10-09-P

DEPARTMENT OF JUSTICE

[OMB Number 1117-0049]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision without change of a previously approved collection

Recordkeeping for Electronic Prescriptions for Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice

ACTION: 60-day Notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]

FOR FURTHER INFORMATION CONTACT:

If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Heather E. Achbach, Regulatory Drafting and Policy Support Section, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776-3882; Email: Heather.E.Achbach@dea.gov or DEA.PRA@dea.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Revision of a currently approved collection.
2. *Title of the Form/Collection:* Recordkeeping for Electronic Prescriptions for Controlled Substances.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* No form number is associated with this collection. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.
4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

   Affected public (Primary): Business or other for-profit.

   Affected public (Other): Not-for-profit institutions; Federal, State, local, and tribal governments.

   Abstract: DEA is requiring that each registered practitioner apply to an approved credential service provider approved to obtain identity proofing and a credential.

Hospitals and other institutional practitioners may conduct this process in-house as part of their credentialing. For practitioners currently working at or affiliated with a registered hospital or clinic, the hospital/clinic have to check a government-issued photographic identification. This may be done when the hospital/clinic issues credentials to new hires or newly affiliated physicians. For individual practitioners, two people need to enter logical access control data to grant permissions for practitioners authorized to approve and sign controlled substance prescriptions using the electronic prescription application. For institutional practitioners, logical access control data is entered by two people from an entity within the hospital/clinic that is separate from the entity that conduct identity proofing in-house. Similarly, pharmacies have to set logical access controls in the pharmacy application so that only authorized employees have permission to annotate or alter prescription records. Finally, if the electronic prescription or pharmacy application generates an incident report, practitioners, hospitals/clinics, and pharmacies have to review the incident report to determine if the event identified by the application represents a security incident.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 158,884 registrants participate in this information collection, taking an estimated 40 minutes for Practitioner, 128 minutes for Hospital/Clinic, and 20 minutes for Pharmacy.
6. *An estimate of the total public burden (in hours) associated with the proposed collection:* DEA estimates that this collection takes 107,733 annual burden hours.
7. An estimate of the total annual cost burden associated with the collection, if applicable: $0.

Total Burden Hours

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)

Practitioner	154,571	1	154,571	0.67 (40 minutes)	103,563 hrs.
Hospital/Clinic	1,526	1	1,526	2.13 (128 minutes)	1,526 hrs.
Pharmacy	2,787	1	2,787	0.33 (20 minutes)	2,787 hrs.
Unduplicated Totals	***158,884***	***N/A***	***158,884***	***1.043***	***107,733 hrs.***

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street, NE, 4W-218, Washington, DC.

Dated: November 21, 2024.

Darwin Arceo,

Department Clearance Officer for PRA,

U.S. Department of Justice.

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