services. Upon issuance of an EMS agency registration, the EMS agency should use the online system to identify all of the locations it intends to designate under the EMS agencies' DEA registration.

To lessen the burden for EMS agencies with several stationhouses in a single state, DEA proposes to allow EMS agencies to choose the option of a single registration in each state where the EMS agency operates. If the agency operates EMS facilities in multiple states, the agency must have a separate registration in each state where the agency operates.

DEA estimates the following number of respondents and burden associated with this collection of information:

Number of respondents: 621,472.

Frequency of response: 1 per year.

Number of responses: 621,472 per year.

Burden per response: 0.10 hour.

Total annual hour burden: 65,943 hours.

Figures are rounded.

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected agencies concerning the proposed collections of information are encouraged. Consistent with 44 U.S.C. 3506(c)(2), DEA solicits comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of DEA.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB37/Docket No. DEA-377.

All comments must be submitted to OMB on or before November 4, 2020. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

21 CFR Part 1307

Drug traffic control.

For the reasons stated in the preamble, the Drug Enforcement Administration proposes to amend 21 CFR parts 1300, 1301, 1304, 1306, and 1307 as follows:

PART 1300-DEFINITIONS

- 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

- 2. Add § 1300.06 to read as follows:

§ 1300.06 Definitions relating to emergency medical services agencies.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802).

(b) As used in parts 1301, 1304, 1306, and 1307 of this chapter, the following terms shall have the meanings specified:

(1) *Authorizing medical professional* means an emergency or other physician, or other medical professional (including an advanced practice registered nurse or physician assistant)-

(i) Who is registered under 21 U.S.C. 823;

(ii) Who is acting within the scope of the registration; and

(iii) Whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(2) *Designated location* means a location designated by an emergency medical services agency under 21 U.S.C. 823(j)(5).

(3) *Emergency medical services* means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(4) *Emergency medical services agency* means an organization providing emergency medical services, including such an organization that-

(i) Is governmental (including fire-based and hospital-based agencies),

non-governmental (including hospital-based agencies), private, or volunteer-based;

(ii) Provides emergency medical services by ground, air, or otherwise; and

(iii) Is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(5) *Emergency medical services professional* means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(6) *Emergency medical services vehicle* means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(7) *Hospital-based* means, with respect to an emergency medical services agency, owned or operated by a hospital.

(8) *Medical director* means a physician who is registered under 21 U.S.C. 823(f) and provides medical oversight to an emergency medical services agency.

(9) *Medical oversight* means supervision of the provision of medical care by an emergency medical services agency.

(10) *Registered emergency services agency* means-

(i) An emergency medical services agency that is registered under 21 U.S.C. 823(j); or

(ii) A hospital-based emergency medical services agency that is covered by the registration of the hospital.

(11) *Registered location* means, for purposes of emergency medical services, a location that appears on a DEA certificate of registration issued to an emergency medical services agency, which shall be where the agency receives controlled substances from distributors.

(12) *Specific State authority* means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops

clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(13) *Standing order* means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(14) *Stationhouse* means an enclosed structure that houses one or more emergency medical services agency vehicles within a State in which that emergency medical services agency is registered, and that is actively and primarily being used for emergency response by that emergency medical services agency.

(15) *Verbal order* means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical

presence of the medical director or authorizing medical professional.

PART 1301-REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 is revised to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965.

■ 4. In § 1301.12, add paragraph (b)(5) to read as follows:

§ 1301.12 Separate registrations for separate locations.

* * * * *

(b) * * *

(5) A designated location that is identified to the Administration by a registered emergency medical services agency at least 30 days prior to first delivering controlled substances to that unregistered location.

■ 5. In § 1301.13:

- a. Revise paragraph (d);
- b. Redesignate rows (e)(1)(v) through (x) as rows (e)(1)(vi) through (xi); and
- c. Add new row (e)(1)(v).

The revision and addition read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(d) At the time a retail pharmacy, hospital/clinic, practitioner, emergency medical services agency or teaching institution is first registered, that business activity shall be assigned to one of twelve groups, which correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is not less than 28 months nor more than 39 months from the date such business activity was registered. After the initial registration period, the registration expires 36 months from the initial expiration date.

(e) * * *

(1) * * *

Business activity	Controlled substances	DEA Application forms	Application fee (\$)	Registration period (years)	Coincident activities allowed
(v) Emergency Medical Services Agency.	Schedules 11-V	New-224 Renewal-224a	731	3	

* * * * *

■ 6. Add § 1301.20 under undesignated heading "Registration" to read as follows:

§ 1301.20 Registration for emergency medical services agencies.

(a) An emergency medical services agency shall be issued a registration under § 1301.13 if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices, unless the Administration determines that the issuance of such a registration would be inconsistent with the requirements of 21 U.S.C. 823(j) or the public interest based on the factors listed in 21 U.S.C. 823(f).

(1) An agency has the option of requesting a single registration in each State where the agency administers controlled substances in lieu of a separate registration for each location of the agency within a State.

(2) If a hospital where an emergency medical services agency is based is registered under § 1301.13, the agency may use the registration of the hospital to administer controlled substances in accordance with § 1306.07(e) of this chapter, without being separately registered as an emergency medical services agency.

(b) A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency designates the type of unregistered location as a stationhouse for such delivery; and notifies the Administration at least 30 days prior to the first delivery of controlled substances to the unregistered location. The delivery of controlled substances by a registered emergency medical services agency pursuant to this section shall not be treated as distribution. To notify the Administration, the emergency medical services agency must submit the name

and physical address of the designated location online at www.DEAdiversion.usdoj.gov.

§§ 1301.78 and 1301.79 [Added and Reserved]

■ 7. Add and reserve §§ 1301.78 and 1301.79 under undesignated heading "Security Requirements";

■ 8. Add § 1301.80 under undesignated heading "Security Requirements" to read as follows:

§ 1301.80 Security controls for emergency medical services agencies.

(a) A registered emergency medical services agency may store controlled substances at any of the following secured locations:

- (1) A registered location of the agency;
- (2) A designated location of the agency 30 days following notification to DEA in accordance with § 1301.20;
- (3) In an emergency medical services vehicle situated at a registered location or designated location of the agency; or

(4) In an emergency medical services vehicle used by the agency that is traveling from, or returning to, a registered location or designated location of the agency in the course of responding to an emergency, or otherwise actively in use by the agency.

(b) A registered emergency medical services agency may store controlled substances in a storage component that is identified as:

(1) A securely locked, substantially constructed cabinet or safe that cannot be readily removed; which is located at a secured location specified in § 1301.B0(a)(1) through (4); or

(2) An automated dispensing machine as defined in § 1300.01; which is

(i) Located at a secured location specified in 1301.B0(a)(1) and (2);

(ii) Installed and operated by the emergency medical services agency;

(iii) Not used to directly dispense controlled substances to an ultimate user; and is

(iv) In compliance with the requirements of State law.

PART 1304-RECORDS AND REPORTS OF REGISTRANTS

■ 9. The authority citation for part 1304 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 827, 831, 871(b), 958(e)-(g), and 965, unless otherwise noted.

■ 10. In § 1304.03, add paragraphs (i) and (j) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(i) For each emergency medical services professional employed by a registered emergency services agency, the registered agency must maintain in a readily retrievable manner those documents (as required by the State in which an emergency medical services professional practices), which describe the conditions and extent of the professional's authorization to dispense controlled substances, and must make such documents available for inspection and copying by authorized employees of the Administration. Examples of such documentation include protocols, practice guidelines, or practice agreements.

(j) A registered emergency medical services agency shall maintain records, as described in § 1304.27, of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration.

■ 11. In § 1304.04, revise paragraph (a) introductory text and add paragraphs (a)(4) and (5) to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (2) of this section, every inventory and other record required to be kept under this part must be kept by the registrant, and be available for inspection and copying by authorized employees of the Administration, for at least 2 years from the date of such inventory or record.

* * * * *

(4) Records shall include records of deliveries of controlled substances between all locations of the agency.

(5) Records shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

* * * * *

■ 12. Add § 1304.27 to read as follows:

§ 1304.27 Additional recordkeeping requirements applicable to emergency medical services agencies.

(a) Each emergency medical services agency registered pursuant to § 1301.20 of this chapter (including a hospital-based emergency medical services agency using a hospital registration under § 1301.20(a)(2) of this chapter) must maintain records for each dose of controlled substances administered or disposed of in the course of providing emergency medical services. The following information shall be included in each record:

- (1) Name of the substance;
- (2) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- (3) Date administered or disposed of;
- (4) Identification of the patient (consumer), if applicable;
- (5) Amount administered;
- (6) Initials of the person who administered the controlled substance;
- (7) Initials of the medical director or authorizing medical professional issuing the standing or verbal order;
- (8) Whether a standing or verbal order was issued and adopted;
- (9) Amount disposed of, if applicable;
- (10) Manner disposed of; and
- (11) Initials of person who disposed and witness to disposal.

(b) For each acquisition of a controlled substance from another registrant, or each distribution of a controlled substance to another registrant, each emergency medical services agency registered pursuant to § 1301.20 of this chapter must maintain records with all of the following information:

(1) For each acquisition of a controlled substance from another registrant:

- (i) Name of the substance;
- (ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- (iii) Number of units or volume of finished form in each commercial container;
- (iv) Number of commercial containers acquired (e.g., 100-tablet bottle or 3-milliliter vial);
- (v) Date of the acquisition;
- (vi) Name, address, and registration number of the person from whom the substance was acquired; and
- (vii) Name and title of the person acquiring the controlled substance.

(2) For each distribution of a controlled substance to another registrant:

- (i) Name of the substance;
- (ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- (iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
- (iv) Number of commercial containers distributed;
- (v) Date of the distribution;
- (vi) Name, address, and registration number of the person to whom the substance was distributed; and
- (vii) Name and title of the person in receipt of the distributed controlled substances.

(3) For each delivery of controlled substances between a designated location and a registered location:

- (i) Name of the substance;
- (ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- (iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
- (iv) Number of units or volume of finished form in each commercial container and number of commercial containers delivered (e.g., 100-tablet bottle or 3-milliliter vial);
- (v) Date of the delivery;
- (vi) Name and address of the designated location to which the substance is delivered; and
- (vii) Name and title of the person in receipt of the controlled substances.

(4) For destruction of a controlled substance:

- (i) Name of the substance;
- (ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram

concentration per fluid ounce or milliliter);

(iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iv) Number of units or volume of finished form in each commercial container and number of commercial containers destroyed (e.g., 100-tablet bottle or 3-milliliter vial);

(v) Date of the destruction;

(vi) Manner of disposal of the substance, if applicable;

(vii) Name, address, and registration number of the person to whom the substance was distributed, if applicable; and

(viii) Name and title of the person destroying the controlled substance.

(c) A designated location of an emergency medical services agency that receives controlled substances must notify the agency's registered location within 72 hours of receipt of the controlled substances, in the following circumstances:

(1) An emergency medical services vehicle primarily situated at a designated location of the emergency medical services agency acquires controlled substances from a hospital while restocking following an emergency response;

(2) The designated location of the emergency medical services agency receives controlled substances from another designated location of the same agency.

PART 1306-PRESCRIPTIONS

■ 13. The authority citation for part 1306 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 829, 831, 871(b), unless otherwise noted.

■ 14. Revise § 1306.01 to read as follows:

§ 1306.01 Scope of part 1306.

This part sets forth the process and procedures for dispensing, by way of prescribing and administering controlled substances to ultimate users. The purpose of such procedures is to provide safe and efficient methods for dispensing controlled substances while providing effective controls against diversion.

■ 15. Amend § 1306.07 by adding paragraphs (e) and (f) to read as follows:

§ 1306.07 Administering or dispensing of narcotic drugs.

* * * * *

(e) An emergency medical services professional of a registered emergency medical services agency may administer directly (but not prescribe) controlled

substances in schedules II-V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is authorized by law of the State in which it occurs; and is pursuant to:

(1) A standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State's authority; or

(2) A verbal order that is:

(i) Issued in accordance with a policy of the agency; and

(ii) Provided by a medical director or an authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient -

(A) In the case of a mass casualty incident; or

(B) To ensure the proper care and treatment of a specific patient.

(f) An emergency medical services agency shall maintain, at a registered location of the agency, a record of the standing or verbal orders issued or adopted in accordance with § 1304.13 of this chapter.

PART 1307-MISCELLANEOUS

■ 16. The authority citation for part 1307 is revised to read as follows:

Authority: 21 U.S.C. 821, 822(d), 823(j), 871(b), unless otherwise noted.

■ 17. Add § 1307.14 under undesignated heading "Special Exceptions for Manufacture and Distribution of Controlled Substances" to read as follows:

§ 1307.14 Delivery of controlled substances to designated locations of emergency medical services agencies.

(a) Notwithstanding the definition of registered location in § 1300.06 of this chapter, a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of § 1305.03 of this chapter, provided all of the following criteria are met:

(1) The registered or designated location of the agency operating the vehicle maintains the record of such receipt in accordance with § 1304.27(b) of this chapter;

(2) The hospital maintains a record of such delivery to the agency in accordance with § 1304.22(c) of this chapter; and

(3) If the vehicle is primarily situated at a designated location of an emergency medical services agency, such location

notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

■ 18. Add § 1307.15 under undesignated heading "Special Exceptions for Manufacture and Distribution of Controlled Substances" to read as follows:

§ 1307.15 Delivery of controlled substances in emergency situations.

(a) Hospitals and emergency medical services agencies' registered locations, and designated locations may deliver controlled substances to each other, with written approval from the Special Agent in Charge of DEA for the area or DEA Headquarters, in the event of:

(1) Shortages of such substances;

(2) A public health emergency; or

(3) A mass casualty event.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020-21675 Filed 10-2-20; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 127

[Docket No. USCG-2019-0444]

RIN 1625-AC52

Operational Risk Assessments for Waterfront Facilities Handling Liquefied Natural Gas as Fuel, and Updates to Industry Standards

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its regulations concerning waterfront facilities handling liquefied natural gas (LNG) and liquefied hazardous gas (LHG). The proposed rule would make the following three changes. First, the proposed rule would revise the Coast Guard's existing regulations to allow waterfront facilities handling LNG as fuel to conduct an operational risk assessment instead of a waterway suitability assessment (WSA) without first obtaining Captain of the Port approval. Second, the proposed rule would revise existing regulations to update incorporated technical standards to reflect the most recent published editions. Third, for waterfront facilities handling LNG that must comply with the WSA requirements, the proposed rule would require these facilities to provide information to the Coast Guard regarding the nation of registry for vessels transporting natural gas that are