medicine and surgery.'' *Id.* at 18 (emphasis in original).

According to DI, on December 17, 2019, DI queried the Pennsylvania Department of State licensing verification website at *https://www.pals.pa.gov/#/page/searchresult* and determined that Registrant's medical physician license was still suspended at that time and that Registrant was without authorization to handle controlled substances or practice medicine in Pennsylvania. RFAAX 10, at 3. According to Pennsylvania's online records, of which I take official notice, Registrant's license is still revoked.[5] Pennsylvania Licensing System Verification, *https://www.pals.pa.gov/#/page/search* (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is neither licensed to engage in the practice of medicine nor registered to dispense controlled substances in Pennsylvania, the state in which Registrant is registered with the DEA.

III. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

Under the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, ''no controlled substance in Schedule II shall be dispensed without an electronic prescription of a practitioner.'' 35 PA. Stat. and Const. Stat. Ann. § 780–111(a) (West October 24, 2019). Further, ''no controlled substance in Schedule III, IV or V shall be dispensed without an electronic prescription of a practitioner.'' *Id.* at § 780–111(b). The definition of ''practitioner,'' as used in the state Act, includes a ''physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance . . . in the course of professional practice . . . in the Commonwealth of Pennsylvania.'' *Id.* at 780–102(b).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in Pennsylvania. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in Pennsylvania. Thus, because Registrant lacks a license to practice medicine in Pennsylvania and, therefore, is not authorized to handle controlled substances in Pennsylvania, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FS1471818 issued to Milad I. Shaker, 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 Milad I. Shaker, M.D. to renew or modify this registration or for any other registration in Pennsylvania. This Order is effective March 22, 2021.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–03358 Filed 2–18–21; 8:45 am]

BILLING CODE 4410–09–P

[5] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–33]

Michael W. Carlton, M.D.; Decision and Order

On April 18, 2017, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Michael W. Carlton, M.D. (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause), at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. BC3579969 pursuant to 21 U.S.C. 824(a)(4) ''because [his] continued registration is inconsistent with the public interest . . . .'' *Id.* (citing 21 U.S.C. 823(f)).

I. Procedural History

The OSC alleged that ''between May 8, 2015 and November 21, 2015, on approximately forty-two (42) occasions, [Respondent] unlawfully prescribed controlled substances to thirty-one (31) patients by issuing prescriptions for other than a legitimate medical purpose and outside the usual course of professional practice.'' OSC, at 1–2. The OSC alleged violations of 21 U.S.C. 841(a), 21 CFR 1306.04(a), and Ariz. Rev. Stat. Ann. § 32–1401(27). *Id.* at 2. The OSC stated that ''a medical expert has concluded that [Respondent's] issuance of the [forty-two] prescriptions

listed [in the OSC] violated minimal medical standards applicable to the practice of medicine in the state of Arizona.'' *Id.* For each of the forty-two prescriptions listed in the OSC, the Government alleged that Respondent's deficiencies ''include [his] failure to conduct a physical examination, take an adequate medical history, and assess and discuss functional issues'' prior to their issuance. *Id.* at 2; *see also id.* at 3–10.

The OSC notified Respondent of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 10 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 11 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated May 18, 2017, Respondent timely requested a hearing.[1] ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and was initially assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ). On May 22, 2017, the Chief ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1. The Government filed its prehearing statement on May 31, 2017. ALJX 4 (Government's Prehearing Statement), at 1. After twice requesting and receiving additional time, Respondent filed his Prehearing Statement on July 5, 2017. *See* ALJX 5 (Letter from Respondent dated June 9, 2017), ALJX 6 (Government Opposition to Continuance Request), ALJX 7 (Order Granting Respondent's First Extension Request), ALJX 8 (Respondent's Request for Extension to File Prehearing Statement), ALJX 9 (Order Granting Respondent's Second Extension Request), and ALJX 10 (Respondent's Prehearing Statement).

On July 6, 2017, the Chief ALJ issued a Prehearing Ruling that, among other things, set out one agreed upon stipulation and established schedules for the filing of additional joint stipulations and for the hearing. ALJX 11 (Prehearing Ruling), at 1, 4. The Prehearing Ruling stated that ''[n]o later than July 28, 2017, the parties are to serve each other with copies of all identifiable documents listed in their prehearing statements.'' *Id.* at 2 (emphasis omitted). The parties were also directed to file supplemental prehearing statements and exchange ''any additional documents identified in the parties' supplemental prehearing statements'' by no later than August 21, 2017. *Id.* Thereafter, the matter was reassigned to Administrative Law Judge Mark M. Dowd (hereinafter, the ALJ). ALJX 15 (Order Reassigning Case). The Government timely served the exhibits identified in its prehearing statement on Respondent on July 28, 2017. Government's Certificate of Service Regarding Government's Proposed Exhibits 1–34; ALJX 11, at 2. Respondent did not serve the exhibits identified in its prehearing statement on the Government at that time. The Respondent filed a supplemental prehearing statement on July 27, 2017, which identified the same exhibits as were listed in his original prehearing statement. ALJX 16 (Respondent's First Supplemental Prehearing Statement). The Government timely filed a supplemental prehearing statement on August 21, 2017. ALJX 17 (Government's Supplemental Prehearing Statement). The Respondent missed the July 28, 2017 deadline to exchange exhibits, which set off a variety of motions (including additional requests for continuances and a motion *in limine*) and a variety of procedural rulings. See ALJX 18–30. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

The hearing in this matter took place in Phoenix, Arizona, and spanned two days. *See generally* Transcript of Proceedings in the Matter of Michael W. Carlton, M.D. (hereinafter, Tr.). Both parties filed posthearing briefs. *See* Government's Proposed Findings of Fact, Conclusions of Law, and Argument (hereinafter, Govt Posthearing), and Respondent's Post-Hearing Brief (hereinafter, Resp Posthearing). Both parties also briefed the issue of whether or not Respondent should receive an adverse inference for failing to provide behavioral health records, which Respondent claimed existed, but were not produced by RIM pursuant to the subpoena [2] or by Respondent on his own behalf. *See* Govt Posthearing, and Respondent's Brief on RIM Medical Records. Then on April 12, 2018, 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 forty prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in Arizona in violation of federal law, and I find that Respondent committed violations of state law. I agree with the ALJ that revocation is the appropriate sanction. RD, at 96. 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 data-waived DW/100 practitioner able to handle controlled substances in schedules II through V under DEA Certificate of Registration No. BC3579969, at 15721 North Greenway-Hayden Loop, Suite 205, Scottsdale, Arizona 85260. ALJX 11, at 1; and GX 1 (Controlled Substance Registration Certificate).

B. The Investigation

The Diversion Investigator assigned to this matter (hereinafter, DI) first interacted with Respondent in 2007 for a ''scheduled regulatory investigation.'' Tr. 149. During the scheduled investigation, DI discovered potential violations,[3] resulting in DEA's issuance of an Order to Show Cause, which was dismissed following the execution of a Memorandum of Agreement (hereinafter, MOA) between Respondent and DEA. Tr. 150–52; GX 35 (MOA). The MOA did not require Respondent to admit any wrongdoing, but it did remind Respondent of his obligation to abide by all federal, state, and local laws and regulations pertaining to controlled substances and placed additional obligations and conditions on Respondent that remained in effect until 2013. Tr. 151, 153–54, 213; GX 35. One of those obligations stated that ''[Respondent] must conduct an initial examination validating the necessity to

[1] I find that the Government's service of the OSC was adequate.

[2] The Diversion Investigator testified that the subpoena request was for ''all medical records for any patient who was treated at Recovery in Motion and received a controlled substance prescription from Dr. Carlton.'' Tr. 164. She also testified that ''because of the privacy concerns with opioid patients . . . [DEA] had to apply for a court order that protected, saying that yes, in fact, we can have these, but we'll handle these records in a particular way, and [DEA was] to get that court order.'' Tr. 156–57. Both the subpoena and the court order were served on RIM. Tr. 157, 165. Ultimately, I do not find that the missing behavioral health records, if they existed, are relevant to the standard of care as discussed in *infra* II.E.1 & n.13.

[3] It was alleged that Respondent exceeded the number of patients he was permitted to treat for addiction; he operated an illegal take-back program wherein he took patients' unused controlled substances and redistributed them to other patients; and he failed to maintain required records. Tr. 150–52; GX 35, at 1–2.

prescribe Suboxone or Subutex to each [new] OBOT patient. This paragraph does not preclude initiation of medication in an emergent/urgent detoxification setting, provided Dr. Carlton conducts an examination within twenty-four (24) hours of initiation.'' GX 35, at 3.

DEA opened this investigation into Respondent after DI received a call from a former employee of Recovery in Motion (hereinafter, RIM). Tr. 154–55, 213–14. The former employee, who was a physician, expressed concerns that Respondent's patients ''were receiving drugs but had never received any sort of visit or examination from the doctor first.'' Tr. 155. She told DI that she left RIM because she was concerned about the way the facility operated; more specifically, ''[s]he was very concerned about patient welfare, and she was afraid that somebody was going to die.'' Tr. 213–14. During the investigation, DI interviewed several employees of RIM, and DI stated that ''every one of the employees that [she] spoke with was . . . concerned because the patients were starting drugs without ever having been treated or evaluated by the doctor first.'' Tr. 156. DI also interviewed some of Respondent's patients, none of whom ''said that they saw [Respondent] upon admission,'' and most of whom ''didn't recall anything that would be a physical examination to include vital signs.'' Tr. at 194.

Thereafter, DEA subpoenaed RIM for the medical records of patients for whom Respondent had prescribed controlled substances. Tr. 156–57. RIM promptly responded to the subpoena, and DI reviewed the records that were produced. Tr. 157. DI believed that she had received all of the necessary records from RIM. Tr. 158, 161, 163. Thereafter, DEA retained a medical expert, Dr. Loes, to review the patient files and provide his expert opinion. Tr. 199–200. The Government expert concluded that Respondent's prescribing of controlled substances fell below the standard of care, and the OSC forming the basis of this action was issued. OSC, at 2; GX 36 (Government's Expert Report), at 2.

C. Government's Case

The Government's documentary evidence consisted primarily of patient records for thirty-one [4] individuals prescribed controlled substances by Respondent between May 8, 2015, and November 21, 2015. The Government's evidence also contained prescription records for those same thirty-one patients, the Curriculum Vitae and draft report for its expert witness, and a Memorandum of Agreement between the DEA and Respondent that predates the issues raised in this case. *See* GX 1–36. Additionally, the Government called three witnesses: Respondent (whose testimony is summarized in the Respondent's Case, *see infra* Section II.D.), DI, and the Government's expert Dr. Michael W. Loes.

DI testified regarding her professional background, Tr. 147–49, and about her 2007 interactions with Respondent that resulted in a Memorandum of Agreement between DEA and Respondent. *See supra* Section II.B; Tr. 149–54; RD, at 3–4. She also testified about her investigation-related actions in this matter including her role in requesting and receiving records from RIM in connection with this matter. *See supra* Section II.B & n. 2; Tr. 154–201; RD, at 4–6. Having read and analyzed all of the record evidence, I agree with the ALJ that DI's testimony ''was candid and straightforward.'' RD, at 6. I also agree that DI's testimony was ''sufficiently objective, detailed, plausible, and internally consistent to be considered fully credible.'' *Id.*

Dr. Loes testified regarding his professional and educational background. Tr. 217–28. He obtained a medical doctorate from the University of Minnesota, completed a clinical pharmacology fellowship, and later an internal medicine residency. Tr. 219–21; GX 34 (Curriculum Vitae of Dr. Loes); RD, at 7. Dr. Loes is board certified in internal medicine, addiction medicine, and pain medicine. Tr. 221–22; GX 34; RD, at 7. Dr. Loes first began practicing medicine in Arizona in 1994, when he became the Director of the Maricopa County Pain Program. Tr. 222–23; RD, at 7. He has held a variety of positions since then [5] in private practice, at inpatient treatment facilities, and at outpatient treatment facilities.[6] Tr. 222–25; GX 34; RD, at 7. Dr. Loes is licensed in Arizona and was accepted in this matter ''as an expert in the field of addiction medicine in the State of Arizona.'' Tr. 234; RD, at 7. Dr. Loes' 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.[7] *See infra* Section II.F; Tr. 234–424; RD, at 8–28, 70–83. ''Dr. Loes testified that his opinion was based upon both his analysis of the Arizona and federal regulations, as well as his almost 40-years' experience in the field.'' RD, at 80.

With regard to credibility, the ALJ found that ''Dr. Loes demonstrated limited familiarity herein with the relevant Arizona regulatory scheme [which led the ALJ] to discount his opinion somewhat . . . where such opinion [was] contrary or unsupported by the text of the relevant Arizona regulatory scheme.'' *Id.* For example, the ALJ found that the Arizona regulations did not support Dr. Loes' testimony ''that a physician at an outpatient facility can never prescribe a controlled substance before physically examining a patient.'' RD, at 81. *But see infra* II.E.4. The ALJ did not discount Dr. Loes' opinion as to the relevant standard of care on the basis of his experience. *Id.* The ALJ explained ''[he was] convinced that Dr. Loes, by actively working in this field for nearly 40-years, [was] familiar with acceptable standards of care within the relevant medical community in Arizona as [it] related to the general requirements for establishing a doctor-patient relationship, and the permissive 48-hour delay in examining patients admitted to inpatient facilities after [being] prescribed controlled substances.'' [8] *Id.*

As explained below, I find that Dr. Loes' opinions regarding the standard of care as it applied outpatient facilities, such as the one in this case, were supported by Arizona law and regulations and I therefore find Dr. Loes' testimony to be fully credible. *See infra* Section II.E.

D. Respondent's Case

The Respondent's documentary evidence consisted solely of what appears to be a scholarly article: *Louis A. Trevisan et al., Complications of Alcohol Withdrawal: Pathophysiological Insights,* 22 Alcohol Health & Res.

[4] The Government appears to have abandoned the allegations regarding one of the patients, A.A., because the expert testified that these prescriptions were issued within the standard of care; therefore, I am not including findings of fact related to patient A.A. RD, at 83; Tr. 316; *see generally* Gov Posthearing. *See also,* GX 2, at 22–23; GX 20 (Patient Records for A.A.); GX 36, at 18.

[5] Dr. Loes worked with Respondent for approximately six months providing physician coverage at Phoenix Recovery at Ellsworth. Tr. 223, 228, 381–82. Dr. Loes left, on good terms, to focus on private practice. Tr. 224. None of the parties raised any issues about Dr. Loes' previous contact with Respondent.

[6] The majority of Dr. Loes' work since 1994 has been in Arizona, but he briefly relocated to Minnesota in 2012. Tr. 223.

[7] Dr. Loes identified the following controlled substances as being at issue in this case: Buprenorphine (Suboxone, Zubsolv), Category III; diazepam (Valium), Category IV; phenobarbital, Category IV; tramadol (Ultram), Category IV; hydrocodone (Vicodin), Category II; amphetamine salts (Adderall), Category II; pregabalin (Lyrica); Category V. GX 36, at 3.

[8] *But see infra.* II.E.4, which discusses the Arizona regulations' support of Dr. Loes' opinion and addresses the 48-hour delay referenced here.

World, 61 (1998).[9] *See* Respondent's Exhibit (hereinafter, RX) 1. Respondent testified on his own behalf and presented no other testimony in support of his case.

Respondent testified that he completed a combined residency in internal medicine and pediatrics, that he is board certified in addiction medicine, and that he has been treating chemically dependent patients since 1994. Tr. 78, 125–26, 429–31. Respondent testified that he has been the medical director at RIM since its inception in March of 2015. Tr. 23. As the medical director Respondent testified that it was his duty ''[t]o make sure that medical policies [were] established and to see patients.'' Tr. 23. RIM provided partial hospitalization and intensive outpatient therapy. RD, at 41 (citing Tr. 66, 212–13).

Respondent testified that he went to Europe between July 24, 2015, and August 8, 2015. Tr. 60, 260, 290. While in Europe, Respondent testified that he received phone calls and emails from his staff regarding patients, and he continued to treat those patients to include writing prescriptions for controlled substance. Tr. 61–64, 67, 71, 81; RD, at 41. Respondent further testified that he conducted telephone evaluations (audio only) of patients while in Europe,[10] but that he did not have video capabilities. Tr. 72–73. Respondent did not document in his medical records the fact that he was performing evaluations of patients remotely. Tr. 72.

Throughout his testimony, Respondent maintained that he acted within the standard of care for two reasons. First, Respondent argued that the ''trained staff'' at RIM conducted a ''sufficient and appropriate evaluation'' of each patient upon admission to constitute a physical examination. Tr. 112–13. Second, Respondent argued that a physical examination of the patients identified in the OSC was not required because withdrawal is an emergent situation that qualifies as an ''emergency medical situation,'' and therefore allows a physician to prescribe without first conducting an examination. Resp Posthearing, at 2. Respondent testified to an alternative version of the standard of care in Arizona.[11] Tr. 144, 435–36; *infra* Section II.E. Respondent testified that at RIM, as he claimed was common within the industry,[12] new patients would enter treatment and be examined by staff, then the doctor would consult the staff (over phone or email), authorize a prescription if appropriate, and would complete paperwork after the fact. Tr. 108, 144–45. Respondent testified that not all of the staff at RIM held medical licenses, but that they were trained to ''take an appropriate history and physicals.'' Tr. 145–46. Respondent testified that the staff's admission notes, which he claimed justified the issuance of the initial prescriptions, were contained in the behavioral health portion of the medical record.[13] Tr. 26–27, 33, 57–58. Respondent testified that he would see new patients anywhere between 8 hours and 96 hours after intake depending on when the patient entered the facility (as Respondent only saw patients twice a week). Tr. 23, 106. Respondent also testified that patients would typically complete the initial history and physical records on the day that Respondent saw the patient. Tr. 106.

I agree with the ALJ that the ''Respondent overall did not express any sense of wrongdoing.'' RD, at 36. While at times Respondent acknowledged mistakes or deficiencies in recordkeeping (such as an undated record), he stated that it was an ''oversight'' and that he otherwise had followed the standard of care. Tr. 121, 122.

The ALJ found, and I agree, that Respondent's credibility was mixed. RD, at 38. The ALJ found that Respondent's testimony regarding his background and experience was credible. RD, at 38. The ALJ found that Respondent did not testify credibly regarding: (1) His knowledge of RIM's withholding of the behavioral health records, (2) his claim that all of the patients at issue had received physical exams within RIM's protocol time period (ninety-six hours) where the evidence suggested that at least seven patients were not examined within ninety-six hours, (3) his claim that he properly reviewed the admission protocol, personally directed the ordering of medication, and actively monitored patients while he was in Europe. RD, at 38–39. I agree with the ALJ's credibility findings on all of these matters. However, the ALJ found that the Respondent's testimony regarding RIM's policies and protocols was credible and I, as discussed below, find that testimony to not be credible. RD, at 38; *infra* II.E.4.

E. The Standard of Care in the State of Arizona

The crux of this case is the appropriate standard of care in Arizona for prescribing controlled substances as it applies to outpatient treatment centers, such as RIM. In accordance with Dr. Loes' testimony and the record as a whole, I find that the standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances when a relevant exception does not apply. In finding this standard of care, I note that there was significant confusion at the hearing stage regarding a number of issues: (1) Who can perform the physical examination; (2) when the exceptions apply, such as what constitutes an emergency medical situation or telemedicine appointment; (3) when the physical examination must be performed, such as whether Arizona law provides an exception that allows the examination to be performed later for addiction services. I will address each of these issues in turn.

1. Generally, the Record Evidence Supports a Finding That the Standard of Care in Arizona Requires That a Physician Perform a Physical Examination of a Patient Prior To Prescribing Controlled Substances

Dr. Loes testified that the general standard of care in Arizona requires that a doctor-patient relationship be established through a physical or mental[14] exam prior to a physician

[9] Respondent offered this evidence to support his testimony regarding the potentially deadly side effects of withdrawal, and to support his argument that withdrawal treatment is always an emergency. Tr. 431–38.

[10] Respondent's exact words were ''I evaluated a patient in person telephonically.'' Tr. 72. When asked how he evaluated Patient A.H.'s appearance as being clean and neat with a telephonic evaluation, Respondent stated ''I—I can't answer that.'' Tr. 73.

[11] The Respondent was not offered as an expert witness; however, he was permitted to testify as to his understanding of the Arizona standards of care in order to explain why he believed his actions were in compliance with the Arizona standard of care. *See* 144, 435–37; RD, at 76–77.

[12] Respondent testified that this practice was followed by several well-known outpatient addiction treatment facilities and a prominent physician. Tr. 438–40.

[13] As the ALJ noted, Respondent did not produce any records to support his proposition that the medical justification for the controlled substance prescriptions was contained in the behavioral health portion of the patients' corresponding electronic medical record. RD, at 29, 62–68. However, it is unclear how the behavior health records, if they exist, could have impacted the standard of care as I have found it. *See infra* II.E. Any records documenting what Respondent's staff did to evaluate the patients upon admission are not relevant to determining whether or not a physician or a medical practitioner examined the patients prior to the issuance of the controlled substance prescriptions. *See infra* II.E & n.17.

[14] There is no evidence of, nor has Respondent argued that, any mental exam was performed by Respondent in lieu of a physical exam prior to prescribing. The evidence establishes that Respondent did not see or perform any type of examination on the patients prior to prescribing. *See supra* II.F.

prescribing controlled substances. Tr. 222–23, 234, 422–23. Dr. Loes' opinion is supported by Arizona statute which states that it is ''unprofessional conduct'' to ''[p]rescrib[e], dispens[e] or furnish[ ] a prescription medicine . . . 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) (2014).

According to Dr. Loes, a physical examination sufficient to create a doctor-patient relationship for the purposes of prescribing controlled substances, ''requires that (1) the physician sees the patient, (2) examine[s] the patient, (3) assesses and diagnose[s] the condition(s) that establish the need for the controlled substance(s) and then (4) develops and executes an appropriate plan to improve or eliminate the medical condition wherein controlled substance(s) are integral to that plan.'' GX 36, at 2. Similarly, Dr. Loes testified that in order to establish a doctor-patient relationship at an outpatient treatment facility, the physician must take a medical history, take an addiction history, review the patient's symptoms, use the physical examination to determine whether the patient is in withdrawal, and develop a treatment plan—all prior to prescribing. Tr. 232–33.

Respondent argued that in an outpatient treatment center, the standard of care does not require a physician to perform the physical examination, but instead the standard of care ''is to take patients who get admitted in acute withdrawal settings and to treat them based on the history that—the history that's obtained from the staff . . . .'' Tr. 49. Respondent testified that his use of the word ''staff'' referred, not to persons with a medical license, but to people who were trained to ''take an appropriate history and physicals'' Tr. 145–46; *see also* Tr. 112–113.

Dr. Loes opined unequivocally that ''it's not appropriate for a staffer to do a physical exam.'' [15] Tr. 376. Dr. Loes testified that the physical examination had to be performed by a physician, but that the authority to perform the physical examination could be delegated to another physician [16] or a nurse practitioner. Tr. 282, 398. Dr. Loes' testimony appears to be supported by Arizona law and regulations. The plain language of the statute states that a doctor cannot prescribe controlled substances, ''unless *the doctor* first conducts a physical or mental health status examination . . . .'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (emphasis added). Additionally, the Arizona regulations governing outpatient treatment centers provide that, for a patient receiving opioid treatment services, ''a physician, or a medical practitioner under the direction of a physician performs a medical history and physical examination on the patient . . . within 48 hours after admission.'' Ariz. Admin. Code § R9–10–1020(c)(2) (2014). Medical practitioner is defined as ''a physician, physician assistant, or registered nurse practitioner.'' Ariz. Admin. Code § R9–10–101(128). Under Arizona state law, physicians, physician assistants, and registered nurse practitioners are required to be licensed as such. Ariz. Admin. Code § R9–10–101(128), citing to Ariz. Rev. Stat. Ann 32–1601(21)&(22), and 32–2501(12)&(13). Based on Dr. Loes' testimony and the record as a whole, I find that Respondent's ''staff'' could not perform a physical examination to meet the requirements under Arizona law, unless the staff met the definition of a medical practitioner.[17] During cross examination, Government's attorney specifically asked Respondent whether these ''trained staff'' were licensed by ''some type of medical board in the state of Arizona'' to which Respondent answered, ''They were trained by our staff.'' Tr. 112–13.

Based on Dr. Loes' testimony as supported by Arizona law, I find that the applicable standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances, unless an exception applies.

2. Emergency Medical Situation Exception

Neither the Government nor the Respondent disputed that the requirement that a physician conduct a physical or mental health status examination and develop a doctor-patient relationship before prescribing controlled substances does not apply in a medical emergency; however, the parties disagree over what qualifies as an ''emergency medical situation.'' *See* Govt Posthearing, at 26; Resp Posthearing, at 8–9. Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) provides that a doctor is not required to conduct a physical or mental health status examination before prescribing when there is an ''(ii) [e]mergency medical situation as defined in § 41–1831.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss). Section § 41–1831 states that ''[e]mergency medical situation means a condition of emergency in which immediate medical care or hospitalization,[18] or both, is required by a person or persons for the preservation of health, life, or limb.'' Ariz. Rev. Stat. Ann. § 41–1831(9) (2012).

Dr. Loes testified that an emergency occurs when there are ''[u]nstable vital signs, . . . the Clinical Opioid Withdrawal Scale[ ] was done and was very elevated, showing a shaky, vomiting painful type patient that looked like they could seize.'' Tr. 238–39. Respondent, on the other hand, testified that ''the way that the statute defines emergency, it does not say that a patient has to be unstable for there to be an emergency . . . what we do is prevent instability by providing treatment.'' Tr. 443. Respondent implies that treatment meant to prevent a patient from entering a state of medical emergency itself constitutes an ''emergency medical situation.'' [19] Tr. 431–35, 443.

[15] Dr. Loes further testified that it is ''common for a history to be taken by staffers . . . A staff might take vital signs, but that's not a physical exam.'' Tr. 376.

[16] Dr. Loes testified that it is permissible for one doctor to prescribe based on another doctor's (which he called a coverage physician) performance of the physical examination. Tr. 254. This testimony appears consistent with the exception laid out in Ariz. Rev. Stat. Ann. § 32–1401(27)(ss)(i).

[17] As noted throughout, Respondent raised an argument that his staff conducted physical examinations on his behalf and documented those examinations in records which had not been produced by RIM in response to the Government's subpoena. If these records existed, in order for them to even be relevant to whether or not Respondent was acting within the standard of care, the staff would have had to fall within the Arizona state statutory definition of medical practitioner. The record evidence, based on Respondent's own testimony does not indicate that these staff fell within the statutory definition, and therefore, I find that the records, if they existed, could have limited relevance to whether Respondent acted within the standard of care.

[18] The same section defines an ''[e]mergency receiving facility'' as ''a licensed health care institution that offers emergency medical services, that is staffed twenty-four hours a day and that has a physician who is licensed pursuant to title 32, chapter 13 or 17, on call.'' Ariz. Rev. Stat. Ann. § 41–1831(10) (2012). There is no evidence on the record, nor did Respondent make any argument, that RIM is an emergency receiving facility.

[19] Although not specific to the statutory definition, the Arizona Medical Board (hereinafter, Board) discussed the application of a life-threatening emergency in *In the Matter of: Darrell J. Jessop, M.D., Respt.,* 11A–23441–MDX, 2012 WL 432838 (Ariz.Med.Bd. Feb. 6, 2012). Jessop was a practitioner at an urgent care clinic who, pursuant to a consent agreement with the Board, was prohibited from prescribing or administering controlled substances for three years. *Id.* at 2. However, there was an exception in the agreement that allowed the Jessop to administer controlled

Continued

The ALJ found, and I agree, that ''the plain language of the statute in limiting the covered conditions to those requiring 'immediate' medical care would rebut the Respondent's overly broad interpretation of the statute . . . as encompassing potential or even non-medical eventualities.'' RD, at 82 (citing Ariz. Rev. Stat. Ann. § 41–1831).[20] I find that Dr. Loes' description of an emergency is in line with the statutory definition.

Dr. Loes further testified that ''an outpatient program doesn't handle acute emergencies,'' Tr. 226. Dr. Loes' opinion appears to be supported by Arizona law and regulation. It appears that an outpatient treatment center is required to have additional authorization in order to provide emergency room services. *See* Ariz. Admin. Code § 09–10–1019 (An outpatient treatment center authorized to provide emergency room services must have emergency room services available on the premises at all times, and must ensure that both a physician and a registered nurse are present in the area designated for emergency room services). Respondent has not argued that RIM is authorized to provide emergency room treatment services, nor does it appear that RIM would qualify to provide emergency treatment services.

I find that where an emergency medical situation—instability requiring immediate medical care—exists, the applicable standard of care as testified to by Dr. Loes and supported by Arizona law does not require a physician to conduct a physical or mental health status examination and develop a doctor-patient relationship before prescribing controlled substances; however, as explained further herein, Dr. Loes credibly testified that there is no evidence in this case to support that the prescriptions were issued pursuant to an emergency medical situation.

3. Telemedicine Exception

The second exception to the physical examination requirement that is potentially relevant to this case applies when there are ''(viii) [p]rescriptions written by a licensee through a telemedicine program that is covered by the policies and procedures adopted by the administrator of a hospital or outpatient treatment center.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss). Arizona law states that ''[t]he physical or mental health status examination may be conducted during a real-time telemedicine encounter with audio and video capability if the telemedicine audio and video capability meets the elements required by the centers for medicare and medicaid services . . . .'' *Id.* Dr. Loes testified to the same, and indicated that telemedicine requires the use of a television portal or other video capability. Tr. 377–78. Dr. Loes testified that, ''a telephonic call with the patient, in [his] opinion, is not sufficient to develop a . . . strategy for treatment and the . . . doctor patient relationship.'' Tr. 233. In other words, ''a phone interview doesn't entail a kind of physical exam,'' and a physician cannot ''start controlled substances without a physical exam.'' Tr. 239.

I find that where a facility has a telemedicine program, and a telemedicine visit has audio and video capability, the applicable standard of care as testified to by Dr. Loes and supported by Arizona law, does not require a physician to conduct an in-person physical or mental health status examination and develop a doctor-patient relationship before prescribing controlled substances; however, as further explained herein, there is no evidence that Respondent conducted physical examinations using telemedicine with audio and video capability in this case. *See supra* II.D & n.10.

4. Respondent's Claimed Regulatory/Policy Exception

Respondent argues that there is an additional exception to the statutory requirement that a physician first conduct a physical examination prior to prescribing controlled substances found in RIM's policies, which were drafted pursuant to Arizona's Health Care regulations.[21] Arizona Regulations require an outpatient treatment facility, such as RIM, to ensure that ''[p]olicies and procedures for services provided at or by an outpatient treatment center are established, documented, and implemented to protect the health and safety of a patient . . . .''[22] Ariz. Admin. Code § R9–10–1003(D)(2) (2015).

Respondent argues that, under RIM's policies, a physician at an outpatient treatment facility can prescribe medication to a patient for a limited period of time prior to the physician performing a physical examination so long as trained staff first evaluated the patient. Tr. 107–08. Respondent testified that RIM's policy[23] was that upon admission, ''trained staff''[24] would evaluate the patient and consult telephonically with the physician, then, if deemed appropriate, the physician would issue a prescription to the patient—the physician would conduct a physical examination of the patient up to seventy-two or ninety-six[25] hours after admission. Tr. 112–13; *see also* Tr. 107–08.

In contrast, Dr. Loes credibly testified that it was his expert opinion that no outpatient facility can prescribe to a patient without first having a physical examination performed by a physician.[26] Tr. 396, 405, 407. Dr. Loes' opinion of the standard of care as it is relevant to this case appears to be consistent with and supported by Arizona's statutes and regulations, the application of which to outpatient

substances in ''life threatening emergencies.'' *Id.* Jessop argued that a life-threatening emergency did not require that death be imminent and that a ''life-threatening emergency'' existed ''anytime that the practitioner . . . determines that the patient's condition might deteriorate if he does not prescribe medication . . . .'' *Id.* at 9; *see also id.* at 2. The Board disagreed and stated, ''[u]nder Respondent's own authorities, an urgent care clinic is not equipped to handle life-threatening emergencies and if such an emergencies [sic.] arise, the urgent care physician must refer the patients to an emergency room.'' *Id.* at 9.

[20] Moreover, the Arizona Supreme Court noted that although there are various definitions of emergency care, ''the need for immediate attention seems to be the common thread.'' *Thompson* v. *Sun City Community Hospital,* 688 P.2d 605, 611 (1984); *see also Callen* v. *Rogers,* 216 Ariz. 499, 509 (2007).

[21] The ALJ stated that ''[t]he Respondent's testimony that RIM had policies and procedures governing aspects of treatment protocol were sufficiently credible to credit, as they appeared to be corroborated by the Arizona Administrative Code.'' RD, at 38. I agree with the ALJ the regulations required RIM to have policies and procedures.

[22] By regulation, these policies are required to, amongst other things: ''a. [c]over patient screening, admission, assessment, . . . discharge plan, and discharge; . . . d. [c]over obtaining, administering, storing, and disposing of medications, including provisions for controlling inventory and preventing diversion of controlled substances; e. [c]over prescribing a controlled substance to minimize substance abuse by a patient; . . . g. [c]over telemedicine, if applicable.'' Ariz. Admin. Code § R9–10–1003(D)(2) (2015).

[23] Respondent's description of RIM's policies was similar to Respondent's version of the standard of care. Respondent testified that, ''the standard of care is to take patients who get admitted in acute withdrawal settings and to treat them based on the history that—the history that's obtained from the staff, and then see [the patient] afterwards. And in some programs, that is within 24 hours, and in some programs it's within five to seven days.'' Tr. at 49.

[24] As already discussed, trained staff would be required to fall within the definition of medical practitioner under the statute. *See supra* II.E.1 & n.17.

[25] Respondent first testified that a physician had 72 hours to evaluate a patient after admission. Tr. 107. He then testified that RIM changed its policies and procedures to say that a physician had 96 hours to evaluate a patient after admission. *Id.* Respondent did not clarify whether RIM's policy was 72 hours or 96 hours at the time relevant to this case. The ALJ applied 96 hours to his standard of care. Ultimately this is irrelevant, because I do not find that RIM's policies provide an exception to the requirement that a physician examine a patient prior to prescribing.

[26] *See also supra* II.E.1.

treatment centers is complex.[27] Article 9, Chapter 10 of Arizona's Administrative Code covers ''Department of Health Services Health Care Institutions: Licensing'' (hereinafter, licensing regulations). Chapter 10 of the licensing regulations sets forth the licensing requirements for, and a number of requirements covering various types of health care institutions. It seems likely that these are the ''licensing regulations'' that Dr. Loes referenced, without citing, in his testimony. *See* Tr. 405, 407. Within the licensing regulations, there are sub-articles for ''Behavioral Health Inpatient Facilities'' (Article 3) (hereinafter, inpatient regulations) and for ''Outpatient Treatment Centers'' (Article 10) (hereinafter, outpatient regulations).

With regard to outpatient facilities,[28] Dr. Loes opined that that no outpatient facility can prescribe to a patient without first having a physical examination performed by a physician. Tr. 396, 405, 407. Pursuant to Arizona's regulations, an outpatient treatment center that provides opioid treatment[29] services:

> . . . shall ensure that for a patient receiving opioid treatment services:
>
> 2. A physician or a medical practitioner[30] under the direction of a physician:
>
> a. Performs a medical history and physical evaluation on the patient within 30 calendar days before admission or within 48 hours after admission, and
>
> b. Documents the medical history and physical examination in the patient's medical record within 48 hours after admission.

Ariz. Admin. Code § R9–10–1020(C) (2014). *See* Ariz. Admin Code § R9–10–1020(C) and § R9–10–1003(D). Although the outpatient regulations permit the physical examination to occur within 48 hours of admission, nowhere do they state that controlled substances can be prescribed before the physical examination is completed.[31] The requirement to conduct a physical examination after admission is separate from the requirement to conduct one prior to prescribing controlled substances and the two should not be conflated. In light of the above, I find Respondent's testimony regarding the substance of RIM's policy, which was not supported by any corroborating evidence, to lack credibility; if I were to credit Respondent's testimony, RIM's policies would appear to be in conflict with the licensing regulations and statute.[32] Tr. 107–08. Instead I credit Dr. Loes' opinion, which appears to be more consistent with the licensing regulations and statute. Accordingly, I find that the standard of care in Arizona as described by Dr. Loes requires that, at an outpatient facility, a physician, not ''trained staff,'' must conduct the physical examination, and that a physical examination is required before a physician can prescribe controlled substances.

Indeed, there are a variety of options available for patients upon admission besides receiving controlled substances. Respondent testified that there are 12-step meetings, group meetings, therapy sessions, and other behavioral health counselings. Tr. 130. There is no evidence to give credence to Respondent's claim that Arizona's statutory requirements should be usurped by a health care facility's policy, even where the existence of the policy is mandated by regulation.

The outpatient regulations do not appear to conflict with, nor be an exception to, the statutory requirement that a physician must conduct a physical examination prior to treating a patient with controlled substances. Therefore, in accordance with Dr. Loes' testimony and the record as a whole, I find that where, as in this case, there is not an emergency medical situation and no appropriate telemedicine examination was conducted, the applicable standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances.

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[27] The ALJ discounted ''[Dr. Loes'] opinion somewhat . . . where such opinion was unsupported by the text of the relevant Arizona regulatory scheme.'' RD, at 80. The ALJ was ''unable to identify any provision in the Arizona Administrative Code, which specifically addressed [whether there could be a ''delay between prescribing a controlled substance and the physician physically examining the patient''] as to any of the various classes and subclasses of health care facilities in Arizona.'' RD, at 78. Additionally, the RD was unable to find support within the regulations for Dr. Loes' opinion that is was permissible for a physician to prescribe controlled substance prior to a physical exam in the inpatient, but not outpatient, context. RD, at 78–79. I find support in Arizona law for Dr. Loes' testimony where there is an emergency, as Dr. Loes' explained was frequent in the inpatient context; however, I agree with the ALJ that there was some confusion in Dr. Loes' testimony about when treatment can be initiated in an inpatient facility when there is no emergency. RD, at 75–76. However, ultimately, based on my examination of Arizona law, I credit and do not discount Dr. Loes' opinion regarding the applicable standard of care for the patients at issue in this case in the outpatient context, which, along with the substantial evidence in this case has led to my finding that prescriptions issued to thirty patients, instead of seven (RD, at 93), were issued outside the standard of care.

[28] With regard to inpatient facilities (unlike RIM), Dr. Loes opined that an emergency patient may be prescribed medication before a physical examination, which must be conducted within forty-eight hours, so long as the patient is examined by a registered nurse in direct communication with a physician. Tr. 405–09; RD, at 72, 74. Dr. Loes' testimony appears to be mostly consistent with the inpatient regulations and with the emergency exception found in Ariz. Rev. Stat. Ann. § 32–1401(27)(ss)(ii) *supra* II.E.2. The inpatient regulations state that a ''medical practitioner must perform a medical history and physical examination on a patient within . . . 72 hours after admission. . . .'' Ariz. Admin Code § R9–10–307(8). The inpatient regulations state that ''[e]xcept when a patient needs crisis services, a behavioral health assessment of a patient is completed before treatment for the patient is initiated.'' Ariz. Admin Code § R9–10–307(10) (emphasis added). The inpatient regulations explicitly allow for a behavioral health technician, registered nurse, or behavioral health paraprofessional to conduct the initial behavioral health assessment necessary to initiate treatment. *Id.* at (11). There was some confusion in Dr. Loes' testimony about when a physician can prescribe in an inpatient facility when there is no emergency. Tr. 407–08; *see supra* n.27. However, Dr. Loes' testimony was clear regarding when a physician can prescribe in an outpatient facility, which according to Dr. Loes is not equipped to handle emergencies (Tr. 226, 230, 407, 410–11) and is bolstered by Arizona law. Tr. 396, 405–06.

[29] Under the regulation, '' '[t]reatment' means a procedure or method to cure, improve, or palliate an individual's medical condition or behavioral health issue.'' Ariz. Admin Code § R9–10–101(236). It appears that ''treatment'' includes, but is not limited to, prescribing medication (*e.g.* '' '[o]pioid treatment' means providing medical services, nursing services, behavioral health services, health-related services, and ancillary services to a patient receiving an opioid agonist treatment medication for opiate addiction opioid-related substance use disorder.''). Ariz. Admin Code § R9–10–101(151). *See also id.* at § R9–10–101(221).

[30] As explained *supra* at II.E.1, the definition of medical practitioner is limited. There is nothing on the record to suggest that Respondent's staff would have qualified as medical practitioners, nor is there any documentation suggesting that a physical examination was conducted.

[31] The Government, in its exceptions, argued that that Respondent's claim that he was permitted to prescribe 72 or 96 hours prior to conducting a physical examination of a patient is not relevant to this litigation because the inpatient licensing regulation ''merely requires taking a medical history and performing a physical examination of a patient within 72 hours of admission. It neither addresses nor governs the prescribing or dispensing of controlled substances.'' Gov Exceptions, at 5 & n.4. This argument is similar to what I have found regarding the outpatient licensing regulations which are applicable here (but within 48 hours).

[32] Portions of RIM's established policies, as required by Arizona regulations, are documented in the public record. According to these records, RIM's policy (for much of the time relevant to this case) states that ''[p]rior to initiation of treatment, all Clients will be assessed by a medical practitioner for a medical assessment which shall include: a. [m]edical history b. [p]hysical examination c. [p]ain screen d. [n]utrition screen.'' Gov Exceptions, Attachment B, at 1. The RIM policy further states that ''[a] Client admitted to Recovery in Motion will see the medical provider within 72 hours for a medical assessment.'' *Id.* As such, the provider must see the client within 72 hours; however, the policy does not permit a provider to initiate treatment prior to the conduct of a physical examination. RIM's established policies appear inconsistent with Respondent's testimony, but appear more consistent with Arizona's statute and regulations and the testimony of Dr. Loes regarding the applicable standard of care in Arizona.

F. Patients

1. Patient L.H.[33]

On May 8, 2015, Respondent prescribed a controlled substance, Suboxone 8 mg., to Patient L.H. GX 2 (Prescription Records), at 1; GX 3 (Patient Record for L.H.), at 38; GX 36, at 7; RD, at 42. Dr. Loes testified that at the time the May 8, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient L.H. Tr. 237–38; *see also* GX 36, at 7. In support of his opinion, Dr. Loes testified that ''there was no physical, . . . no documentation of [an] interview or exam or lab; no assessment . . . about what kind of state of withdrawal that patient was in and then, of course, no comprehensive plan prior to that prescription being started.'' Tr. 238. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 238; RD, at 42. Respondent first examined Patient L.H. on May 9, 2015, and Dr. Loes testified that a doctor-patient relationship was established at that time. GX 36, at 7; GX 3, at 39; RD, at 42.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient L.H. at the time the prescription was issued, the Suboxone prescription that Respondent issued to Patient L.H. on May 8, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

2. Patient D.P.

On May 13, 2015, Respondent prescribed a controlled substance, diazepam (Valium) 5 mg., to Patient D.P. GX 2, at 2; GX 4 (Patient Record for D.P.), at 22–23; GX 36, at 7; RD, at 42; Tr. 41–43, 244–45. Dr. Loes testified that at the time the May 13, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient D.P. Tr. 245, 247; *see also* GX 36, at 7. In support of his opinion, Dr. Loes testified that ''the patient was started on Valium on May 13th and not seen until May 22nd.'' Tr. 245. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 250; RD, at 42. Respondent first examined Patient D.P. on May 22, 2015. GX 36, at 7; Tr. 245; GX 4, at 53; RD, at 42.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient D.P. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient D.P. on May 13, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

3. Patient N.B.

On June 1, 2015, Respondent prescribed a controlled substance, diazepam (Valium) 10 mg. tablets, to Patient N.B. GX 2, at 3; GX 5 (Patient Records for N.B.), at 84; GX 36, at 8; RD, at 42. Dr. Loes testified that at the time the June 1, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient N.B. Tr. 249; *see also* GX 36, at 8. In support of his opinion, Dr. Loes testified that ''[t]here was no documentation of anything that constituted an interview, physical exam, assessment, lab, urine, vitals, none of that was present that [Dr. Loes] could see to justify a doctor-patient relationship.'' Tr. 249. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 250; RD, at 42. Respondent first examined Patient N.B. on June 3, 2015. GX 36, at 8; GX 5, at 1–4; RD, at 42.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient N.B. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient N.B. on June 1, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

4. Patient A.J.C.

On June 28, 2015, Respondent prescribed a controlled substance, 20 tablets of phenobarbital 64.8 mg., to Patient L.H. GX 2, at 4; GX 6 (Patient Records for A.J.C.), at 26; GX 36, at 8; RD, at 43. Dr. Loes testified that at the time the June 28, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient A.J.C. Tr. 251; *see also* GX 36, at 8. In support of his opinion, Dr. Loes testified that ''there's no documentation of a telephonic or a physical exam or assessment or treatment plan to justify this particular prescription.'' Tr. 251–52. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. A.J.C. was first examined by a physician (not by Respondent, but by a collaborating physician Dr. T.J.)[34] on July 2, 2015. GX 36, at 8; GX 6, at 87–116; RD, at 43.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.J.C. at the time the prescription was issued, the phenobarbital prescription that Respondent issued to Patient A.J.C. on June 28, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

5. Patient S.S.

On July 4, 2015, Respondent prescribed a controlled substance, 45 tablets of buprenorphine 8 mg., to Patient S.S. GX 2, at 5; GX 7 (Patient Records for S.S.), at 79; GX 36, at 9; RD, at 43. Dr. Loes testified that at the time the July 4, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient S.S. Tr. 255; *see also* GX 36, at 9. In support of his opinion, Dr. Loes testified that ''[t]here's no information that a patient visit, interview, examination, assessment, lab, collaborating lab or urine test was done prior to this [prescription] . . .'' Tr. 255. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. S.S. was first examined by a physician (not by Respondent, but by collaborating physician T.J.) on July 6, 2015. GX 36, at 9; GX 7, at 25–54; RD, at 43.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient S.S. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient S.S. on July 4, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

6. Patient J.L.

On July 5, 2015, Respondent prescribed a controlled substance, 20 tablets of diazepam (Valium) 10 mg., to

[33] Patient L.H. is referred to by the initials E.H. in the OSC. *See* OSC, at 2.

[34] Dr. Loes testified that where there is an issue of resources in medical coverage, one physician, in this case Dr. T.J., can follow the treatment course established by the physician who issued the controlled substance prescription, in this case Respondent. Tr. 253–54; *see also* Ariz. Rev. Stat. Ann. § 32–1401(27)(ss)(i). However, in this case, this physical examination did not occur until well after the controlled substance prescription was issued by Respondent and therefore, the prescriptions were issued beneath the standard of care and outside of the usual course of the professional practice.

Patient J.L. GX 2, at 6; GX 8 (Patient Records for J.L.), at 39; GX 36, at 9; RD, at 43. Dr. Loes testified that at the time the July 5, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.L. Tr. 257, 259; *see also* GX 36, at 10. In support of his opinion, Dr. Loes testified that there was ''no doctor presence interview, physical exam, corroborating lab assessment or plan.'' Tr. 257. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. J.L. was first examined by a physician (not by Respondent, but by collaborating physician T.J.) on July 6, 2015. GX 36, at 10; GX 8, at 40–69; RD, at 43.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.L. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient J.L. on July 5, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

7. Patient K.R.K.

On July 15, 2015, Respondent prescribed a controlled substance, 23 tablets of buprenorphine 2 mg., to Patient K.R.K. GX 2, at 7; GX 9 (Patient Records for K.R.K.), at 80; GX 36, at 10; RD, at 44. Dr. Loes testified that at the time the July 15, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient K.R.K. Tr. 260–61; *see also* GX 36, at 11. In support of his opinion, Dr. Loes testified that there was ''[n]o face-to-face interview, exam; no corroborating lab, urine, no assessment or plan.'' Tr. 261. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. Respondent first examined Patient K.R.K. on July 18, 2015. GX 36, at 10; GX 9, at 81–110; RD, at 44.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient K.R.K. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient K.R.K. on July 15, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

8. Patient J.Z.

On July 15, 2015, Respondent prescribed a controlled substance, 23 tablets of buprenorphine 2 mg., to Patient J.Z. GX 2, at 8; GX 10 (Patient Records for J.Z.), at 35; GX 36, at 11; RD, at 44. Dr. Loes testified that at the time the July 15, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.Z. Tr. 270; *see also* GX 36, at 11. In support of his opinion, Dr. Loes testified that there was ''no evidence of an interview, a history by the doctor, a physical exam, any lab or diagnosis, comprehensive evaluation of the clinical situation or treatment plan documented.'' Tr. 270–71. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. For these reasons, Dr. Loes opined that the treatment provided to J.Z. with regard to the July 15, 2015 prescription was outside of the standard of care in Arizona.[35] Tr. 271–72. Respondent first examined Patient J.Z. on July 18, 2015. GX 36, at 11; GX 10, at 36–65; RD, at 44.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.Z. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient J.Z. on July 15, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

9. Patient A.H.

On July 31, 2015, Respondent (while outside of the country) issued two prescriptions for controlled substances, one for 9 tablets of buprenorphine 8 mg. and one for 9 tablets of buprenorphine 2 mg, to Patient A.H. GX 2, at 9–10; GX 11 (Patient Records for A.H.), at 33; GX 36, at 11; RD, at 44. Dr. Loes testified that at the time the July 31, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient A.H. Tr. 273; *see also* GX 36, at 12. In support of his opinion, Dr. Loes testified that there was ''no history, physical exam, or diagnosis or treatment plan that was done prior to the prescription.'' Tr. 274. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 279–280, 311. Respondent appears to have first examined Patient A.H. on August 29, 2015.[36] GX 36, at 12; GX 11, at 2–9; RD, at 44.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.H. at the time the prescription was issued, the two buprenorphine prescriptions that Respondent issued to Patient A.H. on July 31, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

10. Patient C.S.

On August 2, 2015, Respondent (while outside of the country) prescribed a controlled substance, 20 tablets of diazepam 10 mg., to Patient C.S. GX 2, at 11; GX 12 (Patient Records for C.S.), at 57; GX 36, at 12; RD, at 45. Dr. Loes testified that at the time the August 2, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient C.S. Tr. 286–87; *see also* GX 36, at 13. In support of his opinion, Dr. Loes testified that there was no record of a physical exam, mental exam, medical history, or assessment of the patient's function. Tr. 287–88. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient C.S. on August 18, 2015. GX 36, at 12; GX 12, at 1–8; RD, at 45. Dr. Loes opined that the treatment provided to C.S. was beneath the standard of care in Arizona. Tr. 288.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient C.S. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient C.S. on August 2, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

11. Patient J.A.

On August 7, 2015, Respondent (while outside of the country) prescribed a controlled substance, namely 64 tablets of buprenorphine 2 mg., to Patient J.A. GX 2, at 12; GX 13 (Patient Records for J.A.), at 23; GX 36,

[35] Dr. Loes later testified that Respondent's treatment of each one of the patients at issue in this case fell below the standard of care because in all the cases the Respondent did not establish a doctor-patient relationship before prescribing. Tr. 404.

[36] Dr. Loes pointed out that the medical records suggest that Respondent evaluated Patient A.H. on July 31, 2015. This is because the ''Comprehensive Physical Evaluation and Examination'' record in the file is dated July 31, 2015, on the first page and is signed by Respondent on the last page (which is undated). Tr. 272–73; GX 36, at 12; GX 11, 34–63. However, Respondent was out of the country on July 31, 2015, and according to Dr. Loes, the RIM staff could not have transmitted sufficient material to Respondent to justify the creation of a doctor-patient relationship on July 31, 2015. Tr. 71–73, 281. I find that the evidence does not support a finding that Respondent or any other physician performed a physical examination of A.H. on July 31, 2015. Tr. 71–73, 272–273, 276, 278–79.

at 13; RD, at 45. Dr. Loes testified that at the time the August 7, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.A. Tr. 290; *see also* GX 36, at 13. In support of his opinion, Dr. Loes testified that there was ''no doctor-patient relationship established based on the records, the absence of a history, the physical by the physician, and any associated lab or other documentation wasn't there.'' Tr. 290. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient J.A. on August 27, 2015. GX 36, at 13; GX 13, at 2–8; RD, at 45. Dr. Loes opined that the treatment provided to J.A. was beneath the standard of care in Arizona. Tr. 291.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.A. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient J.A. on August 7, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

12. Patient Z.J.

On August 7, 2015, Respondent (while outside of the country) prescribed a controlled substance, namely 45 tablets of buprenorphine 2 mg., to Patient Z.J. GX 2, at 13; GX 14 (Patient Records for Z.J.), at 7; GX 36, at 13; RD, at 45. Dr. Loes testified that at the time the August 7, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient Z.J. Tr. 293–94; *see also* GX 36, at 14. In support of his opinion, Dr. Loes testified that there was a ''lack of history, physical, and diagnosis, treatment plan, and associated lab.'' Tr. 294. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Also, ''[t]here is no documentation that this patient was ever seen by a physician.'' GX 36, at 14; *see also* GX 14; RD, at 45; Tr. 293. Dr. Loes opined that the treatment provided to Z.J. was beneath the standard of care in Arizona. Tr. 294.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient Z.J. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient Z.J. on August 7, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

13. Patient L.O.[37]

On August 12, 2015,[38] Respondent prescribed a controlled substance, 20 tablets of diazepam 10 mg., to Patient L.O. GX 2, at 14; GX 15 (Patient Records for L.O.), at 105; GX 36, at 14; RD, at 46. Dr. Loes testified that at the time the August 12, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient L.O. Tr. 298; *see also* GX 36, at 14. In support of his opinion, Dr. Loes testified that at the time of the prescription there was not an adequate medical history taken, adequate physical exam, or adequate mental exam to establish a doctor-patient relationship. Tr. 298. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient L.O. on August 15, 2015. GX 36, at 14; GX 15, at 1–30; RD, at 46. Accordingly, Dr. Loes opined that Respondent's August 13, 2015 prescription to L.O. ''fell below the standard of care.'' Tr. 298.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient L.O. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient L.O. on August 13, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

14. Patient T.G.[39]

On, August 21, 2015, Respondent prescribed two controlled substances, ten tablets of buprenorphine 8 mg. and nine tablets of buprenorphine 2 mg., to Patient T.G. GX 2, at 15–16; GX 16 (Patient Records for T.G.), at 113; GX 36, at 15; RD, at 46. Dr. Loes testified that at the time the August 21, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient T.G. Tr. 301; *see also* GX 36, at 15. In support of his opinion, Dr. Loes testified that there was an ''[a]bsence of physical exam and associated labs and assessment and a treatment plan.'' Tr. 301. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient T.G. on August 23, 2015. GX 36, at 15; GX 16, at 1–30; RD, at 46. Accordingly, Dr. Loes opined that Respondent's treatment of T.G. fell beneath the standard of care in Arizona. Tr. 301–02.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient T.G. at the time the prescriptions were issued, the buprenorphine prescriptions that Respondent issued to Patient T.G. on August 13, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

15. Patient A.S.

On August 25, 2015, Respondent issued two prescriptions for controlled substances, 22 tablets of buprenorphine 2 mg. and 30 tablets of phenobarbital 32.4 mg., to Patient A.S. GX 2, at 17–18; GX 17 (Patient Records for A.S.), at 9–10; GX 36, at 16; RD, at 47. Although the prescriptions were dated August 25, 2015, the medical records reflect that Patient A.S. began taking both controlled substances on August 24, 2015. GX 17, at 9–10; GX 36, at 16; RD, at 47. Dr. Loes testified that at the time the August 25, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient A.S. Tr. 304–05; *see also* GX 36, at 16. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, or mental examination performed prior to August 25, 2015. Tr. 305. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Patient A.S. discontinued her treatment on August 25, 2015, and was never seen by Respondent. GX 36, at 16; GX 17, at 1, 3; RD, at 47. Accordingly, Dr. Loes opined that Respondent's treatment of A.S. fell beneath the standard of care in Arizona. Tr. 305.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.S. at the time the prescriptions were issued, the buprenorphine and phenobarbital prescriptions that

[37] Patient L.O. (referencing her nickname) is referred to by the initials E.O. (referencing her legal name) in the OSC. *See* OSC, at 4.

[38] The pharmacy records indicate that the prescription was dated August 12, 2015, but not picked up until August 13, 2015. GX2, at 14. The August 13, 2015 was used in the Recommended Decision and Expert Report. RD, at 46; GX 36, at 14. Regardless of whether the prescription was issued on August 12th or 13th, Respondent did not perform a physical examination until August 15, 2015.

[39] T.G., the initials used in the Recommended Decision, is referred to as R.G. in the OSC, and as R.T.G. in the Expert's Report—all three identify the same patient. *See* RD, at 46; OSC, at 4; GX 36, at 15.

Respondent issued to Patient A.S. on August 25, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

16. Patient J.P.

On September 4, 2015, Respondent prescribed two controlled substances, 40 tablets of phenobarbital 32.4 mg. and 15 tablets of buprenorphine (Zubsolv) 5.7 mg., to Patient J.P. GX 2, at 19–20; GX 18 (Patient Records for J.P.), at 166–68; GX 36, at 17; RD, at 47. Dr. Loes testified that at the time the September 4, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.P. Tr. 309; *see also* GX 36, at 17. In support of his opinion, Dr. Loes testified that there was a ''lack of history, physical examination, assessment, [and] associated lab.'' Tr. 310. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient J.P. on September 5, 2015. GX 36, at 17; GX 18, at 97–127; RD, at 47. Accordingly, Dr. Loes opined that Respondent's treatment of A.S. fell beneath the standard of care in Arizona. Tr. 311.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.P. at the time the prescriptions were issued, the phenobarbital and buprenorphine prescriptions that Respondent issued to Patient J.P. on September 4, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

17. Patient K.M.

On September 8, 2015, Respondent prescribed a controlled substance, 20 tablets of diazepam (Valium) 10 mg., to Patient K.M. GX 2, at 21; GX 19 (Patient Records for K.M.), at 36; GX 36, at 17; RD, at 47. Dr. Loes testified that at the time the September 8, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient K.M. Tr. 313; *see also* GX 36, at 18. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, or mental examination performed, nor any attempt to assess K.M.'s psychological or physical function prior to September 8, 2015. Tr. 313. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 314. Respondent first examined Patient K.M. on September 11, 2015. GX 36, at 17; GX 19, at 37–66; RD, at 47. Accordingly, Dr. Loes opined that Respondent's treatment of K.M. fell beneath the standard of care in Arizona. Tr. 314.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient K.M. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient K.M. on September 8, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

18. Patient T.K.

On September 11, 2015, Respondent prescribed a controlled substance, 20 tablets of Valium 10 mg., to Patient T.K. GX 2, at 24; GX 21 (Patient Records for T.K.), at 30; GX 36, at 18–19; RD, at 48. Dr. Loes testified that at the time the September 11, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient T.K. Tr. 317; *see also* GX 36, at 19. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, or mental examination performed prior to the September 11, 2015 prescription. Tr. 317–18. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 318. Respondent first examined Patient T.K. on September 12, 2015. GX 36, at 19; GX 21, at 141–170; RD, at 48. Accordingly, Dr. Loes opined that Respondent's treatment of T.K. fell beneath the standard of care in Arizona. Tr. 318.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient T.K. at the time the prescription was issued, the Valium prescription Respondent issued to Patient T.K. on September 11, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

19. Patient B.F.[40]

On September 12, 2015, Respondent prescribed a controlled substance, 20 tablets of Valium 10 mg., to Patient B.F. GX 2, at 25; GX 22 (Patient Records for B.F.), at 259; GX 36, at 19; RD, at 48. Dr. Loes testified that at the time the September 12, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient B.F. Tr. 321; *see also* GX 36, at 20. In support of his opinion, Dr. Loes testified that there was ''no history of physical or exam of any sort prior to the prescribing.'' Tr. 321. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 322. Respondent first examined Patient B.F. on September 24, 2015. GX 36, at 19; GX 22, at 261–77; RD, at 48. Accordingly, Dr. Loes opined that Respondent's treatment of B.F. fell beneath the standard of care in Arizona. Tr. 321.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient B.F. at the time the prescription was issued, the Valium prescription Respondent issued to Patient B.F. on September 12, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

20. Patient J.G.

On September 16, 2015, Respondent prescribed three controlled substances, 13 tablets of buprenorphine 8 mg., 10 tablets of Zubsolv 5.7 mg./1.4 mg., and 12 Zubsolv 1.4 mg./.36 mg., to Patient J.G. GX 2, at 26–28; GX 23 (Patient Records for J.G.), at 24–25; GX 36, at 20; RD, at 49. Dr. Loes testified that at the time the September 16, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient J.G.[41] Tr. 325; *see also* GX 36, at 20. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, mental examination, or attempt to assess psychological and physical function prior to the September 16, 2015 prescriptions. Tr. 325. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 325–26. Respondent first examined Patient J.G. on October 3, 2015. GX 36, at 20; GX 23, at 27–58; RD, at 49. Accordingly, Dr. Loes opined that Respondent's treatment of J.G. fell beneath the standard of care in Arizona. Tr. 325.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship

[40] Patient B.F. (referencing her nickname) is referred to by the initials E.F. (referencing her legal name) in the OSC. *See* OSC, at 6.

[41] I note that the record is unclear as to whether the patient took Zubsolv; however, the pharmacy records indicate that the Zubsolv prescriptions were issued and dispensed and, therefore, Dr. Loes testified that they were issued outside the standard of care. *See* GX 2, at 26–28; GX 23; GX 36, at 20; Tr. 325. The record clearly indicates that the patient took buprenorphine. GX 23, at 24.

established between Respondent and Patient J.G. at the time the prescriptions for buprenorphine and Zubsolv were issued, the buprenorphine and two Zubsolv prescriptions that Respondent issued to Patient J.G. on September 16, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

21. Patient N.R.

On September 26, 2015, Respondent prescribed a controlled substance, 12 tablets of buprenorphine 2 mg., to Patient N.R. GX 2, at 29; GX 24 (Patient Records for N.R.), at 53; GX 36, at 21; RD, at 49. The pharmacy records show that the prescription was picked up on September 28, 2015; however, the patient records show that Patient N.R. began receiving buprenorphine on September 24, 2015, prior to the prescription being picked up. GX 2, at 29; GX 24, at 53; GX 36, at 21; RD, at 49. Dr. Loes testified that at the time the September 26, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient N.R. Tr. 327; *see also* GX 36, at 21. In support of his opinion, Dr. Loes testified that there was no documentation in the patient record to indicate that there was any kind of examination of N.R. prior to September 28, 2015. Tr. 328. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 333. The date Respondent first examined N.R. is unknown as the corresponding medical records were undated—the first dated examination of N.R. was October 3, 2015.[42] GX 36, at 21; GX 24, at 61–91; 92; RD, at 49. Accordingly, Dr. Loes opined that Respondent's treatment of N.R. fell beneath the standard of care in Arizona. Tr. 330.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there is no evidence of a legitimate doctor-patient relationship established between Respondent and Patient N.R. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient N.R. on September 26, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

22. Patient A.C.F.[43]

On October 17, 2015, Respondent prescribed a controlled substance, 15 tablets of buprenorphine (Zubsolv) 5.7/1.4 mg., to Patient A.C.F. GX 2, at 30; GX 25 (Patient Records for A.C.F.), at 46; GX 36, at 21; RD, at 49. Dr. Loes testified that at the time the October 17, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient A.C.F. Tr. 334; *see also* GX 36, at 22. In support of his opinion, Dr. Loes testified that at the time of the prescription, there was not an adequate medical history taken, adequate physical or mental examination performed, nor attempt to assess A.C.F.'s physical or psychological function. Tr. 334–35. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 335. Respondent first examined Patient A.C.F. on October 20, 2015. GX 36, at 20; GX 25, at 62–80; RD, at 49. Accordingly, Dr. Loes opined that Respondent's treatment of A.C.F. fell beneath the standard of care in Arizona. Tr. 335.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.C.F. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient A.C.F. on October 17, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

23. Patient L.R.

On October 23, 2015, Respondent issued prescriptions for two controlled substances, 12 tablets of buprenorphine 8 mg. and 12 tablets of buprenorphine 2 mg., to Patient L.R. GX 2, at 31–32; GX 26 (Patient Records for L.R.), at 64; GX 36, at 22; RD, at 50. Dr. Loes testified that at the time the October 23, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient L.R. Tr. 337; *see also* GX 36, at 22. In support of his opinion, Dr. Loes testified that there was ''no doctor-patient relationship documented to [have been] established.'' Tr. 337. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 340. Respondent first examined Patient L.R. on October 24, 2015. GX 36, at 22; GX 26, at 74–103; RD, at 50.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient L.R. at the time the two prescriptions were issued, the buprenorphine prescriptions that Respondent issued to Patient L.R. on October 23, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

24. Patient F.H.

On October 24, 2015, Respondent issued prescriptions for two controlled substances, 12 tablets of buprenorphine 8 mg. and 12 tablets of buprenorphine 2 mg., to Patient F.H. GX 2, at 33–34; GX 27 (Patient Records for F.H.), at 33; GX 36, at 22; RD, at 50. Dr. Loes testified that at the time the October 24, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient F.H. Tr. 343; *see also* GX 36, at 23. In support of his opinion, Dr. Loes testified that there was ''[a] lack of documentation for physical[,] interview, assessment, [and] plan'' and there was no evidence that any examination was performed. Tr. 343. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 343–44. Respondent first examined Patient F.H. on October 27, 2015. GX 36, at 22; GX 27, at 40–73; RD, at 50.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient F.H. at the time the prescriptions were issued, the buprenorphine prescriptions that Respondent issued to Patient F.H. on October 24, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

25. Patient A.J.

On October 24, 2015, Respondent prescribed a controlled substance, 20 tablets of Valium 10 mg., to Patient A.J. GX 2, at 35; GX 28 (Patient Records for A.J.), at 46; GX 36, at 23; RD, at 50. On October 25, 2015, Respondent prescribed another controlled substance, 12 tablets of Zubsolv .36/1.4 mg., to Patient A.J. GX 2, at 35; GX 28, at 42; GX 36, at 23; RD, at 50. Dr. Loes testified that at the time the October 24 and 25, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient A.J. Tr. 346; *see also* GX 36, at 23. In support of his opinion, Dr. Loes testified that ''[t]he first medical visit [was] October 27th, so there is no evidence that a doctor-patient relationship was

[42] Even if the patient records are incorrect and N.R. did not begin receiving the controlled substance until September 28, 2015, the delay in conducting the physical exam on October 3, 2015, was still outside the standard of care.

[43] Patient A.C.F. is referred to by the initials A.F. in the OSC. *See* OSC, at 7.

established prior to those prescriptions.'' Tr. 346. *See also* GX 36, at 23; GX 28, at 102–107, 110–113, 127–148; RD, at 50. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 347. Accordingly, Dr. Loes opined that Respondent's treatment of A.J. fell beneath the standard of care in Arizona. Tr. 347.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.J. at the time the prescriptions were issued, the Valium and Zubsolv prescriptions that Respondent issued to Patient A.J. on October 24 and 25, 2015, respectively, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

26. Patient J.A.2 [44]

On October 27, 2015, Respondent prescribed a controlled substance, 9 tablets of buprenorphine 8 mg., to Patient J.A.2. GX 2, at 37; GX 29 (Patient Records for J.A.2), at 86; GX 36, at 23; RD, at 51. Dr. Loes testified that at the time the October 27, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.A.2. Tr. 349; *see also* GX 36, at 24. In support of his opinion, Dr. Loes testified that ''[t]here was no doctor-patient relationship prior to prescribing or the initiation of that medication.'' Tr. 349. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 351–52. Respondent first examined Patient J.A.2 on October 31, 2015. GX 36, at 22; GX 29, at 2–39; RD, at 51.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.A.2 at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient J.A.2 on October 27, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

27. Patient H.S.

On October 28, 2015, Respondent prescribed a controlled substance, 12 tablets of buprenorphine (Zubsolv) 5.7/1.4 mg., to Patient H.S. GX 2, at 38; GX 30 (Patient Records for H.S.), at 43; GX 36, at 24; RD, at 51. Although there is no record that H.S. ever received the Zubsolv tablets (*see* GX 30, at 111 and 113), Dr. Loes testified that at the time the October 28, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient H.S.[45] Tr. 354; *see also* GX 36, at 24. In support of his opinion, Dr. Loes testified that as of October 28, 2015, there was no documentation of a medical history, physical or mental examination, or assessment of physical or psychological function. Tr. 354. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 354–55. Respondent first examined Patient H.S. on October 31, 2015. GX 36, at 24; GX 30, at 114–143; RD, at 51. Accordingly, Dr. Loes opined that Respondent's treatment of H.S. fell beneath the standard of care in Arizona. Tr. 355.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient H.S. at the time the prescription was issued, the Zubsolv prescription that Respondent issued to Patient H.S. on October 28, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

28. Patient J.K.

On November 5, 2015, Respondent prescribed two controlled substances, 15 tablets of Zubsolv 5.7/1.4 mg. and 15 tablets of Zubsolv 1.4/.36 mg., to Patient J.K. GX 2, at 39–40; GX 32 (Patient Records for J.K.), at 27; GX 36, at 25; RD, at 51. Dr. Loes testified that at the time the November 5, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient J.K. Tr. 358; *see also* GX 36, at 25. In support of his opinion, Dr. Loes testified that there was ''no documentation of the history, physical, no associated labs, and no associated interaction.'' Tr. 358. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 359. Respondent first examined Patient J.K. on November 7, 2015. GX 36, at 25; GX 32, at 36–69; RD, at 51. Accordingly, Dr. Loes opined that Respondent's treatment of J.K. fell beneath the standard of care in Arizona. Tr. 359.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.K. at the time the prescriptions were issued, the Zubsolv prescriptions that Respondent issued to Patient J.K. on November 5, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

29. Patient J.W.

On November 21, 2015, Respondent prescribed a controlled substance,[46] 20 tablets of diazepam 10 mg., to Patient J.W. GX 2, at 41; GX 31 (Patient Records for J.W.), at 6; GX 36, at 25; RD, at 52. Dr. Loes testified that at the time the November 21, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.W. Tr. 360–61; *see also* GX 36, at 25. In support of his opinion, Dr. Loes testified that there was ''no documentation for the history, physical, evaluation, [or] treatment initiation.'' Tr. 361. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 363. Respondent was discharged on November 24, 2015, and there is no record of him ever being seen by a physician between his November 21, 2015 admission and November 24, 2015 discharge. GX 36, at 25; GX 31; RD, at 52. Accordingly, Dr. Loes opined that Respondent's treatment of J.W. fell beneath the standard of care in Arizona. Tr. 364–65.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.W. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient J.W. on November 21, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

30. Patient K.C.

On November 21, 2015, Respondent prescribed a controlled substance, 15 tablets of Zubsolv 5.7/1.4 mg., to Patient K.C. GX 2, at 42; GX 33 (Patient Records for K.C.), at 15; GX 36, at 26; RD, at 52. Dr. Loes testified that at the time the November 21, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient K.C. Tr. 366; *see also* GX 36, at

[44] Patient J.A.2 is referred to by the initials J.A. in the OSC. *See* OSC, at 9.

[45] Dr. Loes testified that, regardless of whether or not H.S. received the controlled substance, the prescription ''was ordered prior to a doctor-patient relationship being established. So, therefore, it fell below the standard of care because of the actual ordering of the prescription.'' Tr. 355. Here the pharmacy records indicate that the Zubsolv prescription was issued and dispensed. GX 2, at 38.

[46] The record indicates that there may have been other controlled substances issued by Respondent to Patient J.W. prior to him being evaluated by a physician; however, they were not included in the OSC or prehearing filings and I have not considered them as part of my analysis. *See* GX 36, at 25; OSC, at 9.

26. In support of his opinion, Dr. Loes testified that there was ''no evidence in the chart that this patient was ever seen by a physician.'' Tr. 366. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 368. Respondent was discharged on November 23, 2015, and there is no record of her ever being seen by a physician between her November 21, 2015 admission and November 23, 2015 discharge. GX 36, at 26; GX 33; RD, at 52. Accordingly, Dr. Loes opined that Respondent's treatment of K.C. fell beneath the standard of care in Arizona. Tr. 367.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient K.C. at the time the prescription was issued, the Zubsolv prescription that Respondent issued to Patient K.C. on November 21, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

31. Summary of Fact Findings Relevant to All Patients

I find that forty prescriptions were issued by Respondent to thirty patients without Respondent having first performed a physical or mental examination. I find that forty prescriptions were issued by Respondent to patients without first developing a doctor-patient relationship. I credit Dr. Loes' opinion ''that none of the cases that [he] reviewed would have qualified [as emergency medical situations].'' Tr. 401, *see also* Tr. 376–77, 402. Accordingly, I find that none of the thirty patients at issue in this case were suffering from an emergency medical situation at the time that Respondent prescribed the controlled substances at issue in this case. Ultimately, I find that there is substantial evidence that Respondent issued forty prescriptions without a legitimate medical purpose and outside the usual course of professional practice and beneath the applicable standard of care in Arizona.

III. Discussion

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

Under Section 304 of the CSA, ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' 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.

Respondent has argued broadly that he has not committed acts that render his Registration inconsistent with the public interest. Resp Posthearing, at 16. Rather, Respondent argued, the evidence in the record was that the patients identified in the OSC suffered from addiction and were medically benefitted by the treatment provided by Respondent. *Id.* at 6–7, 16. The CSA requires me to consider Respondent's controlled substance dispensing experience, among other things, not whether Respondent's practice of medicine as a whole was beneficial to the community. 21 U.S.C. 823(f)(2); *see Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45239 (2020) (declining to accept community impact arguments); *see also Richard J. Settles, D.O.,* 81 FR 64940, n.16 (2016).

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,[47] 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 Controlled Substances Act's (hereinafter, CSA) implementing regulations, a lawful

[47] As to Factor One, the evidence in the record is that Respondent has an Arizona medical license, Tr. 431, 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.*

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).[48] [49] Under the CSA, it is fundamental that a practitioner must establish and maintain a bona fide doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Laurence T. McKinney,* 73 FR 43260, 43365 n. 22 (2008); *see also United States* v. *Moore,* 423 U.S. 122, 142–43 (1975). The CSA generally looks to state law to determine whether a doctor and patient have established a doctor-patient relationship. *See Kamir Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007).

I found above that the Government's expert credibly testified as supported by Arizona law that the standard of care in Arizona is that a physician must perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances unless one of the statutory exceptions applies. *See supra* II.E. I also found above that Respondent issued forty prescriptions to thirty patients without first performing a physical examination or otherwise establishing a doctor-patient relationship. *See supra* II.F.31. Accordingly, I found that Respondent dispensed controlled substances beneath the applicable standard of care and outside of the usual course of the professional practice in Arizona. *See supra* II.F.31. I find that in issuing forty prescriptions beneath the applicable standard of care and outside the usual course of professional practice in Arizona, Respondent violated 21 CFR 1306.04(a).

Respondent's arguments otherwise are without merit. Respondent testified that he believed that it was proper ''to take patients who get admitted in acute withdrawal settings and to treat them based on the history . . . that [is] obtained from the staff, and then see [the patient] afterwards.'' Tr. 49. Respondent testified that his practice was followed by several well-known outpatient addiction treatment facilities and a prominent physician, but he provided no corroborating evidence of this assertion. Tr. 438–40. Even if Respondent believed his dispensing was within the usual course of professional practice, DEA has found that ''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.,* 80 FR 28643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51592, 51601 (1998). And in fact, four of the thirty patients (Patients Z.J, A.S., J.W., and K.C.) were issued controlled substances by Respondent and left treatment without ever being physically examined by or developing a doctor-patient relationship with Respondent. *See supra* II.F.

The Respondent asserted that ''[t]he government provided no testimony or evidence that any patient suffered harm or even potential harm from [Respondent's] practice of medicine[,] . . . [and that] [w]ithout this, the government cannot prove that [Respondent's] practice is inconsistent with the public interest.'' Resp Posthearing, at 16 (internal quotations omitted). Respondent does not, however, cite legal authority for the proposition that I must find harm before I may suspend or revoke a registration. Agency decisions have found that ''diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .'" *Id.* (citing *Roy S. Schwartz,* 79 FR 34360, 34363 (2014)). In this case, I have found that Respondent issued prescriptions without complying with his obligations under the CSA and Arizona law. *See George Mathew, M.D.,* 75 FR 66138, 66148 (2010)). I therefore find that Factors Two and Four weigh in favor of revocation.

(b) Violation of State Law

In addition to finding a violation of 21 CFR 1306.04(a), I also find that the Government has proven by substantial evidence that Respondent's failure to physically examine or otherwise establish a doctor-patient relationship prior to prescribing controlled substances violated Ariz. Rev. Stat. Ann. § 32–1401(27). Arizona law states that it is ''unprofessional conduct'' to ''[p]rescrib[e], dispens[e] or furnish[] a prescription medicine . . . 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) (2014). Respondent argues that in spite of this Arizona statute, Arizona law allows a doctor to ''take patients who get admitted in acute withdrawal settings and to treat them based on the history . . . that [is] obtained from the staff, and then see [the patient] afterwards . . . within 24 hours . . . [or] within five to seven days.'' Tr. 49.

Respondent's argument would necessitate a finding that the statutory term in Ariz. Rev. Stat. Ann. § 32–1401(27) ''the doctor'' includes what Respondent described as ''staff who had training at taking a history and physical from a patient.'' Tr. 113. Further, in this case, Respondent's staff did not appear to take a full physical examination of the patients; therefore, his interpretation would require that the statutory phrase ''physical or mental health status examination'' must be able to be satisfied by trained staff taking an ''appropriate evaluation,'' which, according to Respondent, could include vital signs and soliciting a medical history from the patient. Tr. 112. Respondent made an alternative argument that RIM's purported policies permitted treatment of patients followed by an examination within a certain timeframe. Such an interpretation of the Arizona statute would necessitate a reading of the statutory phrases ''first'' and ''previously'' to be replaced with whatever timeline may be established by the facility's individual policies. Respondent's interpretation conflicts with the plain language of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss).

Arizona interprets Ariz. Rev. Stat. Ann. § 32–1401(27)(ss), in *Golob* v. *Arizona Medical Bd. of State,* 217 Ariz. 505 (2008). In *Golob,* 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. After conceding that she performed no physical examinations, Dr. Golob argued that she fulfilled the requirements of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) because she created ''a previously established . . . doctor-patient relationship'' in each case by accepting a consultation fee and reviewing the individual's responses to

[48] Respondent suggested that the only ground for revocation was Ariz. Rev. Stat. Ann. § 32–1401(27). Tr. 191; Resp Posthearing, at 4. The ALJ thoroughly analyzed the notice allegation and found that there were multiple instances where the Respondent was placed on notice of the factual and legal basis upon which the government relied in proposing to revoke Respondent's Registration including, amongst other things, 21 CFR 1306.04. RD, at 56–62. Respondent's Posthearing Brief alone makes clear that Respondent understood the basis of the allegations against him, had the opportunity to litigate those allegations, and did, in fact, litigate those allegations. *See* Resp Posthearing, at 2–4. Like the ALJ, I am not persuaded by Respondent's notice argument.

[49] Similarly, the law in Arizona states that it is ''unprofessional conduct'' to ''[p]rescrib[e], dispens[e], or administer [ ], any controlled substance or prescription-only drug for other than accepted therapeutic purposes.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(j) (year).

the questionnaire, occasionally directing an operator to ask the person additional questions before she prescribed. *Id.* at 510. The court wholly rejected her 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* stating that a ''valid patient-physician relationship'' is formed when the physician, among other things, ''obtain[s] a reliable medical history and perform[s] a physical examination of the patient'' and has ''sufficient dialogue with the patient regarding treatment options.'' *Id.* at 511 (*citing American Medical Association's Guidance for Physicians on Internet Prescribing,* H–120.949 (June 2003)). Although not directly applicable to the facts here, the finding in *Golob* is consistent with my finding that the standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances.

I have found that Respondent did not personally examine any of the thirty patients at issue in this case nor otherwise establish a doctor-patient relationship with those patients prior to prescribing.[50] Next I must consider whether or not an exception to Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) applies.

While there are several statutory exceptions to Ariz. Rev. Stat. Ann. § 32–1401(27)(ss), one that could arguably be relevant to these facts is that a doctor is not required to conduct a physical or mental health status examination before prescribing when there is an ''(ii) [e]mergency medical situation as defined in § 41–1831.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss). Section § 41–1831 states that ''[e]mergency medical situation means a condition of emergency in which immediate medical care or hospitalization, or both, is required by a person or persons for the preservation of health, life, or limb.'' Ariz. Rev. Stat. Ann. § 41–1831(9) (2012). As I discussed above, Respondent argued that an ''emergency medical situation'' should be interpreted to include preventing a patient from entering a state of medical emergency itself. *See supra* II.E.2. To adopt Respondent's definition of medical emergency, I would have to ignore the statutory requirement of ''immediate medical care or hospitalization.'' Again, Respondent's interpretation is irreconcilable with the plain language of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (*incorporating* Ariz. Rev. Stat. Ann. § 41–1831(9)). Moreover, based on the credible opinion of Dr. Loes, I found above that there is no evidence in the patient records or otherwise that any of the thirty patients at issue in this case were suffering from an emergency medical situation at the time that the prescriptions at issue in this case were issued. *See supra* II.F.31.

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

In conclusion, I find that the Government has proven by substantial evidence that Respondent issued forty controlled substance prescriptions without a legitimate medical purpose and 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)(ss). 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 he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases). Respondent has made no effort to establish that he can be trusted with a registration.

The CSA authorizes the Attorney General to ''promulgate and enforce any 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,* 546 U.S. 243, 259 (2006). 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 he has presented ''sufficient mitigating evidence to assure the Administrator that 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. Kennnedy, 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, I agree with the ALJs's finding that ''[t]he Respondent overall did not express any sense of wrongdoing.'' RD, at 36. Even if I had accepted Respondent's version of the standard of care in Arizona that, pursuant to RIM policies, trained staff can perform an initial assessment of a patient to support the issuance of a controlled substance prescription and the physician can perform the physical examination up to ninety-six hours later, his actions on many occasions fell outside of his version of the standard. Tr. 144; *supra* II.D–E; *see* RD, at 93 (ALJ finding that Respondent failed to physically examine seven patients within ninety-six hours of prescribing controlled substances.) Despite the fact that the prescriptions he issued to these patients clearly did not fall within even his own characterization of the standard of care,

[50] When asked whether a valid doctor patient relationship existed with these patients prior to Respondent's prescriptions, Respondent did not directly answer the question and replied: ''I believe that when you walk into a treatment program and you begin getting evaluated by the treatment staff, that that is the first step—that, that, that is—that that is the initial process that has—that is the initial step that evaluates, that determines the doctor-patient relationship.'' Tr. 112.

Respondent did not accept any responsibility for his failure to physically examine those seven patients within ninety-six hours of admission. The ALJ also found that four of the seven patients were admitted for treatment at RIM and received controlled substance prescriptions while the Respondent was out of the country and there was no other physician coverage provided. RD, at 94; *see also supra* II.F. Respondent not only failed to accept responsibility for his failures here, he seemed to pass blame for his lack of coverage onto another physician who left the practice shortly before Respondent's trip abroad. Tr. 74; RD, at 94. Additionally, the ALJ found, and I agree, that Respondent's testimony regarding the work he did perform while in Europe lacked credibility.[51] RD, at 38, 95.

In all, Respondent failed to explain why, in spite of his misconduct, he 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 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 46,968, 49,973.

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). Here, the ALJ found, and I agree, that the evidence suggests that Respondent's ''offending practices had been ongoing and patterned behavior.'' RD, at 89. The ALJ found that Respondent's care for four patients while he was in Europe was a ''particularly aggravating circumstance.'' RD, at 94. I agree with the ALJ that Respondent's conduct was egregious, particularly in the prescriptions issued while in Europe and those where he delayed seeing the patients for long periods of time. Additionally, I have found many more instances of misconduct than the ALJ, who nonetheless recommended revocation.

The Government argued that the Respondent was on notice, by virtue of the 2010 MOA, that he could not prescribe controlled substances prior to personally examining his patients. Tr. 12; RD, at 69. The MOA stated that ''Respondent must conduct an initial examination validating the necessity to prescribe Suboxone or Subatex to each [new] OBOT patient.'' I agree with the ALJ that the MOA does not clearly indicate that the examination was required by existing law and that Respondent could have read it to be merely an enhanced requirement placed on Respondent only for the length of the agreement. RD, at 69–70. As such, I will agree with the ALJ and find that the MOA, in and of itself, does not put Respondent on notice that his conduct was illegal per se, even though state law on this matter certainly should have. However, I find the fact that DEA previously gave Respondent an opportunity to correct his behavior and Respondent reverted back to his prior practices upon the expiration of the MOA to be relevant to whether I can entrust the Respondent with a registration. As Respondent did not seem to learn from his prior experience and, as discussed, made no efforts to accept responsibility, I do not trust that a sanction less than revocation will deter Respondent from engaging in this behavior again in the future.

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. There is simply no evidence that Respondent's egregious behavior is not likely to recur in the future such that I can entrust him with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.

I will therefore order that Respondent's registration 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 No. BC3579969 issued to Michael W. Carlton, M.D. This Order is effective March 22, 2021.

D. Christopher Evans,

Acting Administrator.

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[51] Generally, Respondent described his failures as being an ''[o]versight.'' Tr. 122; *see also* Tr. 123; RD, at 36.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–788]

Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API Manufacturing, Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 20, 2021. Such persons may also file a written request for a hearing on the application on or before April 20, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on November 12, 2020, Patheon API Manufacturing, Inc., 309 Delaware Street, Greenville, South Carolina 29605, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I
5-Methoxy-N-N-Dimethyltryptamine.	7431	I
Psilocybin	7437	I
Oxymorphone	9652	II

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient (API) for distribution to its customers. In reference to dug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

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