

Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: October 20, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

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DEPARTMENT OF JUSTICE

[OMB Number 1117-0049]

Agency Information Collection Activities: Proposed eCollection, eComments Requested; Reinstatement of a Discontinued Collection: Recordkeeping for Electronic Prescriptions for Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: 30-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 30 days until November 24, 2021.

FOR FURTHER INFORMATION CONTACT: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

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 agency, 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 proposed 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 forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Reinstatement of a discontinued collection.

2. *Title of the Form/Collection:* Recordkeeping for Electronic Prescriptions for Controlled Substance.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no form number. 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 requires that each registered practitioner apply to an approved credential service provider 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 permission 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 conducts 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 below table presents information regarding the number of respondents, hour burden per responses and associated burden hours.

| | Number of respondents | Hour burden per response | Burden hours |
|------------------------|-----------------------|--------------------------|---------------|
| Practitioners | 78,164 | 0.67 | 52,370 |
| MLP | 49,067 | 0.67 | 32,875 |
| Hospital/Clinics | 1,482 | 2.13 | 3,157 |
| Pharmacies | 3,984 | 0.33 | 1,315 |
| Total | 132,697 | | 89,717 |

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* DEA estimates that this collection takes 89,717 annual burden hours.

If additional information is required please contact: Melody Braswell,

Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

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