

remains, mandatorily excluded from federal health care programs pursuant to 42 U.S.C. 1320a-7(a).⁸ Accordingly, the Agency finds that substantial record evidence establishes the Government's *prima facie* case for revocation of Registrant's registration under 21 U.S.C. 824(a)(5).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's registration should be revoked, the burden shifts to Registrant to show why she can be entrusted with a registration. *Morall v. Drug Enf't Admin.*, 412 F.3d. 165, 174 (D.C. Cir. 2005); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 FR 18882 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual practitioner. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that the registrant will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). Historically, the Agency has considered acceptance of responsibility, egregiousness, and deterrence when making this assessment. *See Michael Bouknight*, 90 FR 31247, 31250 (2025); *Sasha Melissa Ikramelahai*, 90 FR 32017, 32020-21 (2025); *Frank Joseph Stirlacci, M.D.*, 85 FR 45229, 45239-40 (2020).

The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.*, 83 FR 29569, 29573 (2018); *see Jones Total Health Care Pharmacy*, 881 F.3d at 830-31. In addition, a registrant's candor during the investigation and hearing, if one is requested, is an important factor in determining acceptance of responsibility and the appropriate

sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 830-31; *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 483-84 (6th Cir. 2005). Further, the Agency has found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Jones Total Health Care Pharmacy*, 881 F.3d at 833 n.4, 834. The Agency also considers the need to deter similar acts by a registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR at 46972-73.

Here, Registrant did not timely request a hearing or answer the allegations in the OSC and was deemed to be in default. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrant has thus failed to properly answer the allegations contained in the OSC and has not otherwise availed herself of the opportunity to refute the Government's case. As such, Registrant has not accepted responsibility for the proven violations, has made no representations regarding her future compliance with the CSA, and has not demonstrated that she can be trusted with registration.

Accordingly, the Agency will order the revocation of Registrant's registration.⁹

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BV4657485, issued to Esther Villanueva Valdes, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Esther Villanueva Valdes, M.D., to renew or modify this registration, as well as any other pending application of Esther Villanueva Valdes, M.D., for additional registration in Puerto Rico. This Order is effective October 21, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 11, 2026, by DEA Administrator Terrance C. 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**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Qualification/Certification Program Request for MSHA Individual Identification Number (MIIN)

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety & Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before October 21, 2026.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202-693-0213, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: MSHA issues certifications, qualifications and approvals to the nation's miners to conduct specific work within the mines. Miners requiring qualification or certification from MSHA will register for an "MSHA Individual Identification Number" (MIIN). MSHA uses this unique number in place of individual SSNs for all MSHA collections. The MIIN identifier fulfills Executive Order 13402, Strengthening Federal Efforts Against Identity Theft, which requires Federal agencies to better secure government held data. For additional substantive information about this ICR,

⁸ The underlying conviction forming the basis for mandatory exclusion from participation in federal health care programs need not involve controlled substances to provide the grounds for revocation or denial pursuant to Section 824(a)(5). *Jeffrey Stein, M.D.*, 84 FR 46968, 46971-72 (2019); *Narciso Reyes, M.D.*, 83 FR 61678, 61681 (2018); *KK Pharmacy*, 64 FR 49507, 49510 (1999) (collecting cases).

⁹ In this matter there are two separate and distinct grounds by which the Government proposed revocation, Registrant's lack of state authority and her mandatory exclusion; each ground, standing alone, supports the Agency's decision to revoke.

see the related notice published in the **Federal Register** on May 8, 2026 (91 FR 25383).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Qualification/Certification Program Request for MSHA Individual Identification Number (MIIN).

OMB Control Number: 1219–0143.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 9,000.

Total Estimated Number of Responses: 9,000.

Total Estimated Annual Time Burden: 720 hours.

Total Estimated Annual Other Costs Burden: \$180.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,
Senior PRA Analyst.

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BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0015]

Proposed Extension of Information Collection: Refuse Piles and Impoundment Structures

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program for all information collections, to provide the public and Federal agencies with an opportunity to comment on proposed collections of information, in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection titled “Refuse Piles and Impoundment Structures.”

DATES: All comments must be received on or before November 20, 2026.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below. Please note that comments received after the deadline will not be considered.

- *Federal E-Rulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments for docket number MSHA–2026–0563.

- *Mail/Hand Delivery:* DOL–MSHA, Office of Standards, Regulations, and Variances, 200 Constitution Avenue NW, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9440 to make an appointment.

- MSHA will post all comments as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Corliss A. Josephs-Conway, Acting Director, Office of Standards, Regulations, and Variances, MSHA, at MSHA.information.collections@dol.gov (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legal Authority

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), as amended, 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal and metal and nonmetal mines.

The Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) governs paperwork burdens imposed on the public by Federal agencies when using identical questions to collect information from 10 or more persons. The PRA defines paperwork burden in 44 U.S.C. 3502(2) as the time, effort, or financial resources expended to generate, maintain, or provide information to or for a Federal agency. Under 44 U.S.C. 3507, the PRA also establishes policies and procedures for information collection to control paperwork burdens imposed by Federal agencies on the public, including evaluating public comments.

To fulfill its statutory mandate to promote miners' health and safety, MSHA requires information collected under the OMB request titled “Refuse Piles and Impoundment Structures.” This information collection is intended to ensure that refuse piles and impoundments provide adequate safety protection by preventing or eliminating hazardous conditions for coal miners.

B. Information Collection

To fulfill its statutory mandate to promote miners' health and safety, MSHA requires information under the information collection request (ICR) titled “Refuse Piles and Impoundment Structures.” This information collection is intended to ensure that refuse piles and impoundments provide adequate safety protection by preventing or eliminating hazardous conditions to coal miners.

Burden costs associated with the ICR include:

1. Developing Fire Extinguishing Plans for Refuse Piles and Impoundments
2. Posting Permanent Identification Markers for Refuse Piles and Impoundments
3. Developing New Plans for Refuse Piles and New and Modified Plans for Impoundments