

respondent for the protection of the public at large. *Id.* In this case, I agree with the Chief ALJ that “the absence of a sanction where a DEA registrant has been convicted of actually intentionally distributing crack cocaine would send a powerful message to the regulated community that even the most blatant intentional diversion will carry no consequences.” RD, at 40.

In Respondent’s favor, Respondent has been held accountable for his criminal behavior—having been sentenced to prison and temporarily losing his medical license. He has met the requirements for rehabilitation and for obtaining a conditional medical license. However, based on the facts of this case, I find it difficult to find that this accountability will have a deterrent effect on the potential for Respondent’s relapse, because he has faced serious consequences many times in his life—losing his wife and family, getting expelled from medical school, losing his job, getting arrested, going to jail, etc.—and none of those things seemed to deter him from repeating his behavior until now.

Although Respondent testified extensively about the accountability to which he is held pursuant to his agreement with the Tennessee Medical Foundation, and many of his character witnesses testified about how much that accountability comforted them, I cannot find that accountability necessarily to be a sufficient deterrent from abuse of his controlled substances registration due to his history of repeatedly ignoring accountability measures,<sup>20</sup> even at the risk of incarceration. Therefore, in spite of his commendable sobriety thus far, I have reason to doubt his claim that he would always be a compliant registrant. *See George R. Smith, M.D.*, 78 FR 44972, 44980 (2013). Particularly, I remain concerned that if he relapsed, which the record has demonstrated previously occurred on several occasions, while entrusted with a controlled substances registration, he could harm himself and others too quickly for detection by this Agency or his monitoring. Ensuring that a registrant is trustworthy to comply with all relevant aspects of the CSA without constant oversight is crucial to the Agency’s ability to complete its mission of preventing diversion within

<sup>20</sup> There is also evidence on the record that at the time of the hearing that Respondent might not have been in compliance with his monitoring requirements due to his monitor’s illness and that he did not inform the state board or the Tennessee Medical Foundation of the lapse in monitoring. *See supra* n.14. I find that this lapse is mitigated by its circumstances, but that it is further evidence that Respondent has repeatedly demonstrated disregard for accountability measures.

such a large regulated population.

*Jeffrey Stein, M.D.*, 84 FR at 46974.

As discussed above, to receive a registration when grounds for denial exist, a respondent must convince the Administrator that his acceptance of responsibility and remorse are sufficiently credible to demonstrate that the misconduct will not reoccur and that he can be entrusted with a registration. Having reviewed the record in its entirety, I find that Respondent has not met this burden. Accordingly, I will order the denial of Respondent’s application for a certificate of registration.

#### Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the pending application for a Certificate of Registration, Control Number W18124612C, submitted by Robert Wayne Locklear, M.D., as well as any other pending application of Robert Wayne Locklear, M.D. for additional registration in Tennessee. This Order is effective July 26, 2021.

#### D. Christopher Evans,

*Acting Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 18–50]

#### Carol Hippenmeyer, M.D.; Decision and Order

On August 20, 2018, a former Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Carol Hippenmeyer, M.D. (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1. The OSC proposed the revocation of Respondent’s DEA Certificates of Registration BH3877733, FH2922119, FH2922121, FH2922133, FH2922157, and FH2922169, on the ground that her “continued registrations are inconsistent with the public interest.” *Id.* (citing 21 U.S.C. 823(f) and 824(a)(4)).

#### I. Procedural History

The OSC alleged that Respondent “violated Federal and Arizona state law by issuing controlled substance prescriptions outside the usual course of professional practice and for other than

a legitimate medical purpose” to three patients between February 3, 2017, and December 6, 2017. *Id.* at 3–5 (citing violations of 21 U.S.C. 841(a)(1), 21 CFR 1306.04(a), and Ariz. Rev. Stat. Ann. § 32–1401(27)). The OSC alleged that Respondent issued these prescriptions “without performing an adequate physical exam, without taking a sufficient patient history, without determining the frequency and intensity of the patient’s pain, without arriving at a legitimate diagnosis, and without maintaining adequate medical records.” *Id.* at 5. The OSC also alleged that Respondent issued these prescriptions “despite the fact that all three of these individuals had manifested one or more ‘red flags’ for abuse and/or diversion.” *Id.* at 5. The OSC stated that by issuing these prescriptions, Respondent committed “numerous acts of unlawful prescribing, any one of which could independently establish the sort of intentional diversion . . . that would justify the revocation of [her] DEA registrations.” *Id.* at 6.

The OSC notified Respondent of her right to request a hearing on the allegations or to submit a written statement while waiving her right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 6 (citing 21 CFR 1301.43). Applicant timely requested a hearing by letter dated September 19, 2018. ALJX 3 (Order for Prehearing Statements), at 1 (interpreting ALJX 2 (Request for Hearing)).

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Charles Wm. Dorman (hereinafter, the ALJ). On September 25, 2018, the ALJ established a schedule for the filing of prehearing statements. Order for Prehearing Statements, at 1. The Government filed its Prehearing Statement on October 5, 2018, and its Supplemental Prehearing Statement on October 30, 2018. ALJX 4 (Government’s Prehearing Statement) and 7 (Government’s Supplemental Prehearing Statement), respectively. Respondent filed her Prehearing Statement on October 19, 2018, and her Supplemental Prehearing Statement on October 30, 2018. ALJX 5 (Respondent’s Prehearing Statement) and 8 (Respondent’s Supplemental Prehearing Statement), respectively.

On October 23, 2018, the ALJ issued a Prehearing Ruling that, among other things, set out the thirteen stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental

prehearing statements.<sup>1</sup> ALJX 6 (Prehearing Ruling) at 1–2.

The hearing in this matter spanned three days and took place in Tucson, Arizona. *See generally* Transcript of Proceedings in the Matter of Carol Hippenmeyer, M.D. (hereinafter, Tr.). Both parties filed posthearing briefs.<sup>2</sup> *See* ALJX 23 (Government's Proposed Findings of Fact, Conclusions of Law, and Argument (hereinafter, Govt Posthearing)), and ALJX 22 (Respondent's Proposed Findings of Fact and Conclusions of Law (hereinafter, Resp Posthearing)). Then, on March 29, 2019, the ALJ issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, RD). The Government filed exceptions to the RD. *See* Government's Exceptions to the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Govt Exceptions).

Having considered the record in its entirety, I find that Respondent issued two hundred and nine prescriptions beneath the applicable standard of care in Arizona and outside of the usual course of the professional practice, in violation of federal and state law. I disagree with the RD's recommended sanction of a three-month suspension followed by registration restrictions. RD, at 127–28. Rather, I find that revocation is the appropriate sanction. I make the following findings of fact.

## II. Findings of Fact

### A. DEA Registration

The parties stipulated that Respondent is registered with DEA as a practitioner in Schedules II through V under DEA registration number BH3877733, at 6530 N Calle Lottie,

<sup>1</sup> The parties subsequently agreed to two additional stipulations concerning the Respondent's registered addresses. The fifteen final stipulations are set out on pages 26 and 27 of the ALJ's Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision, and I hereby incorporate them in this Decision.

<sup>2</sup> I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing, including his decision to grant Respondent's unopposed request for a three-week extension to file Posthearing Briefs. *See* ALJX 20 (Order Granting Respondent's Motion for Extension of Time and Order Scheduling Telephonic Conference); *see also* ALJX 12 (Order Granting Respondent's Motion for Leave to File Affidavit Out of Time and Order to Government); ALJX 13 (Amended Notice of Hearing); ALJX 14 (Letter Enclosing Subpoenas); ALJX 16 (Joint Stipulated Protective Order); ALJX 17 (Order Amending Post-Hearing Briefing Schedule); ALJX 20 (Order Granting Respondent's Motion for Extension of Time and Order Scheduling Telephonic Conference); ALJX 21 (Order Correcting the Transcript).

Tucson, AZ 85718–190.<sup>3</sup> This registration was set to expire on October 31, 2020, but Agency Records show that Respondent submitted a renewal application on September 16, 2020.<sup>4</sup> Respondent was previously registered with the DEA as a practitioner in Schedules II through IV under DEA registration numbers FH2922169, FH2922157, FH2922133, FH2922121, and FH2922119.<sup>5</sup> According to Agency Records, registration number FH2922169 expired on October 31, 2020, and Respondent did not submit a renewal application. The remaining three DEA registrations—FH2922157, FH2922133, FH2922121, and FH2922119—were retired on July 22, 2020.

### B. The Investigation

DEA's investigation of Respondent began in approximately December 2017, when a detective from the Pima County Sheriff's Department received an anonymous complaint that Respondent was “prescribing controlled substances without a legitimate purpose or outside the scope of her practice.” Tr. 66–67. The Diversion Investigator assigned to this matter (hereinafter, DI) and the detective (hereinafter, Investigators) interviewed Respondent on December 19, 2017, at DEA's office in Tucson, Arizona (hereinafter, 2017 Interview). *Id.* at 32, 68–69; Government Exhibit (hereinafter, GX) 3 (Audio recording of the Interview); GX 4 (Transcript of the Interview).

During the Interview, Investigators asked Respondent about prescriptions

<sup>3</sup> The parties stipulated that the registered address for BH3877733 is 1800 East Florence Blvd., Casa Grande, AZ 85123. *See* RD, at 26 (Stipulation No. 1); *see also* Government Exhibit (hereinafter, GX) 1, at 5. However, Agency Records list the registered address as 6530 N. Calle Lottie, Tucson, AZ 85718–190.

<sup>4</sup> Respondent's registration was “automatically [ ] extended” when she submitted a renewal application 45 days before her registration was due to expire. 21 CFR 1301.36(i).

<sup>5</sup> The parties stipulated that each of Respondent's DEA registrations authorized her to handle controlled substances in Schedules II through V. RD, at 26 (Stipulation No. 1). However, according to Agency Records and Government Exhibit 1, registration numbers FH2922169, FH2922157, FH2922133, FH2922121, FH2922119, and BH3877733 do not include Schedule V authority. *See* GX 1, at 1–4, 6. The parties stipulated that the registered addresses for these registrations were 5301 E. Grant Road, Tucson, AZ 85712–2874 (registration number FH2922121); 2023 W. Relation Street, Safford, Arizona 85546 (registration number FH2922133); 901 Rex Allen Drive, Willcox, AZ 85643 (registration number FH2922157); 333 Camino Josephina, Rio Rico, AZ 85648 (registration number FH2922169); 185 S. Mulberry Street, Florence, Arizona, 85132. However, Agency Records list the registered address as 4545 N Hunt Highway, Florence, AZ 85132.

that she had issued to M.D., a former intimate partner who had lived with Respondent until about eight months before. GX 4, at 2–8, 12–13, 17–20. Investigators asked Respondent whether M.D. was a “patient at [Respondent's] practice” or “kind of an on the side thing,” and Respondent said she “would call it more on the side.” *Id.* at 5. Respondent told Investigators that M.D. had many problems, including alcohol problems, endometriosis, gastric issues, anxiety, and a shoulder issue. *Id.* Respondent said that she had treated M.D., but “[o]nly in an effort to get her treatment,” and “not for alcohol related stuff.” *Id.*

Investigators asked Respondent how many patients she treated out of her home. Although she offered various estimates during the Interview—ranging from “[m]aybe a dozen [patients], if that,” to probably less than five—Respondent eventually confirmed that she only treated M.D. and one other individual, H.D., from her home. *Id.* at 8, 14–15, 28, 30. Investigators asked Respondent whether the people that she was “treating out of [her] home” were “patients of [her] practice location,” and Respondent said they were “[m]ore friends.” *Id.* at 11.

Investigators questioned Respondent about a prescription that Respondent had received from S.P., a neurosurgery nurse practitioner. GX 4, at 33–34. Respondent did not recall having received the prescription. *Id.* Although S.P. was discussed at the Interview, Respondent did not tell Investigators that she had prescribed controlled substances to S.P. Tr. 77–79.

Investigators asked Respondent several times whether she maintained medical records for M.D., H.D., or the other patients that she treated at home. Each time, Respondent confirmed that she did not.<sup>6</sup> However, approximately 6 months after the Interview, Respondent produced medical records for H.D., M.D., and S.P. in response to a DEA subpoena dated July 26, 2018. GX 6 (M.D. medical record), GX 7 (H.D. medical record), GX 8 (S.P. medical record), GX 10 (subpoena). Respondent sent Investigators a letter dated August

<sup>6</sup> *See* GX 4, at 8 (confirming that she does not have “a medical file for [M.D.] at [her] home”); *id.* at 8 (confirming that she does not keep medical records for the people she treats at home); *id.* at 13 (confirming that she did not “have a medical file at all” for Patient M.D.); *id.* at 13 (confirming that “there's no medical record” for M.D. “that shows . . . like the diagnostic exam . . . and all that”); *id.* at 15–16 (confirming that “there[']s no record of, like . . . current medical record or, um, like vital signs taken or . . . any of that” for M.D. or H.D.); *see also* Tr. 32 (Respondent's trial testimony confirming that she told Investigators during the Interview that she did not have medical records for H.D. and M.D.).

1, 2018, explaining the contents of the medical records. GX 9. The letter explained that each record has “a brief introduction and discussion of care” and a narcotic log “reflect[ing] the trends and management of these patients.” *Id.* Respondent generated these documents after being interviewed by DEA based on her “recall of encounters with patients.” *Id.* The letter explained that the medical records also include “pathological, surgical and laboratory data [that] was reviewed at the time it was generated.” *Id.*

Investigators attempted to interview H.D., M.D., and S.P. during the investigation. Tr. 74. They opted not to be interviewed, but they wrote letters about Respondent’s treatment of them, which were provided to DEA. Tr. 74–75, 94; GX 12. The letters emphasized that Respondent treated them for legitimate medical conditions and they did not abuse the medication that she prescribed. GX 12.

DEA also received a letter from Respondent’s attorney on August 22, 2018, aimed at “correct[ing] the apparent misperceptions about [Respondent’s] medical practice which have developed from her initial interview by the DEA.” GX 13, at 1. Among other things, the letter stated that Respondent’s “standard practice has always been to prioritize patient care and safety” and emphasized that Respondent established valid doctor-patient relationships with H.D., M.D., and S.P. and treated them for legitimate medical conditions. *Id.* at 1–5.

### C. The Government’s Case

The Government’s documentary evidence consisted primarily of patient files, prescription records, and data from the Arizona Controlled Substance Prescription Monitoring Program (hereinafter, Arizona PMP)<sup>7</sup> for H.D., M.D., and S.P., the three individuals who received controlled substances prescriptions from Respondent between January 2013 and December 2017. *See* GX 5–8, 18. The Government’s evidence also included Arizona opioid prescribing guidelines; an audio recording and transcript of Respondent’s 2017 Interview with Investigators; a subpoena requesting medical records; and letters submitted by H.D., M.D., S.P., and Respondent’s attorney. *See* GX 3–4, 9, 10, 12, 14–16. Finally, the Government’s evidence included copies of Respondent’s DEA Certificates of Registration and a

Curriculum Vitae for the Government’s expert witness. *See* GX 1–2. The Government called three witnesses to testify at the hearing: Respondent (whose testimony is summarized in the Respondent’s case, *see infra* II.D), DI, and the Government’s expert, Dr. Lynch.

DI testified about her investigation-related actions, including her role in interviewing Respondent and obtaining evidence. Tr. 64–163; *see also* RD, at 8–9. Having read and analyzed all of the record evidence, I agree with the RD that DI testified in a “professional, candid, and straightforward manner” and that her testimony was “sufficiently objective, detailed, plausible, and internally consistent.” RD, at 9. Although the ALJ concluded that DI “was an unnecessary witness,” “other than identifying documents,” I credit DI’s testimony about the Agency’s investigation and about aspects of the December 2017 Interview that were not captured in the audio recording or transcript.<sup>8</sup> *Id.*

Dr. Lynch testified about his professional and educational background. Tr. 166–69; *see also* RD, at 10; GX 2 (Curriculum Vitae of Dr. Lynch). After completing medical school, he completed an internship in surgery and anesthesiology at New York University and a fellowship in pain management at Texas Tech Health Sciences Center. Tr. 167; GX 2, at 10. He has been board certified in anesthesiology for twelve years and in pain management for eleven years. Tr. 168–69. He is licensed to practice medicine in Arizona, Nevada, California, Oregon, Colorado, Texas, and Florida, and he has treated patients for pain since he became a physician in 2002. *Id.* at 167, 169. Dr. Lynch is the Chief Medical Officer at Pain Doctor, Inc., a pain management practice in Scottsdale, Arizona. *Id.* at 166–67. For the last ten years, he owned a practice called Arizona Pain Specialists, which has pain clinics throughout Arizona and provides consulting services. *Id.* at 166. Dr. Lynch has managed pain management practices in about 15 states. Tr. 167. He has also served as an assistant professor of anesthesiology and pain management at the Mayo Clinic. *Id.* Dr. Lynch is a member of the American Society of Interventional Pain Physicians, the American Society of

Anesthesiology, and the Spinal Injection Society. *Id.* at 334–35.

Dr. Lynch was qualified as an expert medical witness in Arizona, with an emphasis in pain management. *Id.* at 171. Respondent’s counsel did not object to Dr. Lynch being recognized as an expert. *Id.* Dr. Lynch’s remaining testimony covered the standard of care in Arizona and his professional opinion that Respondent failed to meet the standard of care with regard to all of the prescriptions at issue in this case. *See infra* II.E, II.F; Tr. 171–383; RD, at 10–17, 27–42.

With regard to credibility, the ALJ found that “[a]lthough Dr. Lynch’s education, training, and work experience qualify him as an expert,” he did not find all of Dr. Lynch’s testimony to be “straightforward and internally consistent.” RD, at 13. The ALJ identified five portions of Dr. Lynch’s testimony that he believed were “confusing or inconsistent.” RD, at 13–14. First, the ALJ found that Dr. Lynch’s testimony that a physician must document a patient’s treatment in order to establish a valid doctor-patient relationship was based on Dr. Lynch’s “inference,” not the standard of care. RD, at 14 (referencing Tr. 232, 354, 379, 381). The ALJ determined that “as far as [he could] tell from Dr. Lynch’s testimony, neither the Arizona medical community nor Arizona authorities have reached a settled definition of a doctor/patient relationship.” *Id.* (citing Tr. 233–35). Therefore, the ALJ concluded that “the Government has not proved that to establish a legitimate doctor/patient relationship in Arizona, a doctor must have medical documentation of the treatment provided to the patient.” *Id.* As discussed below, *see infra* II.E.1, I find that Dr. Lynch’s testimony about the requirements for establishing a valid doctor-patient relationship is consistent with the Arizona standard of care and is supported by Arizona courts’ interpretation of Arizona state law. Therefore, I do not find that Dr. Lynch’s testimony on this issue detracted from his credibility as a witness.

Second, the ALJ found that “Dr. Lynch had a difficult time explaining the terminology of substance use, substance abuse, substance misuse, and alcoholism.” RD, at 14. The ALJ identified several instances where he felt that Dr. Lynch’s testimony was inconsistent or confusing. For example, Dr. Lynch testified that “substance use disorder” and “substance abuse disorder” are “pretty much the same thing,” and then he proceeded to offer distinct definitions of “use” and “abuse.” Tr. 257–59; RD, at 14–15. The

<sup>7</sup> The Arizona PMP is a “program administered by the State of Arizona Board of Pharmacy that collects the data from pharmacies for all controlled substance prescriptions filled at pharmacies in Arizona.” Tr. 95.

<sup>8</sup> I agree with the ALJ that DI was not qualified to opine on the requirements of a valid doctor-patient relationship in Arizona. RD, at 9 (referencing Tr. 87, 90, 130–31, 134). Therefore, to the extent that the record contains testimony by DI that could be construed as opinion testimony, I will not consider that testimony in my standard of care analysis.

ALJ also found that Dr. Lynch's characterizations of different abuse patterns were confusing; for example, that a binge drinker is not necessarily an alcoholic, that a patient who abuses a drug does not necessarily have a substance use disorder, and that there are different definitions of an alcoholic. RD, at 15 (citing Tr. 306, 329–30). The ALJ also found that Dr. Lynch misstated the Arizona Department of Health Services' (hereinafter, Arizona DHS) and the Arizona Medical Board's positions on prescribing opioids to individuals with substance abuse disorders. RD, at 15–16. Finally, the ALJ noted that Dr. Lynch is not an addiction psychiatrist. RD, at 10 (citing Tr. 329–30).

I agree with the ALJ that Dr. Lynch over-stated the Arizona DHS's<sup>9</sup> and the Arizona Medical Board's<sup>10</sup> guidance on prescribing to individuals with substance use disorders. Therefore, to the extent that Dr. Lynch's testimony conflicts with the guidelines, I will reference the guidelines directly and disregard Dr. Lynch's testimony about them. But aside from Dr. Lynch's testimony on the guidelines, I found his testimony about substance abuse disorders to be helpful, internally consistent, credible, and supported by other record evidence. For example, Dr. Lynch's testimony that M.D. "has a clear history of alcoholism, [and] potentially other substance abuse disorders as well" was supported by Respondent's statements to Investigators in 2017 that Respondent had "tried to get M.D. to go to rehab," because she had an alcohol "addiction." Tr. 198 (Dr. Lynch's testimony); GX 4, at 5, 7, 21 (Respondent's statements to

<sup>9</sup>Dr. Lynch testified that the Arizona DHS says it is an absolute contraindication to give controlled substances to a patient with an active substance abuse issue. Tr. 181. The RD finds that Dr. Lynch's testimony "slightly mischaracterizes the Arizona Health Department's guidance on this issue," because it "ma[kes] it appear that the Arizona Health Department has issued a blanket prohibition against prescribing any controlled substance to any patient with active substance abuse problems regardless of whether the patient is receiving treatment." RD, at 15 (citing Tr. 181, 261, 307). The RD finds that "[t]he Arizona Health Department's recommendation is narrower than portrayed by Dr. Lynch" because it states that it is an absolute contraindication to prescribe chronic opioid therapy to an individual with a "[d]iagnosed substance use disorder (SUD) not in remission and/or active treatment." RD, at 15 (citing GX 16, at 12). I agree with the RD's interpretation of Dr. Lynch's testimony.

<sup>10</sup>Dr. Lynch testified that the Arizona Medical Board has not issued guidance on prescribing to patients with active substance abuse problems. Tr. 181. This is incorrect. The Arizona Medical Board Guidelines provide that "[p]atients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional." GX 14, at 7.

Investigators); *see also* Tr. 293, 306–07, 327–32, 357. Although the ALJ found that Dr. Lynch's characterization of various abuse patterns was confusing, Dr. Lynch explained that the language in addiction medicine is nuanced. Tr. 258–59. Therefore, I have no reason to discredit that testimony.

I also decline to discredit Dr. Lynch's views on substance abuse issues simply because he is not an addiction specialist. Tr. 329–30. Dr. Lynch was qualified as "an expert medical witness in the State of Arizona, with an emphasis in Pain Management," *see id.* at 171, and pain management physicians must be vigilant about monitoring for substance abuse disorders. The Arizona DHS Guidelines provide that "before initiating opioid treatment," a physician should conduct "a comprehensive medical and pain related evaluation that includes assessing for substance use" and the physician should "assess for risk of misuse, addiction, or adverse effects." GX 16, at 8. Similarly, the Arizona Medical Board Guidelines provide that an "initial evaluation" should include "[a]ssessment of the patient's personal and family history of alcohol or drug abuse." GX 14, at 7. Additionally, Dr. Lynch testified that he has studied alcoholism. Tr. 332.

Third, the ALJ found that Dr. Lynch's testimony that it was "below the standard of care" to "prescrib[e] opioids to someone with whom the prescriber has a personal relationship over a long period of time" conflicted with "the bulk of Dr. Lynch's testimony" that prescribing to friends and family members was an ethical issue, not a standard of care issue. RD, at 16 (*comparing* Tr. 355 *with* Tr. 185–86, 204, 285, 351–53). I agree with the ALJ's assessment of Dr. Lynch's testimony. Therefore, I do not give any weight in my public interest analysis to Dr. Lynch's testimony that long-term prescribing to someone with whom you are in a close personal relationship is a violation of the standard of care.

Fourth, the ALJ disagreed with Dr. Lynch's testimony during cross examination about whether Respondent was prescribing low or moderate-dose therapy. *See* RD, at 16–17. I find that this testimony is irrelevant to Dr. Lynch's overall opinions because Dr. Lynch testified that he does not believe that Respondent prescribed narcotics in excessive quantities, Tr. 254, and he agreed that the low doses of controlled substances that Respondent prescribed to M.D. were a mitigating factor. *Id.* at 294. I do not find that this testimony detracts from Dr. Lynch's credibility as a witness.

Fifth, the ALJ found that Dr. Lynch's testimony that it was a violation of the standard of care in Arizona to prescribe opioids and benzodiazepines concurrently conflicted with his later testimony that "it's hard to say it's below the standard of care" because it "still continues to happen." RD, at 17 (*comparing* Tr. 275 *with* Tr. 371). The ALJ found that this inconsistency "undermine[d] Dr. Lynch's credibility on the issue of co-prescribing." *Id.* I agree with the ALJ that this testimony was inconsistent, but I do not find that this inconsistency detracted from Dr. Lynch's credibility on co-prescribing because he later clarified. Tr. 370–71; *see also id.* at 244–45 (agreeing that the Arizona DHS Guidelines do not ban co-prescribing, they just "strongly recommend[] that docs not do it"). Additionally, I found that Dr. Lynch's testimony on the standard of care for co-prescribing benzodiazepines was consistent with other record evidence, including guidelines from the Arizona DHS, the Arizona Medical Board, and the Centers for Disease Control and Prevention (hereinafter, CDC). *See infra* II.E.4.

The ALJ concluded that "[d]espite these concerns, in general [he] found Dr. Lynch to be a highly qualified expert in the area of pain management who testified in a professional, candid, and objective manner." RD, at 17. The ALJ also concluded that Dr. Lynch's testimony was "detailed, plausible, and, with a few exceptions, internally consistent." *Id.* Finally, the ALJ noted that Dr. Lynch's testimony was unrebutted. *Id.* Therefore, the ALJ concluded that he would "merit most of Dr. Lynch's testimony as credible in this Recommended Decision." Having read and analyzed all of the record evidence, I agree with the ALJ's conclusions regarding credibility and I merit Dr. Lynch's testimony as credible in this Decision.

#### D. Respondent's Case

Respondent's documentary evidence consisted of Curriculum Vitae for Respondent, H.D., M.D., and S.P.; Arizona PMP data for M.D. and S.P.; a prescription that Respondent obtained from S.P.; and an affidavit of John M. Reid, the Medical Director at Carondelet Holy Cross Hospital, where Respondent worked since 2014. *See* Respondent's Exhibits (hereinafter, RX) 1–5, 8, 11, 13. Respondent testified and called three witnesses: H.D., M.D., and S.P.

H.D. testified about his background as an internal medicine and emergency room physician. Tr. 385–86. Although H.D. is a doctor, he was not offered as a medical expert. *Id.* at 387. H.D.

testified about his friendship with Respondent, *id.* at 389; his first encounter with Respondent near the end of 2012, including the examination that she performed on him, *id.* at 390–94, 424–428, 440–43; and offered lay opinions about the quality of care that Respondent provided, *id.* at 393, 396, 419–20. *See also* RD, at 18–19, 42–49. The ALJ concluded that H.D. “presented his testimony in a professional, candid, and straightforward manner.” RD, at 19. The ALJ noted that “[a]lthough H.D.’s answers seemed vague and general when responding to some questions, especially questions about the physical examinations [Respondent] performed, he provided more detail when pressed by counsel, and overall his testimony was sufficiently objective, plausible, and internally consistent.” *Id.* Therefore, the ALJ concluded that H.D.’s testimony was credible. *Id.*

Having read and analyzed all of the record evidence, I agree with the ALJ’s conclusions about H.D.’s testimony. However, I find that H.D.’s testimony has limited probative value because it was based on his memory of examinations and encounters that happened many years before, and his testimony was often vague. I also find that his testimony has limited probative value because he has a strong incentive to provide testimony that supports that Respondent’s prescribing to him was lawful and legitimate. This is especially true because he is a medical professional operating in a regulated profession. Additionally, H.D.’s lay opinions about the quality of care that Respondent provided him were not grounded in the Arizona standard of care.<sup>11</sup> Dr. Lynch observed H.D.’s

<sup>11</sup> For example, H.D. testified that he did not have any concerns about the medical examination that Respondent performed or the medical history that she took. Tr. 396. He also testified that he felt that he had established a valid doctor-patient relationship with Respondent. *Id.* at 419. Finally, he testified that he did not feel that Respondent had harmed him or put his life at risk with her treatment. *Id.* at 419–20. H.D.’s concerns and feelings about Respondent’s prescribing do not have any bearing on whether Respondent’s prescribing was consistent with the applicable standard of care in Arizona. Additionally, even if H.D.’s lay opinions had been couched in terms of the standard of care, they would not be given any weight where they conflict with Dr. Lynch’s expert testimony. *See Zvi H. Perper, M.D., 77 FR 64131, 64140 (2012) (citing Ross v. Gardner, 365 F.2d 554 (6th Cir. 1966)) (“When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge.”); Cf. Jacobo Dreszer, M.D., 76 FR 19,386 (2011) (finding that respondent’s counsel’s posthearing argument that respondent’s medical records were “satisfactory” constituted a “lay evaluation of standards applicable to the nuanced and sophisticated science that is the practice of medicine,” and it could not “supplant the unrefuted view of an accepted expert witness”).*

testimony and testified that it did not change any of his opinions about Respondent’s compliance with the standard of care. Tr. 739. Thus, I give H.D.’s testimony limited weight in this Decision.

M.D. testified about her background as an emergency room nurse, her intimate relationship with Respondent, her patient encounters with Respondent, and her discussions with Respondent about her medical conditions and alcohol problems. *Id.* at 446–527; *see also* RD, at 19–21, 49–57. M.D. also testified that she accepted a loan from Respondent in order to pay for her own attorney in connection with this proceeding. Tr. 487.

Regarding M.D.’s credibility, the ALJ concluded that “M.D.’s testimony about physical examinations seemed vague and general, but she provided more detail when pressed by counsel.” RD, at 21. The ALJ found it “noteworthy, however, that M.D. was unable to recall certain information, such as when she testified that she could not recall whether [Respondent] ever asked her for medical records from past providers, and that she did not pay attention to whether [Respondent] took notes during her examinations.” *Id.* (citing Tr. 468, 488, 489–93, 502). The ALJ found that “[t]hose answers did not seem entirely forthcoming” and “they detract slightly from M.D.’s credibility.” *Id.* The ALJ did not believe that the loan that M.D. received “discredit[ed] her testimony because there [was] no evidence before [him] that receiving the loan was contingent on her testifying in a certain way.” *Id.* at 21. Overall, the ALJ found that M.D.’s testimony was “objective, plausible, and internally consistent, and she presented her testimony in a professional, straightforward, and candid manner in all other respects.” *Id.* Therefore, he merited M.D.’s testimony as credible.

Having read and analyzed all of the record evidence, I agree with the ALJ’s conclusions about M.D.’s testimony. However, I find that M.D.’s testimony has limited probative value for the same reasons discussed with H.D. Dr. Lynch observed M.D.’s testimony and testified that it did not change any of his opinions about Respondent’s compliance with the standard of care. Tr. 738. Thus, I give M.D.’s testimony limited weight in this Decision.

S.P. testified that she is a full-time neurosurgery nurse practitioner at Banner University Medical Center. *Id.* at 529. S.P. testified about her intimate relationship with Respondent and about the medical treatment that they provided to each other. *Id.* at 531–612; *see also* RD, at 21–24, 57–62. S.P. also

testified about medical records that she provided to Respondent in 2018 and throughout the course of Respondent’s treatment of her. Tr. 604–06, 609–11.

The ALJ identified two minor concerns with S.P.’s testimony. RD, at 23–24. First, the ALJ was confused by S.P.’s testimony about the medical records that she provided to Respondent in 2018, after DEA had begun its investigation.<sup>12</sup> *Id.* Second, the ALJ found that S.P. became defensive when she was questioned about controlled substances that she received from providers other than Respondent. RD, at 23. When Respondent’s counsel asked S.P. if she could recall “off the top of [her] head” which providers on her PMP were delegates of her primary care physician, S.P. replied that it would be “completely inaccurate in every way” to say that she has multiple doctors or is doctor shopping. *Id.* (citing Tr. 534–36). The ALJ found that this testimony came across as “advocacy rather than an objective, unbiased testimony,” because nobody had accused S.P. of doctor shopping. *Id.* at 24. However, “[d]espite those minor issues,” the ALJ concluded that S.P. “presented her testimony in a professional and straightforward manner,” and that her testimony was “sufficiently objective, plausible, and internally consistent.” *Id.* Therefore, the ALJ merited S.P.’s testimony as credible.

Having read and analyzed all of the record evidence, I agree with the ALJ’s conclusions about S.P.’s testimony.<sup>13</sup> However, I find that S.P.’s testimony has limited probative value for the same reasons discussed with H.D. and M.D. Dr. Lynch observed S.P.’s testimony and testified that it did not change any of his opinions about Respondent’s compliance with the standard of care. Tr. 739. Thus, I give M.D.’s testimony limited weight in this Decision.

<sup>12</sup> S.P. initially testified that she did not remember which documents she gave to Respondent in 2018. Tr. 605–06. S.P. then testified that she provided Respondent with “everything that [she] had of [Respondent’s] care of her” in 2018. *Id.* at 611–12. S.P. later testified that she gave Respondent copies of the records that she “had immediately available” in 2018. *Id.* at 612. Finally, S.P. testified that she is unsure whether she has more records related to Respondent’s care of her that she did not provide. *Id.*

<sup>13</sup> In addition to the two minor concerns identified by the ALJ, I found that S.P.’s frequent use of the word “extensively” when discussing the conversations that she had with Respondent about her treatment made her testimony seem less neutral. *See, e.g.,* Tr. 543 (testifying that she and Respondent “discussed side effects extensively” and Respondent “talked to her extensively about other options”); *see also id.* at 547–48, 561, 573–74. I also found that S.P.’s testimony that that she “always saw [Respondent] writing” when they met was not supported by other record evidence, which showed that Respondent did not maintain contemporaneous medical records for S.P. Tr. 599.

Respondent testified that she is currently employed as an independent contractor for an emergency department group, Sound Physicians. *Id.* at 30, 635. Respondent began practicing emergency medicine in 1998 and she currently practices internal medicine and emergency medicine. *Id.* Respondent testified about her education, training, and background, and the 2017 Interview. *Id.* at 30–31, 58, 61, 622–36.

Respondent testified about her relationships with M.D., H.D., and S.P. *Id.* at 47–51, 57, 629. Respondent was intimately involved with M.D. from approximately late 2012 or early 2013 until approximately the end of 2015. *Id.* at 47–48. Respondent testified that they lived together from approximately 2014 to 2016. *Id.* at 48. Respondent has known H.D. since 2008 or 2009. *Id.* at 50. Respondent stated that they are friends, but they rarely socialize. *Id.* at 51. Respondent testified that she and S.P. are currently friends, but they were intimately involved from approximately 1998 to 2005. *Id.* at 57, 629. Respondent testified about her treatment of H.D., M.D., and S.P. *See Id.* at 636, 643–44, 653–91, 709–14, 729 (M.D.); *id.* at 628–29, 636, 642–43, 646–47, 691–92, 694, 696, 705–06, 718, 722 (S.P.); *id.* at 636, 646–47, 695, 717–18 (H.D.); *see also* RD, at 24–26, 49–67. Respondent testified that she believes that she entered into a valid doctor-patient relationship with each individual. *Id.* at 639. Finally, Respondent testified about the contents of her medical records for M.D., H.D., and S.P. *Id.* at 33–54.

With regard to credibility, the RD concludes that Respondent “demonstrated a commanding grasp of the medical issues of H.D., M.D., and S.P.” “[e]ven without the benefit of having medical records to review,” and that “[Respondent’s] understanding of M.D.’s medical issues was especially strong.” RD, at 25–26. The RD finds that Respondent “gave detailed, thorough, and objective testimony of the medical care she provided to H.D., M.D., and S.P.” and “[s]he also candidly acknowledged the deficiencies in her medical records.” *Id.* at 8, 26. The RD concludes that Respondent “testified in a professional, candid, and straightforward manner,” and “her testimony was sufficiently objective, detailed, plausible, and internally consistent.” *Id.* Therefore, the RD “merit[s] Respondent’s testimony as credible in [the] Recommended Decision.” *Id.*

Having read and analyzed all of the record evidence, I cannot agree with all of the RD’s characterizations of Respondent’s testimony. For example, I cannot agree that Respondent

demonstrated a commanding grasp of the medical issues of S.P. or H.D., because Respondent offered very little testimony about her treatment of them.<sup>14</sup> Additionally, Respondent’s testimony about H.D. was not always supported by other record evidence. For example, Respondent testified that she began treating H.D. in “approximately 2013,” but the narcotics log that she generated after the 2017 Interview showed that she had prescribed opioids to H.D. at least as early as January 2011. *Compare* Tr. 636 with GX 7, at 5 (showing that Respondent issued at least 11 controlled substance prescriptions to H.D. prior to 2013) and GX 7, at 1 (H.D.’s letter confirming that Respondent began treating him in 2011). Additionally, Respondent testified that she prescribed triazolam<sup>15</sup> to H.D. for shift work disorder, but there is no mention of shift work disorder in H.D.’s medical record.<sup>16</sup> GX 7.

Respondent testified in greater detail about her treatment of M.D. Although I agree with the ALJ that Respondent had a strong grasp on M.D.’s medical issues, I found that Respondent was occasionally limited in her ability to

<sup>14</sup> Based on a review of Respondent’s Prehearing Statement, I believe that Respondent intended to testify in greater detail about her treatment of S.P. than she did at the hearing. *See* Resp Prehearing, at 8–10. After Respondent testified extensively about her treatment of M.D., *see* Tr. 653–92, Respondent’s counsel began questioning Respondent about S.P. *Id.* at 692. However, this line of questioning was interrupted, and Respondent’s counsel shifted his questioning to H.D. *Id.* at 691–94. At that point, Respondent had offered very little testimony about her treatment of S.P., other than testifying about their personal relationship and the triazolam prescriptions that she issued to S.P. for shift work disorder. *See Id.* at 55–57, 629, 636, 643, 646–47. While it is unfortunate that Respondent did not complete her testimony, I am confident that my conclusions about the legality of Respondent’s prescribing to S.P. would not be impacted by any additional testimony that Respondent might have provided. As found herein, Respondent committed numerous violations of the Arizona standard of care and Arizona state law in her treatment of S.P. and she did not maintain any medical records justifying her prescribing decisions. *See infra* II.F.3. Additionally, I find that revocation would be warranted based solely on the unlawful prescriptions that Respondent issued to M.D. and H.D. *See infra* II.F.1, II.F.2 (concluding that Respondent issued one hundred and eighty-five prescriptions to M.D. and H.D. outside the usual course of professional practice and beneath the standard of care in Arizona). The Government can meet its prima facie burden for revocation by proving “only a few instances of illegal prescribing.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 464 (2009).

<sup>15</sup> The parties stipulated that “Halcion is a brand name for triazolam, a Schedule IV controlled substance.” RD, at 27 (Stipulation No. 11).

<sup>16</sup> H.D. testified at the hearing that Respondent prescribed triazolam to him for shift work disorder. Tr. 398. However, the letter that H.D. prepared before the hearing did not mention shift work disorder as one of the conditions that Respondent treated. GX 7, at 2. It mentioned diabetes, hypertension, and chronic pain. *Id.*

recall details of her treatment of M.D., because she did not have contemporaneous medical records to reference. For example, when Respondent was asked about a particular laboratory result in M.D.’s medical file, she did not recall with certainty who had generated the record or why M.D. had gone to that provider. Tr. 683–85 (discussing GX 6, at 16). Respondent initially testified that M.D. went to the clinic “[i]n an attempt to establish primary care,” and then clarified that “[s]he may have also gone there in addition to that if she had a different intercurring [sic] clinical experience that [Respondent] didn’t feel was consistent with her current stable chronic medical problems.” *Id.* at 683–84. Additionally, Respondent testified that when M.D. returned sick from Africa, she referred M.D. to another provider, because she was concerned that she might have an infection. Tr. 686. Respondent was vague in answering whether she had modified her treatment of M.D. based on the hydrocodone that M.D. had received from the other provider. Tr. 687. She testified that “it would depend on whether she received a significant quantity of that medication or what her symptoms were.” *Id.*

I defer to the RD’s assessment that Respondent “testified in a professional, candid, and straightforward manner” and I agree that Respondent’s hearing testimony was “plausible[] and internally consistent.” RD, at 8, 26. However, I identified several inconsistencies between Respondent’s hearing testimony and her statements to Investigators during the investigation. First, when Investigators asked Respondent in December 2017 whether the people that she treated out of her home were “patients of [her] practice location,” Respondent replied, “More friends, I guess.” GX 4, at 11. Investigators also asked Respondent whether M.D. was a “patient at [Respondent’s] practice” or “kind of an on the side thing,” and Respondent replied, “I would call it more on the side.” *Id.* at 5. However, Respondent testified at the hearing that she entered into valid doctor-patient relationships with H.D., M.D., and S.P. Tr. 639.

Second, Respondent told Investigators during the 2017 Interview that she did not maintain medical records for the patients that she treated out of her home. *See* GX 4, at 8, 13, 15. However, after the Interview, Respondent produced medical records for M.D. and S.P. that contained documents that she testified were in her possession at the time of the Interview. *See* Tr. 34–40, 53; GX 6, 8. When Government counsel

asked Respondent why she initially told Investigators that she did not have medical records, she testified that she misspoke and thought they were referring to electronic medical records, because “the current climate in healthcare is exclusively focused on electronic health records.” *Id.* at 58, 62, 648. However, Investigators did not mention electronic medical records during the Interview and their questions were general enough to cover any type of medical records that Respondent might have maintained. GX 4; *see also* Tr. 61, 92–93, 707. For example, Investigators asked Respondent whether she “ha[d] a medical file at all for M.D.,” whether she had file for M.D. “that shows . . . like the diagnostic exam . . . and all that,” and whether she had a “current medical record . . . like vital signs taken or . . . any of that.” GX 4, at 13, 15–16. Respondent confirmed that she did not. *Id.*

Despite the inconsistency, I credit Respondent’s testimony that the medical records that she produced to Investigators after the Interview were in her possession at the time of the Interview. Respondent did not have advance notice of the topics that would be discussed during the Interview and some of the records pertained to treatment that had happened years before. *See* Resp Posthearing, at 4. Thus, Respondent may not have remembered that she possessed records related to these patients’ treatment.<sup>17</sup> Additionally, because the records that Respondent subsequently produced were primarily generated by other physicians, not Respondent, Respondent may have thought that these records were not encompassed by the Investigators’ questions.

Third, Respondent told investigators in December 2017 that triazolam is a detox drug that is used for alcohol withdrawal. GX 4, at 21–22; Tr. 73. At the hearing, however, Respondent testified that she “would never use triazolam for alcohol withdrawal, nor does anyone else that [she’s] aware of.” Tr. 723; *see also id.* at 643–44 (testifying that she prescribed triazolam for sleep, not for alcohol withdrawal). Government counsel asked Respondent what she had told Investigators in December 2017 about the purpose of triazolam. *Id.* at 723. Respondent testified that there had been a lot of “cross-talk and people talking over each other,” and that investigators “show[ed] [her] a piece of paper with other prescriptions on it,” including

diazepam,<sup>18</sup> at the same time they were asking her about triazolam. *Id.* at 723. Respondent testified that she was referring to diazepam when she said the drug was for alcohol withdrawal. *Id.* However, the transcript and audio recording from the Interview clearly capture DI’s question, “Triazolam, I don’t see that a whole lot; is that also sort of like an anti-anxiety?” GX 3, at 24:00–24:25; GX 4, at 21. Respondent replied, “It’s, uh, no; yes, it’s a, it’s a, uh alcohol withdrawal.” *Id.* DI asked, “[d]o they use it a lot like they would with valium?” GX 4, at 22. Amidst the cross talk, Respondent confirmed, “it’s more like . . . it’s a . . . detox drug.” *Id.* DI testified that she understood that Respondent was referring to triazolam when she spoke about a detox drug. Tr. 141 (“I mean, the words are speaking for themselves. She’s saying that it’s a detox drug.”).

Fourth, Respondent testified at the hearing that she “didn’t have any significant reason to utilize [the PMP] because [she] knew each time [the patients] were receiving [controlled substances] from somebody else.” Tr. 733. However, when Respondent was interviewed by Investigators in December 2017, she did not seem to be aware that M.D. frequently receives controlled substances from other providers. *See* GX 4, at 20–21. At the Interview, Investigators asked Respondent whether she knew if M.D. was receiving treatment from any other providers, and Respondent said she had “look[ed] her up one time, [] because with the endometriosis and stuff . . . she did get some narcotics . . . from that person . . . who did the surgery.” *Id.* at 20. Respondent said that she had not checked the PMP in a while, but she thought that “those [prescriptions] kinda went away.” *Id.* Respondent continued, “[S]he got some from her gynecologist . . . or something, and then they kinda disappeared. So, I . . . don’t think that she’s getting em’ from anybody else.” *Id.* at 20. Respondent also said that she did not get the sense that M.D. was being treated by another doctor for these issues. *Id.* at 20–21.

However, Arizona PMP data shows that M.D. received controlled substances from four different practitioners other than Respondent in the 12 months before the interview. GX 18, at 2–3. These practitioners included: (1) D.B., an emergency room physician who treated M.D. for acute alcohol intoxication, Tr. 516–17, 525; (2) A.B., a nurse practitioner at Tucson Family

Medicine who treated M.D. for an ulcer and H. pylori, *id.* at 516; (3) K.T., another provider at Tucson Family Medicine who diagnosed M.D. with pyelonephritis, *id.* at 523; and (4) C.L., an oral surgeon, *id.* at 521. GX 18, at 2–3. M.D. received controlled substances from twelve additional practitioners on seventeen separate occasions from January 2013 to December 2017. GX 18, at 1–8.

Fifth, Investigators asked Respondent in the 2017 Interview how many individuals she was prescribing to from her home. Although Respondent offered various estimates throughout the interview,<sup>19</sup> she ultimately confirmed that she was only prescribing controlled substances for two patients: H.D. and M.D. GX 4, at 15, 30. Respondent did not tell Investigators that she had prescribed controlled substances to S.P., even though S.P. was discussed during the Interview. *See id.* at 34–35. According to the Arizona PMP, Respondent issued twenty-four controlled substances prescriptions to S.P. from January 2013 to July 2017. GX 18, at 16–20. Although Respondent’s most recent prescription to S.P. was issued approximately five months before the Interview—meaning that Respondent was not actively prescribing to S.P. at the time of the Interview—Respondent had regularly prescribed controlled substances to S.P. for at least the last four years and she testified that she had been involved in S.P.’s care for approximately fifteen years. Tr. 636 (testifying that she had treated S.P. from the “early 2000s, [] until the end of 2017”).

At the hearing, Respondent testified that she had not told Investigators about S.P. because “she thought . . . they were referring to opiate therapy,” and she had not prescribed opioids to S.P. since 2013. *Id.* at 642–43; *see also id.* at 699 (“I thought they were referring to more active patients in terms of opiates.”). This testimony was not supported by the record. First, Respondent had prescribed tramadol, an opioid,<sup>20</sup> to S.P. in March 2015,

<sup>19</sup> *See, e.g.*, GX 4, at 4 (“maybe a dozen [patients], if that”); *Id.* at 14 (“a handful, maybe”); *Id.* at 28 (“less than 5, probably”).

<sup>20</sup> The RD took official notice that tramadol is an opioid. *See* RD, at 102 n.61 (citing Diversion Control Division, Drug & Chemical Evaluation Section, Tramadol, [https://www.deadiversion.usdoj.gov/drug\\_chem\\_info/tramadol.pdf](https://www.deadiversion.usdoj.gov/drug_chem_info/tramadol.pdf) (October 2018) (“Tramadol is an opioid analgesic and opioid activity is the overriding contributor to its pharmacological effects.”)). Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding.” U.S. Dept. of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA

<sup>17</sup> Respondent also testified that she felt under “increasing duress” during the Interview and was confused by some of the questions. Tr. 643.

<sup>18</sup> The parties stipulated that “Valium is [sic] brand name for diazepam, a Schedule IV controlled substance.” RD, at 27 (Stipulation No. 8).

according to the Arizona PMP. *See* GX 18, at 18. Second, Investigators were clear with Respondent that they were not only concerned with opioids. So clear, in fact, that Respondent told Investigators that she may have prescribed antibiotics for “somebody’s kid.” GX 4, at 15. Investigators explained that they did not have “jurisdiction over antibiotics,” and asked whether she had prescribed “benzos<sup>21</sup> or . . . pain meds . . . or anything . . .” for any other individuals from home. *Id.* Respondent replied, “I really don’t think so,” “no.” *Id.* Investigators asked, “So, you think just probably [H.D.] and [M.D.] for the controlled written out of your house?” *Id.* Respondent replied, “Mm hm.” GX 3, at 16:23–16:37; GX 4, at 15. Investigators asked Respondent again, approximately 15 minutes later, whether there was anybody else that she was “writing controlled for.” GX 4, at 30; GX, at 36:20–35. Respondent said, “I mean, there might be . . . an occasional antibiotic for someone,” but she confirmed that “[t]here’s nobody else” that she was writing controlled substances prescriptions for other than M.D. and H.D. *Id.*

Respondent argues that her failure to tell Investigators that she had prescribed to S.P. was not “an affirmative attempt to mislead the investigators,” but rather was “a failure to volunteer information regarding a subject not discussed in an interview.” *Resp Posthearing*, at 6. I disagree with Respondent’s contention that this topic was not discussed during the Interview. The primary topic of discussion during the Interview was Respondent’s treatment of patients from her home, and Investigators asked Respondent several times how many patients she treated from home. *See, e.g.*, GX 4, at 4, 14, 28. And although Investigators did not specifically ask Respondent whether she had ever prescribed controlled substances to S.P., S.P. was a topic of discussion during the interview. *See id.* at 34–35.

However, I agree with Respondent that the record does not support a finding that she affirmatively attempted to mislead Investigators. I found that Respondent was sincere and cooperative during the Interview, and I found

and DEA’s regulations, Registrant is “entitled on timely request to an opportunity to show to the contrary.” 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). The RD notified the parties of this right, and advised them that they “may address whether tramadol is not an opioid in any exceptions they may file to this Recommended Decision.” *Id.* Neither party filed exceptions addressing this issue, so I adopt the RD’s finding.

<sup>21</sup> The term “benzos” was used interchangeably with “benzodiazepines” at the hearing. *See, e.g.*, Tr. 170.

Respondent’s hearing testimony to be thorough and credible, despite the inconsistencies outlined above. Therefore, I generally merit Respondent’s testimony as credible in this Decision, except as noted herein, and except where her testimony conflicts with Dr. Lynch’s credible expert testimony.

#### *E. The Applicable Standard of Care in Arizona*

According to the Controlled Substances Act (hereinafter, CSA), “[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute, . . . dispense, or possess with intent to . . . distribute[] or dispense, a controlled substance.” 21 U.S.C. 841(a)(1). The CSA’s implementing regulations state, among other things, that 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).

Respondent is licensed as a physician in the State of Arizona. Tr. 624. Dr. Lynch, the Government’s medical expert, presented un rebutted expert testimony about the applicable standard of care in Arizona for prescribing controlled substances. Dr. Lynch testified that he considered the following materials in forming his opinions: (1) *Ariz. Rev. Stat. Ann.* §§ 32–1401(2) and 32–1401(27)(e), defining adequate medical records; (2) The Arizona Medical Board’s Reference for Physicians on the Use of Opioid Analgesics in the Treatment of Chronic Pain, in the Office Setting (GX 14; hereinafter, the Arizona Medical Board Guidelines); (3) The CDC’s Guideline for Prescribing Opioids for Chronic Pain—United States, 2016 (GX 15; hereinafter, the CDC Guidelines); and (4) The Arizona DHS’s November 2014 Arizona Opioid Prescribing Guidelines, (GX 16; hereinafter, the Arizona DHS Guidelines). Tr. 216–20; 366–68.<sup>22</sup> Dr. Lynch testified that the guidelines are meant to influence the standard of care, but “there’s an art to medicine beyond guidelines,” and the “Arizona standard of care trumps all these documents.” *Id.* at 217; 265–67. Dr. Lynch testified that the “ultimate guide” for the standard of care is “what [] physicians are doing in the marketplace” and what Arizona physicians “believe . . . is right.” *Id.* at 267; *see also id.* at 217 (explaining that the standard of care is determined by

<sup>22</sup> Respondent did not object to the admission of any of these exhibits.

“what the community does based on all the doctors and how they work together”). Dr. Lynch testified that all of his opinions at the hearing were based on the minimum standard of care in Arizona “and the documented regulations from the Arizona Medical Board and the Department of Health.” *Id.* at 216.

There was significant disagreement at the hearing and in the parties’ posthearing briefs on a number of issues: (1) Whether a physician must maintain medical records in order to establish a valid doctor-patient relationship, (2) whether the Arizona standard of care requires physicians to conduct urine drug screens and query the Arizona PMP while prescribing controlled substances, and (3) whether it is a violation of the standard of care to prescribe benzodiazepines and opioids concurrently. In accordance with Dr. Lynch’s uncontroverted expert testimony and the record as a whole, I make the following findings regarding the applicable standard of care in Arizona.

#### 1. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians to Perform a Physical Examination or Otherwise Establish a Valid, Documented Doctor-Patient Relationship Prior to Prescribing Controlled Substances

Dr. Lynch testified that the applicable standard of care in Arizona requires a physician to conduct a physical examination before prescribing controlled substances. Tr. 176–77. Dr. Lynch’s opinion is supported by Arizona statute, which states that it is “unprofessional conduct” to “[p]rescribe[], dispense[] or furnish[] a prescription medication . . . to a person unless the [doctor] first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship.”<sup>23</sup> *Ariz. Rev. Stat. Ann.* § 32–1401(27)(ss) (2017).

Dr. Lynch testified that the Arizona Medical Board and the Arizona DHS typically recommend that physicians do “a complete physical exam as part of prescribing opioids, but [a physician] can do more limited exams.” Tr. 177, 196–97. A physical examination can include “anything from a focused exam on a painful area to a complete exam . . . [of] all the systems, including

<sup>23</sup> Physicians are excused from complying with this statute under certain circumstances, such as in an emergency medical situation. *See Ariz. Rev. Stat. Ann.* § 32–1401(27)(ss)(i)–(ix). There is no evidence that any of these circumstances were present in this case.

neurologic, cardiac, pulmonary, et cetera.” *Id.* at 177. Dr. Lynch’s testimony is consistent with the Arizona Medical Board’s and the Arizona DHS’s Guidelines on prescribing opioids for chronic pain. The Arizona DHS provides that a practitioner should complete “a comprehensive medical and pain related evaluation” that includes a “pain focused physical exam.” GX 16, at 11. The Arizona Medical Board provides that a practitioner should complete an “initial work-up” of every patient that includes “a systems review and relevant physical examination.” GX 14, at 7. Dr. Lynch testified that the results of the physical examination should be recorded in the patient’s medical record. Tr. 196–97 (referencing GX 12).

Dr. Lynch testified about the requirements for establishing a valid doctor-patient relationship. Dr. Lynch testified that a valid doctor-patient relationship is not established unless the physician documents the treatment of the patient. *Id.* at 233, 379, 381. Dr. Lynch testified that the Arizona Medical Board does not define a doctor-patient relationship, but it “goes to great lengths to define how [doctors] should document.” *Id.* at 235. Therefore, he has “always inferred” that documentation and the doctor-patient relationship are “very similar things.” *Id.*<sup>24</sup> Dr. Lynch identified additional aspects of a doctor-patient relationship—that the treatment is “done in an office setting” and “in the normal course of medical practice that occurs [ ] in Arizona every day.” Tr. 232–35.

There was disagreement at the hearing about the requirements for forming a valid doctor-patient relationship. The ALJ discredited Dr. Lynch’s testimony that documentation is required for a valid doctor-patient relationship, because he found that this testimony was based on Dr. Lynch’s “inference,” not the standard of care.<sup>25</sup> RD, at 14

<sup>24</sup> See also Tr. 233 (testifying that the Arizona legislature and the Arizona Medical Board mandate that physicians document, so by not documenting, there is no valid doctor-patient relationship); *id.* at 379 (testifying that it is possible to treat a patient without documentation, but “the fact that [Respondent is] not documenting it makes it not . . . an adequate doctor-patient relationship); *id.* at 381 (“My opinion is medical documentation is an important aspect of a doctor-patient relationship and if you don’t have that it’s hard for me to believe it is appropriate medical doctor-patient relationship.”)

<sup>25</sup> The ALJ also found that Dr. Lynch’s opinion on doctor-patient relationships conflicted with a previous Agency Decision. RD, at 14. The ALJ asked Dr. Lynch whether a physician who prescribed controlled substances to “his or her minor child . . . over a continued period of time” without evidence that he had performed a physical examination or a medical history had formed a doctor-patient relationship with the child. Tr. 359–

(referencing Tr. 232, 235, 354, 379, 381). The ALJ determined that “as far as [he could] tell from Dr. Lynch’s testimony, neither the Arizona medical community nor Arizona authorities have reached a settled definition of a doctor/patient relationship.” *Id.* (citing Tr. 235). Therefore, the ALJ concluded that “the Government has not proved that to establish a legitimate doctor/patient relationship in Arizona, a doctor must have medical documentation of the treatment provided to the patient.”<sup>26</sup> *Id.*

60. Dr. Lynch testified that the physician had not formed a doctor-patient relationship and it was “completely outside the standard of care to treat your own children with [controlled substances].” Tr. 359. The ALJ found that this testimony was “contrary to the Administrator’s finding in *Belinda R. Mori, N.P.*, 78 FR 36582, 36587–88 (2013).” RD, at 14. However, *Belinda* involved a New Mexico practitioner and explored the confines of a valid doctor-patient relationship under New Mexico law. *Belinda R. Mori*, 78 FR at 36588 (“As for whether her failure to create a patient record is, by itself sufficient to establish that she prescribed without a valid practitioner-patient relationship under New Mexico law, I conclude that that was a matter for state authorities.”). “The CSA . . . generally looks to state law and standards of practice to determine whether a doctor and patient have established a legitimate doctor-patient relationship.” *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.*, 80 FR 28643, 28662 (2015) (internal citation omitted). Thus, I need not assess whether Dr. Lynch’s opinion is consistent with the Agency’s decision in *Belinda*. I need only assess whether Dr. Lynch’s opinion is consistent with Arizona law. As discussed below, I find that Dr. Lynch’s testimony that the physician did not form a valid doctor-patient relationship in the ALJ’s hypothetical is consistent with my finding that Arizona law requires physicians to maintain contemporaneous medical records to establish a valid doctor-patient relationship. I also find that Dr. Lynch’s testimony that it is outside the standard of care for a physician to prescribe controlled substances to his minor child is consistent with Arizona law, which prohibits prescribing to family members. See Ariz. Rev. Stat. Ann. § 32–1401(27)(h) (2014) (defining “unprofessional conduct” to include “[p]rescribing or dispensing controlled substances to members of the physician’s immediate family”).

<sup>26</sup> The RD states: “Dr. Lynch agreed that a doctor and patient establish a legitimate doctor/patient relationship when (1) the ‘doctor and patient agree that the patient wishes the doctor to examine them’; (2) the patient and doctor agree that ‘the doctor should diagnose what [the patient’s] medical problems are’; and (3) the ‘doctor agrees to treat a patient and the patient agrees to be treated.’” RD, at 118 (citing Tr. 233–235). I disagree with the ALJ’s assessment of Dr. Lynch’s testimony. Dr. Lynch agreed that these elements are indicative of, and consistent with, a valid doctor-patient relationship, but he did not testify that a valid doctor-patient is established if these three elements are met. Tr. 233–235. Dr. Lynch agreed that a doctor-patient relationship “is a gray area to try to define,” but he reiterated his position that he has always inferred that documentation and a doctor-patient relationship are “very similar things” because the “medical Board goes to great lengths to define how [doctors] should document.” *Id.* at 235. Neither Respondent nor the ALJ provided support for the ALJ’s definition of a doctor-patient relationship in Arizona law or the Arizona standard of care. The ALJ argues that this definition aligns with DEA’s understanding of a doctor-patient relationship, as articulated in *Patrick W. Stodola, MD.*, 74 FR 20727, 20729 (2009). However, *Stodola* is not applicable

I disagree with the ALJ’s conclusions on this issue. I find that Dr. Lynch’s testimony on this issue is consistent with Arizona’s interpretation of the requirements for establishing a valid doctor-patient relationship. In *Golob v. Arizona Med. Bd.*, 217 Ariz. 505 (2008), the Arizona Court of Appeals evaluated the establishment of the doctor-patient relationship in the context of a physician who was prescribing medication over the internet. *Id.* at 508. Although Dr. Golob conceded that she had not performed physical examinations, she argued that she fulfilled the requirements of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) because she created “a previously established . . . doctor-patient relationship” with each individual by accepting a consultation fee, reviewing responses to a questionnaire, and occasionally directing an operator to ask the individuals additional questions. *Id.* at 510. The court wholly rejected Dr. Golob’s argument and upheld the state board’s finding that Dr. Golob deviated from the standard of care because she prescribed medication over the internet without establishing an appropriate physician-patient relationship. *Id.* at 508–09. The court found that the state board’s interpretation of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) was aligned with the *American Medical Association’s Guidance for Physicians on Internet Prescribing*, which states that in order to establish a “valid patient-physician relationship,” a physician “shall” do the following: (i) Obtain a reliable history and perform a physical examination, (ii) have a sufficient dialogue with the patient about the risks and benefits of treatment, (iii) follow up with the patient to assess therapeutic outcomes, as appropriate, (iv) maintain a contemporaneous medical record, and (v) include a copy of the electronic prescription in the record. *Id.* at 511 (citing *American Medical Association’s Guidance for Physicians on Internet Prescribing*, H–120.949 (June 2003)).

The Arizona Court of Appeals rejected Dr. Golob’s argument that the phrase “previously established doctor-patient relationship” was impermissibly vague, noting that the phrase pertains to “trained professionals” who are “expected to be knowledgeable about their profession and the context of the rule.” *Id.* at 513–14 (citing *Brighton Pharmacy, Inc. v. Colorado State Pharmacy Board*, 160 P.3d 412, 419–20 (Colo. App. 2007)) (internal quotations omitted); see also *Low Cost Pharmacy, Inc. v. Arizona State Bd. of Pharmacy*,

because it involves an Illinois practitioner and does not address Arizona law.

No. 1 CA–CV 07–0547, 2008 WL 2154793, at \*6 (Ariz. Ct. App. May 20, 2008) (“[A] previously established doctor-patient relationship is one that a licensed physician, who is expected to be knowledgeable about his or her profession in the context of the rule, should reasonably understand.”). Although *Golob* dealt with internet prescribing, the court stated that physicians who prescribe over the internet are held to the “very same standard of care that is required of all physicians.” *Id.* at 514. Thus, I find that *Golob* is consistent with my finding, based on Dr. Lynch’s un rebutted and credible expert testimony, that physicians must maintain contemporaneous medical records in order to establish a valid doctor-patient relationship in Arizona.<sup>27</sup>

After *Golob* was decided, the Arizona Medical Board published a Substantive Policy Statement providing physicians with additional guidance on Internet prescribing. See Arizona Medical Board Substantive Policy Statement # 12 on Internet Prescribing, Adopted Dec. 6, 2006, available at [https://www.azmd.gov/Files/LawsRules/SPS\\_12\\_PolicyStnt.pdf](https://www.azmd.gov/Files/LawsRules/SPS_12_PolicyStnt.pdf) (hereinafter, the Statement). The Statement references the legislature’s requirement that a physician conduct a physical examination or have previously established a physician-patient relationship prior to prescribing medications. *Id.* at 2 (citing Ariz. Rev. Stat. Ann. § 32–1401(27)(ss)). The Board notes that the nature of the examination

<sup>27</sup> The ALJ found that the Government “place[d] too much weight on *Golob*’s lone reference to ‘a contemporaneous medical record’” in a “lengthy block quote of the AMA’s policy.” RD, at 120. He found that the holding in *Golob* is much narrower than the Government asserts—it is merely that a physician may not “prescrib[e] medication via the internet . . . based exclusively on the results of an internet questionnaire.” *Id.* I find that *Golob* has more weight than the ALJ concludes. Although the block quote in *Golob* may be lengthy, the length of the quote does not minimize the importance of the five critical components of medical treatment that it highlights. Each component is identified by the Arizona Medical Board and the Arizona DHS as critical to safe prescribing. See generally GX 14, 16. The ALJ also finds that “the Government’s reliance on *Golob* conflicts with the testimony of its own expert witness that there’s nowhere you can find the definition of a valid doctor/patient relationship.” RD, at 121. I disagree. Consistent with Dr. Lynch’s testimony, the court in *Golob* acknowledges that the Arizona legislature does not define the phrase “previously established doctor-patient relationship.” See *Golob*, 217 Ariz. at 513. Finally, the ALJ concludes that the Agency’s decision in *Patrick W. Stodola, M.D.*, 74 FR 20727, 20734–45 (2009)—which assessed the establishment of a doctor-patient relationship according to “many state authorities”—is more on point than *Golob*. RD, at 119–20. However, as stated above, I do not find that *Stodola* informs my decision in this case because it involves an Illinois practitioner and it does not address Arizona law.

will “depend on the patient and condition being treated,” but emphasizes that a documented patient evaluation is required: “Prior to providing treatment, including issuing prescriptions, . . . a physician must document a patient evaluation, including taking a history and conducting a physical examination adequate to establish the diagnoses and identify underlying conditions and/or contraindications to the treatment recommended or provided.” *Id.* Although the Statement is “advisory only,” and “does not impose additional requirements or penalties on regulated parties,” it provides further support for my finding that documentation is required in Arizona to establish a valid doctor-patient relationship. *Id.* at 1.

Therefore, based on Dr. Lynch’s un rebutted and credible expert testimony, as supported by evidence in Arizona law and policy, I conclude that in Arizona, a physician must perform a physical examination or otherwise establish a valid doctor-patient relationship prior to prescribing a prescription medication. I also conclude that a valid doctor-patient relationship is not formed unless a physician maintains contemporaneous medical records documenting the treatment of the patient.

## 2. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians To Take a Medical History and Conduct a Review of Past Relevant Medical Records Prior to Prescribing Controlled Substances

Dr. Lynch testified that the applicable standard of care in Arizona requires that a physician take a medical history before prescribing controlled substances. Tr. 176, 239–40. The purpose of the medical history is to “define the disease state.” *Id.* at 176, 239–40. Dr. Lynch testified that a medical history should explore “when the condition started, what’s happened since, what makes it better, what makes it worse, what’s been tried, what’s failed, [and] what works.” *Id.* at 176. Dr. Lynch’s testimony is supported by the Arizona DHS Guidelines, which state that physicians should complete an evaluation that includes “a medical, pain-related, and social history.” GX 16, at 11. The medical history should be documented in the patient’s medical records. GX 14, at 12.

Dr. Lynch testified that a physician also must conduct a “full review of prior records” in order to “understand the condition” and evaluate the effectiveness of past treatments. Tr. 183–84. For example, if a patient is

being treated for shoulder pain, a physician should review past medical records in order to understand the following: “Has there been an MRI or X-rays? Have they seen a surgeon? What was the documentation? What is the diagnosis? Have they been to physical therapy? If so, did it work? If not, you know, what else have they tried?” *Id.* at 183–84. Dr. Lynch testified that it would not be sufficient for the physician to simply review an MRI or laboratory results. *Id.* at 184. Dr. Lynch’s testimony that past medical records must be reviewed is supported by guidance from the Arizona Medical Board and the Arizona DHS. The Arizona Medical Board provides that “[r]eports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible.” GX 14, at 7. The Arizona DHS provides that “[c]linicians treating patients with opioids for chronic pain should obtain and review past medical records when possible.” GX 16, at 8. Dr. Lynch testified that the minimum standard of care in Arizona requires that the review of past medical records be documented in the medical record. Tr. 196–97 (referencing GX 14). Therefore, based on the un rebutted and credible expert testimony of Dr. Lynch, as supported by Arizona guidance, I find that the standard of care in Arizona requires physicians to take a medical history and document that medical history in the patient’s medical record before prescribing controlled substances. I also find that a physician must conduct a review of the patient’s past relevant medical records prior to prescribing.

## 3. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians To Perform Periodic Urine Drug Screens and Regularly Query the Arizona PMP, and Document Those Results in the Medical Record

Dr. Lynch testified that the applicable standard of care in Arizona requires that a physician query the Arizona PMP on a regular basis and document the results in the medical record. Tr. 181–82. He testified that regular PMP monitoring became “strong standard in care” in 2014 when the Arizona DHS Guidelines were published. *Id.* at 181. Dr. Lynch’s testimony is supported by the Arizona DHS Guidelines, which provide that “[a]ppropriate monitoring for [chronic opioid therapy] includes, at a minimum, . . . periodic query of the [Arizona PMP].” GX 16, at 8. Dr. Lynch’s testimony is also supported by the Arizona Medical Board Guidelines, which recommend that physicians

query the PMP and document the results in the record. GX 14, at 8.

According to the Arizona DHS Guidelines, the frequency with which a practitioner checks the PMP should be based on the patient's risk of misuse. GX 16, at 13–14. The PMP should be checked “yearly or more often as indicated” for low-risk patients, “every [six] months or more often as indicated” for moderate-risk patients, and “every [three] months or more often as indicated” for high-risk patients. GX 16, at 13–14, 16; *see also* Tr. 277–80.<sup>28</sup> Risk factors include a “personal or family history of addiction” and “[a]berrant drug-related behaviors,” such as “obtaining opioids from multiple sources.” GX 16, at 13.

The Arizona Medical Board states that it will consider the failure to “mak[e] use of available tools for risk mitigation,” such as the PMP, as “inappropriate management of pain” and a “departure from best clinical practices.” GX 14, at 3–4. The Board also states that “[t]o be within the usual course of professional practice, . . . the prescribing or administration of medications should be . . . accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication.” *Id.* at 5.

Dr. Lynch testified that physicians should also perform “periodic urine drug screening” on patients receiving chronic opioid therapy to “make sure that [the patients are] compliant with therapy.” Tr. 182–83, 238–39, 262–63, 271–72. He testified that this requirement is based on guidance from the Arizona DHS and the Arizona Medical Board. *Id.* at 182–83, 238. The Arizona DHS Guidelines provide that “[a]ppropriate monitoring for [chronic opioid therapy] includes, at a minimum, . . . periodic completion of [urine drug screens].” GX 16, at 8. The Arizona Medical Board Guidelines state that “[p]eriodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs.” GX 14, at 10. Dr. Lynch testified that “there's disagreement on how often” urine drug screens should be performed,” but they should be performed “at some interval.” Tr. 198. Dr. Lynch testified that the frequency of drug testing is based on the risk score of the patient. *Id.* at 238. The

<sup>28</sup> The Arizona Medical Board also provides guidance on the frequency of drug screening. The Board advises that “clinical judgment trumps recommendations for frequency of testing” for patients being treated for pain, but for patients being treated for addiction, testing should occur “as frequently as necessary to ensure therapeutic adherence.” GX 14, at 10.

Arizona DHS recommends that drug testing be conducted with the same frequency as PMP checks, as determined by the patient's risk factors. GX 16, at 13.

Dr. Lynch testified that if a doctor learns that a patient is receiving controlled substances from other providers, the doctor must discuss it with the patient to understand why the patient is receiving controlled substances from other providers and make sure that the doctor is “okay with it.” Tr. 281, 323. The doctor must document those discussions in the record, as well as the patient's reason for receiving controlled substances from multiple providers. *Id.*

Notwithstanding this testimony, the ALJ concluded that neither PMP checks nor urine drug screens were required by the minimum standard of care in Arizona. *See, e.g.,* RD, at 88. The ALJ reached this conclusion primarily because he found that the documents that Dr. Lynch referenced as requiring urine drug screens—the Arizona DHS Guidelines and the Arizona Medical Board Guidelines—do not establish the standard of care. RD, at 27–28, 35–36, 88. The ALJ quotes disclaimers that the guidelines “do[] not replace or constrain the Arizona Medical Board's determination of standard of care in individual cases” and “should not be used to establish any standard of care.” RD, at 27–28 (citing GX 14, at 1; GX 16, at 2). The ALJ also references Dr. Lynch's testimony that the guidelines influence the standard of care, but they do not establish it. *Id.* (citing Tr. 217, 265, 267).

Although I agree with the ALJ's assessment of Dr. Lynch's testimony that the guidelines do not independently establish the standard of care, I decline to discredit Dr. Lynch's testimony merely because he referenced the guidelines in formulating his opinions.<sup>29</sup> Dr. Lynch testified that all of his opinions at the hearing were based on the minimum standard of care in Arizona. Tr. 216. He testified that the “ultimate guide” for the standard of care is “what [] physicians are doing in the marketplace,” *id.* at 267, and physicians began conducting urine drug screens in 2011 when “the CDC started releasing data showing that 19 to 40 percent of patients were abusing or misusing” the drugs that they were prescribed. *Id.* at 271. Dr. Lynch testified repeatedly that urine drug screens are part of the minimum standard of care in Arizona.

<sup>29</sup> I also decline to discredit Dr. Lynch's testimony about the standard of care for treating individuals with substance abuse problems simply because he relied on Arizona prescribing guidelines to formulate his opinions. *See* RD, at 86–87.

*Id.* at 182–83, 238–39, 262–63, 271–72. Dr. Lynch also testified that regular PMP monitoring became “strong standard in care” in 2014. *Id.* at 181. Therefore, based on the uncontroverted testimony of the expert witness as supported by state guidance, I conclude that the minimum standard of care in Arizona requires that physicians prescribing opioids regularly query the PMP and periodically conduct urine drug screens.<sup>30</sup>

4. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians to Document Their Justification for Prescribing Opioids and Benzodiazepines Concurrently, and to Avoid Prescribing This Combination If Possible

Dr. Lynch testified about the applicable standard of care in Arizona for prescribing opioids and benzodiazepines concurrently. Tr. 178–80, 244–45, 275, 299, 300–02, 370–72. He referred to this practice as “co-prescribing.” *Id.* at 245. Dr. Lynch testified that “about 1 in 500 patients who take a pain pill will overdose and die every year, which is a very high death rate.” *Id.* at 182. When opioids and benzodiazepines are combined, the death rate increases by nine times. *Id.* at 180, 302. Dr. Lynch testified that the “second biggest predictor” of overdose and death is “concomitant benzodiazepine use.”<sup>31</sup> *Id.* at 244. In 2014, the Arizona DHS reported that benzodiazepines were involved in thirty to sixty percent of opioid overdose deaths. *Id.*; GX 16, at 19.

Dr. Lynch testified that benzodiazepines are like “alcohol in a pill form,” because they “hit the same receptors in the brain” as alcohol. Tr. 176. He stated, “[They] will make you a little bit tired, a little bit less anxious, [and] more relaxed.” *Id.* Dr. Lynch testified that Xanax,<sup>32</sup> a benzodiazepine, is “one of the most addictive drugs in the U.S. today.” *Id.* at 304. Dr. Lynch concluded that Xanax is “highly sought after,” “has a very high street value,” and “generally shouldn't be used very much.” *Id.*

Dr. Lynch testified that “for at least four years now, the State of Arizona has been urging physicians . . . not to have

<sup>30</sup> “When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge.” *Zvi H. Perper, M.D.*, 77 FR 64,131, 64,140 (2012) (citing *Ross v. Gardner*, 365 F.2d 554 (6th Cir. 1966)).

<sup>31</sup> Dr. Lynch testified that the biggest factor for predicting overdose and death is dose. Tr. 244.

<sup>32</sup> The parties stipulated that “Xanax is a brand name for alprazolam, a Schedule IV controlled substance.” RD, at 27 (Stipulation No. 6).

patients on both [opioids and benzodiazepines].” *Id.* at 180. He further stated that if a physician is going to prescribe both, he should “go to great lengths to document the reasons” and to document the discussions with the patient about the risks and benefits. *Id.* Dr. Lynch discussed the Arizona DHS’s and the CDC’s recommendations on co-prescribing. *Id.* at 179. The Arizona DHS recommends that “[c]ombined use of opioids and benzodiazepines should be avoided if possible. If this combination is used, it should be with great caution and informed consent should be obtained.” GX 16, at 8. The CDC likewise cautions that “[c]linicians should avoid prescribing opioid pain medication and benzodiazepines concurrently wherever possible.” GX 15, at 18. Dr. Lynch testified that the Arizona DHS and the CDC also advise physicians not to prescribe opioids along with carisoprodol,<sup>33</sup> which he described as “a highly diverted and addictive muscle relaxant.” Tr. 200; *see also* GX 16, at 8, 19 (stating that carisoprodol “should be avoided” and “[p]articular caution should [] be exercised when opioids are used with other sedatives/hypnotics”). Dr. Lynch declared that carisoprodol is “one of the top 10 most diverted drugs in the United States, and it’s only FDA approved for two or three weeks of use . . . because patients tend to get addicted to it.” *Id.* Therefore, I conclude that Dr. Lynch credibly testified that the standard of care in Arizona requires physicians to document their justification for prescribing an opioid and a benzodiazepine (or carisoprodol) concurrently, and to avoid prescribing this combination if possible.

#### 5. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians to Take Extra Precautions When Prescribing to Individuals With Active Substance Use Disorders or a History of Substance Abuse

Dr. Lynch further testified about the applicable standard of care in Arizona for prescribing controlled substances to patients with active substance abuse disorders or a history of substance abuse. Prescribing an opioid or a benzodiazepine to a patient with a substance abuse disorder increases the patient’s risk of “abuse, misuse, overdose, and death.” Tr. 198. Dr. Lynch testified that the Arizona Medical Board and the Arizona DHS advise that physicians should “tread very, very

lightly if someone is an alcoholic.” *Id.* at 259. He stated that a physician “should always get an assessment first by an addiction specialist to . . . set the baseline” and figure out “[w]hat exactly is going on? How bad was this? Is it alcohol? Is it poly-substance abuse?” *Id.* at 259; *see also id.* at 261 (testifying that physicians should “document the baseline from an addiction specialist” before prescribing to an alcoholic), 357. Dr. Lynch testified that then, the physician should “balance[e] the risk[s] and benefits of [the] treatment” with the patient. *Id.* at 259. He concluded that in general, it is very difficult to “[b]alanc[e] the risk of opioids . . . because there’s a lot of downside to it,” but if the patient has a “history of alcoholism, it’s going to be almost impossible . . . to balance those scales.” *Id.* at 259–60. Dr. Lynch stated that if a patient is abusing a drug, but does not have a “full-on addiction,” “there should still be extra caution when prescribing opioids or benzos for that person.” *Id.* at 329–30. Dr. Lynch also testified that under the “local standard of care,” “someone who is abusing any medication or alcohol should not be getting benzos and opioids at the same time.” *Id.* at 330–31.

Dr. Lynch’s testimony is supported by guidance from the Arizona DHS and the Arizona Medical Board. The Arizona DHS provides that it is an “absolute contraindication[]” to use chronic opioid therapy on a patient with a “[d]iagnosed substance use disorder (SUD)<sup>34</sup> not in remission and/or active treatment.” GX 16, at 12. Dr. Lynch testified that in the context of the Arizona DHS Guidelines, an “absolute contraindication” means “don’t do it for any reason at all.” Tr. 261. The guidelines state that “[c]linicians should consider consultation, when available, for patients with . . . a history or evidence of current drug addiction or abuse.” GX 16, at 8.

The Arizona Medical Board also distinguishes between patients with an active substance abuse disorder and a history of substance abuse. The Board advises that “[p]atients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional.” GX 14, at 7. The Board advises that a physician treating a patient with a history of

substance abuse “should, if possible, [] consult[] with an addiction specialist before opioid therapy is initiated (and follow-up as needed).” *Id.*; *see also* Tr. 181 (“The Arizona Medical Board . . . mandate[s] that you should have a referral to addiction specialist.”). The Board emphasizes that “[p]atients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse.” GX 14, at 7.

Therefore, I conclude that based on the uncontroverted and credible testimony of Dr. Lynch, as supported by Arizona guidance, the applicable standard of care in Arizona requires that: Physicians must get an assessment by an addiction specialist before prescribing opioids to a patient with a history of substance abuse, and they must document the patient’s baseline; physicians should not prescribe opioids to individuals who have active substance abuse disorders unless those patients are in active treatment; and, physicians should not prescribe opioids and benzodiazepines concurrently to anyone who is abusing any medication or alcohol.

#### 6. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians To Maintain Contemporaneous Medical Records Documenting the Patient’s Treatment

Finally, Dr. Lynch testified that the standard of care in Arizona requires that physicians maintain medical records documenting a patient’s treatment. Tr. 233, 247–48, 301, 354. He further testified that the documentation must be contemporaneous with the treatment, and that it is not consistent with the standard of care for a physician to create medical records years after treatment was provided based on memory. *Id.* at 190–91, 346. Dr. Lynch’s opinion is supported by Arizona statute, which states that it is “unprofessional conduct” to “fail[] or refus[e] to maintain adequate records on a patient.” Ariz. Rev. Stat. Ann. § 32–1401(27)(e). Under Arizona law, “adequate records” must contain, at a minimum, “sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the

<sup>33</sup> The parties stipulated that “Soma is a brand name for carisoprodol, a Schedule IV controlled substance.” RD, at 27 (Stipulation No. 12).

<sup>34</sup> The Arizona DHS defines substance use disorder as “cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems.” GX 16, at 5; *see also* Tr. 305–06, 328.

patient's care at any point in the course of treatment." Ariz. Rev. Stat. Ann. § 32-1401(2).

The Arizona DHS and the Arizona Medical Board provide additional guidance about what information should be contained in a physician's medical records. The Arizona DHS Guidelines state that "[o]ngoing medical records should document the patient evaluation, a treatment plan with clearly defined goals, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant drug-related behavior observed." GX 16, at 8, 16. The Arizona Medical Board Guidelines provide that "[t]he medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation." GX 14, at 6. They further state that:

Every physician who treats patients for chronic pain must maintain accurate and complete medical records" that include the following information:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

*Id.* (internal citations removed). Further, the Arizona Medical Board's "10 essential steps of universal precautions" in assessing and reducing risk include maintaining "careful and complete records of the initial evaluation and

each follow-up visit." *Id.* at 16. Based on the uncontroverted and credible testimony of Dr. Lynch, as supported by Arizona guidance, I find that the applicable standard of care in Arizona requires that physicians maintain contemporaneous medical records documenting the patient's treatment.

Having read and analyzed all of the record evidence, I find that Dr. Lynch's credible and uncontroverted testimony is accurately supported by the Arizona guidelines and Arizona law. As such, I afford Dr. Lynch's standard of care testimony controlling weight in this proceeding.

#### *F. Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of Professional Practice*

I find that Respondent issued two hundred and nine prescriptions to three patients without complying with the minimum requirements of the applicable standard of care in Arizona. Respondent's treatment of each patient was below the applicable standard of care and outside the usual course of the professional practice for numerous reasons outlined below, including that she failed to (1) maintain adequate medical records, (2) perform a physical examination or otherwise establish a valid doctor-patient relationship prior to prescribing, (3) conduct an adequate review of past medical records prior to initiating opioid therapy, (4) query the Arizona PMP and document the results, (5) conduct urine drug screens and document the results, and (6) document a medical justification for co-prescribing opioids and benzodiazepines. Ultimately, I find that there is substantial evidence that Respondent issued two hundred and nine prescriptions outside the usual course of professional practice, and beneath the applicable standard of care in Arizona.

##### 1. Patient M.D.

Respondent issued one hundred and seventeen<sup>35</sup> prescriptions to M.D. from

<sup>35</sup> The OSC alleged that Respondent issued twenty-eight prescriptions to M.D. in violation of federal and state law, but the Government admitted evidence at the hearing that Respondent issued one hundred and seventeen prescriptions to M.D. Compare OSC, at 3-4 with GX 5; GX 18, at 2-7; see also RD, at 85, 110. I find that the Government provided Respondent with adequate notice of these additional prescriptions. The Government included photocopies of some of these prescriptions in Government Exhibit 5, and the remaining prescriptions were listed in Government Exhibit 18 (Arizona PMP report). The Prehearing Statement notified Respondent that Dr. Lynch was expected to testify about all of these prescriptions. See Govt Prehearing, at 7-10, 13. Respondent did not argue that the Government failed to provide adequate notice of these additional prescriptions, nor did she

November 23, 2012, to November 19, 2017, for hydrocodone, oxycodone, alprazolam, triazolam, diazepam, acetaminophen with codeine, and chlorthalidone.<sup>36</sup> Dr. Lynch testified that the controlled substances prescriptions that Respondent issued to M.D. were not issued in the usual course of professional practice. Tr. 199.

Dr. Lynch testified that "there were multiple indications that [M.D.] had a possible substance use disorder." *Id.* at 191-92; see also *id.* at 198, 293, 306-07, 327-32, 357. He stated that these indications included Respondent's statements to Investigators about M.D.'s alcohol problems and Arizona PMP data showing that Respondent received controlled substances from other providers on at least eighteen different occasions while under Respondent's care, from 2012 to 2017.<sup>37</sup> *Id.* at 191-93

dispute that she had issued them. See RD, at 110. Previous Agency Decisions have stated that "[t]he primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior." *Wesley Pope, M.D.*, 82 FR 14,944, 14,947 (2017) (internal citation omitted). "The parameters of the hearing are determined by the prehearing statements," and even when an issue is not raised in the OSC or the prehearing statement, "an issue can be litigated if the Government otherwise timely notifies a [r]espondent of its intent to litigate the issue." *Id.* (internal quotations and citations omitted). Although I am including all of the prescriptions alleged, the difference in the number of violations alleged in the OSC and that I have found proven at the hearing does not ultimately affect the sanction I have ordered in this case. See, e.g., *Kaniz Khan-Jaffery M.D.*, 85 FR 45,667, 45,685 (2020) (finding that "it is truly not the mere number of violations that tip the public interest against Respondent.").

<sup>36</sup> See GX 5, at 1-2, 16-21, 24-25, 32-36, 43-48, 51-56, 65-67, 76-78, 81-82, 88-99, 104-116, 119-20, 123-25, 130-36, 139-44; GX 18, at 2-7; see also RD, at 55-57, 85. The parties stipulated that all of these drugs are controlled substances. See RD, at 26-27 (Stipulation Nos. 4-6, 8-11). The parties also stipulated that "Norco is a brand name for hydrocodone" (Stipulation No. 5), "Librium is a brand name for chlorthalidone" (Stipulation No. 9), "Tylenol # 4 is a brand name for acetaminophen with codeine" (Stipulation No. 10, Tr. 199), and "Percocet is a brand name for oxycodone" (Stipulation No. 4). RD, at 26-27.

<sup>37</sup> The RD notes that Dr. Lynch "failed to mention that during the almost seven years covered by M.D.'s PMP there was only one time where the prescriptions of [Respondent] overlapped the prescriptions of another doctor." RD, at 39-40, n.19. Contrary to the RD's assertion, I find that Dr. Lynch directly addressed this issue. The ALJ told Dr. Lynch that he had observed that Respondent's prescriptions typically did not overlap with the other providers' prescriptions, meaning that the patients had already completed the course of medication from the other providers when Respondent prescribed to them. Tr. 363. Dr. Lynch testified that it does not matter whether the patient has run out of medication from the other provider. *Id.* at 364. He testified that it is a violation of the standard of care if a patient is receiving the same drug from multiple providers during the year. *Id.* Dr. Lynch testified that it is a very high-risk behavior to "jump[] around from doc to doc." *Id.*

(referencing GX 18). Dr. Lynch testified that Respondent violated the standard of care by prescribing controlled substances to M.D. without “get[ting] a referral first and document[ing] the baseline from an addiction specialist.” Tr. 261; *see also id.* at 307 (“[Y]ou should . . . send them to an addiction specialist to figure out how to treat their alcoholism.”); *id.* at 357. Dr. Lynch also testified that Respondent prescribed opioids and benzodiazepines to M.D. at the same time on a number of occasions. *Id.* at 177–78; *see also* GX 18, at 2–7; RX 3, at 2–7. Dr. Lynch testified that under the Arizona standard of care, a physician should not prescribe opioids and benzodiazepines to “someone who is abusing any medication or alcohol,” including someone who is a binge drinker. Tr. 331.<sup>38</sup> Dr. Lynch testified that it is an egregious violation of the standard of care to co-prescribe opioids and benzodiazepines without documentation. *Id.* at 275.

Respondent and M.D. confirmed at the hearing that M.D. had a substance abuse disorder, but they characterized it as “mild.” Tr. 471, 729. M.D. testified that she told Respondent “during [their] initial exams and conversations” that she “had issues with alcohol in the past.” *Id.* at 471. M.D. testified that she was “managing her alcohol problems very well” when “Respondent first started caring for her,” and she did not have “a binge drinking episode until 2014.” *Id.* at 474–75. M.D. testified that she discussed the episode with Respondent and Respondent “referred [her] to a treatment facility in Florida.” Tr. 471–73. M.D. estimated that she got treatment in April 2015. *Id.* at 474. Respondent testified that she recognized that prescribing opioids and benzodiazepines to M.D. was “not ideal,” but she “sp[oke] to [M.D.] about not using these agents together in any capacity” and she “[did not] feel that [M.D.] suffered any negative consequences from it.”<sup>39</sup> *Id.* at 729.

at 363. He testified that if a doctor learns that a patient is receiving controlled substances from other providers, the doctor must discuss it with the patient to understand why the patient is receiving controlled substances from other providers and make sure that the doctor is “okay with it.” *Id.* at 281, 323. The doctor must document those discussions in the record, as well as the patient’s reason for receiving controlled substances from multiple providers. *Id.*

<sup>38</sup> *See also id.* at 307 (“[T]he standard of care on how to treat an alcoholic or someone who has substance use disorder to alcohol is not to put them on opioids and benzos.”), 329–30 (explaining that even if M.D. did not qualify as an alcoholic, she was abusing alcohol, “and there should still be extra caution when prescribing opioids or benzos”).

<sup>39</sup> Dr. Lynch testified that it is “not a very good justification” to say that you told the patient not to take opioids and benzodiazepines together because

Despite Respondent’s and M.D.’s efforts to minimize M.D.’s alcohol problems, it was evident from Respondent’s previous statements to Investigators that M.D.’s alcohol problems were significant and active during the timeframe alleged in the OSC, and they were known to Respondent. Respondent told investigators in December 2017 that M.D. “was removed from [Respondent’s] property one time . . . because she was drunk.” GX 4, at 3. She also told Investigators, “I can’t tell you what this couple years has been like with this addiction, this alcohol issue.” *Id.* at 7. Thus, I credit Dr. Lynch’s expert testimony that Respondent violated the standard of care by prescribing controlled substances to M.D. without getting a referral first and documenting the baseline from an addiction specialist, and I also credit Dr. Lynch’s testimony that Respondent violated the standard of care by prescribing opioids and benzodiazepines to an individual with substance abuse problems.<sup>40</sup>

Dr. Lynch also testified that Respondent failed to establish a valid doctor-patient relationship with M.D. *Id.* at 199. Respondent disagreed. Although Respondent initially told Investigators that the individuals that she treated at home were “more friends” than patients, and that M.D. was “more on the side” than a patient of her practice, GX 4, at 5, 1, Respondent testified at the hearing that she believes that she established a valid doctor-patient relationship with M.D. Tr. 639. I found above based on the credible testimony of Dr. Lynch, as supported by Arizona law, that a physician must document a patient’s treatment in order

“these drugs build up in your system and will stay around for days.” *Id.* at 245.

<sup>40</sup> Dr. Lynch also testified that Respondent violated the standard of care by prescribing controlled substances to an active substance abuser. Tr. 198, 357. I found above based on Dr. Lynch’s uncontroverted expert testimony that it is an “absolute contraindication[.]” in Arizona to use chronic opioid therapy on a patient with a “[d]iagnosed substance use disorder (SUD) not in remission and/or active treatment.” *See* I.L.C. n. 9, I.L.E.5. (citing GX 16, at 12). I find that the record establishes that M.D. had a “diagnosed substance use disorder” at some point during the time period alleged in the OSC, *see, e.g.*, Tr. 471, 729, but the record is less clear on whether M.D. was receiving active treatment. Dr. Lynch’s explanation for why he believed that M.D. had an active substance use disorder appears to contemplate that M.D. may have been in treatment: “I would see someone that’s going to treatment rehab is having active substance abuse.” *Id.* at 357. Although I am unable to conclude that it was an “absolute contraindication” for Respondent to prescribe controlled substances to M.D., I find that the record contains substantial evidence that Respondent violated the standard of care by (1) failing to document a baseline from an addiction specialist before prescribing to M.D., and (2) prescribing opioids and benzodiazepines to M.D.

to establish a valid doctor-patient relationship in Arizona. *See supra* I.L.E.1. Therefore, I credit Dr. Lynch’s credible expert testimony that Respondent failed to establish a valid doctor-patient relationship with M.D.

Dr. Lynch testified that Respondent’s treatment of M.D. fell beneath the standard of care because her medical records do not contain any of the following: (1) Documentation of a sufficient medical history, Tr. 189–90; (2) documentation of a sufficient physical examination, *Id.* at 191; (3) documentation of informed consent, *id.* at 196; (4) documentation justifying the co-prescribing of opioids and benzodiazepines, *id.* at 180; (5) evidence that Respondent properly addressed the co-prescribing of opioids and benzodiazepines, *id.* at 191; (6) documentation justifying the long-term prescribing of alprazolam, *id.* at 196; (7) evidence that Respondent identified and addressed the controlled substances that M.D. received from other providers, *id.* at 194; (8) evidence that Respondent addressed M.D.’s substance abuse problems, *id.* at 192; (9) evidence that Respondent conducted urine drug screens, *id.* at 194; (10) evidence that Respondent checked the Arizona PMP,<sup>41</sup> *id.* at 279, 358; and (11) evidence that Respondent obtained M.D.’s past medical records and put those records in the context of the patient’s treatment plan,<sup>42</sup> *id.* at 194–95.

Despite her failure to document her treatment of M.D., Respondent testified that she conducted a physical examination and took a medical history during her first encounter with M.D. *Id.* at 653–60. Respondent and M.D. testified in detail about the examinations that Respondent performed and the conversations they had about M.D.’s treatment. *See, e.g., id.* at 447–526 (M.D.’s testimony); 653–92 (Respondent’s testimony). However, none of those examinations or discussions was documented. Dr. Lynch testified “it’s possible” to conduct adequate physical examinations and medical histories without documenting them, but the fact that Respondent is not documenting them “makes it not appropriate, not an adequate doctor/patient relationship.” *Id.* at 379.

Dr. Lynch testified that Respondent’s medical records for M.D. do not comply

<sup>41</sup> Respondent testified that she thinks she checked the PMP for M.D. once in approximately 2014. *Id.* at 722. However, she did not document the results in M.D.’s medical record, as Dr. Lynch testified was required by the standard of care. *Id.* at 181–82.

<sup>42</sup> M.D. testified that she did not provide past medical records to Respondent. *See id.* at 450, 452–53, 487–88, 491.

with the minimum requirements of the Arizona standard of care. *Id.* at 196–97. Dr. Lynch testified that the Arizona Medical Board has a “very good document on giving physicians guidance on how to prescribe opioids, and they go into great detail of what must be documented, including informed consent, . . . a sign[ed] [] contract understanding the risks and benefits of the opioids, . . . a thorough review of systems, a thorough physical exam[,] . . . periodic urine drug testing, . . . [and a] review [of] prior records.” *Id.* at 196–97. Dr. Lynch testified that he “[did not] see any of that provided here.” *Id.* at 197. Additionally, Dr. Lynch was asked whether Respondent’s medical records for M.D. “sufficiently identify the patient, support the diagnosis, justify the prescribing of controlled substances, accurately document the results, indicate advice and cautionary warnings provided to the patient, and provide sufficient information for another practitioner to assume continuity of the patient’s care at any point in the course of treatment,” and he confirmed that they do not. *Id.* These elements that Dr. Lynch testified are missing from M.D.’s medical records mirror Arizona law’s requirements for “adequate” medical records. *See* Ariz. Rev. Stat. Ann. § 32–1401(2).

Dr. Lynch testified that Respondent’s efforts after the December 2017 Interview to memorialize past treatment of M.D. were not sufficient to show that a medical history or physical examination were performed, because “memories change over time, and a medical history should be done contemporaneous to doing the medical exam.” *Id.* at 190–91, 195–96. Dr. Lynch testified that “creat[ing] a document to show retrospectively what happened during the year” is “definitely outside the standard of care, not the intent of the Arizona Medical Board, the Arizona Department of Health, or even the Arizona legislature in their direction on how to deal with medical records.” *Id.* at 190.

Dr. Lynch testified that Respondent may have “put [M.D.’s] life at risk” by failing to comply with the standard of care because of M.D.’s “clear history of alcoholism, [and] potentially other substance abuse disorders as well,” which “puts [her] at risk of abuse, misuse, overdose, and death.” *Id.* at 197–98. Dr. Lynch acknowledged that Respondent prescribed low doses of controlled substances to M.D., which is “a mitigating factor,” but he stated that he believed that Respondent “put [M.D.] at undue risk by the way she managed [M.D.]” because of “the history of

alcoholism, plus opioids, plus benzos, plus multiple providers.” *Id.* at 294.

Based on the credible, uncontroverted testimony of Dr. Lynch and the substantial evidence on the record that M.D. had a history of substance abuse with alcohol, I find that Respondent issued one hundred and seventeen prescriptions to M.D. outside the usual course of professional practice, and beneath the applicable standard of care in Arizona.

## 2. Patient H.D.

Respondent issued sixty-eight<sup>43</sup> prescriptions to H.D. from February 8, 2013, to December 6, 2017, for hydrocodone, oxycodone, carisoprodol, triazolam, and acetaminophen with codeine.<sup>44</sup> Dr. Lynch testified that the controlled substances prescriptions that Respondent issued to H.D. were not issued in the usual course of professional practice. Tr. 209–10.

Dr. Lynch testified that Respondent’s medical record for H.D. does not contain sufficient evidence that Respondent took an adequate medical history or performed an adequate physical examination prior to prescribing controlled substances. *Id.* at 204–05. Dr. Lynch also testified that there is no evidence in Respondent’s medical record that Respondent conducted urine drug screens or obtained prior medical records, as required by the standard of care. *Id.* at 205–06. Respondent admitted that she did not check the PMP for H.D. while she was prescribing to H.D. *Id.* at 722.

H.D. testified that Respondent prescribed him opioids for neck and back pain and triazolam for sleep problems related to shift work. *Id.* at 398, 433–34. Respondent also testified that she prescribed triazolam to H.D. for shift work disorder, although there is no mention of shift work disorder in H.D.’s medical file or in the letter that H.D. prepared discussing Respondent’s treatment of him. *Compare id.* at 646–

<sup>43</sup> The OSC alleged that Respondent issued seventeen prescriptions to H.D. in violation of federal and state law, but the Government admitted evidence at the hearing that Respondent issued sixty-eight prescriptions to H.D. *Compare* OSC, at 3 with GX 5 (prescriptions), GX 18, at 10–15 (PMP data); RD, at 91. I find that the Government provided Respondent with adequate notice of these additional prescriptions in its prehearing statement. *See* Govt Prehearing, at 12–13. Respondent did not argue that the Government failed to provide adequate notice of these additional prescriptions, nor did she dispute that she had issued them. *See* RD, at 110. Ultimately, the difference in the number of the violations alleged in the OSC and those demonstrated at hearing does not affect my findings on the public interest in this case. *See supra* n.35.

<sup>44</sup> *See* GX 5, at 3–6, 10–15, 22–23, 28–31, 37–42, 49–50, 57–64, 72–75, 79–80, 83–84, 87, 100–03, 117–18, 126–29, 137–38, 145–46; GX 18, at 10–15; *see also* RD, at 47–49, 91.

47 with GX 7. H.D. testified that Respondent conducted a physical examination, took a medical history, and reviewed past medical records on his computer prior to prescribing controlled substances.<sup>45</sup> *See, e.g., id.* at 389–98. H.D. testified that the physical examination of his back and neck occurred “probably [] sometime in 2012,” and Respondent did not examine his back and neck again because “it was the same continuing problem.” *Id.* at 443. I found above based on Dr. Lynch’s credible expert testimony that the Arizona standard of care requires physicians to document the physical examination and medical history. *See supra* II.E.1, 2. Therefore, I find that Respondent violated the standard of care by failing to document a medical history and physical examination, even if she performed them.

Dr. Lynch testified that Respondent failed to establish a valid doctor-patient relationship with H.D. Tr. 209–10. Respondent testified that she believes that she established a valid doctor-patient relationship with H.D., *id.* at 639, and H.D. testified that he felt that he had a valid doctor-patient relationship with Respondent. *Id.* at 419. However, I found above that a physician must document a patient’s treatment in order to establish a valid doctor-patient relationship in Arizona. *See supra* II.E.1. Therefore, I credit Dr. Lynch’s credible expert testimony that Respondent failed to establish a valid doctor-patient relationship with H.D.

Dr. Lynch further identified several instances where Respondent prescribed H.D. an opioid concurrently with carisoprodol or a benzodiazepine, and he testified that this prescribing pattern occurs throughout the entire file. *Id.* at 199–203. Dr. Lynch testified that there is no documentation in H.D.’s medical record explaining why these two substances were prescribed together. *Id.* at 205. Dr. Lynch testified that with “72,000 deaths per year in the United States due to overdoses, with 1 in 500 patients overdosing and dying[,] [t]here should be great vigilance when a [sic] opioid or benzodiazepines or [carisoprodol] is given to a patient.” *Id.* at 209. Dr. Lynch testified that Respondent could have done harm to H.D. by prescribing this drug combination. *Id.*

<sup>45</sup> H.D. testified that he showed Respondent blood pressure readings, results of an A1C test, and an MRI report, but none of those records were produced at the hearing. *Id.* at 392. Dr. Lynch testified that a full review of medical records is required by the standard of care, and it is not sufficient for the physician to simply review an MRI or laboratory results. *Id.* at 183–84.

Dr. Lynch also testified that the Arizona PMP shows that H.D. received controlled substances from providers other than Respondent while he was under Respondent's care. *Id.* at 206–07; GX 18, at 10–15. Dr. Lynch identified four instances where H.D. obtained prescriptions from other providers for hydrocodone, acetaminophen with codeine, or carisoprodol—the same controlled substances that Respondent was prescribing. Tr. 206–07; GX 18, at 12–13. Dr. Lynch stated that H.D.'s medical record does not address these prescriptions, as required by the standard of care.<sup>46</sup> *Id.* at 207.

Finally, Dr. Lynch testified that Respondent's medical records for H.D. do not comply with the minimum standard of care because “there's no contemporaneous documentation of any of the scripts.” *Id.* at 208. Additionally, Dr. Lynch was asked whether Respondent's medical records for H.D. “sufficiently identify the patient, support the diagnosis, justify the prescribing of controlled substances, accurately document the results, indicate advice and cautionary warnings provided to the patient, and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment,” and he confirmed that they do not. *Id.* at 209. These elements that Dr. Lynch testified are missing from H.D.'s medical records mirror Arizona law's requirements for “adequate” medical records. *See* Ariz. Rev. Stat. Ann. § 32–1401(2).

Based on the credible, uncontroverted testimony of Dr. Lynch and the substantial evidence on the record, I find that Respondent issued sixty-eight prescriptions to H.D. outside the usual course of professional practice and beneath the applicable standard of care in Arizona.

### 3. Patient S.P.

Respondent issued twenty-four<sup>47</sup> prescriptions to S.P. from January 3,

<sup>46</sup>The RD notes that “Dr. Lynch failed to mention that during the almost seven years covered by H.D.'s PMP none of these four instances of obtaining a controlled substance from a provider other than [Respondent] resulted in a situation where the prescriptions of [Respondent] overlapped the prescriptions of another doctor.” RD, at 39 n.18 (citing GX 18, at 10–14). As noted above, *see supra* n.37, I find that Dr. Lynch addressed the fact that the prescriptions did not overlap. Generally, I find that the question of whether or not Respondent's prescriptions overlapped with the other providers' prescriptions was not relevant to Dr. Lynch's opinion. The violation of the standard of care, according to Dr. Lynch, is that Respondent failed to document that H.D. was receiving controlled substances from other providers while she was prescribing to him. *See* Tr. 206–07, 281, 323.

<sup>47</sup>The OSC alleged that Respondent issued seven prescriptions to S.P. in violation of federal and state

2013, to July 16, 2017, for hydrocodone, triazolam, diazepam, tramadol, and clonazepam.<sup>48</sup> During that same timeframe, S.P. was also prescribing controlled substances to Respondent.<sup>49</sup> GX 19, at 1–3. Dr. Lynch testified that the controlled substances prescriptions that Respondent issued to S.P. were not issued in the usual course of professional practice. Tr. 216.

Dr. Lynch testified that Respondent failed to establish a valid doctor-patient relationship with S.P. *Id.* Respondent disagreed. Respondent testified that she believes that she established a valid doctor-patient relationship with S.P. *Id.* at 639. Respondent testified that she treated S.P. from the early 2000s to the end of 2017 “for a myriad primary care issues.” *Id.* at 636, 691. S.P. and Respondent testified that Respondent performed physical examinations on S.P. before prescribing controlled substances. *Id.* at 540, 598, 608, 692. S.P. testified that the examinations usually took place in her home. *Id.* at 598. S.P. testified that Respondent examined her on more than ten occasions but she could not recall precisely how many times. *Id.* at 598–99. S.P. testified that Respondent prescribed Xanax and triazolam for shift work sleep disorder. *Id.* at 546, 646. S.P. also testified that Respondent prescribed controlled substances to her for a shoulder and knee injury. *Id.* at 537–38, 541, 592–93. In her lay opinion, S.P. believed that Respondent prescribed controlled substances to her for a legitimate medical purpose. *Id.* at 549–50.

Despite S.P.'s and Respondent's efforts to describe the treatment that Respondent provided to S.P. over a number of years, I found above based on Dr. Lynch's credible expert testimony that the Arizona standard of care requires physicians to document the physical examination and medical

law, but the Government admitted evidence at the hearing that Respondent issued twenty-four prescriptions. *Compare* OSC, at 3 with GX 5 (prescriptions), GX 18, at 16–20 (PMP data); *see also* RD, at 95. I find that the Government provided Respondent with adequate notice of these additional prescriptions in its prehearing statement. *See* Govt Prehearing, at 11–13. Respondent did not argue that the Government failed to provide adequate notice of these additional prescriptions, nor did she dispute that she had issued them. *See* RD, at 110.

<sup>48</sup>*See* RX 5, at 4; GX 5, at 7, 9, 26–27, 68–69, 70–71, 85–86, 121–122; GX 18, at 16–20; *see also* RD, at 61–62, 95. The parties stipulated that “Klonopin is a brand name for clonazepam, a Schedule IV controlled substance.” RD, at 27 (Stipulation No. 14).

<sup>49</sup>According to the Arizona PMP, S.P. issued thirty prescriptions to Respondent for at least four different controlled substances: Alprazolam, hydrocodone/acetaminophen, triazolam, and testosterone. GX 18, at 1–3.

history. *See supra* II.E.1.2. I also found above that a physician must document a patient's treatment in order to establish a valid doctor-patient relationship in Arizona. *See supra* II.E.1. Therefore, I credit Dr. Lynch's credible expert testimony that Respondent failed to establish a valid doctor-patient relationship with S.P.

Dr. Lynch testified that Respondent's medical records for S.P. do not comply with the minimum standard of care. *Id.* at 214. He reasoned that there is no documentation of a sufficient medical history or a proper physical examination and there is no explanation of why triazolam and hydrocodone were prescribed. *Id.* at 213. Dr. Lynch testified that Respondent obtained some “other records” for S.P. from other physicians, but these records were insufficient to meet the minimal Arizona standard of care because Respondent failed to document “when they were received, what they mean, [and] any kind of follow-up on it.” *Id.* at 214–15. “[T]here's nothing here that anyone could use to treat [S.P.] going forward.” *Id.* Additionally, Dr. Lynch was asked whether Respondent's medical records for S.P. “sufficiently identify the patient, support the diagnosis, justify the prescribing of controlled substances, accurately document the results, indicate advice and cautionary warnings provided to the patient, and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment,” and he confirmed that they do not. *Id.* at 215. These elements that Dr. Lynch testified are missing from S.P.'s medical records mirror Arizona law's requirements for “adequate” medical records. *See* Ariz. Rev. Stat. Ann. § 32–1401(2).

Dr. Lynch testified that S.P.'s PMP shows that she received nine different controlled substances from nine different providers from January 1, 2013, to September 4, 2018. *Id.* at 211–12, 343–44; GX 18, at 16–20. Dr. Lynch testified that getting controlled substances from nine different providers is “a big red flag” and “a high-risk behavior,” even if the patient has an excuse.<sup>50</sup> Tr. 272–73. Dr. Lynch testified

<sup>50</sup>S.P. testified that three providers on the PMP—Dr. Mortazavi, Dr. Nicoletti, and Dr. Wristen—were colleagues of her primary care provider, Dr. Bessette. Tr. 568–70. These three providers wrote prescriptions for S.P. on Dr. Bessette's behalf, but S.P. testified that she never saw these providers. *Id.* Dr. Lynch acknowledged that four of the providers on S.P.'s PMP shared the same address. *Id.* at 349. Dr. Lynch testified that his concerns would be “slightly mitigated” if those doctors worked for the same practice, but he testified that there were still

that there is no documentation in S.P.'s medical file addressing this behavior, as required by the Arizona standard of care. *Id.* at 213–14, 323. Dr. Lynch also testified that it was outside the standard of care for Respondent to prescribe opioids and benzodiazepines to a patient who was getting these drugs from other doctors, even if Respondent's prescriptions did not overlap with the other doctors' prescriptions.<sup>51</sup> *Id.* at 274, 323, 364–65. He testified that this is especially true because there was no documentation. *Id.* at 274–75; 323.

Dr. Lynch testified that there were red flags that S.P. may have been struggling with “opioid use disorder” or “benzo use disorder,” including that S.P. received multiple controlled substances from multiple doctors, and that S.P. was prescribing controlled substances to Respondent at the same time that Respondent was prescribing to her. *Id.* at 213–15, 294–95, 297, 307. Dr. Lynch testified that by failing to address these red flags, Respondent “could have done harm to [S.P.] by her treatment.” *Id.* at 215, 294–95. Dr. Lynch testified that he would have “do[ne] a urine drug test,” “sen[t] for an assessment,” and “ha[d] a conversation about what’s going on.” *Id.* at 295. There is no evidence that Respondent conducted urine drug screens, *id.* at 213, and Respondent admitted that she did not check the PMP for S.P. while she was prescribing to S.P., *id.* at 722.

Based on the credible, uncontroverted testimony of Dr. Lynch and the substantial evidence on the record, I find that Respondent issued twenty-four prescriptions to S.P. outside the usual course of professional practice, and beneath the applicable standard of care in Arizona.

a lot of red flags in the chart. *Id.* at 297. Dr. Lynch also acknowledged that one of the nine providers did not prescribe to S.P. until 2018, and Respondent stopped prescribing to S.P. in 2017. *Id.* at 360–61. Dr. Lynch testified that this fact did not change his opinion. *Id.* at 361.

<sup>51</sup>The RD notes that “Dr. Lynch failed to mention that during the almost six years covered by S.P.’s PMP none of these instances of obtaining a controlled substance from a provider other than [Respondent] resulted in a situation where prescriptions of [Respondent] overlapped the prescriptions of another doctor.” RD, at 41 n.20. As noted above, *see supra* n.37, I find that Dr. Lynch addressed the fact that the prescriptions did not overlap. Generally, I find that the question of whether or not Respondent’s prescriptions overlapped with the other providers’ prescriptions was not relevant to Dr. Lynch’s opinion. The violation of the standard of care, according to Dr. Lynch, is that Respondent failed to document that S.P. was receiving controlled substances from other physicians while she was prescribing to him. *See Tr.* 213–14, 323.

### III. Discussion

#### A. Allegation That Respondent’s Registration Is Inconsistent With the Public Interest

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 section 823 of this title 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 “physician,” Congress directed the Attorney General to consider the following factors in making the public interest determination:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing . . . controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to the . . . distribution [ ] or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003).

According to Agency Decisions, I “may rely on any one or a combination of factors and may give each factor the weight [I] deem [ ] appropriate in determining whether” to revoke a registration. *Id.*; *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); *MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *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 I am required to consider each of the factors, I “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); *see also Hoxie*, 419 F.3d at 482. “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 Tenth

Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

DEA regulations state, “[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.” 21 CFR 1301.44(e). In this matter, while I have considered all of the factors,<sup>52</sup> the relevant evidence is confined to Factors Two and Four. I find that the evidence satisfies the Government’s *prima facie* burden of showing that Respondent’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(a)(4). I further find that Respondent failed to produce sufficient evidence to rebut the Government’s *prima facie* case.

#### 1. Factors Two and Four—the Respondent’s Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

##### (a) Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice

According to the CSA’s implementing regulations, a lawful controlled substance order or prescription is one that is “issued for a legitimate medical purpose by an individual practitioner

<sup>52</sup>As to Factor One, the evidence in the record is that Respondent has an Arizona medical license, Tr. 624, and there is no evidence in the record of any recommendation from Respondent’s state licensing board or professional disciplinary authority. 21 U.S.C. 823(f)(1). State authority to practice medicine is “a necessary, but not a sufficient condition for registration . . .” *Robert A. Leslie, M.D.*, 68 FR at 15230. Therefore, “[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent’s DEA certification is consistent with the public interest.” *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011).

As to Factor Three, there is no evidence in the record that Respondent has a “conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010). Agency cases have therefore held that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.*

As to Factor Five, the Government alleged that Respondent made several false statements to Investigators that should be considered under Factor Five. *See Govt Prehearing*, at 6; *Govt Posthearing*, at 5–13, 45–48. In this case, I found it more appropriate to address these statements in my assessment of Respondent’s credibility as a witness, rather than under Factor Five. *See supra* II.D.

acting in the usual course of his professional practice.” 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA’s requirement that schedule II controlled substances may be dispensed only by written prescription, that “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.” *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

Based on Dr. Lynch’s credible and un rebutted expert testimony and the substantial evidence on the record, I found above that Respondent issued two hundred and nine prescriptions for controlled substances beneath the applicable standard of care in Arizona and outside of the usual course of professional practice. *See supra* II.F. Therefore, I find that Respondent violated 21 CFR 1306.04(a).

Respondent admits that she committed unprofessional conduct by failing to maintain adequate medical records. Resp Posthearing, at 8, 12; Tr. 719. However, aside from that failure, Respondent maintains that her treatment of H.D., M.D., and S.P. was appropriate. *See* Resp Posthearing, at 15 (stating that “[t]he only acknowledged and established deficiency was the maintenance of medical records”).<sup>53</sup> Respondent argues that the Government’s “assumption that the absence of a written record implies the absence of a sufficient medical history or medical examination of each patient” was “rebutted by the credible, sworn testimony of M.D., H.D., S.P., and [ ] the Respondent.” *Id.* at 10. Respondent argues that she conducted “[t]horough medical histories” and “thorough focused physical exams,” she reviewed relevant diagnostic tests, she devised a treatment plan, she “periodically assessed” “the effectiveness of controlled substance treatment,” and she made “referrals . . . to appropriate specialists.” *Id.* at 15. Respondent emphasizes that H.D., M.D., and S.P. were “experienced health care professionals” who “had a comprehensive grasp of their medical treatment.” *Id.* at 9.<sup>54</sup> Finally,

<sup>53</sup> *See also* GX 13 (Respondent’s August 22, 2018 letter to Investigators stating that Respondent’s “standard practice has always been to prioritize patient care and safety,” and emphasizing that Respondent established valid doctor-patient relationships with H.D., M.D., and S.P. and treated them for legitimate medical conditions).

<sup>54</sup> *See also* Tr. 730 (testifying that “[o]ne of the benefits of having medical providers as patients is

Respondent argues that the Government failed to prove that she committed additional violations of the standard of care beyond her failure to maintain adequate medical records. *See* Resp Posthearing, at 7–10, 15.

I am not persuaded by Respondent’s arguments. First, I cannot agree with Respondent that she performed adequate physical examinations, conducted adequate medical histories, and otherwise appropriately treated her patients when there is no documentation of that treatment. The Agency has repeatedly emphasized that “[c]onscientious documentation is . . . not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician’s prescribing practices are within the usual course of professional practice.” *Cynthia M. Cadet, M.D.*, 76 FR 19,450, 19,464 (2011) (internal citation and quotation omitted); *see also Kaniz F. Khan-Jaffery, M.D.*, 85 FR 45667, 45686 (2020) (“DEA’s ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment.”).

The Arizona Medical Board echoes this sentiment, emphasizing that adequate documentation is critical in assessing a physician’s compliance with the standard of care. The Guidelines state: “The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, *is appropriately documented*, and is of demonstrable benefit to the patient.” GX 14, at 5 (emphasis added). The Guidelines further state that “[t]he Board will judge the validity of the physician’s treatment of a patient on the basis of *available documentation*, rather than solely on the quantity and duration of medication administered.” *Id.* at 6 (emphasis added). Finally, the Guidelines state that “[t]he Board will not take disciplinary action against a physician for deviating from this Reference when *contemporaneous medical records* show reasonable cause for such deviation.” GX 14, at 6 (emphasis added). The Arizona legislature, the Arizona Medical Board, and the Arizona DHS provide detailed guidance on what must be documented, including a medical history, a physical

they are very cognitively aware of the situation they’re entering into,” but noting that it “doesn’t negate [her] responsibility” to them).

examination, and sufficient information to support the diagnosis and justify the treatment. *See supra* II.E.6 (citing GX 14, GX 16, and Ariz. Rev. Stat. Ann. § 32–1401(2)). Dr. Lynch testified that the medical record is also known as the “medical/legal record,” because “it’s accepted that when we go through [the] process” of “document[ing] exactly what we talked about, what we did, . . . then it actually happened, and we did it.” Tr. 301; *see also id.* at 354. He has “always been taught if you didn’t document it, you didn’t do it.” *Id.* at 301.

Without documentation, there is no way to adequately assess Respondent’s treatment of her patients. Witness accounts of treatment that happened years before are not reliable.<sup>55</sup> Respondent’s witnesses occasionally acknowledged that their recollection was limited. For example, M.D. and S.P. could not reliably estimate how many times Respondent had physically examined them. M.D. testified, “that’s a lot of years. I don’t recall.” *Id.* at 502. S.P. testified that she “[did not] recall that number” and she could not “give [ ] an estimate.” *Id.* at 598. When pressed, S.P. testified that she was examined “several times” and agreed that it was more than ten. *Id.* at 599. S.P. also could not recall what condition Respondent first treated her for, or when Respondent first prescribed her controlled substances. *Id.* at 536–37. This lack of precision is insufficient to assess Respondent’s compliance with the standard of care.

I am also not persuaded by Respondent’s argument that her only violation of the standard of care was her failure to maintain adequate medical records. I found above that the Government’s expert credibly testified that Respondent committed numerous violations of the Arizona standard of care in her treatment of H.D., M.D., and S.P. *See supra* II.F. For example, I found that Respondent failed to document adequate medical histories and physical examinations, failed to conduct urine drug screens, failed to check the Arizona PMP, failed to document a justification for co-prescribing opioids and benzodiazepines, and failed to adequately review past medical records—all required by the Arizona standard of care. I also found that Respondent violated the standard of care by prescribing opioids and benzodiazepines to an individual with known substance abuse problems.

<sup>55</sup> I also noted above that the witness accounts have limited probative value because the witnesses have a strong incentive to provide testimony that supports that Respondent’s prescribing to them was lawful and legitimate. *See supra* II.D.

Respondent argues that she did not violate the standard of care by failing to conduct periodic urine drug screens and regular PMP checks, because neither tool was required by state law. Resp Posthearing, at 9. Respondent also argues that the patients informed her about all of the controlled substances that they received from other physicians, so she “had sufficient knowledge of all the medical treatment and prescriptions” to enable her to “exercise properly her clinical judgment as to each patient.” *Id.*; see also Tr. 733 (testifying that she had no “significant reason to utilize those [tools] because [she] knew each time they were receiving something from somebody else” and she “believed what [they] were telling [her]”).

I disagree with Respondent that PMP checks and urine drug screens were not required by the standard of care. See *supra* II.E.3. Although Dr. Lynch acknowledged that neither tool was mandated by the Arizona legislature,<sup>56</sup> I found above that Dr. Lynch credibly testified that both are part of the minimum standard of care in Arizona. *Id.* This expert testimony was un rebutted and it was supported by the Arizona DHS Guidelines and the Arizona Medical Board Guidelines. *Id.* I also disagree with Respondent that it was appropriate for her to rely on her patients’ accounts of the prescriptions that they received from other physicians. Dr. Lynch testified that it is important to use objective tools, such as urine drug screens and the PMP, to monitor patient compliance because “1 in 500 patients [is] dying from opioids and 33 percent . . . [are] abusing or misusing” opioids. Tr. 198.<sup>57</sup> Additionally, I found based on Dr.

Lynch’s un rebutted expert testimony that if Respondent knew that her patients were receiving controlled substances prescriptions from other physicians, the standard of care required her to at the very least, document that fact in the patient records, as well as her discussions with the patients resolving the red flag. See *id.* at 281, 293, 323.

Respondent implies that her patients required less monitoring because they are experienced health care professionals who “had a comprehensive grasp of their medical treatment including their controlled substance prescriptions from other medical providers.” Resp Posthearing, at 9. However, Respondent did not offer any evidence that medical providers are less susceptible to drug abuse and diversion than other patients. And in fact, the evidence showed that H.D., M.D., and S.P. were all receiving controlled substances from other providers, while under Respondent’s care, which is considered an “[a]berrant drug-related behavior[]” that requires more frequent monitoring, according to the Arizona DHS. See *supra* II.E.3 (citing GX 16, at 13).

Respondent’s failure to utilize objective monitoring tools was particularly egregious with M.D., due to her known substance abuse problems. Dr. Lynch testified that M.D. is a high-risk patient because she is an alcoholic. Tr. 272. According to the Arizona DHS, high-risk patients should be screened every three months or more often, as indicated. *Id.* at 277–80; GX 16, at 13–14. Objective testing was also important with M.D. because the evidence suggests that Respondent lacked objectivity with M.D. because of their close personal relationship. Respondent told Investigators in 2017 that she had been “duped” by M.D. before and that she can “be a little too trusting sometimes, especially if it’s someone . . . [she] care[s] about.” GX 4, at 7.

Respondent also argues that she did not violate the Arizona standard of care by prescribing opioids and benzodiazepines concurrently because “the use of [these drugs] is allowable and is a matter of medical judgment.” Resp Posthearing, at 7 (citing GX 16; Tr. 262, 299). Respondent references Dr. Lynch’s testimony that co-prescribing is not a violation of the standard of care and his testimony that a physician’s clinical judgment trumps the guidelines. Tr. 280. I find that Respondent’s reliance on Dr. Lynch’s testimony about clinical judgment is misplaced,<sup>58</sup> but I

agree with Respondent that Arizona does not ban co-prescribing in individuals who do not have substance abuse problems.<sup>59</sup> See *supra* II.E.4. However, I found above that the Arizona standard of care requires physicians to document their justification for co-prescribing and their discussions with the patient about the risks and benefits of co-prescribing. *Id.* Because Respondent did not document either, I have found that she violated the standard of care. See *supra* II.F.

In addressing her failure to obtain past medical records, Respondent argues that she was “well acquainted” with each patient and “openly discussed all past medical care” before initiating treatment. Resp Posthearing, at 9. Respondent references M.D.’s testimony that they discussed all of M.D.’s past experiences, medications, and providers before Respondent prescribed any medication. *Id.* (citing Tr. 450). Respondent also cites H.D.’s testimony that Respondent took a complete medical history and reviewed his laboratory and MRI results on his computer before prescribing. *Id.* (citing 391–92, 394, 396).

I disagree with Respondent that these efforts excused her from complying with the requirement of obtaining past medical records. Dr. Lynch testified that physicians should conduct a full review of relevant prior records in order to “understand the condition” and evaluate the effectiveness of past treatments. See *supra* II.E.2. The Arizona Medical Board emphasizes that it is important to verify patients’ reports of past treatment by obtaining past medical records: “Information provided

judgment” and that “clinical judgment trumps the recommendations.” Tr. 262. Dr. Lynch also agreed that a “doctor’s clinical judgment could cause her to prescribe treatment for somebody or not use drug testing, even though the guidelines recommend it, if, in her clinical judgment, it wasn’t necessary.” *Id.* at 262–63. However, Dr. Lynch also testified that the Arizona DHS and the Arizona Medical Board “each give eight to 10 things that you should do,” and while physicians may “have a right to kind of say, well, I’m not going to do that or I’m not going to do this,” they should generally follow the guidance. *Id.* at 263. Dr. Lynch continued, “[I]t doesn’t seem like any of the recommendations are followed, and that’s my concern.” *Id.* Thus, it may have been permissible for Respondent to exercise her clinical judgment not to follow a specific recommendation, but Dr. Lynch testified that she violated the standard of care by ignoring the “totality of” the Arizona DHS’s and the Arizona Medical Board’s recommendations. *Id.* Respondent also violated the standard of care by failing to document why her “clinical judgment” caused her to disregard recommendations of the Arizona DHS and the Arizona Medical Board.

<sup>59</sup> I found above that Respondent violated the standard of care by co-prescribing to M.D. based on Dr. Lynch’s expert testimony that it is a violation of the standard of care to co-prescribe to individuals with substance abuse problems. See *supra* II.F. (citing Tr. 331).

<sup>56</sup> Respondent’s counsel asked Dr. Lynch whether PMP checks and urine drug screens were “required” in Arizona, and Dr. Lynch testified that they were not. *Id.* at 270–71, 280. Dr. Lynch clarified that urine drug screens are part of the minimum standard of care in Arizona, even though they are not required by state law: “[Y]ou keep using words like requirements or standard of care or law. There are a lot of bodies that spend a lot of time trying to influence the standard of care, and they’ll come out in the form of requirements—or not requirements but recommendations. And then the doctors typically will get in line, but they don’t always adopt all of it. But it certainly has been the standard of care to urine drug test in the State of Arizona for the last seven or eight years.” *Id.* at 271.

<sup>57</sup> See also Tr. 183 (“between 19 and 40 percent of patients will be abusing or misusing the opioid that you’re writing . . . so urine drug screening is one objective way that we know that they’re taking the medication”), *id.* at 237–38 (physicians should “trust” what their patients are telling them, “but verify” their reports using tools such as urine drug screens and PMP reports); GX 14, at 10 (“Drug testing is an important monitoring tool because self-reports of medication use are not always reliable and behavioral observations may detect some problems but not others.”).

<sup>58</sup> Dr. Lynch agreed with Respondent’s counsel that a physician is “always supposed to use clinical

by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible.” GX 14, at 7. It is critical that physicians take steps to prevent the abuse and diversion of controlled substances by using objective tools to verify the veracity of patients’ statements and their compliance with their treatment plan. *See Roy S. Schwartz*, 79 FR 34,360, 34,363 (2014) (“[D]iversion occurs whenever controlled substances leave the closed system of distribution established by the CSA . . .”).

Respondent also defends her decision to prescribe controlled substances to M.D. despite M.D.’s substance abuse problems. Respondent states that she had “first-hand knowledge” of M.D.’s alcohol problems because she discussed them with M.D. “during [their] initial conversations and medical examinations.” Resp Posthearing, at 8 (citing 471, 479, 655). Respondent argues that M.D. was “managing her alcohol problems very well” when “Respondent first started caring for her,” and that M.D. did not have “a binge drinking episode until 2014.” *Id.* (citing Tr. 474–75). Respondent discussed the episode with M.D. and “referred [her] to a treatment facility in Florida.” *Id.* (citing Tr. 471–73). Thus, Respondent argues that the Government’s “claim that [her] treatment of M.D. fell below the standard of care because she allegedly [] failed to refer M.D. to an Addiction Specialist . . . is simply not true.” *Id.*

I appreciate that Respondent discussed M.D.’s substance abuse problems with her and referred her to a treatment facility. However, Respondent did not document any of those efforts. Dr. Lynch testified that physicians should “define” and “document the baseline from an addiction specialist” before prescribing to an alcoholic because “addiction docs do a really good job of doing a history.” *See supra* II.E.5, II.F.1 (citing Tr. 261, 357). Dr. Lynch also testified that prescribing opioids and benzodiazepines to anyone who is abusing alcohol is a violation of the standard of care, and that prescribing these drugs with no documentation is an “egregious” violation. *See supra* II.E.5, II.F.1 (citing Tr. 275, 331). There is no evidence that Respondent ever performed a urine drug screen on M.D., despite M.D.’s alcoholism and her high risk behavior of receiving controlled substances from different providers on eighteen occasions. *Id.* (citing Tr. 191–93). And Respondent only checked the PMP once

in at least five years of prescribing controlled substances to M.D. Tr. 722. Thus, Respondent’s standard of care violations with M.D. go beyond her alleged failure to refer M.D. to a treatment facility.

Respondent also argues that Dr. Lynch is not an expert in treating substance abuse disorders<sup>60</sup> and that he “admitted he did not even have enough medical records to render an expert opinion on M.D.’s alcohol consumption.” Resp Posthearing, at 8. Although Dr. Lynch testified that he did not have enough documentation to definitively diagnose M.D. with a substance abuse disorder, he testified that it is “more than likely” that she had a substance abuse disorder. Tr. 338–39; *see also* II.F.1. (citing Tr. 191–92, 198, 293, 306–07, 327–32, 357). There is substantial evidence on the record to support Dr. Lynch’s testimony that M.D. had substance abuse problems, including Respondent’s statements to Investigators in 2017 that M.D. was an alcoholic and M.D.’s testimony that she was diagnosed with a “mild” substance abuse disorder. *See supra* II.F.1. Moreover, it is not necessary to definitively diagnose M.D. with a substance abuse disorder because Dr. Lynch testified that even if M.D. did not have a “full-on addiction,” she was “still [] abusing [alcohol],” and it is a violation of the standard of care to prescribe opioids and benzodiazepines to “someone who is abusing any medication or alcohol.” Tr. 329–31. Dr. Lynch testified that prescribing opioids or benzodiazepines to an individual with a substance abuse disorder “puts the person at risk of abuse, misuse, overdose, and death,” and Respondent may have put M.D.’s life at risk because of her clear history of alcoholism. *Id.* at 197–98.

Finally, Respondent asserts that “[t]he government did not produce any evidence of diversion in three days of testimony,” nor did the government “produce any evidence of harm to the public health of a patient of the Respondent.” Resp Posthearing, at 11. However, Respondent does not cite legal authority for the proposition that I must find evidence of diversion or harm before I may suspend or revoke a registration. Agency Decisions have found that DEA has the authority to revoke a DEA registration in the absence of evidence of diversion if the registrant’s “prescribing practices . . . create a substantial risk of diversion” or even the “opportunity for diversion.” *See, e.g., Garrett Howard Smith, M.D.,*

<sup>60</sup> As discussed above, I find that Dr. Lynch was sufficiently qualified to opine on M.D.’s substance abuse problems. *See supra* II.C.

83 FR 18882, 18905 n.32 (2018) (citing *Dewey C. Mackay, M.D.*, 75 FR 49,956, 49,974 n.35 (2010) (“Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.”); *Paul J. Caragine, Jr.*, 63 FR 51592, 51601 (“Careless or negligent handling of controlled substances creates the opportunity for diversion and could justify revocation or denial.”)). I found that Respondent issued numerous prescriptions beneath the applicable standard of care and outside of the usual course of professional practice in Arizona. I also found that Respondent failed to adequately respond to red flags that her patients may have been abusing or diverting the controlled substances that she prescribed, which constitutes “acts inconsistent with the public interest.” *See supra* II.F; *Wesley Pope, M.D.*, 82 FR 14944, 14966 (2017) (internal quotations and citations omitted).

#### (b) Violation of State Law

In addition to alleging that Respondent violated 21 CFR 1306.04(a), the OSC alleged that Respondent violated Arizona law by prescribing controlled substances (1) without maintaining adequate patient records, (2) without conducting a physical examination or previously establishing a valid doctor-patient relationship, and (3) while engaging in conduct that was or might have been harmful or dangerous to the health of the patient. *See OSC*, at 3 (citing *Ariz. Rev. Stat. Ann.* §§ 32–1401(27)(e), (ss), (q)).<sup>61</sup> I find that the Government has proven these allegations by substantial

<sup>61</sup> This statute has been updated approximately yearly over the last decade. Throughout my Decision, I will refer to the version of the statute that became effective on August 9, 2017, consistent with how the statute is referenced in the OSC. *See OSC*, at 2. Although there have been substantive changes to the statute during the time period at issue, none of them impact my Decision. In September 2013, the statute was modified to clarify that a “mental health status examination” may be performed in lieu of a physical examination. Additionally, various revisions clarified that examinations may be performed virtually through telemedicine encounters. Because there is no evidence that Respondent performed a mental status examination in lieu of a physical examination, or performed examinations virtually, I find that these changes do not impact my Decision.

The lettering of the statute’s various provisions has also changed. On April 26, 2018, subsection (q) was changed to subsection (r) and subsection (ss) was changed to subsection (tt). Throughout my Decision, I will refer to these provisions by their original lettering, consistent with how they were cited in the OSC. *See OSC*, at 2.

evidence, at least with respect to certain prescriptions.

i. Respondent Violated Ariz. Rev. Stat. Ann. § 32–1401(27)(e) by Failing To Maintain Adequate Medical Records

I find that the substantial evidence on the record supports a finding that Respondent violated Arizona law by issuing two hundred and nine prescriptions without “maintain[ing] adequate records.” Ariz. Rev. Stat. Ann. § 32–1401(27)(e). Arizona law provides that “adequate records” must contain, at a minimum, “sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient’s care at any point in the course of treatment.” Ariz. Rev. Stat. Ann. § 32–1401(2). Respondent did not maintain contemporaneous medical records for any patient that satisfied the requirements of the statute. *See supra* II.F; *see also* Tr. 197, 209, 215 (Dr. Lynch’s testimony confirming that Respondent’s medical records failed to meet the above criteria); *id.* at 719 (Respondent’s testimony acknowledging that she committed unprofessional conduct by failing to maintain adequate medical records).

ii. Respondent Violated Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) by Failing to Physically Examine or Otherwise Establish a Doctor-Patient Relationship Prior To Prescribing Controlled Substances

Additionally, I find that the substantial evidence on the record supports a finding that Respondent violated Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) in issuing some, or all, of the prescriptions at issue by failing to physically examine or otherwise establish a doctor-patient relationship prior to prescribing controlled substances. Arizona law states that it is “unprofessional conduct” to “[p]rescrib[e], dispens[e] or furnis[h] a prescription medication . . . to a person unless the [doctor] first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship.” Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (2017). I found above that in order to establish a valid doctor-patient relationship in Arizona, a physician must maintain medical records documenting the patient’s treatment, *see supra* II.E.1, and I concluded that Respondent failed to establish valid doctor-patient

relationships with H.D., M.D., and S.P.<sup>62</sup> *See supra* II.F. I also found above that Respondent failed to document sufficient physical examinations for each patient.<sup>63</sup> *Id.*

Respondent argues that she conducted thorough, focused physical examinations, despite her failure to document them. *See Resp Posthearing*, at 10, 15. However, I found above based on Dr. Lynch’s credible and uncontroverted testimony that the Arizona standard of care requires physicians to document physical examinations. *See supra* II.E.1. (citing Tr. 196–97; GX 12, at 28). Consistent with Dr. Lynch’s testimony, the Arizona Medical Board has deemed physicians’ records to be inadequate under Ariz. Rev. Stat. Ann. § 32–1401(27)(e) based on a failure to document physical examinations. For example, the Board found that a physician violated section (e) when he issued eleven controlled substances prescriptions to a friend without maintaining medical records. *In the Matter of Steven M. Rayle, M.D.*, 2017 WL 3461215, at \*1–2 (Aug. 3,

<sup>62</sup> Although Respondent testified at the hearing that she believes that she established valid doctor-patient relationships with H.D., M.D. and S.P., *see* Tr. 639, I find that my conclusion that Respondent failed to establish valid doctor-patient relationships is consistent with Respondent’s initial statements to Investigators that the individuals that she treated at home were “more friends” than patients, and that M.D. was “more on the side” than a patient of her practice. GX 4, at 5, 11. The Arizona Medical Board has initiated disciplinary actions alleging violations of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) based on similar facts. *See, e.g. In the Matter of Warren Moody, M.D.*, No. MD–07–0874A, 2007 WL 3375035 (Oct. 16, 2007) (summarily suspending physician’s license for various forms of misconduct, including prescribing controlled substances to friends without maintaining medical records); *In the Matter of Brian R. Briggs, M.D.*, No. MD–15–0164A, 2017 WL 554258 (Feb. 2, 2017) (issuing a Letter of Reprimand and placing respondent on probation for prescribing controlled substances to a live-in girlfriend—who was also receiving opioids from other providers—without maintaining medical records and without “perform[ing] and document[ing] an appropriate physical and mental examination”); *In the Matter of David Landau, M.D.*, No. MD–17–0777A, 2018 WL 2192279 (Apr. 16, 2018) (issuing a Letter of Reprimand against a physician for various forms of misconduct, including prescribing controlled substances to a friend without maintaining adequate medical records); *see also In the Matter of Joshua D. Holland, M.D.*, No. MD–08–1020A, 2009 WL 2461330 (Aug. 6, 2009) (entering a Consent Agreement with the respondent for various forms of misconduct, including failing to maintain adequate medical records required by Ariz. Rev. Stat. Ann. § 32–1401(27)(e), because the respondent prescribed controlled substances to two close personal friends without a “documented physician-patient relationship” and without documenting a rationale for the prescriptions). Although I do not rely on these Board decisions as espousing any particular interpretation of Arizona’s laws, I find that they provide support for Dr. Lynch’s testimony and for my ultimate conclusions about Arizona law.

<sup>63</sup> There is no evidence that Respondent performed a mental status examination in lieu of a physical examination prior to prescribing.

2017). In support of its conclusion that the physician’s records were inadequate, the Board stated that a physical examination must be documented:

The standard of care requires a physician to document a patient evaluation, including history and physical examination adequate to establish a diagnosis, identify underlying conditions, and monitor for effectiveness, side effects, and adverse effects of the medication. Respondent deviated from the standard of care by repeatedly prescribing medications to Patient 1 without documenting a history and/or physical exam, and without monitoring for efficacy, side effects or adverse outcomes.

*Id.* at \*1.<sup>64</sup>

Even if I were to conclude that Respondent had performed adequate physical examinations, despite her failure to document them, the substantial record evidence would still support a finding that Respondent violated section Ariz. Rev. Stat. Ann. § 32–1401(27)(ss), at least with respect to certain prescriptions. The record evidence demonstrates that Respondent did not perform a physical examination every time she prescribed a controlled substance,<sup>65</sup> which the statute requires in the absence of a previously-established doctor-patient relationship.<sup>66</sup> Thus, any time

<sup>64</sup> *See also In the Matter of Thomas J. Petrone, M.D.*, No. MD–08–0059A, 2009 WL 349716 (Ariz. Med. Bd. Feb. 5, 2009) (finding that respondent’s records were inadequate because “he did not document a physical examination or include past medical records in the patient’s charts and he prescribed medications and escalated doses of opioids without therapeutic indications”); *In the Matter of Mark D. Goldberg, M.D.*, No. MD–07–0128A, 2009 WL 981092 (Ariz. Med. Bd. Apr. 2, 2009) (finding that respondent’s medical records were inadequate because there was no documentation of a history, a physical examination, or the medication administered).

<sup>65</sup> *See, e.g.,* Tr. 441–44 (H.D.’s testimony that not all of the prescriptions that Respondent issued were based on in-person encounters and Respondent only performed a targeted examination of his back once), Tr. 502 (M.D.’s testimony that Respondent performed focused physical examinations “when things changed or [she] had different symptoms”); CX 13, at 2 (Respondent’s letter dated August 22, 2018, stating that “[p]hysical exams and in person discussions are not utilized each and every time a prescription is called in to a pharmacy.”)

<sup>66</sup> A plain language reading of the statute supports this interpretation. The statute prohibits “prescribing, dispensing, or furnishing a prescription medication . . . unless the licensee first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship.” There is no language limiting the application of the statute to initial prescriptions. The phrase “initial prescription” is used elsewhere in the Arizona code. *See* Ariz. Rev. Stat. Ann. § 32–3248 (2018) (placing restrictions on “initial prescriptions” for Schedule II controlled substances). Additionally, the fact that the statute excuses a physician from performing a physical examination if there is a “previously established a doctor-patient relationship” implies that that statute will be

Respondent prescribed a controlled substance without performing a physical examination, Respondent violated section (ss). I cannot conclude with certainty how many times Respondent violated this statute because Respondent did not maintain any documentation, or offer sufficient evidence of when she performed physical examinations.

Overall, I find that there is substantial evidence that Respondent violated Ariz. Rev. Stat. Ann. § 32–1401(27)(ss), based on Dr. Lynch’s credible expert testimony that Respondent failed to establish valid doctor-patient relationships and document adequate physical examinations. Any such violation weighs against Respondent’s continued registration under Factors Two and Four.

iii. Respondent Violated Ariz. Rev. Stat. Ann. § 32–1401(27)(q) By Committing Conduct That Might Have Been Harmful or Dangerous to the Health of Her Patients

I also find that the substantial evidence on the record supports a finding that Respondent violated Arizona law by issuing two hundred and nine prescriptions while “[c]ommitting any conduct or practice that is or might be harmful or dangerous to the health of the patient or the public.” Ariz. Rev. Stat. Ann. § 32–1401(27)(q). The Arizona Court of Appeals has acknowledged that this statute is “potentially overly inclusive,” because it is broad enough to encompass “many appropriate forms of medical treatment [that] entail potential harm,” such as radiation, chemotherapy, and most prescription drugs. *Webb v. Ariz. Bd. of Med. Exam’rs*, 48 P.3d 505, 511 (Ariz. Ct. App. 2002) (rejecting appellant’s argument that Ariz. Rev. Stat. Ann. § 32–1401(27)(r) was unconstitutionally vague). The court concluded that the Arizona legislature could not have intended to proscribe “any form of treatment that entails potential danger or harm,” but rather must have intended to “proscribe only those forms of treatment whose potential or actual harm is *unreasonable* under the circumstances, given the applicable standard of care.” *Id.* There is no requirement that the state board “make an express finding that potential or actual harm is ‘unreasonable under the circumstances.’” *Osborne v. Arizona Medical Board*, No. 1 CA–CV 16–0250, 2017 WL 2544508, at \*4 (Ariz. Ct. App.

June 13, 2017) (internal citation omitted).

I find that the substantial evidence on the record supports a finding that Respondent’s prescribing to H.D., M.D., and S.P. might have been harmful or dangerous to their health. Dr. Lynch testified that patients who are taking pain pills have a one in five hundred chance of overdosing and dying, “which is a very high death rate.” Tr. 182–83. He stated that when opioids and benzodiazepines are combined, the death rate increases by nine times. *Id.* at 302. Respondent could have caused harm by prescribing this dangerous combination of controlled substances without maintaining medical records; without documenting any justification for the prescriptions; without obtaining past medical records to confirm the patients’ past treatment; without utilizing monitoring tools, such as the PMP and urine drug screens; without adequately addressing red flags of abuse and diversion, such as doctor shopping; and without adequately addressing M.D.’s substance abuse problems. *See supra* II.F; *see also* Tr. 197–98 (Dr. Lynch’s testimony that Respondent’s prescribing may have “put [M.D.’s] life at risk” because of M.D.’s clear history of alcoholism); *id.* at 205, 209 (Dr. Lynch’s testimony that Respondent could have harmed H.D. by prescribing opioids and benzodiazepines without any documented justification); *id.* at 213–15, 294–95, 297, 307 (Dr. Lynch’s testimony that Respondent could have harmed S.P. by failing to address red flags of opiate use disorder or benzodiazepine use disorder). Further, the Arizona Medical Board has initiated disciplinary actions alleging violations of Ariz. Rev. Stat. Ann. § 32–1401(27)(q) based on similar articulations of potential harm.<sup>67</sup>

<sup>67</sup> *See, e.g., In the Matter of Thomas J. Petrone, M.D.*, No. MD–08–0059A, 2009 WL 349716, at \*3 (Ariz. Med. Bd. Feb. 5, 2009) (finding that there was “potential harm of misuse, addiction, overdose, and death” when “[r]espondent dispensed opioids to [three individuals] in the absence of any documented therapeutic indications”); *In the Matter of Leonard A. Jasinski, M.D.*, MD–09–0625A, 2009 WL 6038216, at \*1 (Ariz. Med. Bd. Feb. 11, 2009) (finding that there was potential for harm from respondent’s prescribing to his stepson, who had a prior history of opiate dependence, because the prescribing “may have exacerbated [his stepson’s dependence] and may have prevented him from obtaining appropriate medical treatment and intervention”); *In the Matter of Mark R. Austein, M.D.*, Nos. MD–14–0230A, MD–14–1060A, MD–15–1027B, 2017 WL 554260, at \*3 (Ariz. Med. Bd. Feb. 2, 2017) (finding that “abuse, addiction, and/or diversion” could have resulted from respondent’s failure to monitor his buprenorphine patients for treatment compliance); *Osborne v. Arizona Medical Board*, No. 1 CA–CV 16–0250, 2017 WL 2544508, at \*3–5 (Ariz. Ct. App. June 13, 2017) (affirming the superior court’s order upholding the Arizona Medical Board’s conclusion

For all these reasons, I find that the Government has proven by substantial evidence that Respondent violated Ariz. Rev. Stat. Ann. § 32–1401(27)(q).

In conclusion, I find that the Government has proven by substantial evidence that Respondent issued two hundred and nine controlled substance prescriptions outside of the usual course of professional practice and beneath the applicable standard of care in the State of Arizona in violation of 21 CFR 1306.04(a) and Ariz. Rev. Stat. Ann. § 32–1401(27)(e), (q), and (ss).<sup>68</sup> As Respondent issued these prescriptions without complying with her obligations under the CSA and Arizona law, I find that Factors Two and Four weigh in favor of revocation. *See George Mathew, M.D.*, 75 FR 66138, 66148 (2010). Overall, I find that the Government has established a *prima facie* case that Respondent’s continued registration is inconsistent with the public interest.

#### IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent’s continued registration is inconsistent with the public interest, the burden shifts to the Respondent to show why she can be entrusted with a registration. *Garrett Howard Smith, M.D.*, 83 FR at 18910 (collecting cases). Respondent has not ensured me that she can be trusted with a registration.

The CSA authorizes the Attorney General to “promulgate and enforce any

that respondent caused the “potential for overdose and death” by prescribing excessive dosages of opioids, failing to document a clear rationale for dosage escalations, failing to account for co-morbid conditions, and failing to recognize clear signs of opioid misuse and diversion).

<sup>68</sup> The RD found that Respondent issued two hundred and nine prescriptions to H.D., M.D., and S.P. outside the usual course of professional practice and not for a legitimate medical purpose, in violation of federal law. *See, e.g., RD*, at 90, 94, 99. Although the RD implied that the Government had failed to meet its burden of proving certain state law violations, the RD ultimately sustained all of the Government’s state law allegations. *Compare Id.* (stating that “the Government’s allegation that [Respondent] issued prescriptions outside the usual course of professional practice and without a legitimate medical purpose, in violation of 21 U.S.C. 841(a)(1), 21 CFR 1306.04(a) and Ariz. Rev. Stat. Ann. § 32–1401(27)(e), (q), and (ss), is SUSTAINED”) with *RD*, at 88–90, 92–93, 97, 118–21 (disagreeing with the Government’s conclusion that a physician must maintain medical records in order to establish a valid doctor-patient relationship, and concluding that Respondent physically examined and formed valid doctor-patient relationships with H.D., M.D., and S.P.), *id.* at 83 (stating that the “Arizona Revised Statute, which the Government cited to in the OSC, does not share ‘a substantial relationship to the CSA’s purpose of preventing substance abuse and diversion’”), *id.* at 84 (noting that section (q) is “undeniably broad”); *see also Govt Posthearing*, at 15 (taking exception to the RD’s “fail[ure] to evaluate any of the testimony and exhibits against the backdrop of Ariz. Rev. Stat. Ann. § 32–1401(27)(q)”).

applied to every prescription that a physician issues, because it suggests that a physician who has established a doctor-patient relationship has discretion over when to perform a physical examination.

rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.” 21 U.S.C. 871(b). This authority specifically relates “to ‘registration’ and ‘control,’ and ‘for the efficient execution of his functions’ under the statute.” *Gonzales v. Oregon*, *supra*, 546 U.S. at 259. A clear purpose of this authority is to “bar[] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.” *Id.* at 270.

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and arguments Respondent submitted to determine whether or not she has presented “sufficient mitigating evidence to assure the Administrator that [s]he can be trusted with the responsibility carried by such a registration.” *Samuel S. Jackson, D.D.S.*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.*, 53 FR 21931, 21932 (1988)). “Moreover, because ‘past performance is the best predictor of future performance,’ *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant’s] actions and demonstrate that [registrant] will not engage in future misconduct.” *Jayam Krishna-Iyer*, 74 FR 459, 463 (2009) (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); *see also Jackson*, 72 FR at 23853; *John H. Kennedy, M.D.*, 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62884, 62887 (1995).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency’s interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 FR 8247, 8248 (2016).

Here, Respondent has presented no evidence on the record that I could consider as accepting responsibility. Respondent maintained throughout these proceedings that she believes that her prescribing to the three individuals in question was proper and she made statements throughout the proceeding that minimized her misconduct. *See Resp Posthearing*, at 15; *supra* III.A.1.a.

For example, Respondent testified that she was “not the least bit concerned that any of [the prescriptions that she issued] were given away, diverted, or used inappropriately.” Tr. 729. Respondent also minimized the potential dangers of prescribing controlled substances to M.D., despite M.D.’s substance abuse problems. Respondent testified that she “hope[d] . . . [M.D.] was able to clarify that she has a *mild* alcohol use disorder,” and while she recognized that prescribing opioids and benzodiazepines to M.D. was “not ideal,” she testified that she “sp[oke] to [M.D.] about not using these agents together in any capacity” and “[did not] feel that [M.D.] suffered any negative consequences from it.” *Id.* (emphasis added). Although Respondent and M.D. downplayed M.D.’s struggles with alcohol at the hearing, it was evident from Respondent’s previous statements to Investigators that M.D.’s alcohol problems were significant and disruptive. Respondent told investigators in December 2017 that M.D. “was removed from [Respondent’s] property one time . . . because she was drunk.” GX 4, at 3. She also told Investigators, “I can’t tell you what this couple years has been like with this addiction, this alcohol issue.” *Id.* at 7. Dr. Lynch testified that Respondent put M.D.’s life at risk with her prescribing because of M.D.’s history of alcoholism and her history of receiving controlled substances from multiple providers. Tr. 197–98, 294. I am concerned by Respondent’s unwillingness to acknowledge the dangers of prescribing dangerous combinations of controlled substances to an intimate partner who has substance abuse problems, without utilizing any monitoring tools or maintaining medical records.

Respondent did admit that she failed to maintain adequate medical records. *See, e.g., id.* at 719; *Resp Posthearing*, at 8, 12. However, Respondent occasionally minimized the importance of diligent recordkeeping in her testimony. She testified that she “probably took some notes” when she was providing treatment to H.D., but she “probably threw them away.” Tr. 694–95, 717–18. When asked why she would throw away records pertaining to a patient, Respondent said it was “[b]ecause [she] felt like [she] had the information [she] needed to treat him.” *Id.* at 718. When asked again why she destroyed the records, she replied: “Because I knew what it was. For example, if a patient is being managed for hypertension, it’s a trend phenomenon. If you’re managing two patients for hypertension, it’s usually

fairly easy to remember the trends for two people.” *Id.* Respondent’s implication that she could have safely treated H.D. without maintaining medical records is contrary to Arizona’s emphasis on the importance of maintaining contemporaneous medical records. *See supra* II.E., III.A.1.a.

Regardless, Respondent’s admission that she failed to maintain adequate medical records was not a sufficient acceptance of responsibility, because I found above that Respondent’s standard of care violations went beyond her failure to maintain adequate medical records. *See supra* II.F., III.A.1. Respondent did not accept responsibility for any of those additional violations. In all, Respondent failed to explain why, in spite of her misconduct, she can be entrusted with a registration. “The degree of acceptance of responsibility that is required does not hinge on the respondent uttering ‘magic words’ of repentance, but rather on whether the respondent has credibly and candidly demonstrated that [s]he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.” *Jeffrey Stein, M.D.*, 84 FR 46968, 49973 (2019); *see also Singh, M.D.*, 81 FR at 8248 (“until . . . [a] Respondent can convincingly show he [or she] accepts the authority of the law and those bodies charged with enforcing it and regulating his [or her] activities, granting [] a DEA registration will gravely endanger the public.”).

Even if Respondent’s acceptance of responsibility for her wrongdoing had been sufficient such that I would reach the matter of remedial measures, Respondent has not offered adequate remedial measures to assure me that I can entrust her with a registration. Respondent testified that she has closed her private practice and indicated that she does not intend to resume it in the future. Tr. 637, 731–33; *Resp Posthearing*, at 8, 12–13. Respondent also testified that her documentation will be better in the future because she will only use her registration in the emergency room “where there are electronic medical records that [she] fill[s] out on every single patient.” Tr. 732. Respondent testified that she thinks she is a better documenter in the emergency room than in her private practice because the company that she works for has told her that her documentation is adequate enough for billing. *Id.* at 691.

These remedial measures primarily address Respondent’s documentation failures. They do not address my additional concerns about Respondent’s prescribing, such as prescribing

potentially dangerous combinations of controlled substances, failing to utilize monitoring tools, and prescribing controlled substances to an individual with a substance abuse disorder.<sup>69</sup> The fact that Respondent has closed her private practice is not a sufficient remedial measure. If Respondent retains her registrations, she will continue to prescribe controlled substances in the emergency room. Respondent has not taken any steps to assure me that she will prescribe controlled substances in a lawful manner in any setting, including the emergency room.<sup>70</sup>

The Agency also looks to the egregiousness and extent of the misconduct, which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.*, 83 FR at 18910 (collecting cases). Respondent argues that her misconduct was not egregious enough to warrant revocation because it involved the treatment of “three fellow health care professionals in a small private practice,” “[i]t was not a fee-generating business,” “none of [the individuals] suffered any adverse effects from the care[,] and there was no harm to the public health.” Resp Posthearing, at 12. Respondent characterizes this case as a recordkeeping case involving three recordkeeping failures, and she references an Agency Decision in which

<sup>69</sup> Respondent states in her posthearing brief that she completed courses in “Safe and Effective Opioid Prescribing While Managing Acute and Chronic Pain” and “Introduction to Prescribing Opioids for Pain Management.” Resp Posthearing, at 13. I agree with the RD that these courses should not be considered as remedial evidence because no testimony was offered about them and they are not mentioned in Respondent’s curriculum vitae. See RD, at 80 n.45 (referencing RX 1).

<sup>70</sup> Respondent admitted into evidence an affidavit from the Emergency Department Medical Director at the hospital where she has been working since 2014. RX 11. The affidavit states that “[Respondent] is an outstanding Emergency Room physician, is dedicated to delivering high quality, compassionate patient care and she succeeds at same.” *Id.* at 1. The affidavit also states that “[Respondent] is an exceptional asset to Holy Cross and the vastly underserved population that is treated there,” and “if [Respondent] were to lose her DEA registration she would be unable to work at Holy Cross Hospital, which would be devastating to the community.” *Id.* While I appreciate that Respondent is a highly-qualified and hardworking physician, and that she has made substantial contributions to her community, community impact evidence is considered to be irrelevant to DEA revocation proceedings. See, e.g., *Frank Joseph Stirlacci, M.D.*, 85 FR 45229, 45239 (2020) (declining to consider Respondent’s argument that his revocation “would deprive the low-income and homeless patients . . . of his medical services”); *Mark De La Lama, P.A.*, 76 FR 20011, 20020 n.20 (2011) (declining to consider a registrant’s service to underserved and underinsured persons). Although this affidavit could be relevant to my determination of whether I can entrust Respondent with a DEA registration, I find that this affidavit has little weight because the affiant was not subject to cross examination at the hearing.

the Agency declined to revoke a pharmacy’s registration after the pharmacy accepted responsibility for three recordkeeping violations. *Id.* (citing *Terese Inc.*, 76 FR 46843 (2011)).<sup>71</sup>

The ALJ agreed with Respondent that revocation was not warranted. Although he acknowledged that Respondent had not fully accepted responsibility as previous Agency Decisions have required, he found that Respondent “candidly acknowledged” that she failed to maintain adequate medical records, which was the “main reason her prescriptions violated DEA regulations.” RD, at 114. The ALJ found that the Government had not proven that Respondent’s violations were “egregious enough or severe enough to warrant outright revocation,” because all three patients were healthcare professionals who testified at the hearing, Respondent established a doctor-patient relationship with each individual and demonstrated a commanding grasp of their medical issues, and Respondent closed her private practice. *Id.* at 115–23. Additionally, the ALJ found that Dr. Lynch’s opinions were primarily based on Respondent’s failure to maintain adequate medical records. Thus, the ALJ concluded that “this is a factually unique case” that warrants a “unique sanction,” and recommended a three-month suspension of one of Respondent’s six DEA registrations,<sup>72</sup>

<sup>71</sup> I agree with the RD that *Terese* is not relevant to my sanction determination because it is a pharmacy case that involves three recordkeeping violations of a different nature than those involved in this case. RD, at 126–27.

<sup>72</sup> The RD proposes that registration number BH3877733—which Respondent testified that she uses to prescribe controlled substances in her private clinical practice and in the emergency room, Tr. 631—be suspended for three months. RD, at 127. Following the suspension period, the RD proposes that Respondent may resume using that registration in the emergency room, but she must provide DEA with a signed writing that she will cease private practice. *Id.* It further proposes that Respondent may seek permission from DEA to resume private practice two years after the Agency’s final order, but she must provide evidence that she has attended trainings on medical recordkeeping and prescribing controlled substances. *Id.*

Respondent has five additional DEA registrations that are connected with five air medical bases in Southern Arizona that she supervises: FH2922169, FH2922157, FH2922133, FH2922121, and FH2922119. *Id.* at 630–31. Respondent testified that these registrations are “used exclusively to obtain medications for flight crews” and she does not use them to prescribe controlled substances to patients. *Id.* at 630–31633. The RD recommends that these five registrations remain active during the suspension period, but only “to order, purchase, or obtain controlled substances for the air bases that [Respondent] supervises for Air Methods.” RD, at 128. I reject the RD’s (and Respondent’s) contention that Respondent’s various DEA registrations should be subjected to different sanctions based on the manner in which Respondent uses them. See RD,

followed by various restrictions on Respondent’s registrations.<sup>73</sup> *Id.* at 123, 127 (internal quotations and citations omitted).

I appreciate the ALJ’s careful analysis and hard work on this case. I also appreciate the hard work and dedication of Respondent’s attorney. However, I cannot agree with Respondent that this is a recordkeeping case that deserves a remedy short of revocation, nor can I agree with the ALJ’s conclusion that this is a “unique case” that warrants a

at 122 (stating that the Government “ha[d] advanced no evidence whatsoever concerning [Respondent’s] prescribing of controlled substances in the emergency room or how she has handled controlled substances as director of Air Methods”); Resp Posthearing, at 2, 10 (arguing that “the evidence presented by Government [sic] at the Order to Show Cause hearing related solely to conduct that involved Respondent’s DEA Registration BH 3877733” and there is “no evidence justifying any adverse action against Respondent’s FH DEA Registrations”). My finding that Respondent’s continued registration is inconsistent with the public interest applies equally to all of Respondent’s DEA registrations, regardless of how she uses those registrations. In cases involving pharmacies with multiple DEA registrations, DEA has held that it may revoke the pharmacy’s second registration where misconduct has been proven with respect to “owners, officers, or key employees” of the first pharmacy who “have influence over the management or control of the second pharmacy.” See *Superior Pharmacy I and Superior Pharmacy II*, 81 FR 31310, 31341 n.71 (2016) (citing *Lawsons & Sons Pharmacy and Fenwick Pharmacy*, 48 FR 16140, 16141 (1983); *Orlando Wholesale, LLC.*, 71 FR 71,555, 71,557 (2006)). This rule has also been applied to practitioners who hold multiple registrations. See *Roberto Zayas, MD*, 82 FR 21410, 21430 (revoking physician’s Florida registration based on allegations concerning his Texas registration and where there was no evidence that the Florida registration was being used). In fact, when the Agency orders revocation, as a matter of course it orders revocation of pending applications in the same jurisdiction. See e.g., *Leslie Pompy, M.D.*, 84 FR 57749, 57762 (2019); *Kaniz F. Khan-Jaffery, M.D.*, 85 FR at 45686. In this case, all of the registrations at issue are based in Arizona and I have found that Respondent violated the applicable standard of care in Arizona and state law; therefore, I find that her registrations in Arizona are inconsistent with the public interest and I apply my sanction to all of her Arizona registrations.

<sup>73</sup> The ALJ found that the Agency’s Decision in *Joseph Gaudio, M.D.*, 74 FR 10083 (2009) was instructive in crafting a remedy. RD, at 124–26. However, Dr. Gaudio’s violations were of a different nature than Respondent’s. While *Gaudio* involved a physician who prescribed controlled substances for a short period of time to individuals over the internet, the case before me involves a physician who prescribed controlled substances to close friends over a long period of time without maintaining any medical records. See Tr. 636. Moreover, the sanction imposed in *Gaudio* was more substantial than the remedy proposed by the ALJ in this case. In *Gaudio*, the Agency suspended the respondent’s registration for one year and ordered that the registrant provide a sworn statement accepting responsibility for his violations of the CSA in order to get his registration back. *Id.* at 10,095. By contrast, in this case, the ALJ proposes that only one of Respondent’s registrations be suspended for three months, while her other registrations remain active for certain purposes. RD, at 127–28.

“unique remedy.” Rather, I find that revocation is the appropriate remedy based on the egregiousness of Respondent’s conduct, her failure to accept responsibility, and her failure to ensure that I can entrust her with a registration in the future.

I do not find that Respondent’s misconduct was mitigated by the fact that she prescribed to health care professionals. There was no testimony or evidence at the hearing that the standard of care for treating healthcare professionals is different from the standard of care for treating individuals who are not healthcare professionals. Nor was there any evidence that healthcare professionals are any less susceptible to drug abuse or diversion. In fact, there were red flags that indicated that these individuals may have been abusing or diverting controlled substances. *See supra* II.F, III.A.1.a. And while I appreciate that H.D., M.D., and S.P. all presented as credible witnesses with impressive credentials who believed that Respondent treated them for legitimate medical conditions, and that Respondent was knowledgeable about their medical conditions, there is not sufficient documentary proof to assure me that Respondent was not merely handing out controlled substances to her friends. I found above that a physician must maintain medical records in order to establish a valid doctor-patient relationship in Arizona, and I also found that documentation is critical to effective enforcement of the CSA. *See supra* II.E., III.A.1.a. With a regulated community of nearly two million registrants,<sup>74</sup> DEA must be able to rely on physicians to maintain complete and accurate medical records justifying their prescribing decisions.

In finding that revocation was not warranted, the ALJ concluded that recordkeeping was Respondent’s “primary fault.” RD, at 116. He found that Dr. Lynch’s opinions in the case were primarily based on Respondent’s failure to maintain adequate medical records. *Id.* at 115–16 (citing Tr. 354, 379, 381, 741–42). The ALJ placed much emphasis on Dr. Lynch’s testimony that “we wouldn’t be here today if it was [sic] for the lack of documentation.” *Id.* (citing Tr. 741). He also referenced Dr. Lynch’s testimony that “it’s possible” to conduct adequate physical examinations and medical histories without documenting them, but “the fact [Respondent is] not documenting it makes it not appropriate, not an

adequate doctor/patient relationship.” *Id.* at 115 (citing Tr. 378–79). The ALJ interpreted Dr. Lynch’s testimony as meaning that “Respondent’s DEA registrations would not be subject to revocation had she only documented what she had done.” *Id.* at 116. However, given the extensive testimony of Dr. Lynch regarding Respondent’s multiple violations of the standard of care, I interpret Dr. Lynch’s statement to refer to the fact that without documentation, it is not possible to adequately assess the appropriateness of Respondent’s actions.

Additionally, Dr. Lynch testified that Respondent’s standard of care violations went beyond her failure to document. Specifically, Dr. Lynch testified that Respondent committed “eight standard of care violations” that “add up to pretty substandard care.”<sup>75</sup> Tr. 355; *see also id.* at 742 (testifying that “most of it is the medical record,” but “there are a lot of deficiencies, eight that I pointed out in my report”). Dr. Lynch testified that some of these violations were “egregious” and dangerous and Respondent could have done harm with her prescribing. *See* II.F. Overall, I do not minimize Dr. Lynch’s testimony about Respondent’s many standard of care violations simply because he testified that his decision was primarily based on Respondent’s failure to document.

I decline to adopt the ALJ’s proposed remedy because it imposes administrative burdens on DEA to monitor Respondent’s registrations and it does not adequately protect the public. Respondent has not given me any assurances that she will prescribe controlled substances appropriately in the future nor has she accepted responsibility for any of her violations of the CSA. In the midst of an opioid epidemic where Arizona ranked sixth highest in the nation for drug overdose deaths in 2010, *see* GX 16, at 4, I find that revocation is the appropriate remedy given the egregiousness of Respondent’s conduct and her failure to accept responsibility. I found above that Respondent could have done harm to her patients by prescribing dangerous combinations of controlled substances without maintaining medical records; without documenting any justification

<sup>75</sup> One of the eight violations that Dr. Lynch summarized was prescribing controlled substances to close personal friends. Tr. 355. As discussed above, *see* II.C., I found that Dr. Lynch’s testimony on prescribing to close friends was primarily framed as an ethical violation, not a standard of care violation. Therefore, I do not give any weight in my Decision to Dr. Lynch’s testimony that long-term prescribing to someone with whom you are in a close personal relationship is a violation of the standard of care.

for the prescriptions; without obtaining past medical records to confirm the patients’ past treatment; without utilizing monitoring tools, such as the PMP and urine drug screens; without adequately addressing red flags of abuse and diversion, such as doctor shopping; and without adequately addressing M.D.’s substance abuse problems. *See* III.A.1.b.iii. For those same reasons, I find that Respondent’s conduct was egregious. Respondent acknowledged at the hearing that combining opioids and benzodiazepines might increase the risk of respiratory depression or sedation, Tr. 665–66, yet she prescribed this combination to M.D., even though M.D. had known substance abuse problems. *See supra* II.F.1. Dr. Lynch testified that opioids have a “very high death rate,” and the death rate increases by nine times when opioids are combined with benzodiazepines. Tr. 180, 182, 302. It was dangerous for Respondent to prescribe these controlled substances to M.D., especially without utilizing any monitoring tools to ensure that M.D. was not abusing or diverting the drugs. These tools would have provided the objectivity that Respondent was lacking with regard to M.D., as Respondent stated in the Interview that she had been “duped” by M.D. before and that she can “be a little too trusting sometimes, especially if it’s someone . . . [she] care[s] about.” GX 4, at 7. It was also egregious for Respondent to prescribe controlled substances to S.P.—a former intimate partner who was also prescribing controlled substances to Respondent—without maintaining any medical records documenting that treatment. Dr. Lynch testified that such an arrangement is “way outside the standard of care” and he would “have a real concern” with it because “it’s akin to treating yourself.” Tr. 187.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.*, 74 FR 10083, 10095 (2009); *Singh*, 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case. A sanction short of revocation would send a message to the regulated community that a practitioner can prescribe controlled substances to individuals over long periods of time without maintaining even basic medical records, without performing or documenting objective assessments of whether they were abusing or diverting controlled substances in violation of state and federal law, even in the face of red flags

<sup>74</sup> *See* DEA FY 2020 Budget Request available at <https://www.justice.gov/jmd/page/file/1142431/download>.

indicating such abuse and diversion, and continue to maintain a controlled substances registration in spite of the violations and without accepting responsibility. Further, there is simply no evidence that Respondent's egregious behavior is not likely to recur in the future such that I can entrust her with a DEA registration; In other words, the factors weigh in favor of revocation as a sanction.

I will therefore order that Respondent's registrations be revoked 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), I hereby revoke DEA Certificate of Registration Nos. BH3877733, FH2922119, FH2922121, FH2922133, FH2922157, and FH2922169 issued to Carol Hippenmeyer, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Carol Hippenmeyer, M.D. to renew or modify these registrations, as well as any other application of Carol Hippenmeyer, M.D., for additional registrations in Arizona. This Order is effective July 26, 2021.

**D. Christopher Evans,**

*Acting Administrator.*

[FR Doc. 2021-13526 Filed 6-24-21; 8:45 am]

**BILLING CODE 4410-09-P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

#### Petitions for Modification of Application of Existing Mandatory Safety Standards

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** This notice includes the summaries of three petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

**DATES:** All comments on the petitions must be received by MSHA's Office of Standards, Regulations, and Variances on or before July 26, 2021.

**ADDRESSES:** You may submit your comments including the docket number of the petition by any of the following methods:

1. *Electronic Mail:* [zzMSHA-comments@dol.gov](mailto:zzMSHA-comments@dol.gov). Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202-693-9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202-5452, Attention: Jessica Senk, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

#### FOR FURTHER INFORMATION CONTACT:

Jessica D. Senk, Office of Standards, Regulations, and Variances at 202-693-9440 (voice), [Senk.Jessica@dol.gov](mailto:Senk.Jessica@dol.gov) (email), or 202-693-9441 (facsimile). [These are not toll-free numbers.]

**SUPPLEMENTARY INFORMATION:** Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

#### I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

#### II. Petitions for Modification

*Docket Number:* M-2021-016-C.

*Petitioner:* Consol Pennsylvania Coal Company LLC, 1000 Consol Energy Drive, Canonsburg, Pennsylvania (ZIP 15317).

*Mine:* Itmann No. 5 Mine, MSHA ID No. 46-09569, located in Wyoming County, West Virginia.

*Regulation Affected:* 30 CFR 75.507-1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

*Modification Request:* The petitioner requests a modification of the existing standard, 30 CFR 75.507-1(a), as it relates to the use of an alternative method of respirable dust protection for miners at the Itmann No. 5 Mine in West Virginia. Specifically, the petitioner is applying to use the 3M™ Versaflo™ TR-800 Intrinsic Safety Powered Air Purifying Respirator (PAPR) and the CleanSpace EX in return air outby the last open crosscut.

The petitioner states that:

(a) Currently the petitioner uses the 3M™ Airstream™ helmet to provide additional protection for its miners against exposure to respirable coal mine dust. There are clear long-term health benefits from using such technology.

(b) 3M elected to discontinue the 3M™ Airstream™ helmet, replacing it with a 3M™ Versaflo™ TR-800 which benefits from additional features and reduced weight. Because of its reduced weight, it provides significant ergonomic benefits.

(c) For more than 40 years the 3M™ Airstream™ Headgear-Mounted PAPR System has been used by many mine operators to help protect their workers. During those years there have been technological advancements in products and services for industrial applications. 3M indicated that they had faced multiple key component supply disruptions for the Airstream™ product line that created issues with providing acceptable supply service levels. Because of those issues, 3M discontinued the Airstream™ in June 2020, and this discontinuation is global.

(d) 3M announced that February 2020 was the final time to place an order for systems and components and that June 2020 was the final date to purchase Airstream™ components.

(e) Currently there are no replacement 3M PAPRs that meet applicable MSHA standards for permissibility. Electronic equipment used in underground mines in potentially explosive atmospheres is required to be approved by MSHA in accordance with 30 CFR. 3M and other manufacturers offer alternative products for many other environments and applications.

(f) Following the discontinuation, mines that currently use the Airstream™ do not have an MSHA-approved alternative PAPR to provide to miners. One of the benefits of PAPRs is that they provide a constant flow of air inside the headtop or helmet. This constant airflow helps to provide both respiratory protection and comfort in hot working environments.

(g) Application of the standard results in a diminution of safety at the mine.