

## 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. FM6088997 issued to Carrie Madej, D.O. 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 Carrie Madej, D.O., to renew or modify this registration, as well as any other pending application of Carrie Madej, D.O., for additional registration in Georgia. This Order is effective August 23, 2024.

## Signing Authority

This document of the Drug Enforcement Administration was signed on July 15, 2024, by Administrator Anne Milgram. 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. 2024-16213 Filed 7-23-24; 8:45 am]

BILLING CODE 4410-09-P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 23-42]

#### John Qian, MD; Decision and Order

On May 3, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to John Qian, M.D., (Respondent) of San Diego, CA. OSC, at 1, 7. The OSC proposed the denial of Respondent's application for a DEA Certificate of Registration (Registration), Application Control No. W22061401C, alleging that the issuance of the registration would be inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. 823(g)(1)).

A hearing was held before DEA Chief Administrative Law Judge John J. Mulrooney (the Chief ALJ), who, on October 19, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which

recommended denial of Respondent's application. RD, at 27. Respondent did not file Exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, findings of fact, conclusions of law, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

#### I. Findings of Fact

Respondent was previously registered with the DEA to prescribe controlled substances in California. *John X. Qian, M.D.* (“*Qian I*”), 87 FR 8039, 8058 (2022). The Agency issued an OSC and Immediate Suspension of Registration to Respondent on November 18, 2019 (2019 OSC/ISO), recommending that his previous Registrations be revoked on the grounds that they were inconsistent with the public interest. RD, at 3 (citing 21 U.S.C. 824(a)(4)). Respondent's Registrations were immediately suspended because the Agency determined that there was an imminent danger to the public health or safety from continuing his Registrations during the pendency of the proceeding. RD, at 3 (citing 21 U.S.C. 824(d); 21 CFR 1301.36(e)). On February 11, 2022, following a hearing on the merits (2020 Hearing), the Agency revoked Respondent's previous Registrations. RD, at 3; *Qian I*, 87 FR at 8058.<sup>1</sup>

Approximately three months later, on May 26, 2022, Respondent filed an application for a new registration. RD, at 3. The Agency issued an OSC on May 3, 2023, proposing that the application be denied based on the same conduct alleged in the 2019 OSC/ISO. *Id.* at 2. Following Respondent's request for a hearing, the Government filed a Partial Motion for Summary Disposition (the PMSD), arguing that the Agency's final order in *Qian I* satisfied the Government's prima facie case that it would be inconsistent with the public interest to grant Respondent's application. *Id.* at 2-3; ALJX 8, at 5-17. The Chief ALJ granted the Government's unopposed PMSD and found that the sole remaining issue to determine at the August 2023 Hearing (2023 Hearing) was whether Respondent could be entrusted with a registration. RD, at 2-3. The Chief ALJ also found that the Agency's factual findings, legal

<sup>1</sup> Following publication of *Qian I* in the **Federal Register**, Respondent filed a Petition for Review with the Court of Appeals. *Qian v. DEA*, No. 22-70039 (9th Cir. filed Mar. 2, 2022). After the Court of Appeals extended the initial briefing schedule on four separate occasions, the petition was administratively closed on December 15, 2022. On April 13, 2023, Respondent filed a Motion to Voluntarily Dismiss the Appeal, which the Court of Appeals granted on April 28, 2023.

conclusions, and credibility determinations in *Qian I* should be afforded preclusive effect in this proceeding.<sup>2</sup> The Agency agrees.

Because the Agency's factual findings in *Qian I* serve as the basis for the Government's prima facie case, they are briefly summarized here.<sup>3</sup> In *Qian I*, the Agency found that Respondent had issued one-hundred and fifteen prescriptions to three patients from 2017 through 2019 in violation of federal and state law and beneath the standard of care for prescribing controlled substances in California. RD, at 4; *Qian I*, 87 FR 8057. The Agency found that Respondent had issued these prescriptions without performing or documenting adequate physical examinations, developing or documenting adequate treatment plans, developing or documenting a justification for prescribing controlled substances, or resolving or documenting resolution of diversion red flags. RD, at 4-5; *Qian I*, 87 FR 8039 n.1, 8040, 8045 n.27, 8050, 8055-57. The Agency also found that Respondent had repeatedly copied language verbatim throughout his medical records, which violated the California standard of care and significantly undermined the medical records' credibility. RD, at 5; *Qian I*, 87 FR 8055. Respondent's recordkeeping errors were egregious; for example, in one medical record, Respondent copied forward his description of a physical examination verbatim over twenty-one visits for fifteen months without adding any new information. *Id.* at 8048. Respondent then added an additional

<sup>2</sup> RD, at 3-4, 4 n.9 (citing *Jose G. Zavaleta, M.D.*, 78 FR 27431, 27434 (2013) (“[T]he Agency's factual findings and legal conclusions are entitled to preclusive effect in a subsequent proceeding.”); *Robert L. Dougherty, M.D.*, 76 FR 16823, 16830 (2011) (“[W]here, as here, an applicant has previously been the subject of an Agency Final Order, the doctrine of *res judicata* bars the relitigation of the factual findings and conclusions of law of the prior proceeding absent the applicant's establishing that he falls within one of the doctrine's recognized exceptions.”); see also *Univ. of Tenn. v. Elliott*, 478 U.S. 788, 797 (1986) (“[I]t is sound policy to apply principles of issue preclusion to the factfinding of administrative bodies acting in a judicial capacity.”); *United States v. Utah Constr. & Mining Co.*, 384 U.S. 394, 422 (1966) (“When an administrative agency is acting in a judicial capacity and resolved disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata* to enforce repose.”)).

<sup>3</sup> The Government's only witness at the 2023 Hearing was Diversion Group Supervisor (GS) Ann Malta-Chi, who testified briefly to authenticate and lay foundation for Respondent's Certificate of Non-Registration. RD, at 6; Tr. 21-23; GX. 1. The Agency agrees with the Chief ALJ that the GS presented as an impartial regulator, testifying to matters that were not in serious contention, and that her testimony was sufficiently detailed, plausible, and internally consistent to be fully credited. RD, at 6.

eight physical tests to the description and copied forward the new description verbatim for an additional seventeen months. *Id.* Meanwhile, Respondent was prescribing this patient “astronomically high” dosages of opiates along with a long-acting benzodiazepine—a combination that poses a serious risk of death—without documenting whether safer methods had been tried or even what conditions he was treating with these controlled substances. *Id.* at 8046–48, 8057. The Agency found that Respondent’s documentation was “so egregiously bad that it [was] difficult to determine what steps [he] was taking to ensure this patient’s safety, or even why a particular controlled substance was being prescribed.” *Id.* at 8058. Respondent failed to accept responsibility for his recordkeeping violations, testifying that there may have been “some mistakes,” but “overall [his] charts [were] good” and “above average.” *Id.*

Respondent also failed to resolve red flags presented by his patients, including failing to adequately address an inconsistent urine drug screen that showed that the patient was taking two controlled substances that had not been prescribed and that posed serious risks when taken with the opioids prescribed by Respondent. *Id.* at 8051–52. Respondent’s prescribing patterns were similar with all three patients and they were so dangerous that the Agency determined that Respondent’s prescribing practices created a risk of death. RD, at 5–6; *Qian I*, 87 FR 8047–53, 8057.

As discussed in more detail below (*see infra* § II), the Agency found in *Qian I* that the Government had met its prima facie burden of demonstrating that Respondent’s registration was inconsistent with the public interest under the Controlled Substances Act (CSA), and the burden shifted to Respondent to prove that he could be entrusted with a registration. *Qian I*, 87 FR 8057–58. The Agency found that Respondent did not prove that he could be entrusted with a registration because he did not accept responsibility for his egregious conduct, and determined that the appropriate remedy was revocation. *Id.*

## II. Discussion

### A. The Five Public Interest Factors

Under the CSA, “[a] registration . . . to . . . 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 section 823 of this

title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(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. 21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. The Government satisfied its burden based on the Agency’s findings in *Qian I*, which are binding in this case. In *Qian I*, the Agency considered all of the public interest factors in 21 U.S.C. 823(g)(1),<sup>4</sup> and revoked Respondent’s registration primarily based on evidence under Factors B and D (formerly Factors 2 and 4). 87 FR 8055–58; RD, at 21–22. Evidence is considered under Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See*

<sup>4</sup> In *Qian I*, Respondent argued that Factor A weighed in his favor because the Medical Board of California (MBC) had ordered probation rather than revocation after receiving a complaint against his license. 87 FR 8054. The Agency found that the MBC’s order should receive “minimal to no weight” under Factor A because the conduct at issue in *Qian I* involved different patients, a different timeframe, and altogether different misconduct than the subject of the MBC’s order, and there was no evidence of what the MBC would have concluded if it had considered the same misconduct as the Agency considered in *Qian I*. *Id.* Regarding Factor C, the Agency found that the absence of a conviction related to controlled substances was not dispositive based on longstanding Agency precedent. *Id.* (citing *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010)). Finally, the Agency found that the absence of evidence of “other conduct which may threaten the public health and safety” under Factor E did not militate for or against a finding that Respondent’s registration was inconsistent with the public interest. RD, at 21–22 n.57.

*Sualeh Ashraf, M.D.*, 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). The Agency found that Factors B and D weighed against Respondent’s continued registration because Respondent had issued numerous controlled substance prescriptions in violation of state and federal law and beneath the standard of care in California. *Qian I*, 87 FR 8055–57. Based on the Agency’s findings in *Qian I*, the Agency finds that Respondent’s continued registration is inconsistent with the public interest under 21 U.S.C. 823(g)(1). RD, at 21–22.<sup>5</sup>

### III. Sanction

Where, as here, the Government has established sufficient grounds to deny Respondent’s Application, the burden shifts to Respondent to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18904 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken remedial measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62316, 62339 (2012). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency’s interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33738, 33746 (2021).

At the 2020 Hearing in *Qian I*, Respondent explicitly denied

<sup>5</sup> Respondent offered into evidence four letters drafted by doctors to support his request for early termination of the MBC’s probation. RD, at 17–18; RX L, M, N, O. The Agency considered these letters, but found them to have limited probative value because they do not address whether granting Respondent’s application is in the public interest. RD, at 18 (citing, *e.g., George Pursley, M.D.*, 85 FR 80162, 80180 (2020) (noting that the applicant submitted “written statements of support . . . [that] provided limited evidence relevant to Applicant’s controlled substance prescribing” and therefore were “of limited value”); *Mark P. Koch, D.O.*, 79 FR 18714, 18736–37 (2014) (finding that supportive testimony about a practitioner’s professional reputation “carries little value under the public interest analysis because it does not bear a connection to Respondent’s ability to handle controlled substances”); *Michael S. Moore, M.D.*, 76 FR 45867, 45873 (2011) (“In evaluating the weight to be attached to the representations in the letters provided by the Respondent’s hospital administrators and peers, it can hardly escape notice that, in addition to the fact that the authors were not subjected to the rigors of cross examination, each source has a significant influencing consideration that bears caution.”)).

responsibility for his misconduct, maintaining that his recordkeeping was “above average” and offering other incredulous and false testimony under oath. *Qian I*, 87 FR 8052. The Agency found that some of his testimony was “self-serving to the point it denied belief.” *Id.* at 8042. For example, Respondent defended an inconsistent urine drug screen by suggesting that there might have been “liquid contamination” that caused the substance to show up in the screen without the patient having consumed the substance. *Id.* When asked what “liquid contamination” meant, Respondent suggested that the patient may have been in close proximity to someone else who was taking the drug, and that person may have dropped some of the substance into the patient’s food, causing her to accidentally ingest it. *Id.* at 8051. This illogical testimony was discredited by the Government’s expert. *Id.* at 8042. Another area where the Agency found that Respondent’s testimony was untruthful was his suggestion that rather than mechanically copying forward the same description month-after-month in his medical records, he performed the same exact examination each month and made the same selections in the software, which generated an identical description. *Id.* The Agency called a representative from the software company to testify, who discredited Respondent’s testimony and conclusively established that the medical records had been copied forward repeatedly. *Id.* at 8041. Respondent’s lack of candor during the 2020 Hearing bolstered the Agency’s conclusion that he could not be entrusted with a registration.

Although Respondent was more contrite at the 2023 Hearing, his acceptance of responsibility lacked the requisite remorse and sincerity to be considered unequivocal.<sup>6</sup> During the course of his testimony, Respondent indicated that he accepted responsibility for several defects in his treatment of patients in *Qian I*, as well as defects in his treatment of patients identified in a January 31, 2020

<sup>6</sup> The Agency incorporates herein the entire summary of Respondent’s testimony and the Chief ALJ’s credibility findings with respect to Respondent. RD, at 12–21. The Agency agrees with the Chief ALJ that Respondent was the witness at the 2023 Hearing with the most to gain by his testimony and that there are additional features of his testimony that supply reason for caution, including that he declined to unequivocally accept responsibility for his perjurious statements in *Qian I*. RD, at 20–21. The Agency also agrees with the Chief ALJ that while there are certain portions of this testimony that appear truthful, such as biographical details, his claims of remorse and acceptance of responsibility were not sufficiently credible for him to prevail on this issue. *Id.*

probationary order by the Medical Board of California (MBC Order). For example, Respondent indicated that he accepted responsibility for failing to adequately monitor and assess the patients under his care taking opioids, Tr. 116, 125–27, 135–38, 150–53; failing to recognize signs of drug abuse in cases where some of his patients should have been referred to addictionologists, *id.* at 123–24; failing to adequately document his medication decisions, *id.* at 123–24, 131–132, 139–40, 142–46, 156–57; failing to consider the input of his patients’ family members, *id.* at 136; failing to conduct adequate physical examinations, *id.* at 147–49, 156, 161; and failing to acquire sufficient patient histories, *id.* at 149. RD, at 13. Respondent also acknowledged that he failed to recognize the risks of concurrently prescribing opioids, benzodiazepines, and carisoprodol. RD, at 13; Tr. 116–22, 126, 134–35. Additionally, Respondent testified that he broadly accepted responsibility for the findings in *Qian I*. RD, at 14; Tr. 158.

However, many of Respondent’s statements accepting responsibility were undermined by other portions of his testimony, particularly his explanations for why he committed the errors and omissions in *Qian I*. For example, he blamed his failure to comply with the standard of care on unspecified “guideline changes,” and referred to the pain management guidelines as “rapidly changing.” RD, at 14; Tr. 128; RX R, at 8. He testified that the guidelines had changed three times since he had been practicing, and that the changes were “always indicated for primary care physician,” but as a specialist he became “a little bit [ ] complacent.” Tr. 128. Respondent, however, did not explain what rules had changed, how those rules had changed, or why the rules were different for him as a specialist.<sup>7</sup> This testimony is concerning because the deficiencies outlined in *Qian I*—such as failure to have a medical justification for the controlled substances prescribed, failure to warn about the dangers of concurrent prescriptions for opioids and benzodiazepines, failure to resolve red flags of abuse and diversion, and failure to maintain accurate medical records—

<sup>7</sup> Respondent contends that the guidelines for pain management specialists are less defined than for general physicians, but California law requires all doctors to maintain adequate and accurate records, perform appropriate physical examinations, and establish a medical indication before prescribing controlled substances. RD, at 15, 17; RX R, at 9; Cal. Bus. & Prof. Code sections 2266, 2242(a).

are core failures that violated bedrock principles of the CSA.

Respondent also occasionally blamed others for his violations. For example, when asked why he failed to refer one of his patients to an addictionologist, he testified that he had made the referral, but it “never got carried out.” RD, at 13 n.37; Tr. 123. And while Respondent admitted to errors in his recordkeeping, he also explained that he was new to electronic medical records (EMRs), the copy forward feature was important for patient flow, and the physician’s assistants who worked with him were complaining that the paperwork was arduous. RD, at 14; Tr. 130–33, 161, 163. Respondent also declined an opportunity to accept responsibility for falsifying his medical records. RD, at 14–15; Tr. 143–45. Although he conceded that he probably needed to conduct more detailed examinations, he testified that his examinations had been consistent with his training and that he thought they had been complete. *Id.*

Respondent was also evasive when asked to address the areas in *Qian I* where the Agency found that he had presented false testimony. Respondent initially explained that he was not lying to the prior ALJ and offered various explains for his testimony, including that he had been defensive, hypothetical, nervous, and speculative, and that he had misspoken. RD, at 14; Tr. 158–61, 163, 166–67. After returning from a recess requested by his counsel, Respondent reluctantly conceded that some of his statements were not accurate or truthful. RD, at 14; Tr. 158–61, 166–67). Respondent’s testimony falls short of the unequivocal acceptance that is required from someone who previously lied under oath.

Respondent entered a proposed Corrective Action Plan (CAP) into the record, which contains additional statements that detract from his acceptance of responsibility and minimize the Agency’s findings in *Qian I*.<sup>8</sup> The CAP asserts that “the underlying reasons for the revocation of [Respondent’s registration] did not involve patient harm.” RD, at 16; RX R, at 6. Although it is not necessary for the Agency to find patient harm to revoke

<sup>8</sup> Although the CAP was submitted to the Agency after the deadline set by the OSC, the Agency agrees with the Chief ALJ’s decision to accept it into the record and treat it as a sworn statement, because Respondent testified that he would adhere to its terms and the Government had an opportunity to cross examine him. RD, at 15–16; ALJX 1, at 6; see 21 U.S.C. 824(c)(2)(C). The Agency also agrees with the Chief ALJ that the CAP is of limited utility in supporting Respondent’s application. RD, at 17.

a registration,<sup>9</sup> and the Agency did not find specific evidence of patient harm in *Qian I*, the Agency found that Respondent's prescribing created a risk of death and that his "documentation [was] too deficient to conclusively determine that no harm occurred." 87 FR 8057. Respondent's statement that *Qian I* did not involve patient harm indicates that he does not appreciate the dangers posed by his prescribing.<sup>10</sup>

Further, in *Qian I*, the Agency noted that Respondent's "repeated and systematic violations of [his] obligations to document required elements of the standard of care when prescribing high dosages of opioids manifests a disturbing pattern of indifference." 87 FR 8057. This indifference carried over into Respondent's testimony at the 2023 hearing. He testified that he had become complacent with some of his patients, particularly those who were medical practitioners or personal acquaintances. Tr. 127. For example, he testified, "often you have nurse practitioner, could be a little bit loose, a more combo." *Id.* He also testified that he let his guard down with long-term patients and they became more like friends. *Id.* at 200. This testimony exhibits a lack of appreciation for medical ethics and the dangers of prescribing controlled substances, and Respondent's testimony did little to convince the Agency that he has been sufficiently rehabilitated to be trusted with a registration. Thus, the ALJ found, and the Agency agrees, that Respondent did not unequivocally accept responsibility for his misconduct. RD, at 24.

Although it is not necessary to consider Respondent's remedial measures if he has failed to unequivocally accept responsibility,<sup>11</sup> Respondent presented very little evidence that can be fairly characterized as remedial measures, and most of these measures were either mandated by the MBC or lacked sufficient specificity to

signal meaningful change. *Id.* at 24–25. First, Respondent submitted evidence of approximately 342 hours of continuing medical education (CME) courses from 2020 through 2022,<sup>12</sup> approximately seventy-five of which arguably relate to remedial measures.<sup>13</sup> *Id.* at 19. However, most of these classes were either required by the MBC Order, or had also been previously completed by Respondent in 2013 and 2018 prior to issuing many of the prescriptions in this case. *Id.*; RX E–F; ALJX 15, app. at 118. The Agency has no reason to believe that Respondent would change his practices after taking these same courses again, and the fact that these courses were required by the MBC's Order detracts some from their weight as remedial measures.

Second, Respondent asserts that he has implemented a new EMR software that does not allow for patient examination records to be copied forward, but he did not supply any corroborating documentation confirming that the EMR lacks that feature. RD, at 17; Tr. 130. Even if it does, the implementation of a new EMR requires minimal effort and does not address the Agency's underlying concerns that Respondent does not fully appreciate his obligations under the CSA.

Third, as discussed in more detail *supra*, Respondent offered extensive testimony pledging to follow California's most recent Guidelines for Prescribing Controlled Substances for Pain. RD, at 20. To the extent that this testimony may be considered remedial in nature, the Agency agrees with the Chief ALJ that this testimony was not compelling, and it is unclear why the Agency should trust Respondent to comply with guidelines in the future that he declined to comply with previously. *Id.*

Finally, Respondent has been under mandatory monitoring by an MBC-appointed physician, Dr. Bitonte, since January 2021, and Respondent testified that he is willing to retain Dr. Bitonte as a monitor even if his probation with the MBC ends.<sup>14</sup> However, neither Dr.

Bitonte nor Respondent demonstrated in their testimony that Dr. Bitonte's monitoring has aided in remediating Respondent. Dr. Bitonte did not oversee Respondent's prescribing of controlled substances because Respondent did not possess a DEA registration while Dr. Bitonte monitored him (RD, at 12; Tr. 46, 56, 62, 73; ALJ Ex. 28, at 6). Dr. Bitonte also did not observe any of Respondent's encounters with his patients, which precluded him from addressing one of the Agency's primary concerns in *Qian I*, that Respondent's medical records did not accurately reflect what occurred during the patient encounters. RD, at 8–9. Additionally, Dr. Bitonte testified that he has not prescribed controlled substances since 2014 and is no longer comfortable doing so because opiate prescribing has become a specialty. RD, at 7; Tr. 83–84. This testimony suggests that Dr. Bitonte would not be the ideal candidate for monitoring Respondent's reinstated prescribing of controlled substances. Finally, Dr. Bitonte's opinions at the hearing and in his regular practice monitoring reports (PMRs) were conclusory and repetitive,<sup>15</sup> which suggests that Dr. Bitonte's monitoring lacked the level of involvement necessary to help Respondent reform his recordkeeping practices, which are a vital component of the CSA's efforts to prevent diversion of controlled substances.<sup>16</sup> Thus, the Agency agrees with the Chief ALJ that the potential remedial measures identified by Respondent are not sufficient to establish that Respondent can be trusted with a registration, especially in light of

termination of his probation with the MBC, which would eliminate the monitoring requirement. RD, at 16; RX R, at 3; ALJX 15, app. at 173.

<sup>15</sup> Dr. Bitonte's PMRs primarily consist of statements that Respondent's records were "complete and in order" and "excellent," and that Respondent's practice is "markedly different from the [practice] described in the [MBC Order]" because he is "now almost exclusively providing pain management by interventional procedures, consulta[tions] for outside physicians, and electrodiagnostics for outside providers." RD, at 8–10; Tr. 73, 77–78; RX H at 7, 14, 18, 23, 27, 40, 47.

<sup>16</sup> The Agency incorporates herein the entire summary of Dr. Bitonte's testimony and the Chief ALJ's credibility findings with respect to Dr. Bitonte. RD, at 7–12. The Agency agrees with the Chief ALJ that there were inconsistencies and weaknesses that detracted from Dr. Bitonte's credibility, including that Dr. Bitonte initially testified that he had reviewed *Qian I*, and then later conceded that he had not. *Id.* at 11–12; Tr. 46, 89–94, 99–101. The Agency also agrees that there were portions of Dr. Bitonte's testimony that can be afforded full credibility, such as details of his monitoring assessment and his monitoring methodology. RD, at 12. Ultimately, however, the Agency does not find that Dr. Bitonte's testimony is entitled to significant weight in analyzing whether Respondent can be entrusted with a registration because he did not observe his patient encounters.

<sup>9</sup> *Melanie Baker, N.P.*, 86 FR 23998, 24009 (2021); *Larry C. Daniels, M.D.*, 86 FR 61630, 61660–61 (2021); *Jeanne E. Germeil, M.D.*, 85 FR 73786, 73799 n.32 (2020); *Qian I*, 87 FR 8056 (noting that Respondent had not cited any legal authority for the proposition that the Agency must find patient harm in order to suspend or revoke a registration, and revoking Respondent's registration notwithstanding the absence of a specific demonstration of harm).

<sup>10</sup> The Agency has previously found that a respondent's minimization of his misconduct weighs against a finding of unequivocal acceptance of responsibility. See, e.g., *Morris & Dickson Co.*, 88 FR 34523, 34538 (2023) (citing *Ronald Lynch, M.D.*, 75 FR 78745, 78754 (2010) (finding that Respondent did not accept responsibility after noting that he "repeatedly attempted to minimize his [egregious] misconduct"); *Michael White, M.D.*, 79 FR 62957, 62967 (2014) (similar)).

<sup>11</sup> *Ajay S. Ahuja, M.D.*, 84 FR 5479, 5498 n.33 (2019); *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care*, 81 FR 79188, 79202–03 (2016).

<sup>12</sup> Respondent's records include duplicate certificates and repeated courses, which the Agency does not credit. RD, at 19. Several of Respondent's certificates are also unsigned, and they do not claim any credits for the courses, which calls into question the level of Respondent's participation in these classes. RD, at 19; RX E–F. The courses direct the student to "claim the credit commensurate with the extent of their participation in the activity." *Id.*

<sup>13</sup> These courses related to physician prescribing and medical recordkeeping. RD, at 19.

<sup>14</sup> Although Dr. Bitonte and Respondent testified that they are willing to continue Dr. Bitonte's monitoring if the Agency orders them to do so, the record indicates that Respondent is requesting early

his failure to unequivocally accept responsibility for his actions. RD, at 19–21.

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). In this case, the Agency agrees with the Chief ALJ that Respondent's failure to fully acknowledge his wrongdoing suggests that these revocation proceedings have not sufficiently deterred him from future violations. RD, at 25–26. Although Respondent demonstrated some level of interest in complying with the applicable rules and regulations going forward, which suggests that the likelihood of recidivism may be reduced, on balance the considerations of specific deterrence do not support Respondent's application in this case. *Id.* Further, the Agency agrees with the Chief ALJ that the interests of general deterrence also support revocation. *Id.* at 26. A decision to grant Respondent's application now, despite Respondent's failure to fully accept responsibility for his misconduct, would send a message to the registrant community that lying to the Agency and prescribing controlled substances without conducting and documenting even the most basic examinations and mitigation measures can be overlooked or excused. *Id.*

Moreover, the Agency agrees with the Chief ALJ that Respondent's actions were egregious. *Id.* at 25. Respondent prescribed dangerous combinations of benzodiazepines and high-dose opioids while failing to conduct appropriate examinations, monitor for compliance, or maintain accurate medical records, leading the Agency to conclude that he had put his patients at risk of death. *Id.* Respondent also misled the tribunal in his first hearing and failed to adequately acknowledge the untruthful testimony in his second hearing. In this case, the Agency believes that denial of Respondent's application would encourage the general registrant community to exhibit candor when dealing with the Agency, conduct and document appropriate medical examinations, and monitor their patients carefully to ensure that the controlled substances that they prescribe do not harm their patients or fall into illegitimate channels where they can be abused or diverted.

In sum, Respondent has not offered any credible evidence on the record to rebut the Government's case for denial of his application and Respondent has not demonstrated that he can be entrusted with the responsibility of registration. *Id.* at 26–27. Accordingly,

the Agency will order that Respondent's application be denied.

#### 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 pending application for a Certificate of Registration, Control Number W22061401C, submitted by John Qian, M.D., as well as any other pending application of John Qian, M.D., for additional registration in California. This Order is effective August 23, 2024.

#### Signing Authority

This document of the Drug Enforcement Administration was signed on July 16, 2024, by Administrator Anne Milgram. 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. 2024–16185 Filed 7–23–24; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF LABOR

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of Alleged Safety or Health Hazards

**ACTION:** Notice of availability; request for comments.

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

**DATES:** The OMB will consider all written comments that the agency receives on or before August 23, 2024.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/](http://www.reginfo.gov/public/do/)

*PRAMain*. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Nicole Bouchet by telephone at 202–693–0213, or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**SUPPLEMENTARY INFORMATION:** The OSHA–7 Form is used by OSHA personnel to report unhealthful and/or unsafe conditions in the workplace. The information is given to OSHA by employees who wish to report unhealthful and/or unsafe conditions at their place of employment. Employee reports are authorized by Section 8(f)(1) of the OSH Act. This information is used by OSHA to evaluate the alleged hazards and to schedule an inspection. The form is available in English and Spanish. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 30, 2024 (89 FR 34273).

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

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

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

Agency: DOL–OSHA.