FEDERAL REGISTER

Vol. 90 Friday,

No. 199 October 17, 2025

Pages 48335–48372

OFFICE OF THE FEDERAL REGISTER

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2025–0025]

RIN 0651–AD89

Revision to Rules of Practice Before the Patent Trial and Appeal Board

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) proposes modifications to the rules of practice for inter partes review (IPR) before the Patent Trial and Appeal Board (PTAB or Board) that the Under Secretary of Commerce for Intellectual Property and Director of USPTO and, by delegation, the PTAB will use in instituting IPR.

DATES: Comments must be received by November 17, 2025 to ensure consideration. The Office does not anticipate granting an extension to the comment period, absent extraordinary circumstances.

ADDRESSES: For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at: *https://www.regulations.gov.* To submit comments via the portal, one should enter docket number PTO–P–2025–0025 on the homepage and select the ''Search'' button. The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this notice and select the ''Comment'' button, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe® portable document format (PDF) or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of, or access to, comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Sharon Israel, Vice Chief Administrative Patent Judge, PTAB at 571–272–9797.

SUPPLEMENTARY INFORMATION:

Introduction

The Office is proposing new rules of practice before the PTAB to focus *inter partes* review proceedings on patent claims that have not previously been challenged in litigation or where prior litigation was resolved at an early stage. This proposed rule is intended to promote fairness, efficiency, and predictability in patent disputes.

Background

The USPTO is charged with promoting innovation through the issuance of patents for new and useful inventions. U.S. Const., art. I, section 8. Invention and the issuance of a patent represent just the beginning of the economic cycle of innovation. After an invention is conceived and patented, substantial investment is necessary to bring a product or service to market. Without this additional investment, the invention may remain in the laboratory, never reaching the public as a commercial product or service. Reliable patent rights encourage the inventor or others to invest in the patented technology by giving them confidence that they, not competitors, will reap the benefits of their efforts. However, every party accused of infringing a patent receives a full opportunity to challenge the validity of the patent in district court. If investors lack confidence that a patent will be found valid when it is enforced, the patent will not give them the assurances they need to invest.

District court litigation is not the only forum for challenging patent validity. In 2011, Congress passed the America Invents Act (AIA) to ''provid[e] a quick and cost-effective alternative[ ]'' to district court patent litigation, most notably through *inter partes* review (IPR) proceedings. H.R. Rep. No. 112–98, at 48 (2011). IPR proceedings have many advantages, but are not appropriate in every circumstance. When IPR proceedings cover the same ground as district court litigation, they cease to be an ''alternative'' and can substantially increase litigation costs. That is the opposite of what Congress intended. Serial or parallel IPR proceedings can also be wasteful, because they consume Office and party resources re-litigating issues that the Office is considering, has already considered, or that are being litigated elsewhere, such as in district court or at the U.S. International Trade Commission (ITC). Finally, multiple challenges to the same patent through IPRs jeopardize the reliability of patent rights and incentives to invest in new technologies. This proposed rule is intended to focus IPR proceedings on the most appropriate disputes.

Even extremely strong patents become unreliable when subject to serial or parallel validity challenges.

Determining whether a patent claim meets the statutory requirements of patentability is frequently a matter of judgment about which reasonable minds may disagree. For example, new technologies are often complex. Both the prior art and claim language may be open to multiple interpretations. The possibility of hindsight bias is also an ever-present difficulty. Because reasonable minds may, and frequently do, disagree about whether a particular patent claim meets the statutory requirements, patents cannot serve their economic function if they are perpetually subject to *de novo* review. Consider a hypothetical patent claim where 70% of experienced patent practitioners would conclude that the claim was properly granted, and 30% would oppose that conclusion. Such a patent claim seems reliable, because a substantial majority of practitioners believe it is patentable and was properly issued. However, if the patent is subjected to repeated *de novo* patentability review each time it is enforced, it will no longer be reliable. For example, a patent with a 70% chance of surviving one *de novo* patentability review has less than a 50% chance of withstanding two or more *de novo* patentability challenges. Thus, even extremely strong patents depend on a presumption of validity for their survival.

Congress gave the Director broad discretion to identify the circumstances when IPR proceedings would or would not benefit the patent system.

IPRs are a powerful tool for reassessing patent validity because they subject the patent to essentially *de novo* review. In an IPR proceeding, the petitioner needs to prove unpatentability by only a preponderance of the evidence, which is the same standard the Office used to grant the patent. 35 U.S.C. 316(e). However, when it passed the AIA, Congress ''recognize[d] the importance of quiet title to patent owners to ensure continued investment resources'' and did not want ''repeated litigation and administrative attacks on the validity of a patent.'' H.R. Rep. No. 112–98, at 48 (2011). The AIA House Committee report found that such repeated challenges ''would frustrate the purpose of the'' AIA and could destabilize the patent system. *Id.* In the Senate committee report, Senator Kyl, one of the bill's sponsors, and others agreed. ''Whatever post grant system is ultimately devised, at some point the patent should be final and the inventor should enjoy the benefit of their invention without a cloud of uncertainty lingering over it during the full life of the patent.'' S. Rep. No. 110–259 at 71. ''This uncertainty over the patent'' created by unlimited challenges ''would limit the ability of inventors to attract capital investment and further develop their innovation and bring it to the marketplace.'' *Id.* at 72. Senator Kyl also emphasized that IPRs ''should generally serve as a complete substitute for at least some phase of the litigation.'' *Id.*

To protect quiet title to patent rights necessary to drive investment, Congress left in place the presumption of patent validity in litigation in district court or at the ITC, and provided the Director with broad discretion to determine when the strong medicine of IPR proceedings would be appropriate. H.R. Rep. No. 112–98, at 48; *see* 35 U.S.C. 315(d), 316(b).

Serial and parallel validity challenges remain a significant problem for the patent system.

Approximately 54% of all IPR petitions filed since the passage of the AIA are one of multiple petitions against the same patent. To address the risks from serial and parallel challenges, and from challenges using substantially the same prior art and/or arguments previously presented to the Office, the Office has designated a number of PTAB decisions as precedential. *See, e.g., Gen. Plastic Indus. Co., Ltd.* v. *Canon Kabushiki Kaisha,* IPR2016–01357, Paper 19 (PTAB Sept. 6, 2017) (precedential as to section II.B.4.i) (serial petitions); *Valve Corp.* v. *Elec. Scripting Prods., Inc.,* IPR2019–00062, Paper 11 (PTAB Apr. 2, 2019) (precedential) (serial petitions); *Comcast Cable Commc'ns, LLC* v. *Rovi Guides, Inc.,* IPR2019–00224, Paper 10 (PTAB Apr. 3, 2019) (parallel petitions); *Apple* v. *Fintiv,* IPR2020–00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) (co-pending district court litigation); *Advanced Bionics, LLC* v. *MED–EL Elektromedizinische Geräte GmbH,* IPR2019–01469, Paper 6 (PTAB Feb. 13, 2020) (precedential) (prior art considered during examination). Despite the Office's efforts, serial and parallel patent challenges, including challenges raising the same or substantially similar prior art and/or arguments, remain a significant problem. For example, since 2019, the percentage of petitions that are one of multiple challenges to the same patent has declined, yet remains above 45%.

Additionally, more than 80% of IPRs have co-pending district court litigation where the petitioner is also challenging patent validity. Saurabh Vishnubhakat, Arti K. Rai & Jay P. Kesan, *Strategic Decision Making in Dual PTAB and District Court Proceedings,* 31 Berkeley Tech. L.J. 45 (2016) (available at: *https://ssrn.com/abstract=2731002*). Therefore, even when a patent is challenged by only one IPR petition, it will usually be challenged twice—once in the IPR and once in district court or at the ITC. PTAB precedent stipulations not to pursue invalidity challenges in district court or at the ITC based on an invalidity ground that a petitioner raised or could have raised in an IPR petition, and the AIA IPR estoppel provisions mitigate these problems, but petitioners still frequently bring ''repetitive challenges based on slightly rebranded evidence.'' *Contour IP Holding LLC* v. *GoPro Inc.,* No. 17–cv–04738, 2025 WL 1218748, at *13 (N.D. Cal. Mar. 24, 2025); *see, e.g., Motorola Sols. Inc.* v. *Stellar LLC,* IPR2024–01205, Paper 19 (PTAB Mar. 28, 2025) (Stewart, Acting Director). For example, the district court's opinion in *Contour* catalogs a significant number of cases in which petitioners brought patent challenges in district court based on physical devices that are ''materially identical'' to patents and printed publications. *Contour IP Holding LLC,* 2025 WL 1218748, at *13.

The Office has also recently published additional information on multiple petitions filed at the PTAB at *https://www.uspto.gov/patents/ptab/statistics.*

Moreover, district courts may stay litigation pending the outcome of IPR proceedings. When the PTAB ultimately cancels all the claims being litigated, this can improve litigation efficiency and provide a quicker resolution, but when the patent owner prevails in the IPR, the effect is the opposite, even if only some claims survive. Resolution of the dispute is delayed by at least 18 months during the IPR proceedings, and potentially longer if the stay remains in place pending any appeal or remand.

Furthermore, the simplification of the district court case is often limited because the petitioner rarely reduces the number of invalidity theories it advances in district court. Most often, the petitioner substitutes a new invalidity theory in district court for the ones it may be estopped from raising in district court. For example, patent challengers typically do not receive less summary judgment briefing or trial time to address validity when there is a parallel IPR, and the IPR is not likely to simplify expert discovery. Thus, an IPR proceeding does not often materially reduce the resources necessary to resolve the district court dispute. Additionally, 35 U.S.C. 315(e) provides for estoppel following IPR only after the issuance of a final written decision. Therefore, if the district court case is not stayed, the defendant may raise any invalidity argument in district court while the IPR is pending. In these circumstances, IPRs can add significant expense and delay compared with standalone district court litigation.

These serial and parallel patentability challenges have undermined the reliability of patent rights and deterred investment in new technologies. *See, e.g.,* Adam Mossoff, *Uncertain Patent Rights and a Weakening U.S. Innovation Economy,* 11 LANDSLIDE 40 (Sept./Oct. 2018); Kevin Madigan, *An Ever-Weakening Patent System Is Threatening the Future of American Innovation,* Ctr. for Protection Intell. Prop. (Apr. 28, 2017); les Nouvelles Menno Treffers et al. *Creating SEPs—A Risky Business For SMEs* (Sept. 2017). The weakening of patent rights caused by these repeated patentability challenges presents a threat to America's continued technological leadership. *See* Gupta et al., *Protecting Intellectual Property for National Security,* Center for Strategic and International Studies (Mar. 25, 2025). Finally, there is a bipartisan consensus that small and medium-sized businesses are especially harmed by weakened patent rights because they are more likely to rely on superior technology protected by patent rights to challenge market incumbents. *See* National Economic Council, *The Economics of Investing in America* (2023) at 12 (''The

evidence is clear that new small and medium-sized businesses are drivers of innovation. Yet when a few firms (or one single firm) dominate a market, they can stifle and stymie disruptive startups and other new businesses.''); Kolev *et al., Of Academics and Creative Distruction: Starup Advantage in the Process of Innovation,* National Bureau of Economic Research at 5 (2022) (''We find strong evidence for startup advantage in both average forward citations and the rate of outlier patents (in the top 5% of the citation distribution), supporting our first hypothesis. We also find that startup patents score higher in terms of originality and generality relative to patents from established firms.'').

By far, the most frequent users of IPR proceedings are large technology companies. When a large company is free to copy a patented invention because it believes it can invalidate the patent through multiple validity challenges, the large company's other advantages, such as superior brand recognition and manufacturing scale, will often give it an edge over smaller competitors. Thus, weakened patent rights can contribute to market concentration in innovative industries. *See* Jonathan Barnett, *Why Big Tech Likes Weak IP, Regulation* (Spring 2021).

The proposed rule is intended to enhance fairness, efficiency, and predictability in patent disputes.

Congress provided that the Director ''may not authorize an inter partes review'' unless a petition meets a minimum ''[t]hreshold'' for institution. 35 U.S.C. 314(a). Yet the same provisions provide the Director broad discretion to decide *not* to proceed with institution, even if a petition satisfies the minimum statutory threshold for instituting an IPR. The AIA allocated expansive authority to the USPTO to prescribe regulations governing AIA proceedings, including IPRs. 35 U.S.C. 316(a). Among other things, Congress instructed the Director to provide regulations ''governing . . . the relationship of [inter partes] review to other proceedings under this title.'' 35 U.S.C. 316(a)(4). Title 35 encompasses other challenges before the Office (*e.g.,* under Title 35 Chapters 30 (ex parte reexamination) 31 (*inter partes* review), and 32 (post-grant review)), as well as parallel district court infringement actions (*i.e.,* under Title 35 Chapter 29). *See, e.g.,* 35 U.S.C. 281 (''A patentee shall have remedy by civil action for infringement of his patent.''). In establishing these regulations, the Director ''shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.'' 35 U.S.C. 316(d). Separately, § 315(d) provides that the Director may determine the manner in which an IPR or other USPTO proceeding may proceed during the pendency of an IPR involving the same patent, including ''providing for stay, transfer, consolidations, or termination of any such matter or proceeding.''

In addition to taking the steps discussed above to address inappropriate uses of IPR proceedings, the Office has requested comments on a wide variety of proposals to promote fairness and efficiency in IPR proceedings. *See, e.g., Request for Comments on Discretion To Institute Trials Before the Patent Trial and Appeal Board,* 85 FR 66502 (Oct. 20, 2020); *Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board,* 88 FR 24503 (Apr. 20, 2023); *Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement,* 88 FR 28693 (Apr. 19, 2024). This proposed rule has both similarities and differences with prior proposals and past practices. Accordingly, the Office requests comments on this distinct proposed rule.

The Office believes that this proposed rule will enhance fairness and efficiency in patent disputes by focusing IPR proceedings on cases where the patent has not previously been challenged in litigation or where prior litigation was resolved via settlement at an early stage.

The Office expects that this proposed rule will have a positive impact on the economy. First, as discussed above, the rule will increase the reliability of patent rights and the predictability of patent disputes. This will further innovation and economic growth. The rule will also decrease overall expenditures of patent litigation and the transaction costs for patent licensing. As previously discussed, most IPRs have been one of multiple of petitions against the same patent and a large majority of patents challenged in IPRs are also being challenged in district court or at the ITC. This proposed rule will reduce litigation costs by foreclosing most IPR challenges where patent validity has already been tested during examination at the USPTO and at least once in another proceeding (*e.g.,* at the USPTO, in district court, or at the ITC). Similarly, the proposed rule will also reduce costs by requiring a stipulation by the petitioner regarding litigation issue overlap. Patent owners often spend substantial funds defending their rights against multiple or duplicative challenges, which would be avoided under the proposed rule. Patent challengers also expend significant resources raising such challenges, which would also be avoided. Patent challengers find that this expenditure serves their private interests, because the possibility of patent invalidation reduces the risk that the challenger will be compelled to compensate a patent owner for infringement and may reduce amounts patent owners accept in license fees. The risk-adjusted amounts a petitioner may avoid in licensing fees or litigation judgments may exceed the costs a petitioner expends when filing an IPR, thus making the IPR economically rational from the perspective of the petitioner.

However, the licensing fees or judgments that a patent challenger may avoid paying are reduced compensation for innovators whose patent claims have already been adequately tested. This reduced compensation for patent owners harms the broader public interest in incentivizing innovation and investment in the commercialization of new technologies. Additionally, allowing multiple, often duplicative, patentability challenges against the same patent can reduce competition in the economy by allowing market incumbents to copy the innovations of smaller rivals and maintain their dominant market positions. Michel & Dowd, *Patent Protection: A crucial Antitrust Tool for Increasing Innovation,* Competition Policy International, TechREG Chronicle (Sept. 2024) (''[E]ven after the innovation is created and disclosed in a patent, IP rights enable SMEs to grow into larger, more integrated companies with commercialization and/or manufacturing capabilities. . . . [L]arger firms tend to have lower-cost access to non-patent mechanisms for extracting returns from innovations. . . . [They] can rely on their market dominance and vertically integrated structures to ensure reasonable financial returns on their R&D efforts. . . . Reliable patent protection can allow startups to enter markets and disrupt entrenched firms.''). It is well-established that increased market concentration and reduced competition stifle economic growth.

The Office also believes that the proposed rule will promote consistency across IPR proceedings, which is vital to the ''integrity of the patent system.'' 35 U.S.C. 316(b). The proposed rule draws clearer lines around the circumstances when IPRs should or should not be instituted, thus enabling PTAB panels to render more consistent decisions. By limiting the circumstances in which a district court and the PTAB will consider the same or closely related issues, the proposed rule also reduces the risk of the Office and a district court rendering inconsistent decisions.

Clearer lines will also help parties determine before filing an IPR petition whether the petition is likely to be granted, thus enabling them to focus their briefing on the patentability of the challenged claims, rather than the Director's discretion to institute. This will also improve the reliability of patents by focusing the Office's efforts on the technical merits of disputes.

Finally, in addition to IPR proceedings, the PTAB also handles ex parte appeals from examination and post-grant reviews. The time administrative patent judges (APJs) spend dealing with IPRs reduces an APJ's ability and time to address ex parte appeals and vice versa. The Office must balance the potential benefits of IPR proceedings to the patent system with the costs of taking resources from ex parte appeals. For example, delayed resolution of ex parte appeals can prevent or delay business formation or capital raising which, in turn, delays releasing or launching patented technologies to market. Reducing the time APJs have to consider ex parte appeals increases the risk that the Office will allow unpatentable claims or reject patentable ones. For several years, ex parte appeal pendency has been well-above the Office's pendency goals. The Office believes it is appropriate to focus APJ time on ex parte appeals, because that is the sole forum for reviewing whether patent application claims should issue, or whether patent claims should be confirmed in ex parte reexamination proceedings. Applicants appealing an examiner decision *must* have their case heard by the PTAB in order to either receive their patent or seek judicial review of the Office's rejection. 35 U.S.C. 134(a), 141(a). By contrast, IPRs are not the only mechanism for challenging the validity of an issued patent. In most instances, IPR petitioners are already challenging patent validity in district court litigation. If they are not already in the process of litigating, they could initiate district court litigation challenging patent validity without any action by the Office. 28 U.S.C. 2201. Patent challengers also have the ability to raise a patentability challenge by filing an ex parte reexamination request, which patent examiners handle in the first instance. By focusing IPRs on patents that have not already been tested in litigation or other Office proceedings, the proposed rule will help ensure that sufficient APJs are available for its essential ex parte appeal mission.

The Office invites comments from the public on whether this proposed rule strikes the appropriate balance between efficiency, fairness, and stability in the patent system.

Discussion of Proposed Changes

In this section, the Office describes the proposed changes to specific sections in 37 CFR part 42. Each subsection describes a related group of regulatory changes. The Office solicits comments supporting, opposing, or suggesting modifications on each specific proposed change.

§ 42.108 Institution of Inter Partes Review

Section 42.108(d): *Required stipulation for efficiency.* Under the proposed revisions, this section would provide that the Office will not institute an IPR when a petitioner intends to pursue invalidity challenges under §§ 102 or 103 in other venues, such as district court or the U.S. International Trade Commission. This proposed section would further require the Petitioner to file the stipulation in any other venue where it is litigating with the patent owner. The Office's view is that this requirement would promote fairness and efficiency by channeling similar patent challenges to a single forum and ensure that IPRs ''should generally serve as a complete substitute for at least some phase of the litigation.'' S. Rep. No. 110–259 at 72.

Section 42.108(e): *Claims found valid in prior proceedings.* This proposed section addresses circumstances in which institution of an IPR proceeding may be unwarranted, because the claim (or an independent claim from which it depends) has already been adequately reviewed through both examination at the USPTO and in another proceeding before a district court, the USPTO, or the U.S. International Trade Commission. The rule would extend to dependent claims where the independent claim on which each depends has already received scrutiny, because if an independent claim satisfies §§ 102 and 103, each dependent claim necessarily does as well. Proposed subparagraphs (1) and (2) provide circumstances in which an IPR may not be instituted because the claims were previously found not invalid by a district court. Proposed subparagraph (3) provides circumstances in which an IPR may not be instituted because the claims were previously found not invalid by the U.S. International Trade Commission. Proposed subparagraphs (4) and (5) provide circumstances in which an IPR may not be instituted because the claims were previously found patentable or not unpatentable by the USPTO in an IPR, post-grant review, or reexamination proceeding. Proposed subparagraph (6) provides the circumstances in which an IPR may not be instituted because the Federal Circuit reversed a decision finding the claims invalid or unpatentable. In the circumstances described in this paragraph, the USPTO believes that the claims at issue have received adequate scrutiny in a prior proceeding and it is not in the interests of the patent system or the economy for the USPTO to conduct another review of the claims. Any parties accused of infringing the claims would have a full opportunity to challenge validity again in district court.

Section 42.108(f): *Parallel Litigation.* This proposed section addresses circumstances in which a parallel proceeding is likely to reach a decision regarding the validity of the patent under §§ 102 or 103 before the final written decision.

Section 42.108(g): *Institution in extraordinary circumstances.* This proposed section would allow institution, notwithstanding paragraphs (d), (e), or (f), based on extraordinary circumstances. To ensure the predictability of institution decisions, this proposed section identifies specific examples of potential extraordinary circumstances and examples of circumstances that are not extraordinary.

Rulemaking Considerations

A. Administrative Procedure Act: The changes proposed by this rulemaking involve rules of agency practice and procedure, and/or interpretive rules, and do not require notice-and-comment rulemaking. *See Perez* v. *Mortg. Bankers Ass'n,* 575 U.S. 92, 97, 101 (2015) (explaining that interpretive rules ''advise the public of the agency's construction of the statutes and rules which it administers'' and do not require notice and comment when issued or amended); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency

organization, procedure, or practice''); *In re Chestek PLLC,* 92 F.4th 1105, 1110 (Fed. Cir. 2024) (noting that rule changes that ''do[ ] not alter the substantive standards by which the USPTO evaluates trademark applications'' are procedural in nature and, thus, ''exempted from notice-and-comment rulemaking''); and *JEM Broadcasting Co.* v. *F.C.C.,* 22 F.3d 320, 328 (D.C. Cir. 1994) (''[T]he 'critical feature' of the procedural exception [in 5 U.S.C. 553(b)(A)] 'is that it covers agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency.' '' (quoting *Batterton* v. *Marshall,* 648 F.2d 694, 707 (D.C. Cir. 1980))).

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a Regulatory Flexibility Act analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required. *See* 5 U.S.C. 603. Nonetheless, for the reasons set forth below, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, USPTO, has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes set forth in this notice of proposed rulemaking (''proposed rule'') would not have a significant economic impact on a substantial number of small entities. The changes in this proposed rule would modify the rules of practice before the Patent Trial and Appeal Board (Board) to focus *inter partes* review (IPR) proceedings on patent claims that have not previously been challenged in litigation or where prior litigation was resolved at an early stage. The USPTO does not collect or maintain statistics on the size status of IPR petitioners or patent owners whose patents are being challenged in an IPR proceeding, which would be required to determine the number of small entities that will be affected by the rule. However, in a study on patent litigation and USPTO trials, the USPTO found that roughly 30% of the patents challenged in an IPR proceeding were granted to owners who were small entities.[1] The study did not specifically address the percentage of petitioners to an IPR proceeding that were small entities. But, using the average overall percentage of patent applicants that file as a small (or micro) entity, which is approximately 25%, the USPTO estimates that the percentage of small entities filing petitions is lower than the percentage of small entities whose patents are currently subject to challenge in an IPR. Accordingly, this proposed rule would likely benefit a greater percentage of small entities in the IPR framework. The changes made by this rulemaking are largely procedural as they address the circumstances when the Board will institute an IPR proceeding, and the only new requirement being imposed on impacted entities is the submission of a stipulation by IPR petitioners, which results in only minimal additional cost burden. The USPTO estimates that the overall impact to all impacted small entities would be a net reduction in their overall litigation costs as a result of limiting the avenues for serial and parallel patentability challenges. For the foregoing reasons, the changes in this proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking been determined to be not significant under Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, and as discussed above, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 14192 (Deregulation): This regulation is not an Executive Order 14192 regulatory action because it has been determined to be not significant under Executive Order 12866.

E. Executive Order 13132 (Federalism): This rulemaking pertains strictly to federal agency procedures and does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes, (2) impose substantial direct compliance costs on Indian tribal governments, or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this NPRM are not expected to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this

[1] U.S. Pat. and Trademark Off., Patent Litigation and USPTO Trials: Implications for Patent Examination and Quality 36 (January 2015).

rulemaking is not a ''major rule'' as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this NPRM do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

M. National Environmental Policy Act of 1969: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

N. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

O. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking proposes changes to the PTAB rules of practice for *Inter Partes* Review (IPR) which would result in new information collection requirements that are subject to review and approval by OMB. The provisions pertaining to IPRs have been reviewed and previously approved by OMB under control number 0651–0069 (Patent Review and Derivation Proceedings). This proposed rule modifies the rule of practice for IPR to provide that an *inter partes* review would not be instituted or maintained unless each petitioner files a stipulation with the Board stating that if a trial is instituted, the petitioner and any real party in interest or privy of the petitioner will not raise grounds of invalidity or unpatentability with respect to the challenged patent under 35 U.S.C. 102 or 103 in any other proceeding.

This proposed rule would impact the burden estimates provided in the information collection for the item ''Petitions for *Inter Partes* Review.'' The USPTO currently estimates that 1,300 petitions are submitted annually and 120 hours are needed to file each petition. The USPTO is proposing to add one hour to the estimated time to file to account for the preparation and submission of the stipulation proposed in this rule, thus increasing the time estimate for this petition to 121 hours. Therefore, the USPTO calculates that this information collection's estimated annual burden will increase by 1,300 hours and $581,100 in hourly cost. This rulemaking does not change any fees associated with filing an IPR, and therefore there is no change to the estimated annual non-hourly cost burden in this information collection. A summary of the proposed revisions to the information collection follows.

As required by the PRA, the USPTO has submitted this proposed revision to the information collection to OMB for its review.

Burden Data for the Petition for Inter Partes Review

Provided below is a summary of the current estimates and proposed revisions to the burden data for Petition for *Inter Partes* Review.

Current Estimates

Estimated Number of Annual Responses: 1,300.

Estimated Time for Response: 120 hours.

Estimated Annual Respondent Burden Hours: 156,000.

Estimated Hourly Cost Burden Rate:[2] $447.

Estimated Annual Respondent Hourly Cost Burden: $69,732,000.

Proposed Revisions

Estimated Number of Annual Responses: 1,300.

Estimated Time for Response: 121 hours.

Estimated Annual Respondent Burden Hours: 157,300.

Estimated Hourly Cost Burden Rate:[3] $447.

Estimated Annual Respondent Hourly Cost Burden: $70,313,100.

As a result of this proposed rule, the annual respondent burden hours for the Petition for *Inter Partes* Review will increase by 1,300 hours from 156,000 hours to 157,300 hours. Likewise, the non-hourly cost burden will also increase by $581,100 from $69,732,000 to $70,313,100.

Proposed Total Burden Data for the Information Collection

OMB Control Number: 0651–0069.

Title of Collection: Patent Review and Derivation Proceedings.

Type of Review: Revision of a currently approved information collection.

Summary: This collection covers information submitted by the public to petition the Board to initiate an *inter partes* review, post-grant review, derivation proceeding, and the transitional program for covered business method patents, as well as any responses to such petitions, and the filing of any motions, replies, oppositions, and other actions, after a review/proceeding has been instituted.

Method of Collection: Applicants must submit the information electronically using Patent Trial and Appeal Case Tracking System filing system. Parties may seek authorization to submit a filing by means other than electronic filing pursuant to 42 CFR 42.6(b)(2).

Forms: None.

Affected Public: Private sector.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated Number of Annual Respondents: 7,897 respondents.

Estimated Number of Annual Responses: 11,947 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately 18 minutes (0.3 hours) to 170 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 591,930 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $264,592,710.

Estimated Total Annual Respondent Non-Hourly Cost Burden: $76,099,956. There are no capital start-up costs, maintenance costs, recordkeeping costs, or postage costs associated with this information collection. However, the USPTO estimates that the total annual non-hourly cost burden for this information collection, in the form of filing fees, is $76,099,956.

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

[2] 2023 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association; pg. F–41. The USPTO uses the average billing rate for intellectual property work in all firms which is $447 per hour (*https://www.aipla.org/home/news-publications/economic-survey*).

[3] Ibid.

(b) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) 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).

Please submit comments on the new collection of information requirements at: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review'' or by using the search function and entering the title of the collection. Please send a copy of your comments to the USPTO using the method described under **ADDRESSES** at the beginning of this document. All comments submitted in response to this proposed rule are a matter of public record. The USPTO will include or summarize the comments received in the request to the OMB to approve the new information collection requirements.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

P. E-Government Act Compliance: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 42

Administrative practice and procedure, Inventions and patents, Lawyers.

For the reasons set forth in the preamble, the Office proposes to amend 37 CFR part 42 as follows:

PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 1. The authority citation for 37 CFR part 42 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 3, 6, 21, 23, 41, 134, 135, 143, 153, 311, 312, 314, 316, 318, 321–326, 328; Pub. L. 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

* * * * *

■ 2. Amend § 42.108 by adding paragraphs (d) through (e) to read as follows:

§ 42.108 Institution of inter partes review.

* * * * *

(d) *Required stipulation for efficiency. Inter partes* review shall not be instituted or maintained unless each petitioner files a stipulation with the Board and any other tribunal where it is litigating or later litigates regarding the challenged patent, stating that if a trial is instituted, the petitioner and any real party in interest or privy of the petitioner will not raise grounds of invalidity or unpatentability with respect to the challenged patent under 35 U.S.C. 102 or 103 in any other proceeding.

(e) *Claims found valid in prior proceedings. Inter partes* review shall not be instituted or maintained if a challenged claim or an independent claim from which a challenged claim depends:

(1) *U.S. District Court Trial*—Was found not invalid under 35 U.S.C. 102 or 103 by a district court or jury following a bench trial or jury trial in a decision or verdict that has not been vacated or reversed in relevant part;

(2) *U.S. District Court Summary Judgment*—Was found not invalid by a district court in a summary judgement decision finding no dispute of material fact under 35 U.S.C. 102 or 103 that has not been vacated or reversed in relevant part;

(3) *U.S. International Trade Commission*—Was found not invalid under 35 U.S.C. 102 or 103 in initial or final determination of the U.S. International Trade Commission that has not been vacated or reversed in relevant part;

(4) *PTAB Final Written Decision*—Was found not unpatentable in a final written decision of the Board under 35 U.S.C. 318(a) or 328(a) that has not been vacated or reversed;

(5) *Ex Parte Reexamination*—Was found patentable in an office action or decision by the Board following a reexamination request filed under Chapter 30 of Title 35 United States Code by someone other than the patent owner, the patent owner's real party in interest or privy; or

(6) *Federal Circuit*—Was found unpatentable or invalid under 35 U.S.C. 102 or 103 in a decision, but that decision was reversed in relevant part by the U.S. Court of Appeals for the Federal Circuit.

(f) *Parallel Litigation—Inter partes* review shall not be instituted or maintained if, more likely than not, any of the following will occur, with respect to a challenged claim or an independent claim from which a challenged claim depends, before the due date for the final written decision pursuant to 35 U.S.C. 316(a)(11):

(1) *U.S. District Court*—A district court trial in which a party challenges the patent under 35 U.S.C. 102 or 103;

(2) *U.S. International Trade Commission*—an initial or final determination of the U.S. International Trade Commission with respect to 35 U.S.C. 102 or 103; or

(3) *PTAB Final Written Decision*—issuance of a final written decision by the Board under 35 U.S.C. 318(a) or 328(a).

(g) *Institution in extraordinary circumstances.* If a panel of the Board determines that extraordinary circumstances warrant institution notwithstanding paragraphs (d), (e), or (f) the Panel shall refer to matter to the Director who may personally institute *inter partes* review. Extraordinary circumstances may include a determination by the Director that the prior challenge barring institution was initiated in bad faith, *e.g.,* for the purpose of preventing future challenges, or that the prior challenge is rendered irrelevant in view of a substantial change in a statute or precedent of the Supreme Court of the United States. Unusual and extraordinary circumstances shall not include new or additional prior art, new expert testimony, new caselaw (except as provided above) or new legal argument, or a prior challenger's failure to appeal. Neither the Director nor the Board shall waive the requirements of paragraphs (d), (e), or (f) of this section except as provided in this paragraph. Frivolous or abusive petitions under this paragraph may be appropriately sanctioned, including with an award of attorneys' fees.

John A. Squires,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2025–19580 Filed 10–16–25; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2023–0048]

RIN 0651–AD72

Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Proposed rule; withdrawal.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is withdrawing the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on April 19, 2024, to revise the rules of practice for inter partes review (IPR) and post-grant review (PGR) proceedings before the Patent Trial and Appeal Board (PTAB) that the Director and, by delegation, the PTAB use in exercising discretion to institute IPRs and PGRs.

DATES: The proposed rule published in the **Federal Register** at 89 FR 28693 on April 19, 2024, is withdrawn as of October 17, 2025.

FOR FURTHER INFORMATION CONTACT: Michelle Ankenbrand, Acting Vice Chief Administrative Patent Judge, at 571–272–9797.

SUPPLEMENTARY INFORMATION: This Action withdraws a proposed rule published in the **Federal Register** on April 19, 2024 (89 FR 28693), to revise the rules of practice for IPR and PGR proceedings before the PTAB that the Director and, by delegation, the PTAB use in exercising discretion to institute IPRs and PGRs. The proposed rule modified and built on existing PTAB precedent and guidance concerning serial petitions, parallel petitions, and petitions implicating the same or substantially the same art or arguments previously presented to the Office. The proposed rule also provided a separate briefing process for discretionary institution arguments and aligned the procedures before and after institution regarding settlement agreements and termination. The proposed rule's comment period was open from April 19, 2024 to June 18, 2024.

Reason for Withdrawal

During the proposed rule's 60-day comment period, the USPTO received more than 3,900 submissions from a variety of stakeholders, including both supporting and opposing comments for the proposed rule. The comments are publicly available at the Federal eRulemaking Portal at *www.regulations.gov/docket/PTO-P-2023-0048.* Of the comments received concerning the proposed rule, 110 comments were unique.

The USPTO is withdrawing the rulemaking at this time to evaluate future actions in light of the administration's current priorities. Despite the decision not to move forward with the proposed rule at this time, the USPTO appreciates the thoughtful perspectives that commenters raised. The USPTO welcomes continued stakeholder feedback as it evaluates future actions.

Conclusion

The proposed rule to amend the rules of practice for IPR and PGR proceedings before the PTAB that the Director and, by delegation, the PTAB use in exercising discretion to institute IPRs and PGRs, published in the **Federal Register** on April 19, 2024 (89 FR 28693), is hereby withdrawn.

John A. Squires,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2025–19587 Filed 10–16–25; 8:45 am]

BILLING CODE 3510–16–P

Notices

Federal Register

Vol. 90, No. 199

Friday, October 17, 2025

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: October 16, 2025, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426. Open to the public.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* *Note*—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Debbie-Anne A. Reese, Secretary, Telephone (202) 502–8400.

For a recorded message listing items Stricken from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed online at the Commission's website at *https://elibrary.ferc.gov/eLibrary/search* using the eLibrary link.

1129TH—MEETING

[Open; October 16, 2025, 10:00 a.m.]

Item No.	Docket No.	Company
	Administrative	
A–1	AD26–1–000	Agency Administrative Matters.
A–2	AD26–2–000	Customer Matters, Reliability, Security and Market Operations.
	Electric	
E–1	ER24–1915–002; ER24–1915–003	New York Independent System Operator, Inc.
E–2	EL23–29–000	*Invenergy Energy Management LLC* v. *PJM Interconnection, L.L.C.*
E–3	EL22–83–000	*Invenergy Transmission LLC* v. *Midcontinent Independent System Operator, Inc.*
E–4	EL24–92–002	*Cometa Energia, S.A. de C.V., /o/b/o., Energia Azteca X, S. de R.L. de C.V.* v. *California Independent System Operator Corporation.*
E–5	ER25–2385–000	Duke Energy Carolinas, LLC and Duke Energy Progress, LLC.
E–6	ER10–2126–011; EL26–2–000	Idaho Power Company.
E–7	ER10–2137–028	Beech Ridge Energy LLC.
	ER14–2799–019	Beech Ridge Energy Storage LLC.
	ER10–2138–029	Grand Ridge Energy II LLC.
	ER10–2139–029	Grand Ridge Energy III LLC.
	ER10–2140–028	Grand Ridge Energy IV LLC.
	ER10–2141–028	Grand Ridge Energy V LLC.
	ER14–2187–022	Grand Ridge Energy Storage LLC.
	ER21–258–005	Todd Solar LLC.
E–8	ER25–634–001; ER25–634–000	Manitowoc Public Utilities.
E–9	ER25–3254–000	Elk Creek Solar, LLC and Elk Creek Solar 2, LLC.
E–10	ER25–3031–000	Evergreen Wind Power II, LLC.
E–11	ER20–2878–018; ER22–619–002; ER22–620–002.	Pacific Gas and Electric Company.
	Gas	
G–1	RM96–1–044	Standards for Business Practices of Interstate Natural Gas Pipelines.
G–2	RP25–740–000	*Baltimore Gas and Electric Company and Washington Gas Light Company* v. *Columbia Gas Transmission, LLC.*
	Hydro	
H–1	P–13123–031	Eagle Crest Energy Company.
	Certificates	
C–1	CP25–37–000	Transwestern Pipeline Company, LLC.
C–2	CP25–11–001	NGO Transmission, Inc.

1129TH—MEETING—Continued

[Open; October 16, 2025, 10:00 a.m.]

Item No.	Docket No.	Company
C–3	CP25–535–000	Rover Pipeline LLC.

A free webcast of this event is available through the Commission's website. Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The Federal Energy Regulatory Commission provides technical support for the free webcasts. Please call (202) 502–8680 or email *customer@ferc.gov* if you have any questions.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters but will not be telecast.

Issued: October 9, 2025.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2025–19581 Filed 10–15–25; 11:15 am]

BILLING CODE 6717–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting

DATES: October 28, 2025, at 10:00 a.m. ET.

ADDRESSES: Telephonic. Dial-in (listen only) information: Number: 1–202–599–1426, Code: 402 943 617#; or via web: *https://www.frtib.gov/*.

FOR FURTHER INFORMATION CONTACT: James Kaplan, Director, Office of External Affairs, (202) 864–7150.

SUPPLEMENTARY INFORMATION:

Board Meeting Agenda

Open Session

1. Approval of the September 25, 2025, Board Meeting Minutes
2. Monthly Reports
   (a) Participant Report
   (b) Legislative Report
3. Quarterly Reports
   (c) Investment Review
   (d) Audit Status
   (e) Budget Review
4. Financial Wellness Survey Report
5. Social Science Update
6. OEA Office Presentation

Closed Session

7. Information covered under 5 U.S.C. 552b(c)(6) and (c)(9)(B).

Authority: 5 U.S.C. 552b(e)(1).

Dated: October 14, 2025.

Dharmesh Vashee,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2025–19574 Filed 10–16–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Grace S. Joanita, N.P.; Decision and Order

On February 6, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Grace S. Joanita, N.P., of Cincinnati, Ohio (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, Attachment (Attach.) F, at 1, 4. The OSC proposed the revocation of Registrant's DEA registration, No. MJ5209677, alleging that Registrant materially falsified her December 7, 2021 renewal application for registration. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).[1]

On July 5, 2023, the Government submitted an RFAA to the Administrator requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 1–3. After carefully reviewing the entire record and conducting the analysis as set forth in detail below, the Agency finds that Registrant is in default and finds that Registrant materially falsified her renewal application. Accordingly, the Agency grants the Government's RFAA and revokes Registrant's registration.

I. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request ''within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default'' unless ''good cause'' is established for the failure. 21 CFR 1301.43(a), (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is ''deemed to have waived their right to a hearing and to be in default.'' 21 CFR 1301.43(c)(2).

The OSC notified Registrant of her right to file a written request for a hearing and an answer, and that if she failed to file such a request and answer, she would be deemed to have waived her right to a hearing and be in default.[2] RFAAX 1, Attach. F, at 2–3 (citing 21 CFR 1301.43). Registrant did not request a hearing, file an answer, or respond to the OSC in any way. RFAA, at 1–3. Accordingly, Registrant is in default. 21 CFR 1301.43(c)(1); RFAA, at 1–3.

''A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e). Because Registrant is in default and has not moved to excuse the default, the Agency finds that Registrant has admitted to the factual allegations in the OSC. 21 CFR 1301.43(c)(1), (e), (f)(1).

Further, ''[i]n the event that [a registrant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to

[1] The Government further alleged that Registrant committed acts inconsistent with the public interest. RFAAX 1, Attach. F, at 1–2 (citing 21 U.S.C. 823(g)(1)(E)). However, due to the Agency's finding that Registrant submitted a materially false application, which serves as an independent basis for sanction under 21 U.S.C. 824(a)(1), the Agency declines to analyze the public interest allegation.

[2] Based on the Government's submissions in its RFAA dated July 5, 2023, the Agency finds substantial record evidence that service of the OSC on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on February 10, 2023, DI served the OSC on Registrant in-person. RFAAX 1, at 3.

In addition to DI's Declaration regarding service, the Government attached to the RFAA several substantive evidentiary exhibits that relate to the OSC allegations. Because this matter is a default, only the facts in the OSC are deemed to be admitted, and any facts found based on supplementary information submitted by the Government must be established by record evidence that meets the appropriate evidentiary standard. *See Victor Augusto Silva, M.D.,* 90 FR 16002, 16002 n.4 (2025) (finding that ''a registrant's deemed admission of the factual allegations based on a default applies to the facts in the OSC only''); *see also Hayriye Gok, M.D.,* 90 FR 30266, 30266 n.2 (2025).

[21 CFR] 1316.67.'' 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 1–3; *see also* 21 CFR 1316.67.

II. Material Falsification

A. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant is deemed to have admitted to each of the following facts.[3] On or about December 7, 2021, Registrant submitted a timely renewal application for her DEA registration, No. MJ5209677. RFAAX 1, Attach. F, at 1. The renewal application requested information regarding Registrant's fee exemption status. *Id.* at 1–2. Specifically, the application requested the name, title, phone number, and email address of a certifying official, and the name of a fee exempt institution. *Id.* at 2. Registrant responded to the fee exemption prompts, and provided the name of a certifying official for whom she had not worked since November 20, 2019. *Id.* Based on the information Registrant provided in response to the fee exemption prompts, her registration was granted ''fee exempt'' status and she therefore did not pay the required fee to renew her registration. *Id.* In December 2021, January 2022, and August 2022, DEA provided Registrant opportunities to pay the required registration fee and fill out a Change of DEA Fee Exemption Status form. *Id.* At the time the OSC was issued, Registrant had not paid the required fee or filled out the Change of DEA Fee Exemption Status form. *Id.*

B. Discussion

A DEA registration may be denied, suspended, or revoked upon a finding that the applicant or registrant materially falsified any application filed pursuant to or required by the Controlled Substances Act (CSA). 21 U.S.C. 824(a)(1).[4] To present a *prima facie* case for material falsification, the Government's record evidence must show (1) the submission of an application, (2) containing a false statement and/or omitting information that the application requires, (3) when the submitter knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure, and (4) the false statement and/or required but omitted information is material, that is, it ''connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] 'shall' consider'' when analyzing ''whether issuing a registration 'would be inconsistent with the public interest.' '' *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45238 (2020) (citing 21 U.S.C. 823 and *Kungys,* 485 U.S. at 771); *see also Sasha Melissa Ikramelahai,* 90 FR 32017, 32019 (2025); *Michael Bouknight,* 90 FR 31247, 31249 (2025).

Regarding materiality, *Kungys* holds that a statement is material if it is ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the [Agency's] official decision,'' or stated differently, ''had a natural tendency to influence the decision.'' *Kungys,* 485 U.S. at 771–72. As already discussed, materiality, for the purposes of the CSA, is tied to the factors that the Administrator ''shall'' consider when determining whether issuance of a registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823; *Kungys,* 485 U.S. at 771–72; *Stirlacci,* 85 FR at 45234, 45238.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. The Government must establish material falsification with record evidence that is clear, unequivocal, and convincing. *Kungys,* 485 U.S. at 772; *Stirlacci,* 85 FR at 45230–39. Here, the Agency finds that the Government's clear, unequivocal, and convincing record evidence presents a *prima facie* case that Registrant submitted a materially false application. 21 U.S.C. 823, 824(a)(1).

As the Agency finds above, Registrant submitted a renewal application for DEA registration and the application requested information regarding exemption from paying the required fee. RFAAX 1, Attach. F, at 2; *see also* 21 CFR 1301.13(e) (setting forth the fee schedule); 21 CFR 1301.21 (setting forth the conditions for fee exemption). Registrant responded to the fee exemption prompts and provided employment information—specifically, the name of a certifying official—that was false at the time she submitted her renewal application, because she had not worked for that certifying official in over two years. RFAAX 1, Attach. F, at 2. By responding to the fee exemption prompts, Registrant falsely represented that she was entitled to fee exemption. *Id.* In other words, on her renewal application, Registrant claimed to meet the regulatory requirements for a fee exemption by representing that she worked for a certifying official for whom she did not work for at the time, and she knew or should have known that she did not work for the certifying official when she submitted her application. *Id.; see also Ikramelahai,* 90 FR at 32020 (finding registrant created the false impression that she possessed a state license when, in fact, it belonged to a different practitioner). Thus, Registrant's renewal application contained false statements.

In addition, the false statements were material. Specifically, Registrant's falsities are connected to public interest factor D, under which DEA considers an applicant's compliance or non-compliance with Federal laws relating to controlled substances. 21 U.S.C. 823(g)(1)(D). DEA's registration and renewal process are governed by the CSA and its implementing regulations—in other words, Federal laws which relate to controlled substances. In applying for a DEA registration or renewing a DEA registration, an applicant or registrant must comply with Federal laws that govern the issuance and renewal of controlled substance registrations. *See, e.g.,* 21 U.S.C. 821 (authorizing the Attorney General to promulgate regulations and charge fees relating to the registration and dispensing of controlled substances); 21 U.S.C. 822(a)(2) (''Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.''); 21 U.S.C. 823(g)(1) (setting forth the factors that the Attorney General must consider when determining whether to grant or deny a registration); 21 CFR 1301.13 (establishing application requirements, including registration fees tied to specific regulated activities); 21 CFR 1301.21 (setting forth conditions for fee exemption); *Gonzales* v. *Raich,* 545 U.S. 1, 14 (2005) (''The CSA and its implementing regulations set forth strict requirements regarding registration

[3] According to the Controlled Substances Act (CSA), ''[f]indings of fact by the [DEA Administrator], if supported by substantial evidence, shall be conclusive.'' 21 U.S.C. 877. Here, where Registrant is found to be in default, all the factual allegations in the OSC are deemed to be admitted. These uncontested and deemed admitted facts constitute evidence that exceeds the ''substantial evidence'' standard of 21 U.S.C. 877; it is unrebutted evidence.

[4] A statutory basis to deny an application pursuant to section 823 is also a basis to revoke or suspend a registration pursuant to section 824, and vice versa, because doing ''otherwise would mean that all applications would have to be granted only to be revoked the next day . . . .'' *Robert Wayne Locklear, M.D.,* 86 FR 33738, 33744–45 (2021) (collecting cases).

The Supreme Court's decision in *Kungys* v. *United States,* 485 U.S. 759 (1988), and its progeny, guide the Agency's implementation of these CSA provisions.

. . . .''). Thus, evaluating an applicant's or registrant's compliance with the Federal laws that govern registration and renewal, including DEA's fee schedule and fee exemptions, is appropriately considered under factor D.[5] 21 U.S.C. 823(g)(1)(D).

Accordingly, making a false statement regarding entitlement to fee exemption has a natural tendency to influence the Agency's decision regarding whether issuance of a registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823; *Kungys,* 485 U.S. at 771–72; *Stirlacci,* 85 FR at 45234, 45238; RFAAX 1, Attach. F, at 1–2. Therefore, the falsities in Registrant's application were ''predictably capable of affecting'' DEA's decision to renew her registration, and therefore the Agency finds that they were material. *Kungys,* 485 U.S. at 771–72.

In sum, the Agency finds clear, unequivocal, and convincing record evidence, based on Registrant's admissions, that she submitted a materially false renewal application for registration. 21 U.S.C. 824(a)(1); 21 CFR 1301.43(e).

As a result of this established violation, the Agency finds that the Government has established a *prima facie* case for sanction, that Registrant did not rebut that *prima facie* case, and that there is clear, unequivocal, and convincing record evidence supporting the revocation of Registrant's registration. 21 U.S.C. 824(a)(1).

C. Sanction

Where, as here, the Government has presented a *prima facie* case showing that Registrant submitted a materially false application for registration renewal, the burden shifts to Registrant to show why she can be trusted with a registration. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 181 (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, 18904 (2018). The issue of trust is a fact-dependent determination based on the circumstances presented by the individual practitioner. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Historically, the Agency has considered acceptance of responsibility, egregiousness, and deterrence when making this assessment.

Specifically, the Agency requires the practitioner to accept responsibility for his or her violation. *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). Acceptance of responsibility must be unequivocal. *Janet S. Pettyjohn, D.O.,* 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.,* 83 FR 29569, 29573 (2018); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 830–31.

In addition, the Agency considers the egregiousness and extent of the misconduct in determining the appropriate sanction. *Jones Total Health Care Pharmacy,* 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by Registrant, by current registrants, and by future applicants for registration. *Stein,* 84 FR at 46972–73.

Here, Registrant did not timely request a hearing, or timely or properly answer the allegations, and was therefore deemed to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1–3. 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 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 made any demonstration that she can be trusted with registration.

Moreover, the evidence presented by the Government shows that Registrant provided false information regarding her fee exempt status. Providing false information as part of an application process for controlled substance privileges governed by Federal law calls into question Registrant's honesty, trustworthiness, and ability or willingness to comply with the laws governing controlled substances. To permit Registrant to maintain a registration under these circumstances would send a dangerous message that DEA does not expect compliance with its registration requirements and that the registration fees required by statute and regulation can be circumvented without consequence by making false statements. Registrant and the regulated community must be on notice that DEA's registration and renewal process, to include the required fees, is governed by Federal law, that DEA will strictly enforce those Federal laws, and that DEA expects applicants and registrants to adhere to those Federal laws.

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

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. MJ5209677 issued to Grace S. Joanita, N.P. 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 Grace S. Joanita, N.P., to renew or modify this registration, as well as any other pending application of Grace S. Joanita, N.P., for additional registration in Ohio. This Order is effective November 17, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 1, 2025, by Administrator Terrance 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.

[FR Doc. 2025–19576 Filed 10–16–25; 8:45 am]

BILLING CODE 4410–09–P

[5] To be clear, the Agency is not finding that Registrant violated the above-referenced portions of the CSA or its implementing regulations. This information is presented to give context to the materiality of Registrant's falsification. The Agency's only finding against Registrant is that she materially falsified a renewal application which is grounds for revocation under 21 U.S.C. 824(a)(1).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hovic Pharmacy; Decision and Order

I. Introduction

On October 20, 2021, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Hovic Pharmacy of Houston, Texas (Respondent). Request for Final Agency Action (RFAA), at 1801.[1] The OSC proposes the revocation of Respondent's DEA registration No. FH5569112 (registration), pursuant to 21 U.S.C. 824(a)(4) ''because . . .

[1] The Chief Administrative Law Judge (ALJ) granted the Government's unopposed motion to amend the OSC by Order dated January 10, 2022. RFAA, at 1799–1800. This Decision adjudicates the amended OSC.

[Respondent's] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. [823(g)(1)].''[2] *Id.* According to the OSC, ''Respondent's pharmacists filled many controlled substance prescriptions outside the usual course of pharmacy practice . . . and in contravention of their 'corresponding responsibility.' '' *Id.* at 1802, citing 21 CFR 1306.06 and 1306.04(a).

The OSC more specifically alleges that, according to an ''independent pharmacy expert'' retained by DEA who ''reviewed . . . prescription data'' referenced in the OSC, the ''data present[ ] multiple red flags that were highly indicative of abuse and diversion.'' *Id.* at 1806. With respect to the ''controlled substances purchased by and distributed to'' a recruiter (Recruiter), the expert opined that the ''red flags inherent in those prescriptions could not have been resolved by a pharmacist acting in the usual course of professional practice, and, therefore, each prescription was filled outside the standard of care of pharmacy practice in Texas.''[3] *Id.* As for the prescriptions whose red flags ''could potentially be resolved, the expert concluded that, based on documentation provided by . . . [Respondent, Respondent] made no effort to resolve the red flags and therefore, those prescriptions were also filled outside the standard of care of pharmacy practice in Texas.'' *Id.*

Respondent initially requested a hearing, but submitted a Waiver of Hearing on February 10, 2022, days before the hearing scheduled for February 14 through February 17 was to begin.[4] *Id.* at 1807–08; *infra* section III.A. The Chief ALJ issued his Order Terminating Proceedings on February 11, 2022. RFAA, at 1809. The Government filed its RFAA, and served Respondent, on October 30, 2023. *Id.* at 21.

Having thoroughly analyzed the record and applicable law, the Agency summarizes its findings and conclusions: (1) the OSC includes multiple, specific allegations that Respondent violated the Controlled Substances Act (CSA), the CSA's implementing rules, and Texas law, (2) Respondent requested a hearing, participated during most of the pre-hearing stage, and simply withdrew its hearing request, without explanation or elaboration of any kind, days before the four-day scheduled hearing was to begin, (3) the Government's RFAA presents a *prima facie* case as to all but three of the apparent OSC allegations, and (4) the record includes substantial record evidence, indeed unequivocal and uncontroverted record evidence, that Respondent violated federal and Texas law, thus unlawfully releasing about 13,135 controlled substance tablets, and about a 3,478 days' supply of promethazine with codeine (Schedule V), into the community in a period of about eighteen months.[5] [6] Accordingly, the Agency will revoke Respondent's registration. *Infra,* Order.

II. The CSA and Texas Pharmacists' Professional Responsibility

The main objectives of the CSA, according to the Supreme Court, are to ''conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'' *Gonzales* v. *Raich,* 545 U.S. 1, at 12 (2005). Given these objectives, the Supreme Court states, particular congressional concerns included ''the need to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–13. Further, according to the Supreme Court, to accomplish the CSA's objectives, ''Congress devised a closed regulatory system making it unlawful to . . . dispense[ ] or possess any controlled substance except in a manner authorized by'' the statute.[7] *Id.* at 13.

According to the CSA's implementing rules, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). As the Supreme Court explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.''[8] *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006), *see also United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979) (pharmacist's failed challenge to his federal corresponding responsibility).

While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a).

An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the

[2] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

[3] Recruiter pled guilty to ''conspiracy to dispense and distribute hydrocodone,'' and executed a declaration while serving a sentence of sixty months. RFAA, at 1806.

[4] It is not clear, from the record, that Respondent's emailed hearing request was submitted timely. Given that this matter is now before the Agency on the Government's request for final Agency action, however, there is no need for the Agency to try to clear up this matter.

[5] According to the CSA, ''[f]indings of fact by the [DEA Administrator], if supported by substantial evidence, shall be conclusive.'' 21 U.S.C. 877. Here, as Respondent withdrew its hearing request before the first day of the hearing, when the Agency finds that the evidence that the Government submitted with its RFAA constitutes substantial record evidence of an OSC allegation, that evidence is also unequivocal and uncontroverted evidence of that OSC allegation. Throughout this Decision, therefore, when the Agency finds evidence to be unequivocal and uncontroverted record evidence, the Agency is finding the evidence to be more than the ''substantial evidence'' of 21 U.S.C. 877; it is unrebutted evidence.

[6] The fills are alleged to have spanned the time period of December 17, 2018, through March 15, 2021. RFAA, at 1804.

If the OSC includes an allegation based on Texas Health and Safety Code 481.074(a)(5), ''a pharmacist may not . . . permit the delivery of a controlled substance to any person not known to the pharmacist . . . without first requiring identification of the person taking possession of the controlled substance,'' except in stated circumstances, it is not sustained because the Agency finds unequivocal and uncontroverted record evidence that Recruiter is ''known'' to at least one of Respondent's pharmacists. *Infra* section III.A.2.; RFAA, at 1803, para. 12; RFAA, at 1804, para. 15.

Further, given that the Agency finds unequivocal and uncontroverted record evidence of multiple other OSC allegations, each, alone, being a sufficient basis for revoking Respondent's registration, the Agency need not, and does not, address two OSC allegations: first, allegations concerning the use of cash and cash equivalents to pay Respondent for filling controlled substance prescriptions and, second, allegations concerning Respondent's filling controlled substance prescriptions issued by a physician assistant who, at the time, was allegedly subject to a Texas Physician Assistant Board Order's restrictions and was allegedly not under the supervision of a licensed physician. RFAA, at 1805–06, paras. 16.f. and 16.g.

[7] 21 U.S.C. 841(a)(1) (''[I]t shall be unlawful for any person knowingly or intentionally . . . to . . . distribute[ ] or dispense, or possess with intent to . . . distribute[ ] or dispense, a controlled substance . . . [e]xcept as authorized by'' the CSA.). The CSA defines ''dispense'' to include ''deliver[ing] a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.'' 21 U.S.C. 802(10). It defines ''distribute'' to mean ''to deliver (other than by administering or dispensing) a controlled substance.'' *Id.* 802(11). Thus, according to these CSA definitions, when a pharmacy fills an illegitimate controlled substance prescription, it is ''distributing,'' not ''dispensing,'' controlled substances.

[8] The context of this Supreme Court statement is the Act's requirement that Schedule II controlled substances be dispensed only by written prescription.

Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. Accordingly, a pharmacy's registration authorizes it to ''dispense,'' or ''deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, . . . a practitioner.'' 21 U.S.C. 802(10).

The OSC is addressed to Respondent at its registered address in Texas. Therefore, the Agency also evaluates Respondent's actions according to Texas law, including the applicable Texas pharmacist professional responsibilities. *Gonzales* v. *Oregon,* 546 U.S. at 269–71.

During the period alleged in the OSC, Texas law specifically addressed pharmacists' professional responsibilities. First, according to Texas law, ''[a] pharmacist may not dispense . . . a controlled substance . . . except under a valid prescription and in the course of professional practice.'' Tex. Health & Safety Code § 481.074(a) (2017, 2019). Second, pharmacists ''shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.'' 22 Tex. Admin. Code § 291.29(b) (2018). Further, according to Texas law, a ''pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility.'' *Id.* § 291.29(f). Texas law specifically identifies ''red flag factors'' that are ''relevant to preventing the non-therapeutic dispensing of controlled substances'' that ''shall be considered by evaluating the totality of the circumstances rather than any single factor.'' *Id.* Several of those red flag factors are relevant to the adjudication of the OSC.

According to Texas law, a ''reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner'' is a red flag factor. *Id.* § 291.29(f)(1). Likewise, under Texas law, ''prescriptions by a prescriber . . . [that] are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants containing codeine, or any combination of these drugs'' is a red flag factor. *Id.* § 291.29(f)(3). Another red flag factor is ''prescriptions for controlled substances . . . [that] are commonly for the highest strength of the drug and/or for large quantities (*e.g.,* monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner.'' *Id.* § 291.29(f)(5). Two other red flag factors are ''multiple persons with the same address [who] present substantially similar controlled substance prescriptions from the same practitioner,'' and ''persons [who] consistently pay for controlled substance prescriptions with cash or cash equivalents more often than through insurance.'' *Id.* §§ 291.29(f)(11) and (12).

The Texas Administrative Code clearly sets out the operational standard for a pharmacy to follow when it is presented with a controlled substance prescription exhibiting a ''red flag factor'': ''Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.'' [9] *Id.* § 291.33(c)(2)(A)(iv) (2018–2023). This Texas documentation requirement preludes a *post hoc* oral statement that identification and resolution of a ''red flag factor'' actually took place absent the existence of documentation compliant with Section 291.33(c)(2)(C).

III. Findings of Fact

A. The Government's Case [10]

In sum, the Government charges Respondent with filling controlled substance prescriptions outside the usual course of Texas pharmacy practice in contravention of its corresponding responsibility over the course of many years: (1) Respondent filled controlled substance prescriptions for Recruiter and Recruiter's recruits, knowing that the controlled substances were destined for resale on the street, a clearly illegitimate purpose, and (2) Respondent filled controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice. RFAA, at 1802, 1804–1806.

The RFAA is more than 1,800 pages, mostly documentary evidence, and includes three sworn, under penalty of perjury, Declarations: one by a (now-retired) Diversion Investigator (DI), one by Recruiter, and one by the Government's expert, Dr. Diane Ginsburg, a Registered Pharmacist. *Id.* at 1810–50.

1. DI's Declaration

The DI's Declaration states that its content is based on ''personal knowledge and/or information gained in the course of . . . official duties.'' *Id.* at 1813. Its content includes background about DEA's investigation of Respondent and others, information supporting the OSC's allegations, and material that is consistent with portions of Recruiter's Declaration.[11] *Id.* at 1813–20. The Agency finds that DI's Declaration is internally consistent and supports the Government's request to revoke Respondent's registration. *Id.* The Agency affords DI's Declaration full credibility, due to its internal consistency and its having been sworn to under penalty of perjury.

2. Recruiter's Declaration

Recruiter's declaration, dated February 17, 2022, is sworn to and signed by Recruiter. *Id.* at 1810–12. According to the Declaration, Recruiter is ''currently incarcerated'' in federal prison ''serving a 60-month sentence as a result of pleading guilty to the charge of conspiracy to dispense and distribute hydrocodone.'' *Id.* at 1810. Recruiter's Declaration describes a conspiracy in which Recruiter and Recruiter's recruits unlawfully obtained controlled substance prescriptions. Recruiter then presented the prescriptions to Respondent, and Respondent's pharmacists filled them even though the pharmacists knew or had reason to

[9] Subparagraph (C) states: ''Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph, the pharmacist shall document on the prescription or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information: (i) date the prescriber was consulted; (ii) name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.'' 22 Tex. Admin. Code § 291.33(c)(2)(C).

[10] As already explained, Respondent waived its right to a hearing just before the hearing was scheduled to begin and, as such, the record before the Agency does not include evidence or legal analysis from Respondent. RFAA, at 1807–08 (Respondent's Waiver of Hearing); *supra* section I. Accordingly, this Decision contains no material for a section, comparable to this one, about Respondent's case.

[11] While ''consistent'' with portions of Recruiter's Declaration, there is insufficient information in DI's Declaration about the source(s) of all of those consistencies for the Agency to conclude that DI's Declaration ''corroborates'' the entirety of Recruiter's Declaration. In other words, if the source of the consistent material in DI's Declaration is Recruiter, then DI's Declaration simply repeats Recruiter's information, not independently corroborates it. DI's Declaration does, however, explicitly corroborate portions of Recruiter's Declaration. *Infra.* section III.A.2.

know that the prescriptions were unlawfully obtained. Recruiter then sold the unlawfully obtained controlled substances on the street. *Id.* at 1810–12.

Based on the admissions in Recruiter's Declaration, the Agency finds that Recruiter, ''[f]rom at least 2017 through 2020 . . .[,] participated in a scheme to obtain prescriptions for controlled substances from practitioners and those prescriptions were filled at . . . [Respondent].'' [12] *Id.* The Agency further finds unequivocal and uncontroverted record evidence that Recruiter ''recruit[ed] individuals to pose as patients (recruits) who would obtain prescriptions for controlled substances from two different practitioners,'' that Respondent would fill the controlled substance prescriptions, including prescriptions for hydrocodone-acetaminophen 10-325 (Schedule II), promethazine with codeine, carisoprodol (Schedule IV), and alprazolam (Schedule IV), and that Recruiter ''would then purchase these prescriptions with cash, pick up the drugs[,] and sell the drugs to street level customers.'' [13] *Id.* at 1810. In sum, given the self-incriminating nature of Recruiter's Declaration, the corroboration of its content by DI's Declaration, its internal consistency, and its having been sworn to under penalty of perjury, the Agency affords Recruiter's Declaration credibility.[14]

The Agency finds unequivocal and uncontroverted record evidence that Recruiter ''developed a relationship with the employees'' of Respondent who ''rarely questioned'' the controlled substance prescriptions that Recruiter dropped off for about eleven individuals approximately three times a week for several years.'' [15] *Id.* at 1810–11; *see also id.* at 1812 (''Though I firmly believe . . . [Respondent Pharmacist Two] knew or had reason to know that the prescriptions I purchased and picked up from . . . [Respondent] were not issued for a legitimate medical purpose, . . . [Respondent Pharmacist One] was also aware that I was regularly picking up prescriptions for controlled substances that had been prescribed to others.'').

The Agency also finds unequivocal and uncontroverted record evidence that Respondent Pharmacist Two ''instructed'' Recruiter about how to do business with Respondent. *Id.* at 1811. For example, Respondent Pharmacist Two told Recruiter not to bring the recruits to the store to pick up and purchase the controlled substances. *Id.* Instead, she instructed Recruiter ''to come in and pick up the prescriptions,'' and either to forge the recruits' names on the signature log or to sign Recruiter's own name. *Id.; id.* at 31–89 (Respondent's signature logs, GX 4, that Recruiter annotated with a circle or a circle with a check mark to signify when Recruiter forged the recruit's name (circle only) and when Recruiter signed Recruiter's own name (circle and check mark)); *id.* at 171–237 (Respondent's Dispensed Drug Report for the Period of January 3, 2020, through March 29, 2021, GX 8, showing about twenty-seven prescription number matches between the signature log prescription numbers that Recruiter signed, forging the recruit's name, and controlled substances, such as promethazine with codeine, hydrocodone-acetaminophen 10-325, and carisoprodol 350, that Respondent filled and sold to Recruiter from January 23, 2020, to March 23, 2020).[16]

In sum, the Agency finds unequivocal and uncontroverted record evidence that Respondent did not question, address, prevent, or otherwise take any action when Recruiter asked for, signed the signature log for, paid for, and left Respondent's store with filled controlled substance prescriptions issued for persons other than Recruiter. *Id.* at 1811 (''At no time did anyone at . . . [Respondent] question the fact that I was picking up controlled substances for others. At no time did anyone at . . . [Respondent] refuse to provide me with a prescription that was issued to someone else even though I signed the person's name instead of my own. I was also never asked to provide any proof that I had authority to pick up prescriptions for anyone other than myself.'').

Further, the Agency finds unequivocal and uncontroverted record evidence that at least one of Respondent's pharmacists knew, and even conversed ''often'' with Recruiter, about Recruiter's street resale of the controlled substances that Respondent filled for Recruiter and Recruiter's recruits. *Id.* at 1811–12. For example, Recruiter and at least Respondent Pharmacist Two ''often'' discussed Recruiter's specific controlled substance brand preferences, the brands with a

[12] In addition to the RFAA's documentary evidence that corroborates Recruiter's Declaration, *infra.,* DI's Declaration references a court-authorized Title III wiretap that corroborates Recruiter's Declaration. RFAA, at 1815 (DI Declaration stating that Recruiter's ''role in the enterprise was confirmed by a court-authorized Title III wiretap undertaken on phones utilized by recruiters and clinic staff members'').

The Agency makes the decision that Recruiter's Declaration is credible after evaluating paragraph 20 of DI's Declaration, paragraph 14 of Recruiter's Declaration, and the report of Respondent Pharmacist One. *Id.* at 1817, 1812, and 105, respectively. According to DI's Declaration, DI ''attempted to confirm . . . [Recruiter's] statement regarding an incident'' that Recruiter described involving Respondent Pharmacist One's ''mistakenly'' filling a recruit's carisoprodol (Schedule IV) prescription with hydrocodone-acetaminophen 10-325 tablets (Schedule II). *Id.* at 1817. According to Recruiter, Respondent Pharmacist One contacted Recruiter and asked Recruiter to return the mistakenly issued hydrocodone-acetaminophen 10-325. *Id.* at 1812. According to the report of Respondent Pharmacist One, he ''reached out to'' the recruit, not Recruiter, to ''swap'' those tablets for an equal number of carisoprodol tablets. *Id.* at 105. According to the report of Respondent Pharmacist One, the ''customer'' ''would not come around'' for such a swap. *Id.* at 105.

The Agency concludes that Recruiter's statement is consistent with the report of Respondent Pharmacist One on all salient points, and that the difference between Recruiter's recollection and the report of Respondent Pharmacist One about whom he contacted regarding the matter is not essential. Further, Recruiter's basis for knowing about the incident could very well be from receiving the request of Respondent Pharmacist One to return the hydrocodone-acetaminophen 10-325. After all, Respondent Pharmacist Two instructed Recruiter to transact business with Respondent alone, without bringing the recruits. *Id.* at 1811. Second, had Respondent Pharmacist One only contacted the recruit, as his report states, and had the recruit not returned the hydrocodone-acetaminophen 10-325 as his report also states, Recruiter would not necessarily know about the wrongful hydrocodone-acetaminophen 10-325 dispensing. Third, it is not realistic to expect Respondent Pharmacist One to report that he contacted the ''patient's'' ''recruiter'' about the wrongly issued hydrocodone-acetaminophen 10-325. Regardless, the Agency finds that whether Respondent Pharmacist One contacted Recruiter or the recruit is insignificant, and that this discrepancy between Recruiter's Declaration and the report of Respondent Pharmacist One does not impugn the credibility of Recruiter's Declaration.

[13] The Agency notes that ''hydrocodone'' is used in the RFAA when the actual controlled substance named in the RFAA's documentary evidence is hydrocodone-acetaminophen 10-325. The RFAA brief does not address this abbreviated usage of ''hydrocodone'' for hydrocodone-acetaminophen 10-325. While the Agency prefers precision, including explicit explanations in parties' submissions, it also recognizes that the controlled portion of hydrocodone-acetaminophen 10-325 is hydrocodone. The Agency further notes that the Diversion Control Division issued a public fact sheet in 2019 titled ''Hydrocodone'' that includes Vicodin and Lortab, trade names for hydrocodone with acetaminophen, in its subtitle. Hydrocodone (Trade Names: Vicodin®, Lortab®, Lorcet-HD®, Hycodan®, Vicoprofen®), *https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf* (last visited date of signature of this Order).

[14] The Agency also finds unequivocal and uncontroverted record evidence in the Declaration of Dr. Diane Ginsburg that further corroborates the self-incriminating content of Recruiter's Declaration. RFAA, at 1847–48; *infra.* section III.A.3. The Declaration of Dr. Ginsburg also contains unequivocal and uncontroverted record evidence of Respondent's unlawful controlled substance distribution to Recruiter. *Infra.* section III.A.3.

[15] Recruiter's Declaration includes the names of two such pharmacist employees of Respondent and states that Recruiter identified them both from photographs that DI displayed.

[16] The Agency is considering Respondent's actions during the time frame alleged in the OSC: December 17, 2018, through March 15, 2021. RFAA, at 1804.

''higher resale value'' on the street. *Id.* at 1811 (Recruiter's Declaration identifying specific brands of promethazine with codeine and of hydrocodone products). Further, Respondent ''often required [Recruiter] to pay more than the cash price that was listed on the prescription itself.'' *Id.* at 1812. Regarding promethazine with codeine, for example, Recruiter ''would pay approximately $240 for 8 ounces . . . [t]hough this arrangement seemed unfair, . . . [but Recruiter] accepted it because . . . [Recruiter] was able to sell the controlled substances on the street for more.'' [17] *Id.*

The Agency further finds unequivocal and uncontroverted record evidence that Recruiter was not the only recruiter for whom Respondent filled controlled substance prescriptions. *Id.* at 1811. The record evidence is that Respondent Pharmacist Two interacted with another recruiter, and even catered to him by instructing Recruiter to frequent Respondent ''at approximately 4 p.m. each day to pick up prescriptions, so . . . [Recruiter] would not be seen by'' the other recruiter who did not want Recruiter to ''use'' Respondent ''to fill prescriptions.'' *Id.*

Further, the Agency finds unequivocal and uncontroverted record evidence that one of Respondent's pharmacists even lent Recruiter money to pay for the recruits' doctor visits with the understanding that Recruiter would re-pay the money after selling on the street the controlled substances that Respondent provided. *Id.* at 1811–12. Further, the Agency finds undisputed record evidence that one of Respondent's pharmacists lent Recruiter as much as $800 for this purpose. *Id.* at 1812.

In sum, the Agency finds unequivocal and uncontroverted record evidence that, ''[f]rom at least 2017 through 2020,'' Respondent, by its pharmacists, filled controlled substance prescriptions for Recruiter, and for at least one other recruiter, with knowledge that those controlled substances would be diverted. *E.g., id.* at 1810.

3. The Declaration of the Government's Expert, Dr. Ginsburg

The Agency finds that Dr. Ginsburg qualifies as an expert in pharmaceutical controlled substance dispensing in Texas, and accepts her as such in this adjudication.[18] *Id.* at 1725–84 (sixty-page curriculum vitae of Dr. Ginsburg, a Texas Registered Pharmacist, listing her accomplishments; education; publications on a broad variety of pharmacy-related topics; invited papers and presentations on the national, international, state, and local levels with a primary focus on pharmacy- and pharmacist-related topics; professional affiliations; honors and awards, and her work experience as a pharmacist and educator). The Agency recognizes Dr. Ginsburg as an expert in pharmaceutical controlled substance dispensing in Texas.[19] *Id.* at 1725–84, 1821–50. The Agency, because Dr. Ginsberg is an expert in pharmaceutical controlled substance dispensing in Texas, because her Declaration accurately states Respondent's legal responsibilities according to relevant federal and Texas law, because her Declaration is sworn to under penalty of perjury, and because her Declaration asserts that she reviewed Government exhibits 4 through 36, affords Dr. Ginsburg's Declaration full credibility.[20] *Id.* at 31–1724, 1822–23, 1825.

Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that Respondent's ''pharmacists failed to carry out their corresponding responsibility when they dispensed controlled substances to . . . customers, in that they ignored red flags indicating a risk of diversion and failed to ensure that the prescriptions dispensed were issued for a legitimate medical purpose in the usual course of professional practice.'' *Id.* at 1823 (Dr. Ginsburg's Declaration is based on the record evidence she reviewed); *see also id.* (Dr. Ginsburg's Declaration stating that ''all minimally competent pharmacists can and should be able to recognize 'red flags' related to prescriptions, and they are required to do so in the usual course of pharmacy practice in Texas.''); *id.* at 1823–24 (Dr. Ginsburg's Declaration stating that ''a 'red flag' is anything about a prescription that would cause the pharmacist to be concerned that the prescription was not issued for a legitimate medical purpose in the usual course of professional practice.''); *id.* at 1824 (Dr. Ginsburg's Declaration stating that, ''When confronted with a red flag or red flags concerning a prescription for controlled substances, a pharmacist must try to resolve the red flags to determine whether or not the prescription is legitimate. A pharmacist must resolve the red flag(s) prior to filling the prescription. Depending on the type of red flag, there are different steps that the pharmacist can take to determine whether or not the prescription is legitimate. These steps involve obtaining more information from the physician or the patient, or both.''); *id.* at 1825; *infra* (Dr. Ginsberg's Declaration explaining ''unresolvable'' red flags, offering the example of Recruiter's picking up controlled substance prescriptions issued to others, and concluding that both Respondent Pharmacists filled controlled substance prescriptions in the face of unresolvable red flags).

According to the OSC's allegations, controlled substance ''cocktail prescriptions'' are controlled substance prescriptions including ''various combinations of the highly abused hydrocodone, carisoprodol, alprazolam . . . [,] and promethazine with codeine.'' RFAA, at 1804–05. Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that ''hydrocodone, promethazine with codeine, carisoprodol, and alprazolam . . . [are] highly abused controlled substances,'' and that these types of combination controlled substance ''cocktail prescriptions have long been recognized as a red flag for abuse and/or diversion in Texas and significantly increase a patient's risk of morbidity and overdose.'' *Id.* at 1832; *see also id.* at 1823 (Dr. Ginsburg's Declaration stating that ''[h]ydrocodone, alprazolam, promethazine with codeine, and carisoprodol are several of the more commonly diverted and abused drugs in Texas.''). Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that ''[t]here is nothing in any of the [record] documents [that Dr. Ginsburg reviewed] to show that . . . [Respondent]

[17] The Agency further finds unequivocal and uncontroverted record evidence that at least Respondent Pharmacist Two helped Recruiter buy the specific brand of a controlled substance that brought the higher street resale value. RFAA, at 1811 (Recruiter's Declaration stating that Respondent Pharmacist Two even suggested that Recruiter fill a controlled substance prescription at another pharmacy because Respondent did not have Recruiter's preferred brand in stock).

[18] This decision is consistent with prior Agency decisions accepting Dr. Ginsburg as an expert. *E.g., Lewisville Medical Pharmacy,* 87 FR 59456 (2022) (Texas), *Medical Pharmacy,* 86 FR 72030 (2021) (Louisiana).

[19] Dr. Ginsburg's credentials also include the academic appointment of Clinical Professor in the Division of Pharmacy Practice in the College of Pharmacy at the University of Texas (Austin), and multiple pharmacist positions in Texas. RFAA, at 1725–29; *see also id.* at 1822 (''Based on my training and experience, I am an expert in the practices of a pharmacist in Texas, and in particular, the dispensing of controlled substances by Texas pharmacists.'').

[20] The Agency determines that the statement in paragraph 5 of Dr. Ginsberg's Declaration, that her *curriculum vitae* is included in the RFAA as GX 36, is a typographic error; it is RFAA GX 37. RFAA, at 1821.

recognized these cocktail prescriptions as a red flag for abuse and/or diversion, and nothing to indicate that . . . [Respondent] took any steps to resolve the red flags prior to dispensing'' them. *Id.* at 1832; *id.* at 1825–32.

Accordingly, based on these expert-based, undisputed findings and opinions, the Agency finds unequivocal and uncontroverted record evidence that, from July 17, 2019, to July 10, 2020, Respondent filled about 138 controlled substance cocktail prescriptions involving five individuals without resolving those red flags of abuse and/or diversion. *Id.* at 106–237, 425–616, 1824–32. By failing to exercise its corresponding responsibility and filling these controlled substance prescriptions, Respondent released into the community about 3143 hydrocodone-acetaminophen 10-325 mg tablets, about 2680 carisoprodol 350 mg tablets, about 1326 days' supply (or more than three and a half years' supply) of promethazine with codeine, about 190 alprazolam 1 mg tablets, and about 90 alprazolam 2 mg tablets. *Id.* at 106–237, 425–616.

According to the OSC's allegations, Respondent filled monthly prescriptions for promethazine with codeine to three individuals from March 4, 2019, to June 18, 2020. *Id.* at 1804. Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that Respondent failed to exercise its corresponding responsibility and filled ''[r]epeated and continuous'' prescriptions for promethazine with codeine to three individuals from March 4, 2019, to June 18, 2020, approximately monthly.[21] *Id.* at 1832 (describing the promethazine with codeine prescriptions for the three individuals as ''monthly prescriptions,'' ''continuous prescriptions,'' and ''continuous prescriptions,'' respectively). Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that promethazine with codeine is a ''highly abused cough suppressant normally prescribed for short term use,'' and that its ''repeated prescribing . . . has long been recognized in Texas as a red flag for abuse and/or diversion.'' *Id.* at 1834; *see also id.* at 1824. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that Respondent failed to exercise its corresponding responsibility as ''[t]here is nothing . . . [in the record] to show that . . . [Respondent] recognized these prescriptions as a red flag for abuse and/or diversion, and nothing to indicate that . . . [Respondent] took any steps to resolve the red flag prior to dispensing.'' *Id.* at 1834.

Accordingly, consistent with the expert's undisputed Declaration, the Agency finds unequivocal and uncontroverted record evidence that, from March 4, 2019, to June 18, 2020, Respondent released about 1,089 days' (or almost 3 years') worth supply of promethazine with codeine into the community by its ''[r]epeated and continuous'' failures to exercise its corresponding responsibility and filling three individuals' almost monthly illegitimate controlled substance prescriptions. *Id.* at 294–324, 425–93, 1610–1714, 1832–34. Taking into account overlap with the promethazine with codeine involved in the cocktail calculations, Respondent, violating its corresponding responsibility, released about an additional 285 days' worth supply of promethazine with codeine into the community by its ''[r]epeated and continuous'' filling of three individuals' prolonged, and almost monthly, promethazine with codeine controlled substance prescriptions. *Id.* at 294–324, 425–93, 1610–1714.

According to the OSC's allegations, ''pattern prescribing'' is ''when a practitioner prescribes the same controlled substances in identical or substantially similar dosages and quantities, thus indicating a lack of individualized care.'' *Id.* at 1805. According to Dr. Ginsburg's Declaration, ''pattern prescribing'' is a prescriber's employment of a '' 'one size fits all' approach to prescribing potentially dangerous narcotics, usually by prescribing the narcotics in identical or nearly identical quantities to each patient regardless of the patient's individualized medical condition.'' *Id.* at 1824. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency finds unequivocal and uncontroverted record evidence that two physicians engaged in ''pattern prescribing,'' that both doctors' pattern prescribing involved their issuing controlled substance prescriptions for hydrocodone-acetaminophen 10-325 mg, carisoprodol 350 mg, and promethazine with codeine, and that they issued these controlled substance prescriptions to at least seven individuals. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that ''[t]here is nothing . . . [in the record] to show that . . . [Respondent] recognized these prescriptions as a red flag for abuse and/or diversion, and nothing to indicate that . . . [Respondent] took any steps to resolve the red flag prior to dispensing.'' *Id.* at 1843, *see also id.* at 1834–43.

In sum, according to evidence that is unequivocal and uncontroverted, from March 8, 2019, to July 3, 2020, Respondent released about 1,456 days' (or almost a 4 years') worth supply of promethazine with codeine 240 mL, about 303 days' (or about two months shy of one year) worth supply of promethazine with codeine 180 mL, about an additional 2,666 tablets of carisoprodol 350 mg, and about an additional 3,328 tablets of hydrocodone-acetaminophen 10-325 into the community by filling controlled substances prescriptions without resolving the red flag of pattern prescribing.[22] *Id.* at 325–424, 617–804, 1610–1714, 1834–43.

The OSC states that ''pharmacy shopping'' is when an individual ''fill[s] prescriptions for controlled substances at multiple pharmacies.'' *Id.* at 1805. Dr. Ginsburg's Declaration states that ''pharmacy shopping'' may indicate that a customer is trying to avoid being suspected of abuse and/or diversion while obtaining controlled substances. *Id.* at 1847; *see also id.* at 1824, 1843–47. The Ginsburg Declaration further states that ''[p]harmacy shopping has long been recognized as a red flag for abuse and/or diversion in Texas because it may indicate the customer is attempting to obtain prescriptions and avoid suspicion.'' [23] *Id.* at 1847. Based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds

[21] The Agency finds unequivocal and uncontroverted record evidence that, for the first individual, S.L., Respondent filled monthly prescriptions for promethazine with codeine (240 mL) from March 4, 2019, to December 6, 2019, and then again from March 9, 2020, to May 21, 2020; for the second individual, M.R., Respondent filled twelve prescriptions for promethazine with codeine (180 mL) more frequently than monthly, from March 15, 2019, to November 20, 2019, and five prescriptions, monthly, from February 7, 2020, to June 5, 2020; and for the third individual, C.G., Respondent filled fourteen promethazine with codeine (240 mL) prescriptions from March 29, 2019, to June 18, 2020, almost monthly.

[22] The amount of promethazine with codeine 240 mL that Respondent distributed that has not already been counted in this Decision is about a 1,108 days' worth supply. RFAA, at 325–424, 1610–1714.

[23] According to Recruiter's Declaration, Recruiter obtained controlled substances from pharmacies other than Respondent when, for example, Respondent Pharmacist Two ''suggested . . . [that Recruiter] fill the hydrocodone prescription at another pharmacy'' because Respondent did not have Recruiter's ''preferred brand in stock.'' RFAA, at 1811. Recruiter's Declaration also states that Recruiter ''utilized'' Respondent after ''develop[ing] a relationship with the employees'' and because the ''prescriptions that were submitted were rarely questioned.'' *Id.* at 1810.

unequivocal and uncontroverted record evidence that controlled substance prescriptions for three individuals, including for Recruiter, were filled by ''pharmacy shopping,'' that is, by filling one of three controlled substance prescriptions issued at, or at about, the same time (including hydrocodone-acetaminophen 10-325 in all but one case) at a different pharmacy from where they filled the other two, typically at Respondent. *Id.* at 1843–47. Based on Dr. Ginsburg's Declaration and the Agency's careful analysis of the evidence before it, the Agency further finds that ''[t]here is nothing . . . [in the record evidence] to show that . . . [Respondent] recognized these prescriptions as a red flag for abuse and/or diversion,'' and that there is ''nothing [in the record evidence] to indicate that . . . [Respondent] took any steps to resolve the red flag prior to dispensing.'' *Id.* at 1847.

Accordingly, based on these expert-based, undisputed findings, the Agency finds unequivocal and uncontroverted evidence that, from December 17, 2018, to May 22, 2020, Respondent released about an additional 1,038 tablets of carisoprodol 350 mg and about an additional 456 days' (or over one year's) worth supply of promethazine with codeine 240 mL into the community by filling controlled substance prescriptions issued to individuals who engaged in ''pharmacy shopping'' without resolving that red flag. *Id.* at 1594–1609, 1843–47.

In sum, based on Dr. Ginsburg's Declaration and the entirety of the record evidence before the Agency, the Agency finds unequivocal and uncontroverted record evidence that Respondent's pharmacists failed to recognize and resolve red flags of abuse and/or diversion, ''failed to carry out their corresponding responsibility,'' and ''failed to ensure that the dispensed prescriptions were issued for a legitimate medical purpose in the usual course of professional practice.'' *Id.* at 1823.

B. The Unlawful Distribution Allegations: in 2019 and 2020, Respondent's Employees Knowingly Participated in a Scheme To Distribute Controlled Substances to a Known Street Dealer

As already discussed, the Agency finds that the evidence the Government submitted with the RFAA, in conjunction with Respondent's not having submitted any evidence, is unequivocal and uncontroverted record evidence that Recruiter, ''[f]rom at least 2017 through 2020,'' participated in a scheme to obtain illegitimate controlled substance prescriptions, to present them to Respondent to fill, and to sell the Respondent-filled controlled substances on the street. *Supra* section III.A.2. As already discussed, the Agency also finds unequivocal and uncontroverted record evidence that Respondent Pharmacists One and Two knowingly participated in the scheme by filling the illegitimate controlled substance prescriptions without identifying, let alone resolving, those prescriptions' red flags. *Supra* sections III.A.2, III.A.3. For example, as already discussed, Respondent Pharmacist Two instructed Recruiter on how to carry out parts of the scheme, lent Recruiter money to enable accomplishment of the scheme's goals, and charged inflated costs for fills. *Supra* section III.A.2. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law because, at least in 2019 and 2020, Respondent's employees knowingly participated in a scheme to distribute controlled substances to a known street dealer. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074(a) (2017, 2019); 22 Tex. Admin. Code §§ 291.29(b) and (f) (2018), 291.33(c)(2)(A)(iv) and (C) (2018–2023); *supra* section II.

C. The Unlawful Distribution Allegations: Between September 16, 2019, and March 23, 2020, Respondent Distributed Controlled Substances to a Recruiter Pursuant to Prescriptions Issued to Other Individuals, and With Reason To Believe That the Recruiter Intended To Resell Them

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that Recruiter, ''[f]rom at least 2017 through 2020,'' participated in a scheme to obtain illegitimate controlled substance prescriptions, to present them to Respondent to fill, and to sell the Respondent-filled controlled substances on the street. *Supra* section III.A.2. For example, as the Agency already found, Respondent Pharmacist Two told Recruiter not to bring the recruits to the store to pick up and purchase the controlled substance prescriptions. *Id.* Instead, Respondent Pharmacist Two instructed Recruiter ''to come in and pick up the prescriptions,'' and either to forge the recruits' names on the signature log or to sign Recruiter's own name. *Id.* By way of further examples, as the Agency already found, Respondent Pharmacist Two and Recruiter ''often'' discussed Recruiter's specific controlled substance brand preferences, the brands with a ''higher resale value'' on the street; a Respondent pharmacist helped Recruiter buy the specific brand of a controlled substance that brought the higher street resale value; and one of Respondent's pharmacists even lent Recruiter money to pay for the recruits' doctor visits with the understanding that Recruiter would re-pay the money after selling on the street the controlled substances that Respondent provided. *Id.* Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law between at least September 16, 2019, and March 23, 2020. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074(a) (2017, 2019); 22 Tex. Admin. Code §§ 291.29(b) and (f) (2018), 291.33(c)(2)(A)(iv) and (C) (2018–2023); *supra* section II.

D. The Unlawful Distribution Allegations: Between March 4, 2019, and June 18, 2020, Respondent Filled Monthly Prescriptions for Promethazine With Codeine to Three Individuals

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that, monthly from March to December of 2019, and from February to June of 2020, Respondent filled prescriptions for promethazine with codeine for two individuals. *Supra* section III.A.3.; n.21. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law, monthly, as to the two individuals' monthly, or more frequently than monthly, prescriptions for promethazine with codeine. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023). *Supra* section II.

E. The Unlawful Distribution Allegations: Between December 27, 2019, and July 10, 2020, Respondent Filled ''Cocktail'' Prescriptions for Five Different Individuals Including Various Combinations of Hydrocodone, Carisoprodol, Alprazolam, and Promethazine With Codeine

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that Respondent filled about 138 controlled substance cocktail prescriptions involving five individuals without resolving those red flags of abuse and/or diversion from July 17, 2019, to July 10, 2020. *Supra* section III.A.3. Also as already discussed, the Agency finds unequivocal and uncontroverted record evidence that these cocktail prescriptions involved various combinations of hydrocodone-acetaminophen 10-325 mg, carisoprodol 350 mg, alprazolam 1 mg, alprazolam 2 mg, and promethazine with codeine.

Supra section III.A.3. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law by filling controlled substance cocktail prescriptions involving five individuals without resolving those red flags of abuse and/or diversion from July 17, 2019, to July 10, 2020. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023); *supra* section II.

F. The Unlawful Distribution Allegations: Between March 8, 2019, and July 3, 2020, Respondent Distributed Controlled Substances Pursuant to Prescriptions Issued by Practitioners Engaged in ''Pattern Prescribing''

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that, between March 8, 2019, and July 3, 2020, Respondent filled controlled substance prescriptions issued by two practitioners to at least seven individuals without resolving the prescriptions' pattern prescribing red flags. *Supra* section III.A.3. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law, between March 8, 2019, and July 3, 2020, by filling controlled substance prescriptions without identifying and resolving those prescriptions' pattern prescribing red flags of abuse and/or diversion. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023); *supra* section II.

G. The Unlawful Distribution Allegations: Between December 17, 2018, and May 22, 2020, Respondent Filled Controlled Substances for Three Individuals Despite Prescription Histories That Indicated Each Was Engaged in ''Pharmacy Shopping,'' or Filling Prescriptions for Controlled Substances at Multiple Pharmacies

As already discussed, the Agency finds unequivocal and uncontroverted record evidence that Respondent filled controlled substance prescriptions for three individuals without identifying and resolving their pharmacy shopping red flags from December 17, 2018, to May 22, 2020. *Supra* section III.A.3. Accordingly, the Agency finds unequivocal and uncontroverted record evidence that Respondent violated federal and Texas law. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074 (2017, 2019); 22 Tex. Admin. Code §§ 291.29 (2018), 291.33 (2018–2023); *supra* section II.

IV. Discussion

A. The CSA and the Public Interest Factors

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under . . . [21 U.S.C. 823] inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''pharmacy,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[24]

The five factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. at 292–93 (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive'' (quoting *In re Arora,* 60 FR 4447, 4448 (1995))); *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). The Agency may give each factor the weight it deems appropriate. *Gonzales* v. *Oregon,* 546 U.S. at 293 (Scalia, J., dissenting) (quoting *In re Arora,* 60 FR 4447, 4448 (1995)), *e.g., Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007) (importer); *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 174 (D.C. Cir. 2005) (practitioner), *quoting Henry J. Schwarz, Jr., Denial of Application,* 54 FR 16422, 16424 (Apr. 24, 1989).

The Agency ''may properly rely on any one or a combination of factors.'' *Gonzales* v. *Oregon,* 546 U.S. at 293 (Scalia, J. dissenting) (quoting *In re Arora,* 60 FR 4447, 4448 (1995)); *Morall,* 412 F.3d at 185 n.2 (Henderson, J. concurring and referring to pages 173–74 of the majority opinion); *see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (*citing Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016)); *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while the Agency is required to consider each of the factors, it ''need not make explicit findings as to each one.'' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (the Agency ''must consider each of these factors'' but ''need not make explicit findings as to each one'') (quoting *Volkman,* quoting *Hoxie,* and citing *Morall*). ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009) (on remand). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44(e); *see also Morall,* 412 F.3d. at 174.

B. Factors B and/or D—Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Relating to Controlled Substances

Allegation That Respondent's Continued Registration Would Be Inconsistent With the Public Interest

While the Agency considered all of the 21 U.S.C. 823(g)(1) factors in this matter, the Agency finds that the Government's *prima facie* case is confined to factors B and D. The Agency finds that the Agency-found facts regarding Respondent's conduct with respect to factors B and D, its unlawful conduct under applicable federal and Texas law, constitute a *prima facie* showing that Respondent's continued registration would be inconsistent with the public interest. 21 CFR 1306.04(a); Tex. Health & Safety Code § 481.074(a) (2017, 2019); 22 Tex. Admin. Code §§ 291.29(b) and (f) (2018), 291.33(c)(2)(A)(iv) and (C) (2018–2023); *MacKay,* 664 F.3d at 819; *supra* section II.

Accordingly, the Government has satisfied its *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4) in conjunction with 823(g)(1); *supra* sections II, III.A.1. III.A.2., III.A.3., III.B., III.C., III.D., III.E., III.F., III.G. Respondent, who chose not to submit any evidence for the Agency's consideration, also did not attempt to rebut the Government's *prima facie* case.

[24] The five factors of 21 U.S.C. 823(g)(1)(A–E) are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

V. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration would be inconsistent with the public interest due to its experience dispensing controlled substances and its failure to comply with applicable laws relating to controlled substances, the burden shifts to Respondent to show why the Agency should continue to entrust it with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy,* 881 F.3d at 830; *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 respondent. *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 (citing authority including *Alra Labs., Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995) (''An agency rationally may conclude that past performance is the best predictor of future performance.''). ''[T]hat consideration is vital to whether continued registration is in the public interest.'' *MacKay,* 664 F.3d at 820. A registrant's acceptance of responsibility must be unequivocal. *Jones Total Health Care Pharmacy,* 881 F.3d at 830–31.

Further, DEA 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 respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Here, Respondent chose to withdraw its request for a hearing just days before the hearing was scheduled to begin. *Supra* section I. As such, the record includes no evidence submitted by Respondent. Nor did Respondent attempt to convince the Agency that it understands that its issuance of controlled substances fell short of the applicable legal standards, and that this substandard controlled substance issuance has serious negative ramifications for the health, safety, and medical care of individuals who come to it with controlled substance prescriptions to be filled. *E.g., Jones Total Health Care Pharmacy,* 881 F.3d at 834 and n.4; *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases) (''The egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction.''). As such, it is not reasonable to believe that Respondent's future issuance of controlled substances will comply with legal requirements.

The unequivocal and uncontroverted record evidence is the Respondent's founded violations resulted in the release of about 13,135 controlled substance tablets, and about a 3478 days' supply of promethazine with codeine into the community in a period of about eighteen months. *Supra* sections I, III.A.3., III.B., III.C., III.D., III.E., III.F., III.G. The controlled substances unlawfully released into the community were hydrocodone-acetaminophen 10–325 mg tablets, carisoprodol 350 mg tablets, alprazolam tablets, and promethazine with codeine, controlled substances known to be abused and diverted. *Id.*

There is no record evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the founded violations.

There is no record evidence from which the Agency may reasonably conclude that Respondent's future controlled substance-related actions will comply with legal requirements. Accordingly, Respondent did not convince the Agency that it should continue to entrust Respondent with a registration.

The interests of specific and general deterrence weigh in favor of revocation. Further, given the foundational nature and vast number of Respondent's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not essential to maintaining a registration.

Accordingly, I shall order the sanction the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. FH5569112 issued to Hovic Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending application of Hovic Pharmacy to renew or modify this registration, as well as any other pending application of Hovic Pharmacy for registration in Texas. This Order is effective November 17, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 1, 2025, by Administrator Terrance 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.

[FR Doc. 2025–19578 Filed 10–16–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 24–69]

Shannon Wagner, D.O.; Decision and Order

On August 13, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Shannon Wagner, D.O., of Green Bay, Wisconsin (Respondent). OSC, at 1, 3. The OSC proposed the denial of Respondent's application for a DEA Certificate of Registration (registration), Control No. W23130415C, alleging that Respondent has been mandatorily excluded from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a–7(a). *Id.* at 1–2 (citing 21 U.S.C. 824(a)(5)).

A hearing was held before DEA Administrative Law Judge (ALJ) Teresa A. Wallbaum who, on February 21, 2025, issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD). The RD recommended that Respondent's application be granted. RD, at 20. The Government filed exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[1] findings of fact, conclusions

[1] The Agency adopts the ALJ's summary of the witnesses' testimonies as well as the ALJ's assessment of the witnesses' credibility. RD, at 3–

of law, sanctions analysis, and recommended sanction in the RD, and summarizes, and expands upon portions thereof herein.

I. Applicable Law

Pursuant to 21 U.S.C. 824(a)(5), the Attorney General is authorized to suspend or revoke a registration upon finding that the registrant ''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' The Agency has consistently held that it may also deny an application upon finding that an applicant has been excluded from a federal health care program. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 n.3 (2016) (''[W]here a registration can be revoked under [21 U.S.C.] 824, it can, *a fortiori,* be denied under [21 U.S.C.] 823 since the law would not require an agency to indulge in the useless act of granting a license on one day only to withdraw it on the next.'') (quoting *Kwan Bo Jin, M.D.,* 77 FR 35021, 35021 n.2 (2012)).

II. Findings of Fact

On August 21, 2014, in the United States District Court for the Western District of Michigan, Respondent pleaded guilty to one count of conspiracy to pay and receive health care kickbacks, in violation of 42 U.S.C. 1320a–7b(b) and 18 U.S.C. 371; and one count of filing a false tax return, in violation of 26 U.S.C. 7206(1).[2] RD, at 3; Government Exhibit (GX) 3. On November 28, 2014, the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG), mandatorily excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a) for a period of thirteen years. RD, at 3; GX 7. The exclusion became effective on December 18, 2014, and imposed an exclusion for a minimum period of thirteen years.[3] *Id.* Accordingly, the Agency finds substantial record evidence that Respondent has been, and continues to be, excluded from participation in federal health care programs.[4]

III. Discussion

The Agency agrees with the ALJ and finds substantial record evidence that Respondent has been, and remains, mandatorily excluded from federal health care programs pursuant to 42 U.S.C. 1320a–7(a),[5] and Respondent has admitted to the same. RD, at 3, 18; GX 7. Accordingly, the Agency finds that substantial record evidence establishes the Government's *prima facie* case for denying Respondent's application under 21 U.S.C. 824(a)(5). *See also* 21 U.S.C. 823(g)(1).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's application for a registration should be denied, the burden shifts to Respondent 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 respondent. *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 respondent who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that he or she will not engage in future misconduct. *Jones Total Health Care Pharmacy,* 881 F.3d at 833. A respondent's acceptance of responsibility must be unequivocal. *Id.* at 830–31. In addition, a respondent's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 & n.4. DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Here, the Agency agrees with the ALJ that Respondent unequivocally accepted responsibility for her conduct. Respondent acknowledged at every opportunity that her conduct was wrong. RD, at 12. Respondent testified directly and credibly that she had committed the charged crimes and that, in doing so, she made a significant mistake that had harmed her patients. *Id.* at 13. Respondent addressed, and accepted responsibility, for all her misconduct, including the illegal kickback conspiracy, the tax evasion, and her failure to take action to stop her husband. *Id.* Respondent testified credibly that she had learned to never allow anyone or anything to come between her and her patients. *Id.* Respondent directly and unequivocally acknowledged her crimes and her responsibility for her crimes during cross-examination and questioning from the ALJ. *Id.* Respondent acknowledged her fault and provided credible, persuasive clarifications as to other statements she had made. *Id.*

Having found that Respondent has unequivocally accepted responsibility for her conduct, the Agency considers whether Respondent has implemented sufficient remedial measures to demonstrate that she will not engage in future misconduct and can be trusted with a registration.[6] The Agency considers the fact that Respondent is no longer married to her co-conspirator, a significant remedial measure.[7] Tr. 39. Since Respondent's conviction and loss of license, Respondent has taken

19. The Agency agrees with the ALJ that the DEA Diversion Investigator (DI) was a credible, knowledgeable witness. *Id.* at 3. The testimony from the DI was primarily focused on the introduction of the Government's documentary evidence. *Id.*

[2] Respondent has stipulated to this fact. *See* ALJ Exhibit 9, at 2.

[3] Respondent has stipulated to this fact. *See* ALJ Exhibit 9, at 3.

[4] Where Respondent has stipulated to a fact, the Agency exceeds the substantial record evidence standard.

[5] 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); *see also Narciso Reyes, M.D.,* 83 FR 61678, 61681 (2018); *KK Pharmacy,* 64 FR 49507, 49510 (1999) (collecting cases).

[6] The Agency disagrees with the Government's exception that the ALJ shifted the burden of proving unequivocal acceptance of responsibility and the taking of remedial measures onto the Government. Government Exceptions, at 2. Respondent had the burden to establish, and indeed did establish, unequivocal acceptance of responsibility and sufficient remedial measures; however, the Government disagreed. The portion of the RD that the Government calls burden shifting is actually the ALJ's assessment of the Government's argument that Respondent did not meet her burden. The Agency does not consider this shifting the burden of proof to the Government.

[7] Respondent testified that her husband at the time managed the business. Tr. 38–39. Respondent admitted that she did not oversee her husband's activities. *Id.* When she did try to oversee, she was ''shut down'' and ''suffered'' if she interfered, as her husband was both verbally and physically abusive. Tr. 40–41. Moreover, if she attempted to supervise him, he would defy her and do what she told him not to do. Tr. 41. Respondent admitted her fault and that she should have had control of her own business. RD. at 6. Respondent testified that the abuse she suffered did not excuse her lack of oversight of the business because it was ultimately her practice. *Id.* Respondent testified that it was all her responsibility and that she should have interfered and stopped him. *Id.*

concrete steps to reestablish trust and rebuild her practice. RD, at 17.

According to Respondent, her time in prison affected how she viewed medicine and her own past actions. Tr. 46–48; RD, at 6. Respondent testified that she saw multiple inmates receive inadequate medical care for serious conditions, and she herself was refused treatment. *Id.* Respondent testified that these experiences made her a better doctor and made her think more about health care in general in that there are segments of the population that are completely neglected. *Id.* Respondent candidly and credibly testified that her time in prison changed her and made her realize that medical care involved not just treatment, but all administrative duties. RD, at 13.

After Respondent's release from prison in 2016, she did not immediately return to the practice of medicine. RD, at 7. Respondent worked a variety of jobs such as food delivery, waitressing, trucking, and cleaning. *Id.;* Tr. 55–56. On multiple occasions, she had to wait on former colleagues and other doctors that she knew. *Id.* Respondent testified that working these positions humbled her and made her aware of how valuable her license was and what an honor it was to have it. *Id.* Respondent eventually secured a medical license in Wisconsin, for which she disclosed her criminal convictions and exclusion from federal health care programs. Tr. 56. To do so, she was required to work under a limited license for a year, with quarterly reports from a supervisor to the Wisconsin Medical Board. *Id.* After one year, she applied for and received a full medical license in Wisconsin. Tr. 57. Respondent obtained employment at a clinic in Wisconsin. Tr. 62–64. Respondent is seeking a DEA registration because she plans to work with incarcerated people and a DEA registration is required for a position within the corrections system. RD, at 7. Respondent has also taken approximately 240 hours of continuing medical education credits.[8] Tr. 61. Finally, in terms of mitigation and remedial measures, Respondent has paid, and continues to pay, the ordered restitution of $270,000.[9] RD, at 17. The Agency agrees with the ALJ that Respondent has taken ''significant, concrete remedial steps'' to ensure the misconduct will not reoccur. *Id.* at 18.

Regarding egregiousness, there is no dispute that the conduct that led to Respondent's conviction and subsequent exclusion from all federal health care programs was egregious. In a case brought under 21 U.S.C. 824(a)(5), the length of the exclusion, the nature of the misconduct, and the period of incarceration are relevant considerations in determining egregiousness. *George Roussis, M.D.,* 86 FR 61316, 61322–23 (2021) (citing *Michael Jones, M.D.,* 86 FR 20728, 20732 (2021)). In the instant case, Respondent has been excluded for 13 years, with that exclusion ending in 2027. RD, at 18. As for the underlying conviction, Respondent pleaded guilty to a seven-year conspiracy, to commit health care fraud and filed a false tax return. *Id.* The egregious nature of Respondent's lengthy exclusion from federal health care programs and the egregious nature of the criminal conduct underlying the conviction would typically weigh in favor of denial of her application. *Id.* However, the conspiracy ended in April 2011, and the tax offense occurred in March 2012. GX 3, at 3. Thus, Respondent's criminal conduct ended over 13 years ago. RD, at 18, and Respondent has taken significant remedial measures during that time. *Id.*

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74810 (2015). Because these administrative proceedings are intended to be remedial, rather than punitive, the Agency has previously found that, under appropriate circumstances, ''criminal convictions and sanctions by state licensing authorities can sufficiently deter physicians from engaging in misconduct, making the denial of an application . . . unnecessary to achieve the goal of general deterrence.'' *Gilbert Y. Kim, D.D.S.,* 87 FR 21139, 21145 (2022) (citing *Kansky J. Delisma, M.D.,* 85 FR 23845, 23854 (2020)). The Agency has also held that, sometimes, ''such punitive measures can suffice to deter the registrant or applicant from future misconduct, making revocation or denial of an application unnecessary to achieve specific deterrence.'' *Id.*

Here, the Agency does not find that imposing further sanction is necessary to deter Respondent from engaging in future misconduct. Respondent received significant criminal punishment for her criminal conduct. RD, at 19. Respondent's plea agreement imposed a significant price for her crimes, 24 months of imprisonment, the forfeiture of thirteen real properties and cash, and detailed obligations for cooperation in her case. *Id.* Respondent served 17 months of her 24-month prison sentence, successfully completed supervised release, forfeited two clinics along with other properties, and continues to pay restitution for her crimes of conviction. Thus, the Agency finds that the punitive, remedial, and personal consequences that Respondent suffered are sufficient to deter her from engaging in future misconduct. The Agency also finds that the significant consequences that Respondent has faced are sufficient to deter the general registrant community from committing similar misconduct.

Ultimately, the determination of the appropriate sanction turns on whether the Agency can trust Respondent with a registration and that Respondent will not repeat her misconduct. *See Heavenly Care Pharmacy,* 85 FR 53402, 53420 (2020). Respondent testified candidly, unequivocally accepted responsibility, and demonstrated genuine insight into the nature and scope of her criminal misconduct. RD, at 19. In sum, Respondent's candid, genuine testimony, coupled with her concrete remedial actions, convince the Agency that she can be trusted with a registration. Therefore, the Agency will grant her application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823 and 824, I hereby dismiss the Order to Show Cause issued to Shannon Wagner, D.O., and grant the pending application for a DEA Certificate of Registration, Control No. W23130415C, submitted by Shannon Wagner, D.O. This Order is effective *immediately.*

Signing Authority

This document of the Drug Enforcement Administration was signed on October 1, 2025, by Administrator Terrance 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

[8] The state of Wisconsin requires 30 hours of Continuing Medical Education (CME) credits for physicians every two years. *See* American Medical Association Ed Hub, Wisconsin State CME Requirements, *https://edhub.ama-assn.org/state-cme/Wisconsin.* Since Respondent has gone over the minimum required hours of CME for physicians, the Agency accepts this as a sufficient remedial measure and rejects the Government's argument that Respondent needs to explain the subject matter of the courses taken. Government Exceptions, at 7–8.

[9] The Agency also rejects the Government's argument that Respondent has failed to show sufficient remedial measures by paying $150 in restitution each month. Government Exceptions, at 6–7. Respondent has consistently paid restitution since being released from prison and continues to do so. RD, at 17. Respondent also testified that she will pay more once she obtains a higher paying job and intends to pay the amount in full. Tr. at 93.

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.

[FR Doc. 2025–19577 Filed 10–16–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

David S. Pecora, P.A.; Decision and Order

On August 16, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to David S. Pecora, P.A., of Bemidji, Minnesota (Applicant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 15. The OSC proposed the denial of Applicant's application for DEA registration, Control Number W23054133M, alleging that he materially falsified multiple applications for registration and that his registration would be inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. 823(g)(1), 824(a)(1)).[1]

On September 30, 2024, the Government submitted a RFAA to the Administrator requesting that the Agency issue a default final order denying Applicant's application. RFAA, at 1, 3–4. After carefully reviewing the entire record and conducting the analysis as set forth in detail below, the Agency grants the Government's request for final agency action and denies Applicant's application. As a preliminary matter, this Decision addresses whether or not Applicant is in default and finds that he is. Thereafter, this Decision makes specific factual findings on the alleged violations as set forth in the OSC. Specifically, this Decision considers whether Applicant submitted a materially false application and finds that he did. Additionally, this Decision considers whether Applicant's registration would be inconsistent with the public interest and finds that it would be. Lastly, this Decision determines that the appropriate sanction is denial of Applicant's application.

[1] The Agency need not adjudicate the criminal violations alleged in the OSC. *See Ruan* v. *United States,* 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

I. Default Determination

Under 21 CFR 1301.43, a registrant or applicant entitled to a hearing who fails to file a timely hearing request ''within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default'' unless ''good cause'' is established for the failure. 21 CFR 1301.43(a), (c)(1). In the absence of a demonstration of good cause, a registrant or applicant who fails to timely file an answer also is ''deemed to have waived their right to a hearing and to be in default.'' 21 CFR 1301.43(c)(2).

The OSC notified Applicant of his right to file a written request for a hearing and an answer, and that if he failed to file such a request and answer, he would be deemed to have waived his right to a hearing and be in default.[2] RFAAX 1, at 14 (citing 21 CFR 1301.43). Here, Applicant did not request a hearing, file an answer, or respond to the OSC in any way. RFAA, at 1–3. Accordingly, Applicant is in default. 21 CFR 1301.43(c)(1).

''A default, unless excused, shall be deemed to constitute a waiver of the [applicant's] right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e). Because Applicant is in default and has not moved to excuse the default, the Agency finds that Applicant has admitted to the factual allegations in the OSC. 21 CFR 1301.43(c)(1), (e), (f)(1).

Further, ''[i]n the event that [an applicant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.'' 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on Applicant's default pursuant to 21 CFR 1301.43(c)(1), (f)(1). RFAA, at 1–3; *see also* 21 CFR 1316.67.

II. Findings of Fact

The Agency finds that, in light of Applicant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Applicant is deemed to have admitted to each of the following facts.[3]

A. Material Falsification

January 2012 Application, Number W12001098M

On January 6, 2012, Applicant submitted an application for DEA registration, which was assigned control number W12001098M. RFAAX 1, at 9.

The application's Liability Question 3 asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.*

Applicant answered ''no'' to Liability Question 3. *Id.* In doing so, Applicant failed to disclose that: (a) in July 2007, Applicant's West Virginia registered nursing license, number 53904, was suspended; and (b) in October 2008, Applicant's Florida registered nursing license, number RN9221251, was suspended. *Id.* Applicant's January 2012 application was approved and assigned DEA registration number MP2562432. *Id.*

October 2013 Application, Number W13085169M

On October 12, 2013, Applicant submitted an application for DEA registration, which was assigned control number W13085169M. RFAAX 1, at 9.

The application's Liability Question 3 asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.*

Applicant answered ''no'' to Liability Question 3. *Id.* In doing so, Applicant failed to disclose that: (a) in July 2007, Applicant's West Virginia registered nursing license, number 53904, was suspended; (b) in October 2008, Applicant's Florida registered nursing license, number RN9221251, was suspended; and (c) in July 2012, Applicant's application for a physician assistant license in North Dakota was denied. *Id.* at 9–10. Applicant's October 2013 application was approved and assigned DEA registration number MP3221417. *Id.*

[2] Based on the Government's submissions in its RFAA dated September 30, 2024, the Agency finds that service of the OSC on Applicant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on August 26, 2024, DI served the OSC on Applicant in-person and Applicant signed and initialed each page of the OSC. RFAAX 2, at 1; RFAAX 3. Accordingly, the Agency finds that due process notice requirements have been satisfied. *Jones* v. *Flowers,* 547 U.S. 220, 226 (2006).

[3] According to the Controlled Substances Act (CSA), ''[f]indings of fact by the [DEA Administrator], if supported by substantial evidence, shall be conclusive.'' 21 U.S.C. 877. Here, where Applicant is found to be in default, all the factual allegations in the OSC are deemed to be admitted. These uncontested and deemed admitted facts constitute evidence that exceeds the ''substantial evidence'' standard of 21 U.S.C. 877; it is unrebutted evidence.

January 2016 Application, Number W16005281M

On January 21, 2016, Applicant submitted an application for DEA registration, which was assigned control number W16005281M. RFAAX 1, at 10.

The application's Liability Question 2 asked: ''Has the applicant ever surrendered (for cause) or had a federal controlled substances registration revoked, suspended, restricted, or denied, or is any such action pending?'' *Id.*

Applicant answered ''yes'' to Liability Question 2. *Id.* In response to the application's direction to provide the date and location of the incident that prompted the affirmative answer, Applicant stated: ''January 30, 2015,'' and ''BEMIDJI, MINNESOTA.'' *Id.*

In response to the application's direction to provide the nature of the incident, Applicant stated: ''ON 10/01/2014, I MISTAKENLY TOOK TABLETS OF SOMA.[4] DURING MY PREVIOUS ABUSE OF SOMA, I HAD PLACED SOME SOMA TABLETS IN THE SAME CONTAINER AS MY ASPIRIN. ON 10/01/2014, I DEVELOPED A HEADACHE AND WENT INTO MY BATHROOM WITHOUT TURNING ON THE LIGHT (AS LIGHT INCREASES MY HEADACHES). I TOOK OUT THE BOTTLE OF ASPIRIN AND POURED THEM INTO MY HAND. I TOOK TWO TABLETS. THIS WAS AN UNINTENTIONAL INJECTION OF SOMA.'' *Id.*

In response to the application's direction to provide the result of the incident, Applicant stated: ''I WAS BEING MOUNTED BY MINNESOTA HEALTH PROFESSIONALS SERVICES PROGRAM. I DID A UA THE NEXT DAY. IT WAS POSITIVE FOR SOMA. AFTER AN INVESTIGATION BY MINNESOTA BOARD OF MEDICAL PRACTICE, THEY DETERMINED TREATMENT WAS NOT NECESSARY. FLORIDA PROFESSIONALS RESOURCE NETWORK BEGAN MONITORING ME (I ALSO HAVE A FLORIDA PA LICENSE). FLORIDA DID MANDATE TREATMENT. I WENT TO HAZELDEN BETTY FORD IN CENTER CITY, MN. I WAS THERE FOR 60 DAYS OF IN-PATIENT TREATMENT IN THE HEALTH CARE PROFESSIONALS SEC.'' *Id.*

These descriptions most closely resemble circumstances relating to DEA registration number MP3221417, which Applicant surrendered for cause on January 30, 2015. *Id.*

The application's Liability Question 3 asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.* at 11.

Applicant answered ''yes'' to Liability Question 3. *Id.* In response to the application's direction to provide the date and location of the incident that prompted the affirmative answer, Applicant stated: ''September 15, 2013,'' and ''MINNEAPOLIS, MN.'' *Id.*

In response to the application's direction to provide the nature of the incident, Applicant stated: ''SOMETIME DURING THE FALL OF 2013, AND AFTER I COMPLETED 90-DAYS OF IN-PATIENT TREATMENT AT TALBOTT RECOVERY CAMPUS, I MEET WITH JACK HENDERSON & ANDY BIRD WITH THE MINNESOTA DEA AND SURRENDERED MY DEA LICENSE.'' *Id.*

In response to the application's direction to provide the result of the incident, Applicant stated: ''MY DEA LICENSE WAS RE-ISSUED TO ME ABOUT A YEAR LATER.'' *Id.*

These descriptions most closely resemble circumstances relating to DEA registration number MP2562432, which Applicant surrendered for cause on June 4, 2013, and not any state professional license or state controlled substance registration. *Id.*

While Applicant made some disclosures in response to Liability Question 3, Applicant failed to disclose that: (a) in July 2007, Applicant's West Virginia registered nursing license, number 53904, was suspended; (b) in October 2008, Applicant's Florida registered nursing license, number RN9221251, was suspended; (c) in July 2012, Applicant's application for a physician assistant license in North Dakota was denied; (d) in January 2014, Applicant's Minnesota physician assistant license, number 10593, was suspended and the suspension was stayed; (e) in November 2014, Applicant's Minnesota physician assistant license, number 10593, was suspended; (f) in January 2015, Applicant's Minnesota physician assistant license, number 10593, was indefinitely suspended; and (g) in November 2015, Applicant's Minnesota physician assistant license, number 10593, was reinstated, suspended, and the suspension was stayed. *Id.* Applicant's January 2016 application was approved and assigned DEA registration number MP4140478. *Id.*

Renewal Application of DEA Registration, Number MP4140478

On February 11, 2020, Applicant submitted an application to renew DEA registration number MP4140478. RFAAX 1, at 12. The application's Liability Question 3 asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.* Applicant answered ''yes'' to Liability Question 3. *Id.*

In response to the application's direction to provide the date and location of the incident that prompted the affirmative answer, Applicant stated: ''February 11, 2020,'' and ''NOTHING NEW TO REPORT.'' *Id.* In response to the application's direction to provide the nature of the incident, Applicant stated: ''NOTHING NEW TO REPORT SINCE LAST REGISTRATION.'' *Id.* In response to the application's direction to provide the result of the incident, Applicant stated: ''NOTHING NEW TO REPORT.'' *Id.*

Applicant's follow-up responses to Liability Question 3 were false because Applicant again failed to disclose the incidents in West Virginia, Florida, North Dakota, and Minnesota that made his application, number W16005281M, false. *Id.* Applicant's February 2020 renewal application for registration number MP4140478 was approved. *Id.*

May 2023 Application, Number W23054133M

On May 2, 2023, Applicant submitted an application for DEA registration, which was assigned control number W23054133M. RFAAX 1, at 12.

The application's Liability Question 2 asked: ''Has the applicant ever surrendered (for cause) or had a federal controlled substances registration revoked, suspended, restricted, or denied, or is any such action pending?'' *Id.* Applicant answered ''yes'' to Liability Question 2. *Id.* In response to the application's direction to provide the date and location of the incident that prompted the affirmative answer, Applicant stated: ''February 10, 2022,'' and ''MINNESOTA.'' *Id.*

In response to the application's direction to provide the nature of the incident, Applicant stated: ''MY MN PHYSICIAN ASSISTANT LICENSE WAS SUSPENDED DUE TO MY DIVERSION OF PROPOFOL FOR SELF USE. I THEN HAD TO SURRENDER MY MN DEA REGISTRATION DUE TO MY MN PHYSICIAN ASSISTANT LICENSE BEING SUSPENDED.''[5] *Id.* In response to the application's direction to provide the result of the incident, Applicant

[4] Soma is a brand name for carisoprodol. *See infra* n.7.

[5] Propofol is a Schedule IV depressant. 21 CFR 1308.14(c)(27); RFAAX 1, at 8.

stated: ''I SURRENDERED MY MN DEA REGISTRATION.'' *Id.*

These descriptions most closely resemble circumstances relating to DEA registration number MP4140478, which Applicant surrendered for cause on November 16, 2021. *Id.*

Though Applicant made some disclosures, he failed to disclose that he surrendered two additional DEA registrations. Specifically, he failed to disclose that on June 4, 2013, he surrendered for cause DEA registration number MP2562432, and on January 30, 2015, he surrendered for cause DEA registration number MP3221417. *Id.* at 13.

Liability Question 3 asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.* Applicant answered ''yes'' to Liability Question 3. *Id.* In response to the application's direction to provide the date and location, Applicant stated: ''May 1, 2021,'' and ''MINNESOTA.'' *Id.*

In response to the application's direction to provide the nature of the incident, Applicant stated: ''I DIVERTED PROPOFOL FOR SELF-USE IN AUGUST OF 2020 IN THE COUNTRY OF CURACAO WHILE ON A COVID–19 RAPID RESPONSE TEAM. I SELF-REPORTED THIS DIVERSION TO THE MINNESOTA HEALTH PROFESSIONALS SERVICES PROGRAM.'' *Id.*

In response to the application's direction to provide the result of the incident, Applicant stated: ''MY MINNESOTA PHYSICIAN ASSISTANT LICENSE WAS SUSPENDED.'' *Id.* These descriptions most closely resemble circumstances relating to the indefinite suspension of Applicant's Minnesota physician assistant license, number 10593, on September 11, 2021. *Id.*

Again, Applicant failed to disclose the incidents in West Virginia, Florida, North Dakota, and Minnesota that made his application, number W16005281M, and his renewal application of registration number MP4140478, false. *Id.* at 13–14. Additionally, Applicant failed to disclose that on March 11, 2023, Applicant's Minnesota physician assistant license, number 10593, was suspended and the suspension was stayed. *Id.* at 14.

B. Public Interest

Applicant is deemed to have admitted that in 2007, he was addicted to zolpidem [6] and underwent treatment at a chemical addiction recovery program for sedative-hypnotic addiction. RFAAX 1, at 4.

In 2013, Applicant was abusing carisoprodol [7] and was being monitored by the Florida Professionals Resource Network. *Id.* at 6. In April 2013, Applicant wrote a prescription for a volleyball teammate for 90 tablets of carisoprodol that authorized refills, and in exchange, Applicant's volleyball teammate promised to fill the prescription and provide Applicant with 30 carisoprodol tablets. *Id.* Applicant's volleyball teammate supplied Applicant with 30 of the carisoprodol tablets, which Applicant consumed. *Id.*

Approximately one month later, Applicant wrote another prescription for a different volleyball teammate for 90 tablets of carisoprodol that authorized refills, and in exchange, Applicant's second volleyball teammate promised to fill the prescription and provide Applicant with 30 carisoprodol tablets. *Id.* Applicant's second volleyball teammate supplied Applicant with 30 of the carisoprodol tablets, which Applicant consumed. *Id.*

In the summer of 2013, Applicant ordered carisoprodol tablets through the internet not for a legitimate medical purpose and not within the usual course of Applicant's professional practice. *Id.* The carisoprodol tablets were delivered to Applicant while he was a patient at a chemical addiction recovery program, which he attended from June 2013 to August 2013. *Id.*

On October 8, 2014, and October 20, 2014, Applicant tested positive for carisoprodol on two separate toxicology screens, when he did not have a prescription for carisoprodol. *Id.* at 7.

In November 2015, Applicant consented to a stipulation and order issued by the Minnesota Board of Medical Practice after Applicant demonstrated completion of in-patient chemical dependency treatment, regular attendance at self-help program meetings, and random drug testing administered by the Florida Professionals Resource Network. *Id.* The stipulation and order required Applicant to demonstrate three years of uninterrupted recovery from substance abuse. *Id.*

In November 2020, Applicant stole propofol from an operating room for his own personal use. *Id.* at 8.

In September 2021, Applicant was subject to a stipulation and order issued by the Minnesota Board of Medical Practice that required Applicant to demonstrate six months of uninterrupted recovery from substance abuse, negative results on twelve random toxicology screens per quarter, regular attendance at self-help meetings in support of recovery, completion of a neuropsychological evaluation, and certification from medical professionals that Applicant was competent to safely resume practice. *Id.*

III. Discussion

A. Material Falsification

A DEA registration may be denied, suspended, or revoked upon a finding that the applicant or registrant materially falsified any application filed pursuant to or required by the Controlled Substances Act (CSA). 21 U.S.C. 824(a)(1).[8] To present a *prima facie* case for material falsification, the Government's record evidence must show (1) the submission of an application, (2) containing a false statement and/or omitting information that the application requires, (3) when the submitter knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure, and (4) the false statement and/or required but omitted information is material, that is, it ''connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] 'shall' consider'' when analyzing ''whether issuing a registration 'would be inconsistent with the public interest.' '' *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45238 (2020) (citing 21 U.S.C. 823 and *Kungys,* 485 U.S. at 771). The Government must establish material falsification with record evidence that is clear, unequivocal, and convincing. *Kungys,* 485 U.S. at 772; *Stirlacci,* 85 FR at 45230–39.

First, the Government must prove that the applicant or registrant submitted an application for registration pursuant to the CSA. 21 U.S.C. 824(a)(1); *see also* 21 U.S.C. 822 (persons required to register); 21 U.S.C. 823(g)(1) (registration requirements).

Second, the Government must prove that the application contained a false

[6] Zolpidem is a Schedule IV depressant. 21 CFR 1308.14(c)(58); RFAAX 1, at 4.

[7] Carisoprodol is a Schedule IV depressant. 21 CFR 1308.14(c)(7); RFAAX 1, at 6.

[8] A statutory basis to deny an application pursuant to section 823 is also a basis to revoke or suspend a registration pursuant to section 824, and vice versa, because doing ''otherwise would mean that all applications would have to be granted only to be revoked the next day . . . .'' *Robert Wayne Locklear, M.D.,* 86 FR 33738, 33744–45 (2021) (collecting cases).

The Supreme Court's decision in *Kungys* v. *United States,* 485 U.S. 759 (1988), and its progeny, guide the Agency's implementation of these CSA provisions.

statement or omitted information that the application required, either of which may constitute a material falsity. *See, e.g., Emed Medical Company LLC and Med Assist Pharmacy,* 88 FR 21719, 21720 (2023) (applicant falsely answered ''no'' to Liability Question 3 on seventeen applications when the true answer was ''yes''); *Richard J. Settles, D.O.,* 81 FR 64940, 64945–46 (2016) (applicant failed to disclose an interim consent agreement restricting his license based on findings that he issued controlled substance prescriptions without federal or state legal authority to do so). In making this assessment, the Agency will examine the entire application, including registrant's ''yes/no'' answers to the liability questions and any follow-up response(s). *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74802, 74808–09 (2015). To establish an omission, the Government must show both that omitted information existed and that the application required inclusion of that information. *See, e.g., Richard A. Herbert, M.D.,* 76 FR 53942, 53956 (2011) (omission of a probation which the application required to be identified); *Michel P. Toret, M.D.,* 82 FR 60041, 60042 (2017) (Voluntary Surrender Form alone is insufficient evidence to find material falsification based on registrant's ''no'' answer to the question regarding ''surrender[s] (for cause)'').

Third, the Government must prove that the applicant or registrant knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure. *See John J. Cienki, M.D.,* 63 FR 52293, 52295 (1998) (''[I]n finding that there has been a material falsification of an application, it must be determined that the applicant knew or should have known that the response given to the liability question was false.''); *Samuel Arnold, D.D.S.,* 63 FR 8687, 8688 (1998) (''It is also undisputed that Respondent knew that his Ohio dental license had previously been suspended.''); *Bobby Watts, M.D.,* 58 FR 46995, 46995 (1993) (''Respondent knew that the Tennessee Board of Medical Examiners had suspended his medical license on May 7, 1987, and had placed his state medical license on probation on May 2, 1988.''); *see also Stirlacci,* 85 FR at 45236–37 & nn.22–23 (collecting cases).

Fourth, the Government must prove that the false statement and/or required but omitted information is ''material.'' *Kungys* holds that a statement is material if it is ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the [Agency's] official decision,'' or stated differently, ''had a natural tendency to influence the decision.'' *Kungys,* 485 U.S. at 771–72. As already discussed, materiality, for the purposes of the CSA, is tied to the factors that the Administrator ''shall'' consider when determining whether issuance of a registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823; *Kungys,* 485 U.S. at 771–72; *Stirlacci,* 85 FR at 45234, 45238.

The Government has the burden of proof in this proceeding, and the Agency must make its findings based on clear, unequivocal, and convincing record evidence. 21 CFR 1301.44(d); *Kungys,* 485 U.S. at 772; *Stirlacci,* 85 FR at 45230–39. Here, the Agency finds that the Government's record evidence presents a *prima facie* case that Applicant submitted five materially false applications. 21 U.S.C. 824(a)(1).

January 2012 Application, Number W12001098M

The Agency finds the following facts based on clear, unequivocal, and convincing record evidence. On January 6, 2012, Applicant submitted an application for DEA registration, which was assigned control number W12001098M. RFAAX 1, at 9. Liability Question 3 asked whether Applicant had ever had any adverse action against a state professional license, to include revocation, suspension, probation, or denial. *Id.* Applicant falsely answered ''no.'' *Id.* Applicant's ''no'' answer to Liability Question 3 was false because he knew or should have known that information existed that the application required to be disclosed in response to Liability Question 3. *Id.* Specifically, Applicant knew or should have known that in July 2007 his West Virginia nursing license was suspended and that in October 2008 his Florida nursing license was suspended. *Id.*

Additionally, Applicant's false answer was material. The CSA provides that suspension of a state license is one basis by which the Attorney General may suspend or revoke a DEA registration, and therefore, it is a relevant statutory factor for determining whether issuance or maintenance of a registration is inconsistent with the CSA.[9] 21 U.S.C. 823(g)(1), 824(a)(3); *Emed Medical Company LLC and Med Assist Pharmacy,* 88 FR at 21720. Thus, whether an applicant has had a state license suspended is a relevant factor DEA must consider when reviewing an application, and failure to disclose such information has ''a natural tendency to influence the [Agency's] decision.'' *Kungys,* 485 U.S. at 771–72.

Accordingly, the falsity in Applicant's January 2012 application directly affected the statutory analysis that DEA was required to make when it reviewed his application. 21 U.S.C. 823(g)(1), 824(a)(3). Thus, the falsity was material because it was ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Applicant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771.

In sum, the Agency finds clear, unequivocal, and convincing record evidence that Applicant's January 6, 2012 application for DEA registration, control number W12001098M, was materially false. 21 U.S.C. 824(a)(1); RFAAX 1, at 9.

October 2013 Application, Number W13085169M

The Agency finds the following based on clear, unequivocal, and convincing record evidence. On October 12, 2013, Applicant submitted an application for DEA registration, which was assigned control number W13085169M. RFAAX 1, at 9. Liability Question 3 asked whether Applicant had ever had any adverse action against a state professional license, to include revocation, suspension, probation, or denial. *Id.* Applicant falsely answered ''no.'' *Id.* Applicant's ''no'' answer to Liability Question 3 was false because he knew or should have known that information existed that the application required to be disclosed in response to Liability Question 3. *Id.*

Specifically, Applicant knew or should have known that in July 2007 his West Virginia nursing license was suspended, in October 2008 his Florida nursing license was suspended, and in 2012 his application for a physician assistant license was denied in North Dakota. *Id.* at 9–10.

Additionally, Applicant's false answer was material. The CSA provides that suspension or lack of a state license is one basis by which the Attorney General may suspend, revoke, or deny a DEA registration, and therefore, it is a relevant statutory factor for determining whether issuance or maintenance of a registration is inconsistent with the CSA. 21 U.S.C. 823(g)(1), 824(a)(3); *Emed Medical Company LLC and Med Assist Pharmacy,* 88 FR at 21720. Thus, whether an applicant has had a state license suspended or denied is a relevant factor DEA must consider when reviewing an application, and failure to disclose such information has ''a natural tendency to influence the [Agency's] decision.'' *Kungys,* 485 U.S. at 771–72.

[9] Because the bases for revocation listed in 21 U.S.C. 824 may also serve as bases to deny an application, *see supra* n.8, a finding of materiality may also be tied to 21 U.S.C. 824(a)(1)–(5).

Accordingly, the falsity in Applicant's October 2013 application directly affected the statutory analysis that DEA was required to make when it reviewed his application. 21 U.S.C. 823(g)(1), 824(a)(3). Thus, the falsity was material because it was ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Applicant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771.

In sum, the Agency finds clear, unequivocal, and convincing record evidence that Applicant's October 12, 2013 application for DEA registration, control number W13085169M, was materially false. 21 U.S.C. 824(a)(1); RFAAX 1, at 9–10.

January 2016 Application, Number W16005281M

The Agency finds the following based on clear, unequivocal, and convincing record evidence. On January 21, 2016, Applicant submitted an application for DEA registration, which was assigned control number W16005281M. RFAAX 1, at 10. Liability Question 2 asked, in part, whether Applicant has ever surrendered for cause a federal controlled substances registration. *Id.* Liability Question 3 asked whether Applicant had ever had any adverse action against a state professional license, to include revocation, suspension, probation, or denial. *Id.* at 11. Applicant answered ''yes'' to Liability Questions 2 and 3 and provided additional information to the follow-up prompts regarding date, location, nature, and result. *Id.* at 10–11.

Despite truthfully answering ''yes,'' Applicant failed to disclose all the required information in response to Liability Question 3. Specifically, Applicant's follow-up responses failed to disclose that in July 2007 his West Virginia nursing license was suspended; in October 2008 his Florida nursing license was suspended; in 2012 his application for a physician assistant license was denied in North Dakota; and in January 2014, November 2014, January 2015, and November 2015, his Minnesota physician assistant license was suspended. *Id.* Accordingly, Applicant's response to Liability Question 3 was false because he knew or should have known information existed that the application clearly required be disclosed in response to Liability Question 3.[10] *Id.*

Additionally, Applicant's false answer was material. The CSA provides that suspension or lack of a state license is one basis by which the Attorney General may suspend, revoke, or deny a DEA registration, and therefore, it is a relevant statutory factor for determining whether issuance or maintenance of a registration is inconsistent with the CSA. 21 U.S.C. 823(g)(1), 824(a)(3); *Emed Medical Company LLC and Med Assist Pharmacy,* 88 FR at 21720. Thus, whether an applicant has had a state license suspended or denied is a relevant factor DEA must consider when reviewing an application, and failure to disclose such information has ''a natural tendency to influence the [Agency's] decision.'' *Kungys,* 485 U.S. at 771–72.

Accordingly, the falsity in Applicant's January 2016 application directly affected the statutory analysis that DEA was required to make when it reviewed his application. 21 U.S.C. 823(g)(1), 824(a)(3). Thus, the falsity was material because it was ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Applicant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771.

In sum, the Agency finds clear, unequivocal, and convincing record evidence that Applicant's January 21, 2016 application for DEA registration, control number W16005281M, was materially false. 21 U.S.C. 824(a)(1); RFAAX 1, at 10–11.

February 2020 Renewal Application, Registration Number MP4140478

The Agency finds the following based on clear, unequivocal, and convincing record evidence. On February 11, 2020, Applicant submitted an application to renew DEA registration number MP4140478. RFAAX 1, at 12. Liability Question 3 asked whether Applicant had ever had any adverse action against a state professional license, to include revocation, suspension, probation, or denial. *Id.* Applicant answered ''yes.'' *Id.*

Despite truthfully answering ''yes,'' Applicant failed to disclose all the required information in response to Liability Question 3. In response to the application's request for the date of the incident that prompted the ''yes'' answer, Applicant stated, ''February 11, 2020,'' the date he submitted the application. *Id.* In response to the application's request for the location, nature, and result of the incident, Applicant stated: ''NOTHING NEW TO REPORT.'' *Id.* Applicant's response to Liability Question 3 was false because he continued to fail to disclose the incidents that made his January 21, 2016 application, control number W16005281M, false. *Id.* Specifically, Applicant failed to disclose that in July 2007 his West Virginia nursing license was suspended; in October 2008 his Florida nursing license was suspended; in 2012 his application for a physician assistant license was denied in North Dakota; and in January 2014, November 2014, January 2015, and November 2015, his Minnesota physician assistant license was suspended. *Id.* at 11–12. Accordingly, Applicant's response to Liability Question 3 was false because he knew or should have known information existed that the application required be disclosed in response to Liability Question 3. *Id.*

Additionally, Applicant's false answer was material. The CSA provides that suspension or lack of a state license is one basis by which the Attorney General may suspend, revoke, or deny a DEA registration, and therefore, it is a relevant statutory factor for determining whether issuance or maintenance of a registration is inconsistent with the CSA. 21 U.S.C. 823(g)(1), 824(a)(3); *Emed Medical Company LLC and Med Assist Pharmacy,* 88 FR at 21720. Thus, whether an applicant has had a state license suspended or denied is a relevant factor DEA must consider when reviewing an application, and failure to disclose such information has ''a natural tendency to influence the [Agency's] decision.'' *Kungys,* 485 U.S. at 771–72.

Accordingly, the falsity directly affected the statutory analysis that DEA was required to make when it reviewed Applicant's application. 21 U.S.C. 823(g)(1), 824(a)(3). Further, the falsity was material because it was ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Applicant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771.

In sum, the Agency finds clear, unequivocal, and convincing record evidence that Applicant's February 11, 2020 application to renew DEA registration number MP4140478 was materially false. 21 U.S.C. 824(a)(1); RFAAX 1, at 12.

May 2023 Application, Number W23054133M

On May 2, 2023, Applicant submitted an application for DEA registration, which was assigned control number W23054133M. RFAAX 1, at 12. Liability Question 2 asked, in part, whether

[10] In response to Liability Question 2, Applicant noted that the Minnesota Board of Medical Practice investigated him after a positive urinalysis but determined that ''treatment was not necessary.'' RFAAX 1, at 10. Applicant also noted that the Florida Professionals Resource Network ''began monitoring [him]'' and ''mandate[d] treatment.'' *Id.* Although these responses indicate that he was investigated in Minnesota and monitored and required to undergo treatment in Florida, they fail to disclose, as Liability Question 3 required, that his nursing license was suspended in Florida in 2008 and his physician assistant license was suspended in Minnesota in 2014 and 2015. *Id.*

Applicant has ever surrendered for cause a federal controlled substances registration. *Id.* Applicant answered ''yes.'' *Id.* In response to the application's follow-up prompts, Applicant provided a date, location, and description of events that most closely resembled circumstances relating to the surrender of DEA registration number MP4140478 in November 2021 in Minnesota. *Id.* at 4, 12.

Applicant, however, failed to disclose that he had previously surrendered two other DEA registrations in Minnesota. Specifically, he failed to disclose that on June 4, 2013, he surrendered for cause DEA registration number MP2562432, and on January 30, 2015, he surrendered for cause DEA registration number MP3221417. *Id.* at 3, 12–13. Although Applicant indicated that he ''SURRENDERED [HIS] MN DEA REGISTRATION,'' the information he provided on the application related to the surrender of only one Minnesota DEA registration, when, in fact, he previously held two additional DEA registrations that he also surrendered. *Id.* at 12–13. Accordingly, Applicant's response to Liability Question 2 was false because he knew or should have known information existed that the application required be disclosed in response to Liability Question 2. *Id.*

Liability Question 3 asked whether Applicant had ever had any adverse action against a state professional license, to include revocation, suspension, probation, or denial. *Id.* at 13. Applicant answered ''yes.'' *Id.* In response to the application's follow-up prompts, Applicant disclosed information that most closely resembled circumstances relating to the suspension of his Minnesota physician assistant license in September 2021. *Id.*

Applicant, however, failed to disclose additional adverse actions against state licenses that he knew or should have known were required to be disclosed in response to Liability Question 3. Specifically, he failed to disclose that in 2007 his nursing license was suspended in West Virginia; in 2008 his nursing license was suspended in Florida; in 2012 his application for a physician assistant license was denied in North Dakota; and in January 2014, November 2014, January 2015, November 2015, and March 2023, his physician assistant license was suspended in Minnesota. *Id.* at 13–14. Although Applicant disclosed one suspension of his physician assistant license in Minnesota in 2021, he failed to disclose suspensions of his Minnesota physician assistant license in 2014, 2015, and 2023. *Id.* Accordingly, Applicant's response to Liability Question 3 was false because he knew or should have known information existed that the application required be disclosed in response to Liability Question 3. *Id.*

Additionally, Applicant's false answers to Liability Questions 2 and 3 were material. The CSA provides that suspension or lack of a state license is one basis by which the Attorney General may suspend, revoke, or deny a DEA registration, and therefore, it is a relevant statutory factor for determining whether issuance or maintenance of a registration is inconsistent with the CSA. 21 U.S.C. 823(g)(1), 824(a)(3); *Emed Medical Company LLC and Med Assist Pharmacy,* 88 FR at 21720. Furthermore, a surrender for cause of a DEA registration implicates an applicant's or registrant's experience handling controlled substances and non-compliance with controlled substances laws, which are relevant considerations under Public Interest Factors B and D. 21 U.S.C. 823(g)(1). Thus, whether an applicant has had a state license suspended, an application for licensure denied, and/or has surrendered a previous DEA registration are all relevant factors DEA must consider when reviewing an application, and failure to disclose such information has ''a natural tendency to influence the [Agency's] decision.'' *Kungys,* 485 U.S. at 771–72.

Accordingly, the falsities directly affected the statutory analysis that DEA was required to make when it reviewed Applicant's application. 21 U.S.C. 823(g)(1), 824(a)(3). Further, the falsities were material because they were ''predictably capable of affecting . . . [DEA's] official decision'' regarding whether Applicant met ''the requirements for'' registration. *Kungys,* 485 U.S. at 771.

In sum, the Agency finds clear, unequivocal, and convincing record evidence that Applicant's May 2, 2023 application for DEA registration, control number W23054133M, was materially false. 21 U.S.C. 824(a)(1); RFAAX 1, at 12–13.

Further, although the instant OSC concerns whether Applicant's May 2023 application should be granted, the Agency's decision to deny this application may also be based on the material falsification of Applicant's January 2012, October 2013, January 2016, and February 2020 applications, because 21 U.S.C. 824(a)(1) provides that a registration may be revoked or denied based on the material falsification of ''any application filed pursuant to or required by'' the CSA. RFAAX 1, at 9–12.

B. Public Interest

Congress enacted the CSA ''to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances.'' *Gonzales* v. *Raich,* 545 U.S. 1, 12 (2005). A particular concern of Congress was ''the need to prevent the diversion of drugs from legitimate to illicit channels,'' and it ''devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Id.* at 12–13. To protect the American people and ensure compliance with the CSA, Congress empowered the Agency [11] to deny, suspend, or revoke a registration if it would be inconsistent with the public interest. 21 U.S.C. 823(g)(1); 21 U.S.C. 824(a)(4); *Gonzales* v. *Oregon,* 546 U.S. 243, 251 (2006).

In determining whether Applicant's proposed registration is inconsistent with the public interest, the Agency analyzes five statutorily established ''public interest factors.'' *Gonzales* v. *Oregon,* 546 U.S. at 251; 21 U.S.C. 823(g)(1)(A)–(E). The five factors are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1)(A)–(E).

These five public interest factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. at 292–93; *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Any one factor, or combination of factors, may be decisive, *Gillis,* 58 FR at 37508, and the Agency ''may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied.'' *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 185 n.2 (D.C. Cir. 2005) (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.,* 70 FR 33207, 33208 (2007)); *see also Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007).

[11] The CSA grants this authority to the Attorney General, who has delegated it to the Administrator of DEA (the Agency). 28 CFR 0.100.

While the Agency is required to consider each of the factors, it ''need not make explicit findings as to each one.'' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Eleventh Circuit has recognized, Agency decisions have explained that findings under a single factor can support the denial of an application for registration. *Jones Total Health Care Pharmacy,* 881 F.3d at 830; *Pharmacy Doctor Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 Fed. Appx. 724, 729 (11th Cir. 2019).

In this matter, the Government's evidence is confined to Factors B, D, and E. RFAA, at 4; RFAAX 1, at 4. Evidence is considered under Factors B and D when it reflects experience dispensing controlled substances and compliance or non-compliance with laws related to controlled substances. *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). Evidence is considered under Factor E when it constitutes ''[s]uch other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E). To determine whether Applicant's registration is in the public interest, the Agency will evaluate the Government's allegations that Applicant has diverted controlled substances by issuing illegitimate prescriptions for the purpose of obtaining pills for personal use and that Applicant has a lengthy history of abusing controlled substances.[12]

The Government has the burden of proof in this proceeding and the Agency must make its public interest findings based on substantial record evidence. 5 U.S.C. 556(d); 5 U.S.C. 706(2)(E); 21 U.S.C. 877; 21 CFR 1301.44(d). If the Government meets its burden of establishing a *prima facie* case that granting Applicant's registration application is not in the public interest, then the burden shifts to Applicant to rebut the Government's case. *Pharmacy Doctor Enterprises,* 789 Fed. Appx. at 729 (citing *Jones Total Health Care Pharmacy,* 881 F.3d at 830). Here, the Agency finds that the Government's record evidence presents a *prima facie* case that Applicant's registration would be inconsistent with the public interest. 21 U.S.C. 824(a)(4).

Public Interest Factors B and D: Diversion

A lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a); RFAAX 1, at 2. Therefore, ''a physician who engages in the unauthorized practice of medicine is not a practitioner acting in the usual course of professional practice.'' *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007).

Further, a registrant acts outside the usual course of professional practice and in a manner inconsistent with the public interest when he or she issues controlled substance prescriptions to individuals for the purpose of receiving some of the pills in return. *See Michael E. Smith, D.V.M.,* 87 FR 4944, 4950–51 (2022) (finding registrant violated 21 CFR 1306.04(a) and his registration was inconsistent with the public interest where he issued fraudulent prescriptions for controlled substances in order to obtain the drugs for personal use); *Roger A. Pellmann, M.D.,* 76 FR 17704, 17709 (2011) (registrant violated federal law by obtaining controlled substances for ''office use,'' when he, in fact, was diverting the drugs to another individual and himself); *Steven B. Brown, M.D.,* 75 FR 65660, 65662 (2010) (finding registrant violated 21 CFR 1306.04(a) by issuing controlled substance prescriptions in exchange for the individual to provide the registrant with half of the pills); *Randall Relyea, D.O.,* 73 FR 40378, 40380 (2008) (finding registrant's registration to be inconsistent with the public interest where he issued controlled substance prescriptions to individuals with no medical need and instructed them to give the drugs to him).

Here, Applicant admits that around April and May 2013, he issued two prescriptions for carisoprodol in order to obtain some of the pills for personal use. RFAAX 1, at 6. Accordingly, the undisputed record evidence establishes, and the Agency finds, that Applicant has issued controlled substance prescriptions outside the usual course of professional practice and not for legitimate medical purposes in violation of 21 CFR 1306.04(a). *See also Smith,* 87 FR at 4950–51; *Pellmann,* 76 FR at 17709; *Brown,* 75 FR at 65662; *Relyea,* 73 FR at 40380.

Further, the Agency finds that this misconduct reflects poorly on Applicant's experience handling controlled substances and demonstrates non-compliance with Federal law governing controlled substances. 21 U.S.C. 823(g)(1)(B), (D). Accordingly, the Agency finds substantial record evidence that Applicant's registration would be inconsistent with the public interest. 21 U.S.C. 824(a)(4).

Public Interest Factor E: Substance Abuse

Past DEA decisions have consistently held that ''registrants who self-abuse controlled substances may endanger public health and safety,'' and that such misconduct may be considered under Factor E. *See Brewster Drug, Inc.,* 85 FR 19020, 19026 (2020) (collecting cases).

Here, Applicant's admissions establish that Applicant has a long history of abusing controlled substances. Specifically, in 2007 Applicant was addicted to zolpidem and underwent treatment at a chemical addiction recovery program. RFAAX 1, at 4. In addition, in 2013 Applicant was abusing carisoprodol and was in a chemical addiction recovery program. *Id.* at 6. Further, despite being in treatment for addiction to carisoprodol, Applicant ordered carisoprodol tablets through the internet not for a legitimate medical purpose and not within the usual course of his professional practice. *Id.* On two occasions in 2014, Applicant tested positive for carisoprodol when he did not have a prescription for carisoprodol. *Id.* at 7. In November 2020, Applicant stole propofol from an operating room for personal use. *Id.* at 8. In 2015 and 2021, Applicant was subject to orders issued by the Minnesota Board of Medical Practice that, among other things, required Applicant to undergo treatment for chemical dependency, attend self-help program meetings, undergo random drug testing, and demonstrate sobriety. *Id.* at 7–8.

In sum, the Agency finds substantial record evidence that Applicant has abused a variety of controlled substances over a period of many years and continued to do so even after he had been monitored and required to undergo treatment for substance abuse. *Id.* at 4, 6–8. The Agency finds that this lengthy history of substance abuse constitutes ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E); *Brewster Drug, Inc.,* 85 FR at 19026. Accordingly, the Agency finds substantial record

[12] Due to the numerous and egregious public interest violations established in excess of substantial record evidence, the Agency need not address the remaining public interest violations alleged in the OSC.

evidence that Applicant's registration would be inconsistent with the public interest. 21 U.S.C. 824(a)(4).

IV. Sanction

The Agency has found by clear, unequivocal, and convincing record evidence that Applicant submitted five materially false applications for DEA registration and substantial record evidence that his registration would be inconsistent with the public interest due to having committed acts of diversion and demonstrating a lengthy history of substance abuse. 21 U.S.C. 823(g)(1)(B), (D), (E); 21 U.S.C. 824(a)(1), (4). When the Government establishes a *prima facie* case for sanction, as it did here, the Agency then determines the appropriate sanction, which may include denial of an application for registration. 21 U.S.C. 823(g)(1); *see also Pharmacy Doctors Enterprises,* 789 Fed. Appx. at 734 (the Agency is entitled to choose a sanction); *Jeffrey Stein, M.D.,* 84 FR 46968, 46972–73 (2019); *Scott Hansen, A.R.N.P.,* 90 FR 27338, 27341 (2025).

At this stage, the burden is on Applicant to show why he can be entrusted with a registration. *Morall,* 412 F.3d at 174; *Jones Total Health Care Pharmacy,* 881 F.3d at 830; *Garrett Howard Smith, M.D.,* 83 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual. *Stein,* 84 FR at 46972; *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833.

As past performance is the best predictor of future performance, the Agency requires that an applicant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that they will not engage in future misconduct. *See 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). Moreover, the Agency requires an applicant'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 also Jones Total Health Care Pharmacy,* 881 F.3d at 830–31. The Agency also considers the need to deter similar acts by the applicant and by the community of registrants. *Stein,* 84 FR at 46972–73.

Here, Applicant failed to request a hearing and answer the allegations contained in the OSC, and did not otherwise avail himself of the opportunity to prove to the Agency that he can be entrusted with a registration. *See supra* Section I. Thus, there is no record evidence that Applicant takes responsibility, let alone unequivocal responsibility, for the misconduct proven by record evidence. Accordingly, he has not convinced the Agency that he can be entrusted with the responsibilities of a registration.

Further, the interests of specific and general deterrence weigh in favor of denial. Applicant's misconduct in this matter concerns the submission of registration applications that contained material falsities, improper prescribing for the purpose of obtaining controlled substances for personal abuse, and a lengthy history of abusing controlled substances. Thus, the proven misconduct goes to the heart of the CSA's ''strict requirements regarding registration'' and its ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'' *Gonzales* v. *Raich,* 545 U.S. at 12–14. If the Agency were to issue a registration to Applicant under these circumstances, it would send a dangerous message that compliance with the law is not essential to obtaining a registration.

In sum, Applicant has not offered any credible evidence on the record that rebuts the Government's case for denial of his application, and Applicant has not demonstrated that he can be entrusted with the responsibility of a DEA registration. Accordingly, the Agency will order the denial of Applicant's application for registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the application for a DEA Certificate of Registration, Control No. W23054133M, submitted by David S. Pecora, P.A., as well as any other pending application of David S. Pecora, P.A., for registration in Minnesota. This Order is effective November 17, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 1, 2025, by Administrator Terrance 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.

[FR Doc. 2025–19579 Filed 10–16–25; 8:45 am]

BILLING CODE 4410–09–P

POSTAL REGULATORY COMMISSION

[Docket Nos. K2025–944; MC2026–20 and K2026–21; MC2026–22 and K2026–22; MC2026–23 and K2026–23; MC2026–25 and K2026–24]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 22, 2025.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance

with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests. The comment due date discussed above does not apply to Section III proceedings (Docket Nos. MC2026–22 and K2026–22; MC2026–25 and K2026–24).

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

II. Public Proceeding(s)

1. *Docket No(s).:* K2025–944; *Filing Title:* USPS Request Concerning Amendment One to Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1158, with Materials Filed Under Seal; *Filing Acceptance Date:* October 14, 2025; *Filing Authority:* 39 CFR 3035.105 and 39 CFR 3041.505; *Public Representative:* Arif Hafiz; *Comments Due:* October 22, 2025.

2. *Docket No(s).:* MC2026–20 and K2026–21; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 94 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 14, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* October 22, 2025.

3. *Docket No(s).:* MC2026–23 and K2026–23; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1439 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 14, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* October 22, 2025.

III. Summary Proceeding(s)

1. *Docket No(s).:* MC2026–22 and K2026–22; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 880, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 14, 2025; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

2. *Docket No(s).:* MC2026–25 and K2026–24; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 881, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 14, 2025; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2025–19584 Filed 10–16–25; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service.

ACTION: Notice of modified systems of records.

SUMMARY: The United States Postal Service (USPS) is proposing to revise one General Privacy Act System of Records (SOR). The proposed modifications will provide notice of, and additional transparency into the collection and use of records for the implementation of an electronic centralized USPS Tort Claims presentment portal. The Postal Service is focused on continuous improvement efforts that increase effectiveness and efficiency, such as enhancements to functionality and processing capabilities that support ongoing administrative and compliance activities.

DATES: These revisions will become effective without further notice on November 17, 2025, unless responses to comments received on or before that date result in a contrary determination.

ADDRESSES: Comments may be submitted via email to the Privacy and Records Management Office, United States Postal Service Headquarters (*uspsprivacyfedregnotice@usps.gov*). To facilitate public inspection, arrangements to view copies of any written comments received will be made upon request.

FOR FURTHER INFORMATION CONTACT: Janine Castorina, Chief Privacy and Records Management Officer, Privacy and Records Management Office, at 202–268–2000 or *uspsprivacyfedregnotice@usps.gov.*

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition, or when the agency establishes a new system of records. The Postal Service has determined General Privacy Act System of Records, USPS SOR 600.100 General Legal Records, should be revised to provide notice and promote transparency into the collection and use of records for the implementation of an electronic centralized USPS Tort Claims presentment portal, designed to enhance ongoing administrative and compliance activities that meet the requirements of the Federal Tort Claims Act.

I. Background

The United States Postal Service (USPS) is an independent federal establishment of the executive branch

and as such, the Federal Torts Claims Act (FTCA) is applicable to USPS under 39 U.S.C. 409(c). The USPS Law Department, led by the General Counsel, effectively functions as a large law firm with an enormously varied practice. Attorneys for the Postal Service practice in many areas, including: labor and employment, commercial, torts, economic regulation, finance, contracts, intellectual property, real estate, legislation, administrative, international, information, government ethics, and consumer protection law.

II. Rationale for Changes to USPS Privacy Act Systems of Records

The Postal Service continuously seeks to improve processes and procedures that enhance functionality, improve efficiency and increase ease of use for the public. The USPS Law Department is sponsoring an initiative to replace a decentralized, paper-based Tort Claims filing process with a centralized electronic Tort Claims portal. The Tort Claims portal will provide secure access to individuals, attorneys, insurance companies, businesses, claimants, and claimant's representatives who are presenting tort claims and uploading supporting documentation. Secure access is ensured by using a login account and password assigned to registered users that have been properly authenticated.

The electronic Tort Claims presentment Portal will be designed to be easily accessible; to provide the Standard Form 95, Claim for Damage, Injury or Death, and instructions on presenting a tort claim; and to provide confirmation that the submission has been successfully uploaded to the portal. The Portal will also be designed to securely receive personally identifiable information necessary to support tort claims, such as medical records; medical bills; wage loss information; etc. to allow for greater efficiency in real time claim presentment and supporting documentation.

III. Description of the Modified System of Records

The Postal Service is proposing modifications to USPS SOR 600.100 General Legal Records as indicated in the summary of changes listed below:

- Updated System Location with updated name.
- Added new Purpose number 2, amended the original Purpose number 2 and split it into Purpose numbers 3 and 4, then renumbered the remaining Purpose as number 5.
- Added new Category of Individuals number 2 and renumbered subsequent Categories of Individuals.
- Added new Category of Records number 2.
- Updated Record Source Categories.

Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed revisions has been sent to Congress and to the Office of Management and Budget (OMB) for their evaluations. The Postal Service does not expect this amended system of records to have any adverse effect on individual privacy rights. USPS SOR 600.100 is provided below in its entirety.

SYSTEM NAME AND NUMBER:

USPS 600.100 General Legal Records.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Law Department, USPS Headquarters and field offices; area and district facilities; Integrated Business Solutions Services Centers; National Tort Center; and Post Offices.

SYSTEM MANAGER(S) AND ADDRESS:

General Counsel and Executive Vice President, United States Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

39 U.S.C. 401, 409, 1206, and 1208.

PURPOSE(S) OF THE SYSTEM:

1. To provide legal advice and representation in NLRB cases, labor or employment litigation, and miscellaneous civil actions and litigation.

2. To facilitate the electronic presentment of Tort Claims and supporting documentation through a secure centralized claims presentment portal system.

3. To adjudicate, settle, or defend against tort claims made under the Federal Tort Claims Act;

4. To support program management by accident prevention and safety officers; and to provide pertinent information regarding safety, accidents, and claims to equipment providers and insurers.

5. To protect USPS intellectual property and patents.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

1. Current or former USPS employees who are parties to National Labor Relations Board (NLRB) cases, or on whose behalf NLRB charges are filed by a collective bargaining representative, and other individuals involved in labor or employment litigation.

2. Claimants and claimant's representatives who are presenting tort claims, including individuals, attorneys, insurance companies, and businesses who claim to be involved in accidents related to USPS operations and who seek money damages under the Federal Tort Claims Act (FTCA).

3. Individuals investigated for possible infringement of USPS intellectual property rights, including inventors seeking patents for devices.

4. Individuals involved in other formal administrative proceedings or litigation in which USPS is a party or has an interest in which information or testimony is sought.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. Records related to proceedings, including individuals' names, Social Security Numbers, postal assignment information, work contact information, finance number(s), duty location, pay location, assigned case or docket numbers, and other details related to the nature of the litigants and litigation subject matter.

2. Records pertaining to Torts Claims including but not limited to the Standard Form 95, Claim for Damage, Injury, or Death: claimant's name, address, claimant's representative name, type of employment, date of birth, marital status, date and day of accident, basis of claim, property damage: name and address of owner (if other than claimant), description of property, nature and extent of the damage and the location of where the property may be inspected; personal injury/wrongful death: nature and extent of each injury or cause of death, if other than claimant, name of the injured person or decedent; witnesses: name and address; amount of claim: property damage, personal injury, wrongful death, total; signature of claimant, phone number of claimant signing form, date of signature; insurance coverage: insurance company name, address, insurance policy number, coverage or deductible with deductible amount, action taken or proposed to be taken by insurer if claim filed; tort claims presented via letter, medical records, medical bills, Explanation of Benefits Forms, medical bill summaries, medical records summaries, lost wage information, tax returns, financial records, photographs, life care plans, economist reports, medical expert reports, business records, property repair estimates, total loss of property documentation, valuation reports, police reports, video footage, statements, birth certificates,

death certificates, estate documentation, titles, deeds, license and registration information, and insurance policy information including declaration pages.

RECORD SOURCE CATEGORIES:

Subject individuals; their counsel or other representative; For FTCA, individuals, their counsel or other representative, insurance companies, corporate entities and businesses; external authorities such as the NLRB, Equal Employment Opportunity Commission, or Merit System Protection Board; customers; police; postal inspectors; witnesses; American Insurance Association Index reports; and other systems of records.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Standard routine uses 1. through 9. apply. In addition:

a. Tort claims records may be disclosed to members of the American Insurance Association Index System; to insurance companies that have issued policies under which the United States is or may be an (additional) insured; to equipment manufacturers, suppliers, and their insurers for claims considerations and possible improvement of equipment and supplies; and in response to a subpoena or other appropriate court order.

b. A record may be transferred and information from it disclosed to the Patent and Trademark Office or the Library of Congress when relevant in any proceeding involving the registration of Postal Service trademarks or issuance of patents.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Automated database, computer storage media, and paper.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

By name of subject individual, litigant, claimant, charging party, or individual on whose behalf a charge has been filed; case number, docket number, or topic title.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSTAL OF RECORDS:

1. Labor litigation records are retained 5 years.

2. Tort claim files are retained 7 years after final adjudication or other closure. Tort litigation files are retained 5 years after closure.

3. Records of investigations of possible infringement of USPS intellectual property rights are retained 25 years after closure of the case.

4. Records of miscellaneous civil actions and administrative proceedings are retained 10 years.

Records existing on paper are destroyed by burning, pulping, or shredding. Records existing on computer storage media are destroyed according to the applicable USPS media sanitization practice.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records, computers, and computer storage media are located in controlled-access areas under supervision of program personnel. Access to these areas is limited to authorized personnel, who must be identified with a badge.

Access to records is limited to individuals whose official duties require such access. Contractors and licensees are subject to contract controls and unannounced on-site audits and inspections.

Computers are protected by mechanical locks, card key systems, or other physical access control methods.

The use of computer systems is regulated with installed security software, computer logon identifications, and operating system controls including access controls, terminal and transaction logging, and file management software.

RECORD ACCESS PROCEDURES:

Requests for access must be made in accordance with the Notification Procedure above and USPS Privacy Act regulations regarding access to records and verification of identity under 39 CFR 266.5.

CONTESTING RECORD PROCEDURES:

See Notification Procedures and Record Access Procedures.

NOTIFICATION PROCEDURES:

Individuals wanting to know if information about them is maintained in this system of records must address inquiries to the system manager. Inquiries must include full name of litigant, charging party, or individual on whose behalf a charge has been filed, case number or docket number, if known, and the approximate date the action was instituted.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Records in this system that have been compiled in reasonable anticipation of a civil action or proceeding are exempt from individual access as permitted by 5 U.S.C. 552a(d)(5). The USPS has also claimed exemption from certain provisions of the Act for several of its other systems of records at 39 CFR 266.9. To the extent that copies of exempted records from those other systems are incorporated into this system, the exemptions applicable to the original primary system continue to apply to the incorporated records.

HISTORY:

October 24, 2011, 76 FR 65756.

Matthew W. Tievsky,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2025–19582 Filed 10–16–25; 8:45 am]

BILLING CODE 7710–12–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21328 and #21329; ARIZONA Disaster Number AZ–20013]

Administrative Declaration of a Disaster for the State of Arizona

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Arizona dated October 10, 2025.

Incident: Gila County Flooding Event.

DATES: Issued on October 10, 2025.

Incident Period: September 25, 2025 through September 27, 2025.

Physical Loan Application Deadline Date: December 9, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: July 10, 2026.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Gila.

Contiguous Counties:

Arizona: Coconino, Graham, Maricopa, Navajo, Pinal, Yavapai.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	6.000
Homeowners without Credit Available Elsewhere	3.000
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 213286 and for economic injury is 213290.

The States which received an EIDL Declaration are Arizona.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 1234.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2025–19575 Filed 10–16–25; 8:45 am]

BILLING CODE 8026–09–P

FEDERAL REGISTER

Vol. 90 Friday,
No. 199 October 17, 2025

Part II

The President

Proclamation 10983—National Day of Remembrance for Charlie Kirk

Federal Register
Vol. 90, No. 199
Friday, October 17, 2025

Presidential Documents

Title 3—

The President

Proclamation 10983 of October 14, 2025

National Day of Remembrance for Charlie Kirk

By the President of the United States of America

A Proclamation

On the afternoon of Wednesday, September 10, 2025, pure evil struck when the legendary Charlie Kirk was assassinated in broad daylight in a campus courtyard, triggering a groundswell of righteous fury all across our land. Today, our Nation honors the immortal memory of Charlie—a father, a husband, a Christian martyr, and a titan of the American conservative movement. We honor his life, we send our condolences to his beautiful family, and we pledge to advance the values for which he laid down his life.

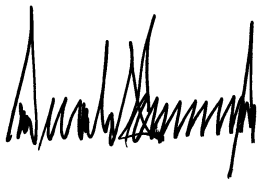
Every day, Charlie devoted himself to a set of simple causes: Defending the truth, encouraging debate, and spreading the Gospel of Jesus Christ. He was gracious and articulate beyond measure, always welcomed opposing perspectives, and never deviated from his noble goal of bridging our political, cultural, and philosophical divides.

As we mourn this extraordinary loss, my Administration will continue to do everything in its power to end this devastating wave of political violence. No civilized country can endure a culture where open debate is met with gunfire, the pursuit of truth is met with bloodshed, and love of country is met with seething hatred. In Charlie's absence, we are now tasked with continuing his mission of giving voice to our cherished American ideals with confidence and clarity. Like him, we must not flinch in the face of darkness and hostility—and we must never waver in speaking the truth with joyful and steadfast resolve.

Today, on what would have been his 32nd birthday, our Nation honors the loving memory of Charlie Kirk. We offer our condolences to his beautiful wife, Erika, and two precious children. We call on every American to pray for peace in our public square. Above all, we renew our resolve to always defend our principles of truth, faith, and the open exchange of ideas.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 14, 2025, as a National Day of Remembrance for Charlie Kirk. I call on the American people to assemble on this day in their respective places of worship, there to pay homage to Charlie's memory. I invite the people of our Nation to pray for the advancement of peace, truth, and justice all across our country.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of October, in the year of our Lord two thousand twenty-five, and of the Independence of the United States of America the two hundred and fiftieth.



[FR Doc. 2025–19594
Filed 10–16–25; 11:15 am]
Billing code 3395–F4–P

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Federal Register

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FEDERAL REGISTER PAGES AND DATE, OCTOBER

CFR PARTS AFFECTED DURING OCTOBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List September 9, 2025

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