Supporting Statement for Paperwork Reduction Act Submissions
Emergency Medical Services Recordkeeping and Notice Requirements (No Form)
OMB Approval #1117-00XX

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a new collection of information, Emergency Medical Services and Recordkeeping and Notice Requirements. This information collection request is associated with DEA's "Registering Emergency Medical Services Agencies under the Protecting Patient Access to Emergency Medications Act of 2017" rulemaking, RIN 1117-AB37.

Part A. Justification

1. Necessity of Information:

DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970), as amended (collectively, the Controlled Substances Act). 21 U.S.C. 801–971. Through the enactment of the Controlled Substances Act (CSA), Congress established a closed system of distribution making it unlawful to handle any controlled substance except in a manner authorized by the CSA…. The "Protecting Patient Access to Emergency Medications Act of 2017," (hereafter the "Act") which became law on November 17, 2017, amended the Controlled Substances Act to allow for a new registration category for emergency medical services agencies that handle controlled substances. It also established standards for registering emergency medical services agencies, and set forth new requirements for delivery, storage, and recordkeeping related to their handling of controlled substances.

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

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

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. Thus, the Act allows non hospital-based EMS agencies to receive controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. 21 U.S.C. 823(j)(8). DEA's proposed § 1307.14(a) codifies this allowance in DEA regulations.

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

2. Needs and Uses:

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

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

DEA proposes in § 1304.27(b)(3) that an EMS agency must maintain records of controlled substances delivered between registered and designated locations of the agency (except agencies restocking at the hospital under which the EMS agency is operating, because the hospital is required to keep records of such restocking). These records, for example, should include the name of the controlled substance(s), finished form, number of units in the commercial container,

date delivered, and the address of the EMS agency location where the controlled substances were delivered. In the event of theft or loss of controlled substances, registrants must report such occurrence in accordance with the theft and loss reporting requirements of 21 CFR part 1304.

Finally, under 21 U.S.C. § 823(j)(8)(c) of the Act, designated locations of an EMS agency must notify the registered location of their EMS agency within 72 hours of receiving controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. DEA's proposed § 1304.27(c) would codify this requirement in DEA regulations. However, EMS agencies that operate under a hospital-based registration and receive restock of controlled substances from the hospital under which the agency is operating would be exempt from these requirements. In this specific instance, under proposed § 1307.14(a)(2), hospitals would already have a record of the controlled substances that the hospital delivered to the EMS agency operating under that hospital's registration. As such, it would be duplicative to require that EMS agency to obtain a receipt of those controlled substances because the EMS agency would be reporting receipt of the controlled substances back to the hospital that issued the controlled substances in the first place.

3. Use of Information Technology:

DEA registrants are required by statute to maintain inventory and continuing records. The form is specified only to the extent that such records must be maintained separately from all other records of the registrant or, alternatively, in the case of non-narcotic controlled substances, be in such a form that required information is readily retrievable from the ordinary business records of the registrant. Such records must be kept and be available for at least two years. 21 U.S.C. 827. These requirements give registrants the flexibility to implement any type of recordkeeping system, whether automated, electronic, mechanical, or any other type of improved information technology.

4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of the collection of information. The collection of this information is unique to DEA. Therefore, there is no duplication of information requested as part of this collection.

5. Impact on Small Businesses or Entities:

DEA has considered alternatives for this collection of information and evaluated the impact of this proposed rule on small entities. DEA has concluded that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601-612. For more information, see DEA's analysis for this rule under the Regulatory Flexibility Act.

6. Consequences of Less Frequent Collection:

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, if the proposed collection of information is not conducted or is conducted less frequently, there is a heightened risk of diversion. This information is vital to the enforcement of the CSA and helps DEA to reduce the diversion of controlled substances outside of legitimate channels into the illicit market.

7. Special Circumstances Influencing Collection:

DEA does not foresee any special circumstances that would cause an information collection to be conducted in a particular manner: requiring respondents to report information to the agency more than quarterly; requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it; requiring respondents to submit more than an original and two copies of any document; requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years; in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study; requiring the use of a statistical data classification that has not been reviewed and approved by OMB; that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Consultation with persons outside the Agency:

Public comment has been solicited in the notice of proposed rulemaking (NPRM), published on October 5, 2020. 85 FR 62634. During the 60-day comment period, DEA received 30 comments concerning this collection**.** Many commenters 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). These commenters 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 permitting 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 meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

9. Payment or Gift to Claimants:

This collection of information does not propose to provide any payment or gift to respondents.

10. Assurance of Confidentiality:

Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. The information is protected by DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by the DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

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. DEA's estimate of 21,283 respondents represents the total number of EMS agencies in operation throughout the U.S. 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:

Total number of respondents: 21,283
Number of responses per respondent per year: 52 (average)
Total annual responses: 1,106,716
Total annual hour burden: 92,226

Average Burden: Per Collection: 0.0833 hour
Per Respondent: 4.33 hour

Burden dollars:

Estimate hourly wage ($/hour):[1]	$17.02
Load for benefits (percent of labor rate):[2]	44.1%

1 Used median hourly wages for 29-2040 Emergency Medical Technicians and Paramedics to represent the type of registrant that will be recording this information. Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2019, (http://www.bls.gov/oes/current/oes_nat.htm).
2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – March 2020" (ECEC) reports that average benefits for private industry is 30.6 percent of total compensation. The 30.6 percent of total compensation

Loaded labor rate ($/hour):[3]		$24.53
Number of responses		1,106,716
Total annual hours		92,226
Average burden per response (hour)		0.0833
Burden dollars per response ($)	$	2.0442
Total burden dollars	**$**	**2,262,349**

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Costs to Federal Government:

The forms are prepared, completed, and maintained by DEA registrants. There is no cost to the federal government.

15. Reasons for Change in Burden:

This is a new regulation; there are no program changes or adjustments reported.

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

Due to the administrative burdens related to replacing expired forms when no information on those forms has been changed, DEA is seeking approval not to display the expiration date on any paper forms printed by the agency.

18. Exceptions to the Certification Statement:

DEA is not seeking an exception to the certification statement "Certification for Paperwork Reduction Act Submissions" for this collection of information.

Part B. Statistical Methods

The Drug Enforcement Administration will not be employing statistical methods in this information collection.

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equates to 44.1 percent (30.6% / 69.7%) load on wages and salaries.
3 $17.02 x (1 + 0.441) = $24.53.