

admitted and the Agency finds that it failed to maintain complete and accurate records of each controlled substance received. As such, the Agency finds substantial record evidence that Registrant violated 21 CFR 1304.21(a).

The Agency further finds that Factors B and D weigh in favor of denial of Registrant's application and that Registrant's registration would be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). Accordingly, the Agency finds that the Government established a *prima facie* case, that Registrant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 823(g)(1).

II. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to Registrant to show why it can be entrusted with a registration. *Morall*, 412 F.3d. at 174; *Jones Total Health Care Pharmacy*, 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 registrant. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also 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 it will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 833. A registrant's acceptance of responsibility must be unequivocal. *Id.* at 830–31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, DEA

However, the OSC/ISO does not contain sufficient factual or legal analysis to enable to Agency to assess the relevance or applicability of these statutes. Section (a)(1)(A) pertains to institutional pharmacies, and the OSC/ISO does not allege that Registrant is an institutional pharmacy. Section (c)(4) outlines requirements for patient records of Schedule II controlled substances to be maintained separately from patient records of controlled substances in other schedules, and it outlines additional requirements related to distribution records and institutional pharmacies. Finally, Section (c)(5) pertains to floor stock records.

Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. DEA Administrators have also considered the need to deter similar acts by the specific registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46972–73.

Here, Registrant did not timely or properly request a hearing and was deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1–9. 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 answer the allegations contained in the OSC and has not otherwise availed itself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to its future compliance with the CSA nor made any demonstration that it can be entrusted with registration. Moreover, the evidence presented by the Government shows that Registrant violated the CSA, further indicating that Registrant cannot be entrusted.

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

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. FM2279431 issued to Mariste Pharmacy. 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 Mariste Pharmacy to renew or modify this registration, as well as any other pending application of Mariste Pharmacy for additional registration in Texas. This Order is effective May 14, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 8, 2025, by Acting Administrator Derek Maltz. 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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BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of Disability Employment Policy

[OMB Control No. 1230–0014]

Proposed Extension of Information Collection: Retaining Employment and Talent After Injury/Illness Network (RETAIN) Demonstration Projects and Evaluation

AGENCY: Office of Disability Employment Policy, United States Department of Labor.

ACTION: Notice of information collections and request for comments.

SUMMARY: The Department of Labor (DOL) Office of Disability Employment Policy is soliciting comments regarding this ODEP-sponsored information collection for the Retaining Employment and Talent After Injury/Illness Network (RETAIN) Demonstration Projects and Evaluation. As part of its continuing effort to reduce paperwork and respondent burden, DOL conducts a pre-clearance request for comment to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This request 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.

DATES: Comments pertaining to this information collection are due on or before June 13, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered.

Electronic Submission: Submit electronic comments in the following way:

Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket, with no changes. Because your comment will be made public, you

are responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as your or anyone else's Social Security number or confidential business information.

- If your comment includes confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission.

Written/Paper Submissions: Submit written/paper submissions in the following way:

- **Mail/Hand Delivery:** Mail or visit DOL, 200 Constitution Ave. NW, Room S-5315, Washington, DC 20210.
- DOL-OSEP will post your comment 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: David Rosenblum by telephone at 202-693-7840 (this is not a toll-free number) or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In FY 2018, the Department of Labor and the Social Security Administration launched a collaboration to develop and test promising stay-at-work/return-to-work (SAW/RTW) early intervention strategies and evaluate outcomes for individuals who are experiencing work disability.¹ Each year, millions of American workers leave the workforce after experiencing an injury or illness, and hundreds of thousands of these workers go on to receive state or federal disability benefits. The socio-economic impacts of these injuries and illnesses on individuals, employers, and all levels of government can be significant and long-lasting. SAW/RTW programs succeed by returning injured workers to productive work as soon as medically possible by providing interim part-time or light duty work and accommodations, as necessary.

The RETAIN Demonstration Projects are modeled after promising programs currently operating in Washington State, including the Centers of Occupational Health and Education (COHE), the Early Return to Work (ERTW), and the Stay at Work programs. While these programs

operate within the state's workers' compensation system and are available only to individuals experiencing work-related injuries or illnesses, the RETAIN Demonstration Projects provide opportunities to improve SAW/RTW outcomes for individuals with both occupational and non-occupational injuries and illnesses.

The primary goals of the RETAIN Demonstration Projects are:

1. To increase employment retention and labor force participation of individuals who acquire, and/or are at risk of developing, work disabilities; and
2. To reduce long-term work disability among project participants, including the need for federal disability benefits (*i.e.*, Social Security Disability Insurance [SSDI] and Supplemental Security Income [SSI]).

During FY 2018, eight states received funding through cooperative agreements to create systems changes by developing and implementing partnerships and strategies to test the effects of the provision of comprehensive, coordinated health and employment-related services and supports to injured or ill workers who have acquired, or are at risk of developing, a work disability. In Phase 1, these grantees completed start-up activities and launched a small pilot. In FY 2021, five of these grantees (Kansas, Kentucky, Minnesota, Ohio, and Vermont) were competitively awarded Phase 2 funding for a performance period of four years (2021–2024), enabling them to expand and scale up their pilot to full implementation. This performance period has been extended to 2025 for all five grantees and subsequently to 2026 for four grantees, as they continue sustainability activities.

The purpose of the RETAIN employee participant information collection is to understand and assess RETAIN program start-up, pilot projects, and full implementation. Two baseline forms are required to be completed for each participant enrolling in RETAIN, whether in the treatment group or in the control group. The first form is completed by the enrollees themselves, while the second form is completed by a combination of the healthcare provider and Return-to-Work Coordinator, based on information provided by the enrollee. This information collection was approved by OMB in May 2019 with an expiration date of May 31, 2022, and it was subsequently approved by OMB on June 1, 2022 for an extension with an expiration date of June 30, 2025. An extension is requested for another year,

to last through the end of Phase 2 for all grantees.

This information collection is subject to the Paperwork Reduction Act (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.

The DOL seeks PRA authorization for this information collection for one (1) year. OMB authorization for an Information Collection Review cannot be for more than three (3) years without renewal. The DOL notes that currently approved information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review.

II. Desired Focus of Comments

DOL is soliciting comments concerning the proposed information collection related to Retaining Employment and Talent After Injury/Illness Network (RETAIN) Demonstration Projects and Evaluation. DOL is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of DOL's estimate of the burden related to the information collection, including the validity of the methodology and assumptions used in the estimate;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the information collection 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.

Background documents related to this information collection request are available at <https://regulations.gov> and at DOL located at 200 Constitution Ave. NW, Room S-5315, Washington, DC 20210. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

¹ For the purposes of RETAIN, the term "work disability" is defined as an illness, injury, or medical condition that has the potential to inhibit or prevent continued employment or labor force participation, and "federal disability benefits" refers specifically to the Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI) programs. See <https://www.ssa.gov/disability/> for more information on SSDI and SSI.

III. Current Actions

This information collection request concerns the Retaining Employment and Talent After Injury/Illness Network (RETAIN) Demonstration Projects and Evaluation. DOL–ODEP has included the number of respondents, responses, burden hours, and burden costs supporting this information collection request below.

Type of Review: Extension.

Agency: DOL–ODEP.

OMB Control Number: 1230–0014.

Affected Public: Individuals or Households.

Number of Respondents: 1,920.

Number of Responses: 1,920.

Annual Burden Hours: 640 hours.

Estimated Time per Response: 20 minutes.

Total Estimated Annual Other Costs Burden: \$0.

Comments submitted in response to this notice will be summarized in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and will be available at <https://www.reginfo.gov>.

(Authority: 44 U.S.C. 3506(c)(2)(A))

Dated: March 28, 2025.

Jennifer Sheehy,

Deputy Assistant Secretary, Office of Disability Employment Policy.

[FR Doc. 2025–06262 Filed 4–11–25; 8:45 am]

BILLING CODE 4510–FK–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Settlement Agreements Between a Plan and a Party in Interest

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-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 May 14, 2025.

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:

Michael Howell by telephone at 202–693–6782, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: This information collection request relates to two prohibited transaction class exemptions (PTEs) that the Department has granted, both of which involve settlement agreements. These two exemptions are described below.

PTE 94–71 exempts from certain restrictions of ERISA and certain taxes imposed by the Code, a transaction or activity that is authorized, prior to the execution of the transaction or activity, by a settlement agreement, to which the Department is a party, resulting from an investigation of an employee benefit plan conducted by the Department. The following information collections are among the conditions for the exemption: (1) A party engaging in a settlement agreement arising out of a Department investigation must provide written notice to the affected participants and beneficiaries of the plan at least 30 days prior to entry into the settlement agreement. The notice must contain an objective description of the transaction or activity, the approximate date on which the transaction will occur, the address of the regional or district office of the Department that negotiated the settlement agreement, and a statement informing participants and beneficiaries of their right to forward their comments to such office. (2) A copy of the notice and a description of the method by which it will be distributed must be approved in advance by the regional or district office of the Department which negotiated the settlement.

PTE 2003–39 exempts from certain restrictions of ERISA and certain taxes imposed by the Code, transactions arising out of the settlement of litigation that involve: the release by the plan or a plan fiduciary of legal claims against parties in interest in exchange for payment given by or on behalf of the party in interest to the plan; an extension of credit by a plan to a party interest in connection with a settlement; and the plan’s acquisition, holding, and disposition of employer securities received in settlement of litigation. The relief is granted provided certain conditions are met, such as the requirement of an independent fiduciary who has no relationship to, or interest in, any parties in the litigation to authorize the settlement and the

settlement terms of the agreement and any extension of credit are reasonable and no less favorable than comparable arm’s length agreement. The other conditions include the following information collections: (1) The terms of the settlement must be specifically described in a written agreement or consent decree. (2) The fiduciary acting on behalf of the plan must acknowledge in writing that the person is a fiduciary with respect to the settlement of the litigation. (3) The plan fiduciary must maintain records of the transaction for six years and must disclose the records on request to the Department and other interested persons. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 9, 2024 (89 FR 56416).

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–EBSA.

Title of Collection: Settlement Agreements Between a Plan and a Party in Interest.

OMB Control Number: 1210–0091.

Affected Public: Private sector, Businesses or other for-profits, Not-for-profit institutions.