12L (CAT II), ILS RWY 12L (CAT III), Amdt 12
Minneapolis, MN, MSP, ILS OR LOC RWY 12R, ILS RWY 12R (SA CAT I), ILS RWY 12R (CAT II), ILS RWY 12R (CAT III), Amdt 13
Minneapolis, MN, MSP, ILS OR LOC RWY 30L, ILS RWY 30L (CAT II), Amdt 48
Minneapolis, MN, MSP, ILS OR LOC RWY 30R, Amdt 17
Minneapolis, MN, MSP, ILS V RWY 35 (CONVERGING), Amdt 6
Minneapolis, MN, MSP, ILS Z OR LOC RWY 35, ILS RWY 35 (SA CAT I), ILS RWY 35 (CAT II), ILS RWY 35 (CAT III), Amdt 6
Minneapolis, MN, MSP, RNAV (GPS) Z RWY 12L, Amdt 6
Minneapolis, MN, MSP, RNAV (GPS) Z RWY 12R, Amdt 5
Minneapolis, MN, MSP, RNAV (GPS) Z RWY 30L, Amdt 6
Minneapolis, MN, MSP, RNAV (GPS) Z RWY 30R, Amdt 5
Minneapolis, MN, MSP, RNAV (GPS) Z RWY 35, Amdt 5
Minneapolis, MN, MSP, RNAV (RNP) Y RWY 12L, Amdt 1
Minneapolis, MN, MSP, RNAV (RNP) Y RWY 12R, Amdt 2
Minneapolis, MN, MSP, RNAV (RNP) Y RWY 30L, Amdt 2
Minneapolis, MN, MSP, RNAV (RNP) Y RWY 30R, Amdt 2
Minneapolis, MN, MSP, RNAV (RNP) Y RWY 35, Amdt 3
Kansas City, MO, MKC, RNAV (GPS) Z RWY 19, Amdt 2A
Smithfield, NC, JNX, ILS Y OR LOC Y RWY 3, Amdt 1B
Smithfield, NC, JNX, ILS Z OR LOC Z RWY 3, Amdt 2B
Smithfield, NC, JNX, RNAV (GPS) RWY 3, Amdt 2A
Smithfield, NC, JNX, RNAV (GPS) RWY 21, Amdt 2
Alamogordo, NM, ALM, RNAV (GPS) RWY 4, Amdt 2C
Ogdensburg, NY, OGS, RNAV (GPS) RWY 27, Amdt 2B
Columbus, OH, CMH, RNAV (GPS) Y RWY 28R, Amdt 3A
Kent, OH, 1G3, NDB RWY 2, Amdt 14
Kent, OH, 1G3, RNAV (GPS) RWY 2, Amdt 3
Kent, OH, 1G3, RNAV (GPS) RWY 20, Amdt 2
Kent, OH, 1G3, Takeoff Minimums and Obstacle DP, Amdt 1
Kent, OH, 1G3, VOR–A, Amdt 15
Piqua, OH, I17, RNAV (GPS) RWY 8, Amdt 1A
Piqua, OH, I17, RNAV (GPS) RWY 26, Amdt 1B
Austin, TX, HYI, RNAV (GPS) RWY 17, Orig-C
Dallas, TX, DAL, RNAV (GPS) Y RWY 13L, Amdt 2
Dallas, TX, DAL, RNAV (GPS) Y RWY 13R, Amdt 1
Fort Worth, TX, 4T2, Takeoff Minimums and Obstacle DP, Orig-A

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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: Final rule.

SUMMARY: The ''Protecting Patient Access to Emergency Medications Act of 2017,'' (the Act) which became law on November 17, 2017, amended the Controlled Substances Act (CSA) 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 is publishing this final rule to conform its regulations to the statutory amendments of the CSA and to otherwise implement its requirements. This final rule adopts, with minor modifications, the notice of proposed rulemaking published on October 5, 2020.

DATES: This rule is effective March 9, 2026.

FOR FURTHER INFORMATION CONTACT: Heather E. Achbach, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Outline

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(k). 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(k)(1). The Act also specifically authorizes the Attorney General (and thus the Administrator of the Drug Enforcement Administration (DEA) by delegation) [1] to issue certain regulations to implement the Act. *Id.* 823(k)(11).

B. Purpose

The purposes of this final rule are two-fold. First, this final rule codifies, in DEA regulations, the statutory amendments made by the Act, conforming DEA's implementing regulations to statutory amendments of the CSA that have already taken effect. Second, this final rule makes limited additional changes that are authorized by the CSA, as amended by the Act, and to further implement the Act and effectuate its purposes.

C. Background

When an individual experiences a medical emergency, the 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 60 million calls in 2024. 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

[1] 21 U.S.C. 871(a); 28 CFR 0.100(b).

[2] Federal Interagency Committee on Emergency Medical Services (FICEMS) 2011 National EMS Assessment.

[3] Kuehl, Alexander. ''25.'' Prehospital Systems and Medical Oversight. Dubuque, IA: Kendall/Hunt

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(k). The new 21 U.S.C. 823(k) makes several notable changes to the CSA.

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(k)(1)(A). Pursuant to 21 U.S.C. 823(k)(1)(B), the Act authorizes the Attorney General to deny the application of an EMS agency if registering it is inconsistent with other requirements of 21 U.S.C. 823(k) or with the public interest based on the factors of 21 U.S.C. 823(g).

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 EMS 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(k)(2). The Act also provides that a hospital-based emergency medical services agency registered under 21 U.S.C. 823(g) may use the registration of the hospital to administer controlled substances under 21 U.S.C. 823(k), without requiring the agency to acquire a separate registration. 21 U.S.C. 823(k)(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 while providing emergency medical services. 21 U.S.C. 823(k)(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(k)(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(k)(11).

E. Summary of the Notice of Proposed Rulemaking

DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** on October 5, 2020 to (1) codify in DEA regulations the statutory amendments of the CSA that have already taken effect; and (2) amend DEA regulations to implement the Act and effectuate its purposes, including by adding new regulations regarding the registration, security, recordkeeping, inventory, and administration requirements for EMS agencies.[7] DEA invited comments from the public on all of the topics covered in the NPRM to be submitted on or before December 4, 2020. This final rule responds to comments received concerning the proposed rule and adopts the proposed regulations with minor modifications.

II. Discussion of Public Comments

DEA received eighty-one comments in response to the publication of the NPRM. The commenters included EMS medical directors, physicians, medical associations, and members of the general public. DEA thanks all commenters for their comments and appreciates the input received during the rulemaking process. While the majority of the commenters expressed support for various provisions in the proposed rule, some commenters offered only partial support for the rule—agreeing with the general purpose of the rule, but disagreeing with particular provisions. Several commenters also disagreed with the proposed changes entirely, and two comments were entirely outside the scope of the rule. These comments and suggested changes to the rule, along with DEA's responses, are further described below.

Designated Location

Issue: DEA received nine comments which suggested eliminating the definition and concept of a stationhouse as a brick-and-mortar building that is primarily used for EMS and houses EMS vehicles. One commenter stated that EMS systems will likely need to designate locations where EMS vehicles, equipment or personnel are housed, even though such locations may not actually house vehicles inside that location. A commenter suggested that this is particularly true in urban systems that use central supply facilities, air ambulance bases, and other arrangements where vehicles are not permanently housed or stored indoors. Some commenters believe that this rule is too narrow an interpretation of congressional intent. Specifically, commenters stated that if Congress wanted to limit the designated location to a physical structure that houses an emergency medical services vehicle, then Congress would have done so. Another commenter objected to any requirement that EMS agencies designate locations to which they deliver controlled substances as unduly interfering with EMS agencies' flexibility.

DEA Response: The CSA and DEA regulations generally require dispensers of controlled substances to separately register each principal place of business from where they dispense controlled substances, allowing DEA to ensure that substances at those locations are not at

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] A non-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] *Id.*

[7] *Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of* 2017, 85 FR 62634 (Oct. 5, 2020).

unnecessary risk of diversion. *See* 21 U.S.C. 822(e)(1); 21 CFR 1301.12. The Act creates an exception to this requirement, authorizing an EMS agency to deliver controlled substances to unregistered locations designated by the agency with advance notice to DEA. 21 U.S.C. 823(k)(5). The Act, however, also expressly provides in 21 U.S.C. 823(k)(11)(A)(i) that DEA may by regulation ''specify[ ] . . . the types of locations that may be designated.'' Thus, Congress intended DEA to be able to place limitations on which locations could be designated, and authorized DEA to determine what those limitations should be, recognizing the need to avoid undermining the CSA's general requirement of registration and to avoid applying this exception in a way that would unnecessarily increase the risk of diversion.

In the proposed rule, DEA sought to fulfill this purpose by limiting designated locations to ''stationhouses'' and defining stationhouses as 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. By limiting designated locations to those clearly being used by EMS personnel to house and resupply EMS vehicles, the proposed rule sought to reduce the opportunities for controlled substances to be stolen by non-EMS personnel or mislaid. Through such limitations, the proposed rule also sought to ensure that designated locations would be readily identifiable to DEA investigators.

Commenters, however, have identified several situations in which EMS agency facilities may be used clearly and primarily for official EMS purposes—generally fulfilling purposes of the proposed rule's limitations—but not actually ''house'' associated EMS vehicles. Such purposes include but are not limited to the storage of medical supplies, controlled substances, and equipment; staff training and education; and administrative functions essential to EMS operations. The commenters were concerned with defining a ''stationhouse'' strictly as a brick-and-mortar structure that houses EMS vehicles. The commenters expressed concern that a narrow definition could inadvertently limit the operational flexibility of EMS agencies, particularly in scenarios where EMS operations are conducted from multiple locations.

In response to these concerns, in this final rule, DEA is amending the definition of ''stationhouse'' by removing the requirement that a stationhouse must house an EMS vehicle, removing the phrase ''for emergency response,'' and adding the phrase ''at its premises'' to accommodate locations where EMS vehicles are not housed or stored indoors. These revisions aim to acknowledge the unique operational demands of EMS agencies and ensure that this rule supports the efficient and effective delivery of emergency medical services. Specifically, the definition of stationhouse is revised to mean an enclosed structure within a State where the emergency medical services agency is registered, which may house EMS vehicles at its premises, and which is actively and primarily being used by that emergency medical services agency. DEA acknowledges the concerns raised about the limitations of the stationhouse definition and recognizes that it is important for EMS agencies to have the flexibility they need to effectively serve their communities. DEA's revised definition of stationhouse addresses the concerns raised and supports how EMS agencies treat patients and provides greater flexibility for EMS agencies to operate.

In response to the commenters' concern that EMS agency facilities may at times be used primarily for various operational EMS purposes, but not actually ''house'' associated EMS vehicles, DEA removed the requirement that a stationhouse must house an EMS vehicle from the stationhouse definition. DEA also removed the phrase ''for emergency response'' from the stationhouse definition in response to the comments received. DEA removed this phrase because in addition to housing EMS vehicles, stationhouses may also be used for various non-emergency EMS activities such as the storage of medical supplies, controlled substances, and equipment; staff training and education; and administrative functions essential to EMS operations. These regulatory changes provide EMS agencies with greater flexibility in fulfilling the operational activities involved in managing emergency medical services and response efforts. For this reason, DEA is removing the requirement that a stationhouse must house an EMS vehicle and removed the phrase ''for emergency response'' from the stationhouse definition. Thus, an EMS agency may house an EMS vehicle at a stationhouse, however it is not required. Additionally, although DEA has removed the phrase ''for emergency response,'' DEA is retaining the requirement that a stationhouse must actively and primarily be used by the emergency medical services agency. This would preclude, for example, an apartment or residence from being designated as a stationhouse.

Further, the addition of the phrase ''at its premises'' to accommodate locations where EMS vehicles are not housed or stored indoors, allows flexibility for an EMS agency to house a vehicle outside of an enclosed registered or designated location. The primary goal for this regulatory change is to provide EMS agencies with the necessary flexibility to effectively serve the public. EMS agencies play a critical role in responding to emergencies and providing life-saving medical care. However, the housing of EMS vehicles inside of a structure posed challenges for EMS agencies, particularly those with larger vehicles and limited space. By allowing EMS vehicles to be housed at the premises of an enclosed structure, but not necessarily within the structure itself, the regulatory changes ensure that agencies can maintain their vehicles in a manner that best suits their operational needs. While an EMS vehicle may be parked outside of a stationhouse, for security purposes, if it stores controlled substances it must be locked, with the controlled substances stored in a securely locked, substantially constructed cabinet or safe that cannot be readily removed.

While emphasizing the need for flexibility, DEA remains diligent in its commitment to preventing diversion and misuse of controlled substances. As such, for security purposes and diversion safeguards, an enclosed structure is necessary to securely store controlled substances at a stationhouse or designated location, if those controlled substances are being stored in the stationhouse or designated location, but not in an EMS vehicle. An enclosed structure is also required to maintain records, ensuring that these items are protected against unauthorized access and potential diversion. The regulatory changes are designed to create a balance between flexibility and diversion safeguards. For instance, although EMS vehicles may now be housed or stored at the premises of an enclosed structure, safeguards are in place to ensure the security of controlled substances. Specifically, EMS vehicles storing controlled substances must be locked when parked outside of an enclosed registered or designated location, with the controlled substances stored in a securely locked, substantially constructed cabinet or safe that cannot be readily removed. This measure mitigates the risk of diversion by ensuring that controlled substances are inaccessible to unauthorized individuals.

The regulatory changes are also driven by a commitment to public health and safety. DEA recognizes that EMS agencies often operate in dynamic and unpredictable environments where rapid emergency response is essential. By providing EMS agencies with greater flexibility in how they house their vehicles, the regulatory changes enable them to respond more effectively to emergencies, potentially saving lives in the process. This public health benefit must be weighed against the risk of diversion, and the regulatory changes are designed to strike an appropriate balance between these considerations.

Additionally, DEA is issuing this final rule to amend its regulations to make them consistent with the changes made to the CSA by the Act and to otherwise implement the Act's requirements. DEA recognizes that EMS agencies may at times need to utilize multiple locations as a regular part of their distribution networks. This final rule does not prevent them from doing so. For this reason and to be consistent with the requirements established by the Act, DEA will allow a single registration in each State where the agency operates.

Security Controls for Emergency Medical Services Agencies

Issue: DEA received five comments related to the possibility of storing controlled substances in a jump bag (*i.e.,* a mobile medical bag that can be removed from the EMS vehicle when responding to an emergency) in order for the EMS personnel to have quick access in an emergency situation. The comments also requested clarification of whether an EMS clinician can keep controlled substances on their person. The commenters further stated that many systems currently do not possess storage on their vehicles and prefer the EMS clinician physically possess a tamper evident package containing the controlled substances. These commenters suggested that this creates easier access to emergency medications at the patient's side because returning to a vehicle is not feasible with time sensitive emergencies like seizures. DEA also received a comment seeking clarification on whether the security requirements in the proposed rule applied in vehicles or only buildings, and a comment suggesting that requiring the use of ''cumbersome'' safes would interfere with the flexibility EMS agencies require.

DEA Response: The proposed rule offered EMS agencies several options for storing and otherwise maintaining the security of controlled substances. That portion of the final rule is unchanged: EMS agencies would 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 locked EMS vehicles stationed at registered or designated locations; and inside EMS vehicles that are actively in use by the agency.

The final rule incorporates changes to provide flexibility for EMS agencies driven by the comments received. Except when EMS personnel are carrying controlled substances on their person or in a jump bag as set forth in § 1301.80(d), a registered EMS agency must store controlled substances in a storage component that is identified as a securely locked, substantially constructed cabinet or safe that cannot be readily removed; which is located at a secured location specified in § 1301.80(a)(1) through (4); or an automated dispensing machine as defined in § 1300.01. In addition, an emergency medical services vehicle storing controlled substances must be locked when parked outside of an enclosed registered or designated location, or when it is actively in use, but unattended during non-emergency stops. An emergency medical services vehicle storing controlled substances does not need to be locked only if it is parked within an enclosed registered or designated location, it is at the scene of an emergency, or emergency services personnel are in attendance. Personnel are considered to be in attendance when personnel are physically present and able to monitor the vehicle; such as when the vehicle is traveling to or from the scene of an emergency, or it is at public displays or educational events. The presence of EMS personnel monitoring the vehicle mitigates the risk of diversion by ensuring that controlled substances are inaccessible to unauthorized individuals.

DEA recognizes the different and unique circumstances of EMS agencies and the practical issues presented in an emergency response. In response to the comments related to carrying controlled substances in a jump bag, DEA revised § 1301.80, adding new section (d). Controlled substances are not considered ''stored'' when they are being dispensed during an emergency response, or when EMS personnel are preparing them to be dispensed to respond to a particular emergency. Thus, this new provision allows EMS personnel to carry (as opposed to store) controlled substances on their person or in a jump bag as long as they are currently engaged in responding to an emergency. The goal is to allow personnel to have immediate and ready access to controlled substances to prepare for and provide emergency services during their active duties. The controlled substances must be returned to a storage component as described in § 1301.80(c)(1), either inside of the emergency medical services vehicle or at the registered or designated location, when emergency medical services agency personnel are not currently engaged in responding to an emergency, for example at the end of the shift and when the EMS vehicle is actively in use but on call and unattended (*i.e.,* such as when personnel stop for a break or meals). Additionally, EMS personnel may store controlled substances in a jump bag, so long as that jump bag itself is stored within a secure cabinet or safe.

Except when emergency medical services personnel are carrying controlled substances on their person or in a jump bag as set forth in (d), a registered emergency medical services agency must 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 § 1301.80(a)(1) through (4); or (2) an automated dispensing machine as defined in § 1300.01; which is located at a secured location specified in 1301.80(a)(1) and (2); installed and operated by the emergency medical services agency; not used to directly dispense controlled substances to an ultimate user; and is in compliance with the requirements of State law.

For purposes of this rule, as described in the definition for actively in use, ''on call'' means that the EMS vehicle and its personnel are ready and available to respond, but may not be responding to an emergency at that precise moment. Examples of ''on call'' would include providing standby medical coverage for public events; participating in educational events; or parking and leaving the vehicle unattended, such as when EMS personnel stop for lunch or a break.

The requirement that an EMS agency use a substantially constructed cabinet or safe to store controlled substances on an EMS vehicle parallels the security requirements for other registrants. *See e.g.,* 21 CFR 1301.72(e), 1301.75(b). The requirement that an EMS vehicle contain some sort of locked cabinet or safe to store controlled substances that is not readily removable should not be onerous, even if some EMS vehicles will need to have such storage installed. DEA believes that such a requirement is necessary to prevent diversion while controlled substances remain in an EMS

vehicle, including when an EMS vehicle is actively in use and left unattended. And Congress clearly contemplated that some such restrictions on storage would be necessary, expressly giving DEA authority to issue regulations regarding ''the storage of controlled substances . . . in emergency medical service vehicles.'' 21 U.S.C. 823(k)(11)(B); *see also* 21 U.S.C. 823(k)(6)(C)(ii) (controlled substances may be stored by EMS agencies ''under circumstances that provide for security of the control substances consistent with the requirements established by regulations of the Attorney General.''). DEA expects most currently unregistered EMS agencies to be operating in a similar manner as registered EMS agencies, and such EMS agencies are already in compliance with the minimum physical security requirements. Therefore, DEA expects the physical security requirements of this rule, on balance, to be a codification of existing practice that will impose minimal costs.

Recordkeeping Requirements

Issue: Roughly thirty commenters, most of whom are members of the National Association of EMS Physicians (NAEMSP), strongly urged DEA to remove the requirement for the medical director or authorizing medical professional to provide initials in the record in proposed § 1304.27(a). The members of the NAEMSP further noted that the standard electronic health records utilized for emergency medical services do not routinely provide a means by which the medical director can initial the chart.

Additionally, many commenters suggested that getting the medical director to initial every time a controlled substance is administered would create an undue burden on the EMS system and the medical professionals overseeing them. The commenters further noted that the law already requires that there be an existing protocol or verbal order in place providing the paramedic permission to administer the medication. Therefore, the commenters stated that physically or electronically tracking down the medical professional giving the order is impractical and problematic.

DEA Response: DEA works diligently to achieve operational efficiencies. The goal of this rule is to create more consistent usage and tracking nationally with respect to controlled substances for EMS agencies. Further, by requiring recordkeeping, this rule provides accountability, consistency, and clarity to the EMS community.

One important point of clarification: proposed § 1304.27(a) stated that the records of registered EMS agencies would be required to include ''initials'' of the person who administered the controlled substance, of the medical director or authorizing medical professional issuing the standing or verbal order, and of the person who disposed of a controlled substance (if applicable) and of the witness to the disposal. The proposed rule, however, did not specify whether the relevant individual had to personally write or input their initials, or whether records merely had to reflect those initials, even if written or entered by someone else.

The commenters objecting to this requirement generally based their objections on the understanding that the medical director or authorizing medical professional issuing the standing or verbal order must personally initial each record. That is, they do not necessarily object to the requirement that the records identify the medical director or authorizing medical professional issuing the relevant standing or verbal order, but they do object to the additional burden that asking such directors or professionals to personally initial each record would place on EMS agency operations or to the incompatibility of this approach with their recordkeeping systems.

DEA, however, did not intend in proposed § 1304.27(a) to require that the person who administered the substance, the medical director or authorizing medical professional who issued the standing or verbal order, the person who disposed of the substance (if applicable), or the witness to the disposal (if applicable) personally initial each record. It is enough for DEA's purposes that the records clearly and accurately reflect their identities to allow DEA to discern under whose authority the controlled substance was administered. In many situations, the best way to ensure that these records are accurately maintained may be for the EMS agency to have individuals personally initial these records themselves. But, as commenters highlight, there are situations in which this is practically difficult, and thus DEA is not requiring such personal initialing.

Accordingly, to further clarify that personal initialing is *not* required in this context, DEA is revising § 1304.27(a) in this final rule. Instead of referring to ''initials,'' this provision now refers to the ''last name *or* initials'' of the relevant people: the person who administered the substance, the medical director or authorizing medical professional who issued the standing or verbal order, the person who disposed of the substance (if applicable), and the witness to the disposal (if applicable). The medical director or other authorizing medical professional is not required to initial the records personally.

DEA also does not believe records need to specifically reference the full name of the medical director or authorizing medical professional that issued that order for that particular patient. If the goal is to create efficiency, then writing the full name of the medical director or authorizing medical professional would create additional work and time for EMS personnel, and initials should generally suffice to identify the relevant individual. For this reason, while a registrant could satisfy this provision by writing out a full name, DEA also will maintain the option that EMS agencies only record these individuals' last name or initials.

Issue: Several commenters expressed other concerns related to the proposed 21 CFR 1304.27(a) recordkeeping requirements, viewing them as duplicative or inefficient. In addition to the requirement of initials discussed previously, proposed § 1304.27(a) would have required any EMS personnel who dispose of or administer controlled substances to a patient in the course of providing emergency medical care to 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). The commenters agree that EMS agencies should maintain a record of all standing or verbal order protocols, but urge DEA to not create new recordkeeping requirements that are duplicative of systems that are currently in place.

Similarly, commenters stated that the Patient Care Record (PCR) should be sufficient as it has the required additional record requirement with the name of the medical director who issued the standing order or the provider who gave a verbal order. Multiple commenters stated that EMS providers are already required to complete PCRs on all patient encounters and include all the information that is being proposed by this regulation and that therefore having a separate recordkeeping system to meet DEA's recordkeeping requirement is overly burdensome and redundant.

DEA Response: Recordkeeping is necessary to allow DEA to conduct meaningful investigations and guard against diversion. It is not DEA's intent to place an undue burden on the public. DEA considers the burden on the public in every rulemaking process by

performing a thorough economic analysis prior to publication.

Contrary to the commenter's suggestions, the recordkeeping provisions of this rule does not impose any additional requirements on EMS agencies other than what they are currently required to do. The recordkeeping requirements outlined in this rule codify existing practices. EMS agencies are required 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.

As explained in the regulatory analyses section below, DEA conducted an analysis of the statutory and regulatory changes of this rule and concluded that benefits of the rule are expected to be generated by reducing regulatory uncertainty among EMS agencies and personnel regarding the administration, transfer, and disposal of controlled substances. Furthermore, DEA believes that because EMS agencies are already collecting and storing these records as a normal course of their business operations, fulfilling the requirements of § 1304.27(a) should not create substantial additional burden.

Issue: NAEMSP members have stated that, instead of the requirements in proposed § 1304.27(a), including the following recordkeeping requirements in the final rule will be far more effective in ensuring compliance and oversight: 1. for standing orders, require that the record specifically reference the standing order utilized to authorize the administration of the controlled substance and that the EMS Agency maintain appropriate copies of these standing orders, to include the name of the authorizing EMS medical director; 2. for verbal orders, require the record to specifically reference the name of medical director or authorizing medical professional that issued that particular verbal order for that particular patient; 3. require that administration of controlled substances be included in the agency's quality assurance or improvement program which is overseen by the medical director to ensure retrospective compliance on a systemic agency level; and 4. require an internal audit to be completed at least annually by the agency and reviewed by the medical director to ensure compliance with standing and verbal orders in the administration of controlled substances. The NAEMSP members also added that the National Emergency Medical Services Information System (NEMSIS) already includes the name of the authorizing EMS medical director or medical professional that issued the standing or verbal order as a data element in the EMS electronic health record. The NAEMSP members further stated that for verbal orders, the name of the physician or authorizing medical professional is entered as well.

DEA Response: DEA appreciates these suggestions. With respect to standing and verbal orders, while initials should generally be adequate to identify the individual who gave the order, DEA has no objection to EMS agencies listing last names instead of initials and has changed the regulatory text in this rule accordingly. Thus, in § 1304.27(a), DEA has changed the requirement that EMS agency records reflect certain individuals' ''initials'' to allow agencies to instead record a ''last name or initials.''

For maintenance of standing orders, the Act (in 21 U.S.C. 823(k)(13)(M)) and proposed 21 CFR 1300.06(b)(13) already require that a standing order be a ''written medical protocol'' containing a determination by the medical director. To satisfy this requirement, an EMS agency already will have to retain a copy of the standing order that indicates the medical director's authorization. EMS agencies are required to maintain complete and accurate records of patient care, including any orders or protocols used in treatment. Retaining a copy of standing orders ensures compliance with established standards of care. No more is necessary.

NAEMSP members' suggestions regarding quality assurance or improvement programs and internal audits provide potentially useful ideas for how EMS agencies may ensure the integrity of their controlled substance dispensing and maintain effective controls against diversion. And DEA agrees that medical directors are responsible for monitoring the dispensing of controlled substances by EMS personnel to ensure that their orders are not being abused to divert controlled substances. DEA has concluded, however, that EMS agencies can accomplish this in a number of ways, and that specifically requiring the recommended programs and audits is beyond the scope of these regulations.

DEA is aware that NEMSIS provides a framework for collecting, storing, and sharing standardized EMS data from States nationwide. DEA must ensure its ability to investigate registrants' dispensing of controlled substances as appropriate. DEA may consider the efficacy of NEMSIS-compliant patient care reporting software to fulfill the recordkeeping requirement to ensure compliance with standing and verbal orders in the administration of controlled substances.

Issue: An anonymous commenter stated that proposed § 1304.27 is sensible in theory, but in reality, EMS work is often chaotic with back-to-back calls and distractions between patients. This commenter further stated that it may be nearly impossible for an individual to collect and retain such detailed information as the names of those who are administered critical care involving controlled substances, beyond the timeframe of the event, so to be recorded properly under proposed § 1304.27. This commenter was concerned about the protections that will be put in place for EMS workers who are unable to provide this information due to extenuating circumstances or who make mistakes in their recordkeeping after a mass casualty.

DEA Response: DEA understands the need to balance the prevention of diversion of controlled substances with the important ability for EMS agencies to dispense controlled substances in the field to patients in need, in challenging circumstances. Maintaining this balance is the precise purpose of the proposed rule. DEA regulations have always required that all registrants maintain effective recordkeeping requirements to prevent diversion of controlled substances and tracking if diversion does occur.

Thus, DEA cannot remove the requirement of recordkeeping here, especially given the increased potential for diversion from EMS vehicles operating in the field, as opposed to in a secure environment, and where unregistered EMS personnel are relying on the authority of others to administer controlled substances. That said, DEA considers all relevant circumstances when assessing the severity of recordkeeping violations by registrants and recognizes that some EMS agencies may have occasional difficulty fully complying with the requirements of § 1304.27. Given the importance of these requirements, however, DEA concludes that such difficulties are not a sufficient reason to eliminate them.

Issue: In contrast to the previously noted comments, a commenter suggested that DEA should consider stringent recordkeeping requirements when allowing administration of controlled substances without direct oversight due to EMS personnel's lack of independent authority to administer controlled substances.

DEA Response: DEA agrees that the unique circumstances of EMS

administrations—and the heightened diversion risk associated with these circumstances—require careful recordkeeping to ensure that EMS agencies can maintain effective controls against diversion. As already discussed, however, such concerns must be balanced against the need to avoid overburdening EMS agencies and allowing them to operate effectively. DEA has concluded that the recordkeeping requirements in this rule strike that balance, ensuring DEA investigators have access to the information they need without imposing unnecessary burdens on EMS agencies.

Educational Training

Issue: Three commenters raised concern about EMS personnel having the appropriate training. One commenter noted that the proposed rule does not address the educational requirements related to delivering emergency medication without physician supervision. This commenter mentioned that there have been instances of over-medicating a patient in the field resulting in death and stated that the proposed rule is widening the scope of authority without mention of proposed additional education on the proper weight-based dosage of schedule II to IV drugs. Another commenter stated that, given that there are large ranges of experience and knowledge among EMS personnel, ranging from volunteers to veteran paramedics, effective certification and safety parameters that EMS personnel are expected to uphold in the course of their training and regular certification renewals should be put in place.

DEA Response: DEA agrees an EMS agency should ensure that its personnel are properly trained before allowing them to dispense controlled substances under the agency registration. Neither the CSA nor the Act, however, authorizes DEA to set medical training requirements or other medical qualifications for EMS personnel. Such requirements may be set by other Federal, State, or local authorities. Thus, the final rule (§ 1300.06(b)(6)), following the Act (21 U.S.C. 823(k)(13)(E)), requires EMS personnel administering controlled substances to be ''licensed or certified by the State in which the professional practices,'' but does not itself set educational or other certification requirements for these professionals.

Other Comments

Issue: A commenter stated that EMS agencies located near State borders respond to emergencies in neighboring States. This commenter asked if EMS agencies could operate in these neighboring States without registering in them.

DEA Response: EMS agencies that wish to operate in multiple States must register with DEA in each State in which they operate. The Act itself indicates this requirement when it directs DEA to allow an EMS agency ''the option of a single registration *in each State* where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.'' 21 U.S.C. 823(k)(2) (emphasis added). Thus, the Act removes the requirement of 21 U.S.C. 822(e)(1) and 21 CFR 1301.12(a) that an EMS registrant separately register at each principal place of business or professional practice for which the EMS agency dispenses controlled substances. But it retains the requirement that registrants separately register in each State in which they dispense controlled substances. Because DEA registrations are based on compliance with applicable State and local laws, including State licenses to dispense controlled substances, a practitioner must maintain a DEA registration in each State in which the practitioner dispenses controlled substances. 21 U.S.C. 823.

Likewise, the Act directly ties DEA's registration of an EMS agency to such State licensing, directing DEA to register an EMS agency if the agency demonstrates that ''it is authorized to conduct [emergency medical services] under the laws of each State in which the agency practices'' and the registration is not inconsistent with the Act or the public interest. 21 U.S.C. 823(k)(1). DEA thus relies on State licensing bodies to determine that EMS agencies are qualified to perform emergency medical services. State authority to conduct these activities only confers rights and privileges within the issuing State; consequently, a DEA registration based on a State license cannot itself authorize controlled substance dispensing outside of the State. This aspect of the CSA and DEA regulations also helps to ensure that each State retains the primary authority to regulate the practice of medicine within its borders.

Issue: A comment requested additional information on how EMS agencies are to dispose of controlled substances under the rule.

DEA Response: DEA regulations regarding the disposal of controlled substances are contained in 21 CFR part 1317. The purpose of the rules set forth in 1317 is to provide prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances. In § 1304.27, this rule sets certain recordkeeping requirements for the disposal of controlled substances by EMS agencies, but does not otherwise alter the existing regulatory requirements for disposing of controlled substances. Any broader changes to DEA's disposal requirements are outside the scope of this rule.

Issue: A commenter requested that DEA clarify the extent of proposed 21 CFR 1307.14, which would allow an EMS vehicle to restock at a hospital under certain circumstances. The commenter, noting EMS vehicles may operate at significant distances from the hospital whose registration they are using, asked DEA to indicate whether such an EMS vehicle may only restock at the hospital under whose registration they are operating or may also restock at other hospitals. Another commenter indicated that many EMS vehicles restock at hospitals far from their registered location as a matter of course under State regulations and objected to any further restrictions on their ability to do so.

DEA Response: Nothing in 21 CFR 1307.14 or 21 U.S.C. 823(k)(8), the statutory text it implements, limits the hospitals at which EMS vehicles may restock to those under whose registration they are operating. Thus, an EMS agency satisfying the conditions of § 1307.14 may restock their vehicle at one hospital even if they are operating under the registration of another hospital. DEA has concluded the proposed regulatory text in § 1307.14 is sufficiently clear as is, and that adding this clarification to the regulatory text would unnecessarily complicate it. Moreover, the requirements of § 1307.14 are not onerous, merely requiring appropriate recordkeeping to document the restocking and notification to the EMS agency's registered location. Thus, DEA has not changed § 1307.14 in this final rule.

Issue: An anonymous commenter had a question regarding the exemption from DEA application fees for EMS agencies. This commenter understood the proposed rule as exempting fire department EMS from paying the application fees, but not EMS-only agencies, and asked why this was so.

DEA Response: Pursuant to the existing provisions of 21 CFR 1301.21(a)(1), ''any hospital or other institution which is operated by an agency of the United States, . . . of any State, or any political subdivision or agency thereof'' is exempt from application fees. If an EMS agency were operated by the fire department, and the

fire department is operated by the local government, it would be exempt from application fees. Even if the EMS agency is not operated by a government fire department, if the EMS agency itself is operated by the local government, it would also be exempt from application fees. A privately-owned EMS agency, which is not operated by the local government, is therefore not exempt from paying application fees due to its non-governmental affiliation.

Issue: A healthcare management student expressed a concern regarding EMS agencies who work under a parent hospital's registration. This commenter stated that EMS agencies working under hospital registration should be required to file for their own registration, rather than operating under a hospital's registration as allowed by proposed § 1301.20(a)(2). This commenter believes that an EMS agency working under a parent company's registration is not receiving proper evaluation by DEA.

DEA Response: DEA has no discretion regarding this requirement. The CSA, as amended by the Act, expressly allows hospital-based EMS agencies to operate under the hospital's registration rather than obtaining their own separate registration. 21 U.S.C. 823(k)(3). The rule simply adds § 1301.20(a)(2) to DEA regulations to reflect this statutory allowance. Moreover, as explained in the NPRM, even before the Act's passage, DEA had historically allowed EMS agencies to operate under hospitals' registrations rather than separately registering.[8] Based on this experience, DEA has found allowing hospitals to extend their registration to certain EMS agencies to be consistent with the public health and safety. This approach still allows DEA to monitor an EMS agency's dispensing of controlled substances and enforce DEA regulations through the hospital's registration. And it is in the best interest of the public to allow certain EMS agencies to operate under the registration of hospitals for purposes of efficiency and reducing operation costs.

Issue: Another commenter expressed a concern about proposed § 1307.15, which would allow EMS agencies to deliver controlled substances to each other with the written approval of the Special Agent in Charge (SAC) for the area or DEA Headquarters during shortages, public health emergencies, or mass casualty events. The commenter stated that this proposed provision is confusing and did not explain why such approval is needed.

DEA Response: Under most circumstances, one hospital or EMS agency cannot distribute controlled substances to another hospital or EMS agency because they are registered with DEA to dispense controlled substances to patients, not to distribute them. *See, e.g.,* 21 U.S.C. 822(b) (registered persons only authorized to engage in activities permitted by their registration); 21 CFR 1301.13(e)(1)(ii) (establishing separate registration category for distributors); 21 CFR 1307.11 (authorizing practitioners registered to dispense to also distribute small amounts of controlled substances to one another under certain conditions without registering as distributors). By generally restricting the distribution of controlled substances to registered distributors, the CSA and DEA regulations allow DEA to better monitor the movement of controlled substances through the closed system of distribution and detect diversion of those substances.

The Act, however, as codified at 21 U.S.C. 823(k)(11)(C), specifically authorizes DEA to issue regulations allowing hospitals and EMS agencies to deliver controlled substances to one another during shortages, public health emergencies, or mass casualty events. This rule does so in 21 CFR 1307.15 and makes written approval from the SAC for the area or DEA Headquarters a condition of this allowance.

This approval requirement serves two primary purposes. First, as noted, the Act only authorized this allowance in limited circumstances: shortages, public health emergencies, and mass casualty events. Requiring SAC or Headquarters approval allows DEA to keep this allowance appropriately limited to the circumstances specified in the Act.

Second, as explained above, generally restricting distribution to registered distributors enables DEA to better monitor distribution and prevent diversion—because DEA is aware which registrants will be distributing controlled substances. Requiring written approval fulfills a similar purpose: hospitals and EMS agencies will be informing DEA that they are also going to be engaged in temporary distributing, thereby better enabling DEA to monitor that distributing and prevent diversion.

To the degree that there is any confusion about how to contact Headquarters or the relevant SAC, contact information is available on the DEA Diversion Control Division's website, *www.DEAdiversion.usdoj.gov.*

Further, although the existence of a mass casualty incident is also relevant to whether controlled substances may be administered pursuant to a verbal order, see 21 U.S.C. 823(k)(4)(B), 21 CFR 1306.07, Headquarters or SAC approval is not required before a medical director or authorizing medical professional may issue such a mass casualty incident verbal order. Headquarters or SAC confirmation of a mass casualty is only necessary to make deliveries pursuant to 21 CFR 1307.15.

Finally, DEA acknowledges that restocking EMS vehicles with controlled substances is a concern for some commenters, particularly regarding the time constraints EMS personnel face after emergency responses. Under § 1307.14(a) of this final rule, a registered EMS agency may receive controlled substances from a hospital for purposes of restocking an EMS 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.

Issue: Multiple commenters voiced concern that the proposed changes would hinder effectiveness in providing services to underserved smaller, rural, and urban communities. These commenters stated that the proposed changes would cause a significant operating cost increase to EMS agencies that are already on extremely tight budgets and struggling to stay afloat.

DEA Response: DEA appreciates the concerns raised by commenters that the proposed changes may hinder the effectiveness of the rule in providing services to underserved small, rural, and urban communities. The intent of the rule is to increase access to these communities, while ensuring that certain recordkeeping and security requirements are met to prevent the diversion of controlled substances. The need to ensure that individuals in the underserved communities and remote locations receive the care they need must be balanced against security and recordkeeping requirements to ensure that the controlled substances are not diverted for illicit use.

The specific reasons commenters gave for why the proposed rule would allegedly hinder the ability of EMS

[8] *Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of* 2017, 85 FR 62634, 62637 (Oct. 5, 2020).

agencies to serve these communities include the definition of stationhouse, difficulty getting a medical director to personally initial records or returning to the hospital to restock, and stringent security requirements.

Some commenters were concerned that the definition of ''stationhouse'' would not apply to some structures used in rural or urban settings because the structures did not house EMS vehicles. Other commenters noted that EMS vehicles operating in rural environments far from their registered location may have difficulty getting a medical director to personally initial records or returning to the hospital at which they are registered to restock.

In this final rule, as discussed above, DEA is amending the definition of ''stationhouse'' to provide clarity by removing the requirement that a stationhouse must house an EMS vehicle, removing the phrase ''for emergency response,'' and adding the phrase ''at its premises'' to accommodate locations where EMS vehicles are not housed or stored indoors. These revisions aim to acknowledge the unique operational demands of EMS agencies and ensure that this rule supports the efficient and effective delivery of emergency medical services. DEA acknowledges the concerns raised about the limitations of the stationhouse definition and recognizes that it is important for EMS agencies to have the flexibility they need to effectively serve their communities.

The addition of the phrase ''at its premises'' is intended to accommodate locations where EMS vehicles are not housed or stored indoors and allows flexibility for an EMS agency to house a vehicle outside of an enclosed registered or designated location. However, an EMS vehicle may be parked outside of a stationhouse, but for security purposes, if it stores controlled substances, it must be locked with the controlled substances stored in a securely locked cabinet or safe. The primary goal for this regulatory change is to provide EMS agencies with the necessary flexibility to effectively serve the public. EMS agencies play a critical role in responding to emergencies and providing life-saving medical care. However, the housing of EMS vehicles inside of a structure posed challenges for EMS agencies, particularly those with larger vehicles and limited space. By allowing EMS vehicles to be housed at the premises of an enclosed structure, but not necessarily within the structure itself, the regulatory changes ensure that agencies can maintain their vehicles in a manner that best suits their operational needs.

The final rule will also allow EMS agencies to administer controlled substances via standing or verbal orders from the medical director, thereby eliminating the requirement to personally initial records.

With respect to commenters' request for more flexible security requirements, the goal of this final rule is to provide flexibility for EMS agencies to operate. DEA recognizes the different and unique circumstances of EMS agencies and the practical issues presented in an emergency response. In response to the commenters' concern about flexible security requirements, this final rule will allow EMS personnel to carry controlled substances on their person or in a jump bag while responding to an emergency to have immediate and ready access to controlled substances while providing emergency services. The final rule also recognizes the critical need for EMS personnel to have swift and easy access to controlled substances during emergencies by allowing EMS personnel to carry controlled substances on their person or in a jump bag during emergencies. This provision ensures immediate access to necessary medications, enhancing the ability to provide rapid and effective care. It maintains strict security protocols to prevent diversion and supports the overall goal of improving patient outcomes in emergency situations. While the rule allows for portability, it maintains strict security measures. Controlled substances must be returned to a storage component consistent with the requirements of 21 CFR 1301.80(c) when EMS personnel are not currently engaged in responding to an emergency. This ensures compliance with regulatory requirements and minimizes the risk of diversion.

Additionally, the Regulatory Flexibility Act (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, such as the small rural or urban EMS agencies, and concluded that the final rule will not have a significant impact on small entities as a whole.

Out of Scope Comments

DEA appreciates all comments that were received during the comment period. DEA received two comments which were outside of the scope of this rule. These comments did not mention content related to actual changes of the proposed regulatory text. An anonymous commenter made a general complaint about alleged evidence of voter fraud and a State representative's alleged deceptive voter registration. This comment was clearly outside the scope of the rulemaking and therefore not addressed. Another commenter sought clarification of certain provisions within State legislation regarding EMS agencies, which is also outside the scope of this rule.

III. Section-by-Section Summary of the Final Rule

The purposes and functions of this rule were discussed in the NPRM. The Act amended the CSA to add regulatory provisions pertaining to the handling of controlled substances by EMS professionals, and the majority of the provisions of this final rule merely reiterate those statutory requirements. The remainder of this rule includes changes to the registration, security, recordkeeping, inventory, and administering requirements for EMS agencies, which are discussed below.

Consistent with the Act, DEA is implementing regulations to explicitly include EMS agencies handling controlled substances as registrants under the CSA [9] and to delineate the security and recordkeeping requirements for EMS registrants who store, transport, and administer controlled substances. DEA is also implementing regulations to codify 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.[10] In

[9] Consistent with 21 U.S.C. 823(k)(3), DEA is implementing regulations that will 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.

[10] 21 U.S.C. 823(k)(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(k)(13)(N) defines *verbal order* as 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

addition, DEA is implementing 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 controlled substances, public health emergencies, or mass casualty events.

In this manner, DEA is bringing its regulations into conformity with the Act's amendments to the CSA. In particular, 21 CFR 1300.06 adds 21 U.S.C. 823(k)(13)'s new definitions of relevant terms to DEA regulations. Section 1301.12 is being amended to reflect the statutory amendments of sections 823(k)(2) and 823(k)(5), and § 1301.13 is being amended to bring it into conformity with section 823(k)(1). Section 1301.20(a) is adapted directly from the statutory amendment, specifically from section 823(k)(1)–(3). The provisions of § 1301.80(a) add provisions from section 823(k)(6). Section 1304.03(j) is taken from section 823(k)(9)(A). Section 1306.07(g) adds the provisions of sections 823(k)(4) and 823(k)(10)(D) to DEA regulations, while § 1307.14 adds those of section 823(k)(8).

Not all of the proposed amendments to DEA regulations, however, directly codify the Act's statutory amendments in DEA regulations. Some of the changes—specifically, §§ 1301.20(b), 1301.80(b), 1304.03(i), 1304.04, 1304.27, 1306.07(h), 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(k)(11), and 21 U.S.C. 871(b).

The regulatory text in this final rule is identical to that in the proposed rule aside from the following changes:

- The definition for ''actively in use'' and ''on call'' were added to 21 CFR 1300.06. The definition of ''actively in use'' was added to provide clarity under 21 U.S.C. 823(k)(6)(C)(ii) as to when an EMS vehicle used by an agency may store controlled substances. This definition would include instances when an EMS vehicle is responding to an emergency, is transporting patients, or is on call. ''On call'' means that personnel are ready and available to respond, but may not be responding to an emergency at that precise moment. EMS vehicles and personnel are considered ''on call'' when they are prepared to respond to emergencies, even if they are not actively engaged in an emergency call. This includes periods when the vehicle is on standby for the next call, which may include waiting in designated standby areas, maintaining readiness for deployment. Examples of ''on call'' also include, but are not limited to, participating in public safety or educational events, and parking and leaving the vehicle unattended, during lunch or a break, for example. The aim is to delineate when an EMS vehicle is considered engaging in an emergency response or waiting for the next call.
- In 21 CFR 1300.06, DEA is amending the definition of ''stationhouse'' to provide clarity by removing the requirement that a stationhouse must house an EMS vehicle, removing the phrase ''for emergency response,'' and adding the phrase ''at its premises'' to accommodate locations where EMS vehicles are not housed or stored indoors. ''At the premises'' specifically refers to the stationhouse premises, where EMS vehicles are parked outside of a stationhouse. This includes areas directly associated with the stationhouse where EMS activities are conducted. DEA also removed the phrase ''for emergency response'' from the stationhouse definition because stationhouses may also be used for various non-emergency EMS activities such as the storage of medical supplies, controlled substances, and equipment; staff training and education; and administrative functions essential to EMS operations. These revisions aim to acknowledge the unique operational demands of EMS agencies and ensure that this rule supports the efficient and effective delivery of emergency medical services. Specifically, the definition of stationhouse is revised to mean an enclosed structure within a State where the emergency medical services agency is registered and may house EMS vehicles at its premises and is actively and primarily being used by that emergency medical services agency.
- The provisions outlined in § 1301.80(b) specify when an EMS vehicle storing controlled substances must be locked. An emergency medical services vehicle storing controlled substances must be locked when parked outside of an enclosed registered or designated location, or when it is actively in use and left unattended during non-emergency stops. An emergency medical services vehicle storing controlled substances does not need to be locked if: (1) It is parked within an enclosed registered or designated location; (2) It is at the scene of an emergency; or (3) Emergency services personnel are in attendance. If an EMS vehicle is not at a registered or designated location of the agency, or traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency, the Act and § 1301.80(a) require that it must be ''actively in use'' in order to store controlled substances.
- § 1301.80(d) will allow EMS personnel to carry (as opposed to store) controlled substances on their person or in a jump bag that remains in their possession at all times while responding to an emergency. When EMS personnel are not responding to an emergency, the controlled substances must be returned to a storage component consistent with the requirements of 21 CFR 1301.80(c), including at the end of the shift and when personnel stop for breaks and meals. This allows EMS personnel to have immediate and ready access to controlled substances in the context of preparing for and providing emergency services. If an EMS vehicle is not at a registered or designated location of the agency, or traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency, then the Act and § 1301.80(a) require that it must be ''actively in use'' in order to store controlled substances.
- In § 1304.27, the requirement that EMS agency records reflect certain individuals' ''initials'' has been changed to allow agencies to instead record a ''last name or initials.''
- The amendments to 21 CFR 1301.13(e) have been updated to reflect the increased registration and reregistration fees for controlled substance dispensers from $731 to $888 for a three-year registration period. On July 24, 2020, DEA published a final rule, 85 FR 44710, to adjust registration and reregistration fees, in which registration and reregistration fees for dispensing or instructing business activities in § 1301.13(e) were adjusted to $888 for a three-year registration period. *See* 85 FR at 44718, 44733. Although the EMS NPRM intended to set the EMS registration fee at the same level as that of other controlled substance dispensers, it did not account for the 2020 fee increase, instead retaining the $731 fee.[11] Thus, this rule reflects the current fee of $888 so that, as intended, the fee for EMS registrants is the same as that for other dispensers of controlled substances.

the medical director or authorizing medical professional.

[11] *Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of* 2017, 85 FR 62634, 62642–62649 (Oct. 5, 2020).

A. Definitions

The Act contains a provision, 21 U.S.C. 823(k)(13), defining the terms used throughout its other provisions. In order to conform to the Act, DEA is adding these new definitions to its regulations as part of a new section, 21 CFR 1300.06. This includes defining the terms ''actively in use,'' ''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,'' ''on call,'' ''registered emergency medical services agency,'' ''registered location,'' ''specific State authority,'' ''standing order,'' ''stationhouse,'' and ''verbal order.''

The definition of ''actively in use'' was added to provide clarity under 21 U.S.C. 823(k)(6)(C)(ii) as to when an EMS vehicle used by an agency may store controlled substances. This definition would include instances when an EMS vehicle is responding to an emergency, is transporting patients, or is on call. The aim is to delineate when an EMS vehicle is considered engaging in an emergency response or waiting for the next call. ''On call'' means that the emergency medical services vehicle and its personnel are ready and available to respond, but may not be responding to an emergency at that precise moment. EMS vehicles and personnel are considered ''on call'' when they are prepared to respond to emergencies, even if they are not actively engaged in an emergency call. This includes periods when the vehicle is on standby for the next call, which may include waiting in designated standby areas, maintaining readiness for deployment. Examples of on call also include participating in public safety/educational events, going to lunch, and parking and leaving the vehicle unattended during a break.

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(k)(5), the types of locations that may be designated. 21 U.S.C. 823(k)(11)(A)(i). In order to conform with the Act, DEA has identified this type of location as a ''stationhouse'' and is adding the definition of a ''stationhouse'' to its regulations as part of 21 CFR 1300.06. As discussed above, the definition of ''stationhouse'' in this final rule differs slightly from that in the proposed rule. In this final rule, the definition of ''stationhouse'' is being amended to provide clarity by removing the requirement that a stationhouse must house an EMS vehicle, removing the term ''for emergency response,'' and adding the phrase ''at its premises'' to accommodate locations where EMS vehicles are not housed or stored indoors. These revisions aim to acknowledge the unique operational demands of EMS agencies and ensure that this rule supports the efficient and effective delivery of emergency medical services. In response to the commenters concern that EMS agencies may at times be used primarily for various operational EMS purposes, but not actually ''house'' associated EMS vehicles, DEA removed the requirement that a stationhouse must house an EMS vehicle from the stationhouse definition. DEA also removed the phrase ''for emergency response'' from the stationhouse definition in response to the comments received. In addition to housing EMS vehicles, stationhouses may also be used for various EMS activities such as the storage of medical supplies, controlled substances, and equipment; staff training and education; and administrative functions essential to EMS operations.

Further, the addition of the phrase ''at its premises'' to accommodate locations where EMS vehicles are not housed or stored indoors, allows flexibility for an EMS agency to house a vehicle outside of an enclosed registered or designated location. However, an EMS vehicle may be parked outside of a stationhouse, but for security purposes, if it stores controlled substances, it must be locked. The primary goal for this regulatory change is to provide EMS agencies with the necessary flexibility to effectively serve the public. ''At the premises'' specifically refers to the stationhouse premises, where EMS vehicles are parked outside of a stationhouse. This includes areas directly associated with the stationhouse where EMS activities are conducted. Examples of permissible locations at the stationhouse premises may include, but are not limited to: nearby docks (secure docking areas used for EMS boats or watercraft, part of the stationhouse premises); airplane hangars (enclosed, secure hangars within the stationhouse premises used for EMS aircraft); or garages and parking areas (designated parking spaces within the stationhouse premises where EMS vehicles are parked and secured). EMS vehicles containing controlled substances must be locked, unless responding to an emergency, at the scene of an emergency, or EMS personnel are in attendance.

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 generally 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.[12] 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 hospital registrations to stock and operate their EMS vehicles at those hospitals in this manner. In the event of shortages of controlled substances, public health emergencies, or mass casualty events, EMS agencies may receive controlled substances from hospitals that they are not affiliated with for the purpose of restocking EMS vehicles to ensure EMS vehicles are adequately restocked. As a current practice, it is important to note that when a DEA registrant obtains controlled substances from a hospital that they are unaffiliated with, the

[12] EMS agencies' use of this option is now explicitly authorized by the Act, 21 U.S.C. 823(k)(3), and DEA is adding this option to its regulations as 21 CFR 1301.20(a)(2).

supplying registrant must follow the five percent rule [13] and a DEA 222 form or an invoice is required to transfer between the supplying registrant and the receiving registrant.

2. 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 II–V to patients receiving emergency medical services. 21 U.S.C. 823(k)(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 is amending 21 CFR 1301.13 and adding 21 CFR 1301.20 to provide for the registration of EMS agencies.

As part of this regulatory change, DEA is adding § 1301.20(a) to its regulations, which describes the registration requirements for EMS agencies registered under § 1301.13. The registration requirements of § 1301.20(a) are taken directly from the Act, 21 U.S.C. 823(k)(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

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(k)(2), and DEA is amending its regulations accordingly through provisions of § 1301.20(a)(1). This rule would allow EMS registrants to consolidate multiple registrations into a single registration for each State in which they currently operate. EMS agencies that operate EMS facilities in multiple States must still have a separate registration in each State where the agency operates. In addition, under the Act and § 1301.20(a)(2) of this regulation, 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(k)(3).

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 the 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 separate (unregistered) stationhouses are not allowed to acquire or store controlled substances at the unregistered stationhouse.

The Act amended the CSA to authorize EMS agencies to designate specific unregistered locations where controlled substances will 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(k)(5). A registered EMS agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency (1) designates the unregistered location for such delivery; and (2) notifies DEA at least 30 days prior to first delivering controlled substances to the unregistered location.

DEA is bringing its regulations into conformity with the Act by adding 21 CFR 1301.20(b). Under this regulatory framework, controlled substances must be delivered to the registered location of the EMS agency or the hospital if the EMS agency operates under the hospital's DEA registration. EMS agencies may then distribute these substances to designated unregistered locations, provided they designate the unregistered location for such delivery and notify DEA at least 30 days prior to first delivering controlled substances to the designated unregistered location. Direct deliveries from distributors to designated unregistered locations are not permitted under DEA regulations. This process ensures secure management of the diversion of controlled substances while accommodating the operational needs of EMS agencies. Consistent with the Attorney General's authority under 21 U.S.C. 823(k)(11)(A)(ii) to prescribe how EMS agencies provide notice of designated locations, this regulation requires notification of the name and physical address of the designated location through DEA's website, *www.DEAdiversion.usdoj.gov.* 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 begin delivering 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(k)(11)(A)(i). Pursuant to this authority, DEA is including a provision in § 1301.20(b) that allows an EMS agency to label stationhouses as the type of location that will be considered a ''designated location'' of the EMS agency. A registered EMS 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 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. Thus, for example, a location that serves primarily as a residence does not meet the 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 an EMS agency, such as a county fire and rescue department that is a part of the EMS agency, for example, would qualify as a stationhouse under this rule (and thus may be selected as a ''designated location'' by an EMS agency that is registered with DEA) regardless of whether the location is also used for other purposes. The final rule, however, does not include a requirement (as did the proposed rule) that the stationhouse

[13] In accordance with 21 CFR 1307.11(a)(1)(iv), the five percent rule permits a practitioner dispenser, under certain circumstances, to distribute controlled substances to another practitioner without having to obtain a separate DEA registration as a distributor: ''[a] practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to . . . [a]nother practitioner for the purpose of general dispensing by the practitioner to patients, provided [inter alia] that . . . [t]he total number of dosage units of all controlled substances distributed by the practitioner . . . during each calendar year . . . does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.''

actually house EMS vehicles in an enclosed structure.

As discussed above, the provisions of § 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, § 1301.80(a) codifies 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(k)(6). A registered EMS agency may store controlled substances at a registered location of the agency, a designated location of the agency 30 days following notification to DEA in accordance with § 1301.20, in an emergency medical services vehicle situated at a registered location or designated location of the agency, or 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 while responding to an emergency, or when the emergency medical services vehicle is actively in use by 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. It is important to emphasize that EMS vehicles must comply with the applicable state laws when traveling to or from a registered or designated EMS agency location while responding to an emergency, or when the EMS vehicle is actively in use by the agency.

D. Emergency Medical Services Vehicles

Both the Act and section 1300.06 define an emergency services vehicle as an ambulance, fire apparatus, supervisor truck, or other vehicle 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(k)(13)(F). Under the control of the practitioner registration or hospital registration, controlled substances can be supplied to and stored in an EMS vehicle. Section 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. ''Actively in use'' for emergency medical vehicles means the vehicle is currently engaged in responding to an emergency call, is transporting patients, or is on call. ''On call'' means that the emergency medical services vehicle and its personnel are ready and available to respond, but may not be responding to an emergency at that precise moment.

Furthermore, in accordance with new section 1301.80(d), registered EMS agency personnel may carry controlled substances on their person or in a jump bag instead of storing the controlled substances in a safe when responding to an emergency. The controlled substances must be returned to a storage component as described § 1301.80(c), either inside of the EMS vehicle or at the registered or designated location, when EMS personnel are not responding to an emergency or the EMS vehicle is actively in use.

E. Recordkeeping Requirements

1. Records and Inventories

The transportation of controlled substances for administration to EMS patients presents unique recordkeeping concerns. Concerning 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 will 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 implementing 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 is implementing § 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.

Section 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(k)(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.[14] 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. This also allows hospital-based EMS agencies operating away from the hospital at which they are registered to be restocked by other hospitals. 21 U.S.C. 823(k)(8). Section 1307.14(a) codifies this allowance—and the associated statutory conditions—in DEA regulations.

[14] Williamson, 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.

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 rule, DEA requires maintenance of records of deliveries of controlled substances between all locations of the agency. Following the Act, 21 U.S.C. 823(k)(9)(B)(ii), DEA also establishes in § 1304.04(a)(5) the requirement 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 adding a new section to its regulations that describes the recordkeeping requirements applicable to EMS agencies. Consistent with the Act's amendments to the CSA, 21 U.S.C. 823(k)(9), § 1304.27(a) requires an EMS agency to maintain records for each controlled substance administered or disposed of in the course of providing emergency medical services. Under the provisions of § 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. In the proposed rule, § 1304.27(a) would have required EMS agencies to record the ''initials'' of the person who administered the substance, of the medical director or authorizing medical professional issues the relevant standing or verbal order, of the person disposing of the substances (if applicable), and of the witness to disposal. As discussed above, the requirement of ''initials'' led to some questions from commenters, and DEA is altering this provision in the final rule to instead indicate that the individual's ''last name or initials'' are required. The medical director or other authorizing medical professional is *not* required to initial the records personally.

DEA provides 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 existing theft and loss reporting requirements of 21 CFR part 1304.

Finally, under 21 U.S.C. 823(k)(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. The provisions in § 1304.27(c) 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 are exempt from these requirements. In this specific instance, under § 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. 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(k)(11)(B). Pursuant to this authorization, DEA will implement physical security requirements for EMS agencies similar to those already established for practitioners in § 1301.75.

a. Storage of Controlled Substances

Pursuant to its authorization under the Act to issue regulations regarding EMS agencies' storage of controlled substances, DEA is adding § 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 secured locations. The provisions of § 1301.80(a)(1) through (4) specify the secured locations within an EMS agency where controlled substances may be stored, and implement the Act's allowance in 21 U.S.C. 823(k)(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.

Pursuant to § 1301.80(a)(1) through (4), an EMS agency may store controlled substances at a registered location of the agency; a designated location of the agency 30 days following notification to DEA in accordance with § 1301.20; in an emergency medical services vehicle situated at a registered location or designated location of the agency; or 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 while responding to an emergency, or when the emergency medical services vehicle is actively in use.

DEA's final rule provides a framework to effectively minimize the risk of diversion while maintaining their readiness to respond to emergencies and to ensure the security of controlled substances in EMS vehicles, when parked outside stationhouses and designated locations. As outlined in § 1301.80, EMS vehicles must be equipped with secure locking mechanisms for cabinets if they are to store controlled substances. These locks are designed to prevent unauthorized access, even when vehicles are parked outside stationhouses. Further, § 1301.80(c)(1) mandates that controlled substances must be stored in a securely locked, substantially constructed cabinet if not being carried in a jump bag or on the person of EMS personnel when responding to an emergency, whether within the vehicle or at a registered or designated location. Alternatively, under § 1301.80(c)(2), controlled substances may also be stored in an automated dispensing machine at a registered or designated location. This ensures secure storage at all times, in order to minimize the risk of diversion.

b. Vehicle Locking Requirements

The provision outlined in § 1301.80(b) specifies when an EMS vehicle storing controlled substances must be locked.

An emergency medical services vehicle storing controlled substances must be locked when parked outside of an enclosed registered or designated location, or when it is actively in use, but unattended (such as when EMS personnel stop for lunch, when EMS personnel are on call and leaves the vehicle unattended, or when the vehicle is actively in use). Because of the Act's requirements, in order to store controlled substances, an EMS vehicle that is not parked at a registered or designated location, or traveling from or returning to such a location in the course of responding to an emergency, must be ''actively in use'' as defined in § 1300.06((b)(1). An emergency medical services vehicle storing controlled substances does not need to be locked only if: (1) It is parked within an enclosed registered or designated location; (2) It is at the scene of an emergency; or (3) Emergency services personnel are in attendance. This includes situations when personnel are physically present and able to monitor the vehicle, such as when the vehicle is traveling to or from the scene of an emergency, or it is at public displays or educational events. Despite the vehicle being unlocked, the risk of diversion is mitigated due to the presence of trained personnel.

Under § 1301.80(b), an EMS vehicle storing controlled substances is not required to be locked when EMS personnel are in attendance, although the controlled substances must themselves still be stored in a securely locked, substantially constructed cabinet or safe that cannot be readily removed. ''In attendance'' refers to the presence of authorized EMS personnel who are responsible for the security and control of the EMS vehicle and its contents, particularly controlled substances. ''In attendance'' could also encompass having the EMS personnel physically present within the immediate vicinity of the EMS vehicle, which allows for effective supervision and immediate response to any security threats or emergencies. Examples of ''in attendance'' include, but are not limited to, being at an emergency scene, on standby at events, or when transporting patients. Being ''in attendance'' at an EMS vehicle plays a critical role in deterring diversion of controlled substances by ensuring continuous supervision and immediate response capabilities, thereby ensuring the secure handling of controlled substances. When EMS personnel are ''in attendance,'' they can continuously monitor the vehicle, which discourages unauthorized access.

By comparison, an EMS vehicle storing controlled substances must be locked whenever the EMS vehicle is unattended, meaning there are no EMS personnel in attendance, with the controlled substances stored in a securely locked, substantially constructed cabinet or safe that cannot be readily removed. This includes when the EMS vehicle is parked at a stationhouse, hospital, or any other location. Additionally, an EMS vehicle storing controlled substances must be locked when the vehicle is actively in use but is not at an emergency scene and is parked in a public or unsecured area, such as when EMS personnel are on call and stop for lunch, or leave the vehicle unattended, such as during a break. Requiring EMS vehicles storing controlled substances to be locked, with the controlled substances stored in a separately locked cabinet or safe that is substantially constructed and cannot be readily removed, mitigates the risk of diversion by ensuring that controlled substances are inaccessible to unauthorized individuals.

c. Storage Components

In addition, DEA is adding § 1301.80(c) to allow several options by 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 . . . the manner in which [controlled] substances must be stored at registered and designated locations, including in EMS vehicles.'' 21 U.S.C. 823(k)(11)(B).

The first option in § 1301.80(c)(1) will 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 § 1301.80(a). Such cabinets or safes can be used in either vehicles or buildings meeting the requirements of a secure location. Premises that are set aside for housing outdoor EMS vehicles are required to securely lock the EMS vehicle and the controlled substances must be stored in a securely locked cabinet or safe. If an EMS vehicle is used to store controlled substances, it must have a secure cabinet or safe. The controlled substances cannot be stored in a vehicle that is locked, without putting them in a safe.

The second option in § 1301.80(c)(2) will 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 will serve as a controlled substance storage locker with advanced capabilities and will 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 conditions in § 1301.80(c)(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. Unlike a safe or cabinet, an ADS machine cannot be used to provide secure storage on an EMS vehicle.

In sum, the provisions of § 1301.80(c)(1)–(2) will provide alternative options for short-term or long-term storage of controlled substances that are actively being transported or stored in a fixed location.

d. Carrying of Controlled Substances During Emergencies

The provisions set forth in § 1301.80(d) will allow EMS personnel to carry controlled substances on their person or in a jump bag when responding to an emergency, instead of storing the controlled substances in a safe during an emergency response. The controlled substances must be returned to a storage component as described in § 1301.80(c)(1), either inside of the EMS vehicle or at the registered or designated location, when EMS personnel are not currently engaged in responding to an emergency.

EMS personnel will have immediate and ready access to controlled substances in the context of preparing for and providing emergency services during active duty. This would eliminate the need to return to the EMS vehicle to get controlled substances from a locked safe during an emergency response. Thus, the provisions of § 1301.80(d) provide options for carrying controlled substances in a jump bag or on EMS personnel's person in preparation for or during an emergency response.

e. Delivery

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(k)(5). Also, pursuant to its authorization to issue regulations regarding the delivery of controlled substances under 21 U.S.C. 823(k)(11), DEA maintains that medical directors determine who accepts deliveries of controlled substances because medical directors provide oversight for EMS agencies. This rule will 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, § 1304.27(b)(3) will 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. These regulations specify the requirements that will be set forth regarding the delivery of controlled substances for emergency medical services.

As codified at 21 U.S.C. 823(k)(11)(C), the Act also authorizes DEA to issue regulations allowing hospitals and EMS agencies to deliver controlled substances to one another during shortages, public health emergencies, or mass casualty events—rather than relying on distributors or hospital restocking. This rule does so in 21 CFR 1307.15 and makes written approval from the SAC for the area or DEA Headquarters a condition of this allowance.

2. Administration Requirements

DEA is adding § 1306.07(g), which implements 21 U.S.C. 823(k)(4) in the 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.[15] 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(k)(4) and § 1306.07(g), 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.

a. 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(k)(13)(M). The provisions of § 1300.06 incorporate this definition into DEA regulations.

The Act and § 1306.07(g) 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(k)(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 § 1306.07(g), 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(k)(4). Also, under both the Act and § 1306.07(g), 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(k)(10)(D).

[15] 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 adding provisions related to the administration of controlled substances by EMS agencies to part 1306, DEA is also amending § 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.''

b. Verbal Orders

In the absence of standing orders, EMS personnel may receive a verbal order. Under the Act and § 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(k)(13)(N). The Act and § 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 or certification includes the ability to provide verbal orders. *See* 21 U.S.C. 823(k)(13)(A).

Under the Act and § 1306.07(g), an EMS professional may administer directly a controlled substance in schedules II–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.

IV. Regulatory Analyses

As explained above, DEA is issuing this final 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 rule, the results of which are discussed below.

Executive Orders 12866, 13563, and 14192 (Regulatory Review)

DEA has determined that this rulemaking is a ''significant regulatory action'' under section 3(f) of Executive Order (E.O.) 12866, Regulatory Planning and Review, but is not a section 3(f)(1) significant action. Accordingly, this rule has been submitted to the Office of

Management and Budget (OMB) for review. This rule has been drafted and reviewed in accordance with E.O. 12866, ''Regulatory Planning and Review,'' section 1(b), Principles of Regulation; E.O. 13563, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation; and E.O. 14192, ''Unleashing Prosperity Through Deregulation.''

This rule is a deregulatory action for the purposes of E.O. 14192. This rule is an enabling rule 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 II–V pursuant to a standing or verbal order, which was previously not authorized.

On July 24, 2020, DEA published a final rule to adjust registration and reregistration fees, effective October 1, 2020.[16] The final rule adjusted registration and reregistration fees for dispensing or instructing business activities to $888 for a three-year registration period. The fees had previously been set at $731 for such activities, which was the fee rate proposed in the EMS NPRM for EMS registrants. Because DEA intended to set EMS registration fees at the same level as fees for other registrants that dispense controlled substances, this final rule sets the fees for EMS registrants at $888 instead of $731. Accordingly, the analysis below has been updated from that in the NPRM to reflect the increase in EMS registration and reregistration fees from $731 to $888 for a three-year registration period, in accordance with 21 CFR 1301.13(e).

DEA expects the annual economic impact of this final rule to range from a decrease of $555,888 to an increase of $1,010,544 in registration fees paid to DEA depending on the number of registrations that can be consolidated and the number of new separate registrations that will be needed as a result of this rule. Detailed analysis is provided below. Fees paid to DEA pertaining to registrations are considered transfer payments and not costs.[17]

Annual changes in labor burden costs as a result of this rule are expected to range from a decrease of $19,594 to an increase of $64,636.

Analysis of the Rule's Economic Impact

DEA analyzed the impact of the following provisions of the rule: allowing EMS agencies to register under the CSA with a single registration for each State in which an agency operates, along with the security and recordkeeping requirements for such a registrant; allowing EMS personnel to administer controlled substances in schedules II–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 rule is incorporating into regulation several new terms defined in the Act.

Benefits of the 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. This 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 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 final 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 rule will have no impact on regulated entities.

Registrations for Emergency Medical Services Agencies

While this 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).[18] 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 $888 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 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 $116,920.[19]

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.[20]

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,

[16] Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants, 85 FR 44710 (July 24, 2020).

[17] OMB Circular A–4.

[18] These existing registrations will be transitioned to the new ''Emergency Medical Services Agency'' registration category created by this rule.

[19] 395 × $888 = $350,760. Dividing this figure by three to account for the three-year registration cycle and rounding to the nearest whole dollar gives $116,920.

[20] *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 (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 × (1 + 0.4577) = $140.79.

hospital-based EMS agencies can continue to operate under the registration of their hospital after promulgation of this 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,[21] or they may hold practitioner registrations separate from their personal place of business registration for each EMS agency location that they oversee. Because this 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 at the location of the EMS agency for each State in which they operate will be required. Additionally, affected non-governmental EMS agencies must pay the $888 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. 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 a reasonable estimate 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,[22] 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.[23]

DEA then analyzed its registration database to match current MLP–AS registrants with the corresponding EMS organizational types defined in the NHTSA research note.[24] 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 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.[25] 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.[26]

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 at 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,[27] and 0.81 for fee-exempt registrants.[28] 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 rule.[29] 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.

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

[22] *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.

[23] CA data were not available.

[24] 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.

[25] For 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.

[26] In 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.''

[27] 1,018/1,413 = 0.72.

[28] 1,697/2,108 = 0.81.

[29] An ''agency-to-location'' ratio is not applied to the estimated 1,236 hospital-based EMS agencies, because this rule does not impact their registration status.

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 $1,127,464 to DEA on an annual basis.[30] Likewise, calculations for the 50 percent scenario yield an estimated increase in fees (transfer payments) of $563,880.[31]

Similarly, if 100 percent of the estimated 1,483 [32] 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 $438,968.[33] This transfer payment reduction is combined with the previously calculated reduction in transfers of $116,920 from the 806 MLP–AS registrations that will be consolidated, resulting in a total reduction in transfers of $555,888. 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 $1,010,544.[34] Calculations for the 50 percent scenario yield an estimated reduction in fees (transfer payments) of $336,552.[35] This results in a net increase of $227,328 for the midpoint scenario.[36] Therefore, DEA estimates the annual net change in transfer payments as a result of this rule will range between a decrease of $555,888 and an increase of $1,010,544, with the midpoint of these estimates resulting in an increase of $227,328.

For the respective 0 percent, 50 percent, and 100 percent scenarios for the estimated annual change in transfer payments, DEA calculated the net present values at a 7 percent discount rate and a 3 percent discount rate over 12 years, or three registration cycles. 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)	$(116,920)	$(116,920)	$(116,920)
Annual Change in Transfer Payments—EMS Not Separately Registered	0	563,880	1,127,464
Annual change in Transfer Payments—EMS Not Separately Registered (CONSOLIDATED)	(438,968)	(219,632)	0
Net Annual Change in Transfer Payments	(555,888)	227,328	1,010,544
Net Present Value Over 12 Years (Discounted 7%)	(4,415,244)	1,805,595	8,026,434
Net Present Value Over 12 Years (Discounted 3%)	(5,533,311)	2,262,824	10,058,959

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 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

[30] 3,809 × $888 = 3,382,392. This figure is divided by three in order to account for the three-year registration cycle, resulting in $1,127,464 (figure is rounded).

[31] 3,809 × .5 = 1,905 (rounded). (1,905 × $888)/3 = $563,880.

[32] Sum 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.

[33] 1,483 × $888 = $1,316,904. This figure is divided by three in order to account for the three-year registration cycle, resulting in $438,968.

[34] $1,127,464 (calculated in note 27) − $116,920 = $1,010,544.

[35] 1,483 × .5 = 742 (rounded). ((742 × $888)/3) + $116,920 = $336,552.

[36] $563,880 (calculated in note 28) − $336,552 = $227,328.

of $16,568,[37] due to the estimated 4,413 [38] 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 17) from the consolidation of existing MLP–AS registrants is added to this total, resulting in an annual total labor burden reduction of $19,594. The $19,594 decrease in labor burden results in a net present value of $155,629 at a 7 percent discount rate and $195,039 at a 3 percent discount rate over three registration cycles, or 12 years.

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 $272,830 [39] due to the initial registration application paperwork for 12,919 registrants, and a triennial labor burden increase of $136,431,[40] 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 burden of $64,636 at a 7 percent rate and $60,131 at a 3 percent rate over three registrations cycles, or 12 years.[41]

Finally, under the 50 percent scenario, there would be a one-time increase in labor burden of $136,426 [42] due to the initial registration application paperwork for 6,460 registrants, and a triennial labor burden increase of $38,824,[43] due to 4,253 registration renewals every three years. DEA converted the one-time burden of $136,426 and the triennial burden of $38,824 into an annualized burden of $25,311 at a 7 percent rate and $22,845 at a 3 percent rate over three registration cycles, or 12 years.[44]

Table 3 summarizes the estimated net change in labor burden cost for both scenarios as a result of this 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%)	$(19,594)	$25,311	$64,636
Annualized Net Change in Labor Burden Over 12 Years (Discounted 3%)	(19,594)	22,845	60,131

Security and Recordkeeping Requirements

Because some EMS agencies are currently registered under the practitioner business activity as MLP–AS, this 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; inside locked EMS vehicles stationed at registered or designated unenclosed 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 rule to be a codification of existing practice that will impose no costs.

The recordkeeping provisions of this 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.

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

[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.* 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.

[38] 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.

[39] *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.

[40] *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 (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 17, resulting in $136,431.

[41] 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. Converting the respective present values into equal annual amounts at 3 percent and 7 percent discount rates for 12 years to account for three registration cycles yields the annualized burdens.

[42] $12,919 \times 0.5 = 6,460$ registrants. $\$140.79 \times 0.15 \times 6,460 = \$136,426$. The result is rounded.

[43] $(12,919 \times 0.5) - (4,413 \times 0.5) = 4,253$. $\$140.79 \times 0.08 \times 4,253 = \$47,902$ (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 17, resulting in $38,824.

[44] 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. Converting the respective present values into equal annual amounts at 3 percent and 7 percent discount rates for 12 years to account for three registration cycles yields the annualized burdens.

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 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 rule will result in a benefit to EMS agencies, EMS professionals, and the public.

Executive Order 12988, Civil Justice Reform

The provisions of this regulation meet the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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 E.O. 13132. The 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 rule does not have tribal implications warranting the application of E.O. 13175. It does not have direct effects on one or more Indian tribes via Indian Health Services.

Executive Order 14294, Overcriminalization of Federal Regulations

Executive Order 14294 specifies that all notices of proposed rulemaking (NPRMs) and final rules published in the **Federal Register**, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense, the authorizing statute, and the mens rea requirement for each element of the offense. Since this final rule does not involve a criminal regulatory offense, E.O. 14294 does not apply.

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.

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 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 rule by considering the full range of possible scenarios. Thus, DEA considered the impact of the 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 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 entities [45] that are affected by this rule. DEA assumes all EMS agencies are affected in some way by this rule; therefore, this final 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 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 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 rule will have no further impact on these entities. The following table summarizes the estimated impact of the provisions of the rule for each type of EMS agency.

[45] 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 rule.

TABLE 4

	Provisions of proposed rule							
	Registration fees		Records & security		DEA form 224		DEA form 224A	
	Affected entities	Impact per entity [46]	Affected entities	Impact per entity	Affected entities	Impact per entity [47]	Affected entities	Impact per entity [48]
Hospital-based EMS	N/A	N/A	1,236	$0	N/A	N/A	N/A	N/A
Private EMS	3,809	$265	4,827	0	3,809	$21	3,809	$4
Government 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 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 0.66 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	General Medical and Surgical Hospitals	1,236	20	$190,600	$0	0.00
621910	Ambulance Services	16,239	373	44,150	290	0.66

While this rule affects a substantial number of small entities, because the economic impact for the smallest entities is not significant, the final 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 will not result in any Federal mandate that may 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.*), OMB approved the following information collections related to this rule on April 11, 2025, issuing the new expiration date of April 30, 2028.[49] This final rule will 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/public/do/PRAMain.*

A. Collections of Information Associated With the Rule

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

OMB Control Number: 1117–0060.

Form Number: N/A.

OMB approved Information Collection 1117–0060: *Emergency Medical Services Recordkeeping and Notice Requirements* on April 11, 2025. This newly approved collection of information establishes new recordkeeping and notice requirements for EMS agencies.

For each EMS professional employed by a registered EMS agency, the agency is required to maintain 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 are also required to maintain records of all controlled substances received, administered, or otherwise disposed of. Such records must 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;

[46] 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 ($1,010,544) by the number of affected private entities (3,809). The final figure is rounded to the nearest whole dollar.

[47] 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.

[48] 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.

[49] On January 10, 2025, DEA submitted Information Collection 1117–0060: Emergency Medical Services Recordkeeping and Notice Requirement, and 1117–0014: Application for Registration (DEA Form 224), Application for Registration Renewal (DEA Form 224A) to the Office of Management and Budget for review and approval. In accordance with the Paperwork Reduction Act, OMB approved these information collections on April 11, 2025. The new expiration date for these information collections is April 30, 2028.

(3) the date the substance was administered or disposed of; (4) identification of the patient, if applicable; (5) amount administered; (6) the last name or initials of the person who administered the substance; (7) the last name or 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 last name or 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 must 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.

OMB approved Information Collection 1117–0014: *Application for Registration-DEA 224, Application for Registration Renewal-DEA 224A* on April 11, 2025. This revised collection of information establishes new registration rules for EMS agencies.

Under § 1301.13, EMS agencies, if authorized by State law, may register as a new type of business activity. A new ''EMS Agency'' business activity is added to the application for registration and application for registration renewal forms to allow EMS agencies to obtain a DEA registration that permits EMS agencies to deliver controlled substances to their designated locations without obtaining a separate registration as a Distributor. This registration allows 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 allows 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.

The activities described in this information collection are usual and ordinary business activities and no additional cost is anticipated.

If you need additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Divisions, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

Any additional comments on this collection of information may be sent in writing 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.

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 is amending 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) *Actively in use* means the vehicle is currently engaged in responding to an emergency call, is transporting patients, or is on call as defined in this Part.

(2) *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.

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

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

(5) *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.

(6) *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.

(7) *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.

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

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

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

(11) *On call* means that the emergency medical services vehicle and its personnel are ready and available to respond but may not be responding to an emergency at that precise moment.

(12) *Registered emergency services agency* means—

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

(ii) A hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection 823(g).

(13) *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 under 21 U.S.C. 823(k) or 21 U.S.C. 823(g), which shall be where the agency receives controlled substances from distributors.

(14) *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.

(15) *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.

(16) *Stationhouse* means an enclosed structure within a State where the emergency medical services agency is registered, which may house EMS vehicles at its premises, and which is actively and primarily being used by that emergency medical services agency.

(17) *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 a registered emergency medical services agency has identified to the Administration at least 30 days prior to first delivering controlled substances to that unregistered location.

* * * * *

■ 5. In § 1301.13:

■ a. Revise paragraph (d);

■ b. Redesignate paragraphs (e)(1)(v) through (x) as paragraphs (e)(1)(vi) through (xi); and

■ c. Add new paragraph (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 II–V	New—224; Renewal—224a	888	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(k) or the public interest based on the factors listed in 21 U.S.C. 823(g).

(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(g) 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 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 [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) *Secured Storage Locations.* 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 while responding to an emergency, or when the emergency medical services vehicle is actively in use by the agency.

(b) *Vehicle Locking Requirements.* An emergency medical services vehicle storing controlled substances must be locked when parked outside of an enclosed registered or designated location, or when it is actively in use and left unattended during non-emergency stops. An emergency medical services vehicle storing controlled substances does not need to be locked only if:

(1) It is parked within an enclosed registered or designated location;

(2) It is at the scene of an emergency; or

(3) Emergency services personnel are in attendance. This includes situations when personnel are physically present and able to monitor the vehicle; such as when the vehicle is traveling to or from the scene of an emergency, or it is at public displays or educational events.

(c) *Storage Components.* Except when emergency medical services personnel are carrying controlled substances on their person or in a jump bag as set forth in paragraph (d) of this section, a registered emergency medical services agency must 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 paragraphs (a)(1) through (4) of this section; or

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

(i) Located at a secured location specified in paragraphs (a)(1) and (2) of this section;

(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.

(d) *Carrying Controlled Substances During Emergencies.* Emergency medical services agency personnel may *carry* controlled substances on their person or in a jump bag instead of storing the controlled substances in a safe when responding to an emergency. The controlled substances must be returned to a storage component as described in paragraph (c) of this section when emergency medical services agency personnel are not currently engaged in responding to an emergency.

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) Last name or initials of the person who administered the controlled substance;

(7) Last name or 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) Last name or initials of person who disposed and witness to disposal, if applicable.

(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(k), 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 (g) and (h) 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 while 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(k), 871(b), unless otherwise noted.

■ 17. Add §§ 1307.14 and 1307.15 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.

§ 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.

(b) Reserved.

Signing Authority

This document of the Drug Enforcement Administration was signed on January 30, 2026, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Alana Moore,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–02288 Filed 2–3–26; 4:15 pm]

BILLING CODE 4410–09–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 64

[WC Docket No. 24–213, MD Docket No. 10–234; FCC 24–135; FR ID 329283]

Improving the Effectiveness of the Robocall Mitigation Database; CORES Registration System

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved the information collections associated with the amendments to § 1.8002(b)(2) under OMB Control Number 3060–0918 and the amendments to § 64.6305(h) under OMB Control Number 3060–1285 adopted by the *Report and Order,* FCC 24–135, 91 FR 343. This document is consistent with the *Report and Order,* which states that Commission will publish a document in the **Federal Register** announcing the effective dates of the delayed amendments.

DATES: The amendments to §§ 1.8002(b)(2) and 64.6305(h), published at 91 FR 343 on January 6, 2026, are effective February 5, 2026. The initial compliance date for the annual recertification requirement under § 64.6305(h) is March 1, 2026.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Merry Wulff, Competition Policy Division, Wireline Competition Bureau, at (202) 418–1084, or email: *merry.wulff@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that OMB approved the information collection requirements associated with the amendments to §§ 1.8002(b)(2) and 64.5305(h) on May 27, 2025 and August 11, 2025, respectively. The amendments to these rules were adopted in the *Report and Order,* FCC 24–135, published at 91 FR 343 on January 6, 2026. The Commission publishes this document as an announcement of the effective date of February 5, 2026.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received final OMB approval for the information collection requirements contained in §§ 1.8002(b)(2) and 64.6305(h) on May 27, 2025, and August