All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

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By email ...	pubcomment-ees.enrd@usdoj.gov.
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Modification to the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the proposed Modification to the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

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Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–39]

David A. Ruben, M.D.; Decision and Order

On February 7, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to David A. Ruben, M.D. (hereinafter, Respondent), of Tucson, Arizona. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, which authorizes him to dispense controlled substances as a practitioner, and the denial of any pending applications to renew or modify his registration, on the ground that his ''continued registration is inconsistent with the public interest.'' ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

More specifically, the Show Cause Order alleged that between April 9 and June 6, 2008, two cooperating sources (CS), who posed as patients, made four visits to Respondent's office seeking controlled substances. *Id.* The Order further alleged that at each visit, Respondent issued the CSs prescriptions for schedule II controlled substances without performing a physical examination, without taking a medical history, without reviewing or obtaining any medical records or test results, and without providing a diagnosis. *Id.* at 1–2. The Order thus alleged that Respondent lacked ''a legitimate medical purpose'' and acted ''outside of the usual course of professional practice'' in issuing the prescriptions and thus violated both federal and state law. *Id.* at 1 (citing 21 CFR 1306.04(a); Ariz. Rev. Stat. § 32–1401(27)(ss)).

The Show Cause Order further alleged that on June 10, 2010, the Arizona Medical Board (AMB or Board) issued an order which found that Respondent had ''deviated from the standard of care in [his] treatment of multiple patients from 2006 to early 2009.'' *Id.* at 2. The Show Cause Order alleged that the AMB found that Respondent ''[f]ail[ed] to perform adequate examinations/evaluations prior to prescribing controlled substances''; that he ''[f]ailed to develop an adequate treatment plan prior to prescribing controlled substances''; that he ''[f]ailed to perform tests and assessments to confirm diagnoses and the necessity of treatment with controlled substances''; that he ''[f]ailed to obtain or review patients' medical records''; that he ''[f]ailed to offer patients adjunct treatments that included non-controlled substances and/or physical therapy''; that he ''[f]ailed to address patients' aberrant drug seeking behaviors''; and that he ''[f]ailed to address or investigate patients' abnormal urinalysis results.'' *Id.* The Show Cause Order further alleged that based on these findings, the AMB had barred Respondent ''from prescribing, administering or dispensing any opioids for a period of one year.'' *Id.*

On March 28, 2011, Respondent requested an extension of time to respond to the Show Cause Order, which was unopposed by the Government. ALJ Ex. 2. The matter was then placed on the docket of the Office of Administrative Law Judges (ALJ) and assigned to ALJ Wing. While the ALJ initially denied Respondent's request because neither party had established the date of service, on March 30, 2011, Respondent filed a Request for Reconsideration, which was also unopposed by the Government, and which showed that Respondent had not been served until February 25, 2008.[1] ALJ Exs. 3 & 4. While Respondent sought an additional thirty days to respond to the Order to Show Cause, on April 1, 2011, the ALJ granted Respondent one additional week to do so. ALJ Ex. 5.

On April 7, 2011, Respondent requested a hearing on the allegations. ALJ Ex. 6. Following pre-hearing procedures, the ALJ conducted a hearing in Phoenix, Arizona on January 10–12, 2012, at which both parties elicited the testimony of multiple witnesses and introduced various exhibits into the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

Thereafter, the ALJ issued his Recommended Decision (hereinafter, cited at R.D.). Therein, the ALJ found that the Government had ''established by substantial evidence a *prima facie* case that Respondent has committed acts inconsistent with the public interest between 2006 and 2009.'' R.D. at 65. However, the ALJ further found that ''Respondent has fully accepted responsibility for his past misconduct and credibly demonstrated that he will not engage in future misconduct.'' *Id.*

With respect to factor one—the recommendation of the state licensing board—the ALJ found that while Respondent currently has a valid Arizona medical license, he has twice been the subject of disciplinary action by the AMB, which found that he had engaged in '' 'unprofessional conduct,' '' as well as '' 'any conduct or practice that is or might be harmful or dangerous to the health of the patient or the public.' '' R.D. at 47 (quoting Ariz. Rev. Stat. § 32–1401(27)(q)). In addition, the ALJ found that Respondent had also committed unprofessional conduct by '' 'failing or refusing to maintain adequate records on a patient.' '' *Id.* (quoting Ariz. Rev. Stat. § 32–1401(27)(e)). However, because in August 2011, the AMB had fully restored Respondent's prescribing privileges, the ALJ concluded that while not dispositive, the Board's action ''weigh[s] against a finding that Respondent's continued registration subject to conditions would be inconsistent with the public interest.'' *Id.* at 48.

With respect to factor three—Respondent's conviction record under federal and state laws relating to the manufacture, distribution, or dispensing of controlled substances—the ALJ noted

[1] Notwithstanding of the date of the Show Cause Order, Respondent's request was timely because the Order was not served until February 25, 2008, and the thirtieth day period for filing his request fell on a Sunday.

that there was no evidence that Respondent has been convicted of such an offense. R.D. at 48. The ALJ thus concluded that while this factor is also not dispositive, it weighed against a finding that Respondent's ''registration would be inconsistent with the public interest.'' *Id.*

The ALJ then considered the evidence with respect to factors two—Respondent's experience in dispensing controlled substances—and four—Respondent's compliance with federal, state, and local laws relating to controlled substances—together. With regard to the allegation that Respondent had ''deviated from the standard of care in [his] treatment of multiple patients from 2006 to early 2009,'' the ALJ noted that the Government's evidence ''rested primarily on the findings by the Board in the 2009 Agreement and 2010 Order'' and that the Government had offered ''[n]o evidence in the form of patient charts or related medical expert testimony'' in either its case-in-chief or in rebuttal of the testimony offered by Respondent and his expert witness. *Id.* at 49–50.

However, the ALJ noted that the 2009 AMB Order found that between ''November 17, 2006 and October 2007[,] 'Respondent deviated from the standard of care by prescribing high dose opioids to DK without proper indications . . . [and] by failing to timely use objective measures, such as urine drug tests, to assess DK's compliance with her treatment even after he was aware of her cocaine addiction.' '' R.D. at 50. The ALJ further found that the 2010 AMB order ''established that Respondent's care and treatment of eleven patients . . . on various dates between 2006 and September 2009, constituted unprofessional conduct contrary to Ariz. Rev. Stat. § 32–1401(27)(e) and (q).'' *Id.* The ALJ then noted some, but not all, of the specific findings made by the AMB with respect to the various patients. *Id.* at 50–51.

With respect to the Board's findings, the ALJ further found that Respondent testified ''that he did not agree with all of the Board's findings with regard to the 2009 Agreement, but otherwise agreed with the sanctioning imposed by the Board.'' *Id.* at 53. With respect to the 2010 AMB order, the ALJ found that ''Respondent credibly testified . . . that he agreed from a regulatory standpoint why the Board censured him, but disagreed with some of the specific factual findings.'' *Id.*

Based on the two AMB orders, the ALJ nonetheless concluded that ''Respondent issued controlled substance prescriptions to multiple patients . . . for other than a legitimate medical purpose and outside the usual course of professional practice in violation of applicable state and federal law.'' *Id.* at 54–55 (citing 21 CFR 1306.04(a); Ariz. Rev. Stat. § 32–1401(27)(a), (e), and (q)). However, the ALJ rejected the Government's allegation based on the four visits of the two CSs, finding that Respondent ''credibly testified'' regarding his treatment of them, and that his testimony was ''supported by patient files.'' *Id.* at 56. In addition, the ALJ noted that Respondent's Expert credibly testified that his prescribing to the two CSs was '' 'well within the standard of care.' '' *Id.* (quoting Tr. 618).

The ALJ further found that Respondent had presented evidence of ''more recent conduct'' [which] weigh[s] significantly'' in his ''favor.'' *Id.* at 60. More specifically, the ALJ noted that Respondent testified that he had been in compliance with the AMB's Order, that he had ''successfully completed'' the one year suspension of his authority to prescribe opioids, and that there was no evidence that he ''has not been fully compliant with state and federal law since the 2010 Order.'' *Id.* Moreover, the ALJ noted Respondent's evidence that he had made improvements in his controlled-substance prescribing practices since the 2010 Order. *Id.*

Thus, the ALJ found that the Government had demonstrated that ''Respondent's prescribing practices and compliance with applicable state and federal law between 2006 and 2009 was inconsistent with the public interest'' and supported a finding that his ''continued registration would be inconsistent with the public interest, at least as of 2010.'' *Id.* at 63. However, the ALJ further found ''that Respondent's recent positive improvements in his prescribing practices and compliance with applicable state and federal law weigh in [his] favor.'' *Id.*

As for factor five—such other conduct which may threaten public health and safety—the ALJ noted that the Government had not alleged, and the evidence did not support a finding that Respondent had engaged in ''any 'other conduct' . . . that is inconsistent with the public interest.'' *Id.* at 64. The ALJ then found that Respondent ''ha[d] credibly accepted responsibility for his past misconduct,'' explaining that ''Respondent testified at various points that he acknowledged and accepted the Board's disciplinary actions.'' *Id.* Also noting the evidence as to Respondent's efforts to improve his prescribing practices, the ALJ concluded that factor five supported ''a finding that Respondent's continued registration would be consistent with the public interest.'' *Id.* at 65.

The ALJ thus concluded that Respondent had rebutted the Government's *prima facie* case. *Id.* He then recommended that Respondent's registration be continued and that any pending applications be renewed subject to two conditions: 1) that Respondent ''comply with all of the terms and conditions specified in the'' AMB's June 2010 order, and 2) that ''Respondent shall promptly forward to the DEA regional office any changes to the terms and conditions of his probation.'' *Id.* at 65–66.

The Government filed Exceptions to the R.D. Thereafter, the record was forwarded to me for Final Agency Action.

Having considered the entire record, I adopt the ALJ's finding that Respondent committed acts which were inconsistent with the public interest during the 2006 through 2009 time period. While I also accept the ALJ's finding that Respondent has accepted responsibility for his misconduct and produced substantial evidence of various remedial measures he has implemented, I nonetheless reject the ALJ's recommended sanction because the ALJ failed to consider both the egregiousness of the violations and the Agency's interest in deterring similar misconduct by Respondent in the future as well as on the part of others. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009).

The ALJ's Rulings on the Government's Motion in Limine To Exclude Evidence

Before proceeding to make factual findings, a discussion of the ALJ's ruling on the Government's Motion in Limine To Exclude Evidence is warranted. During the course of the pre-hearing procedures, Respondent provided notice that he intended to call several physicians to testify, in part, regarding their review of the medical charts of those patients which were the subject of the AMB's 2009 and 2010 orders. ALJ Ex. 46. Respondent also provided notice that he intended to introduce into evidence various letters written by these physicians based on their review of various patient charts which were reviewed by the AMB and discussed in the two orders. *Id.*

Relevant to the Government's motion, Respondent proffered Dr. Jennifer Schneider to testify that she had reviewed the medical charts of patients LP, WO, JF, JR, CJ, ML, AM, MF, DD, and SS, all of which were reviewed by the AMB's consultant as part of the Board's investigation. ALJ Ex. 9, at 5 (Resp. Prehearing Statement). Respondent further proffered that Dr.

Schneider ''will explain that the AMB consultant had missed items in the charts for which Respondent was inaccurately criticized.'' *Id.* Finally, Respondent proffered that Dr. Schneider ''will testify in conformance with information about [Respondent] and Pain Management practices in Arizona in general as the author of Proposed Exhibits 4, 5, and 6.'' *Id.*

Respondent also proffered the testimony of Dr. Bennet Davis to ''testify regarding his review of a chart involving patient DK and his review and evaluation of patient ML, who has a complex set of issues.'' *Id.* Respondent further proffered that Dr. Davis would testify that, ''[i]n his opinion, the AMB consultant did not properly define the standard of care for which Respondent was issued a reprimand per [the 2009] Consent Agreement,'' and that Respondent adhered to a 'reasonable standard [of] care in all aspects of treating . . . [DK].' '' *Id.* at 5–6. Respondent also proffered that ''Dr. Davis was able to synthesize his own evaluation and compare it with the notes and records provided by Respondent [and] will testify that Respondent met the standard of care in his evaluation of Respondent's chart of ML.'' *Id.* at 6.

Finally, Respondent proffered the testimony of Dr. Kevin Goeta-Kreisler, who was to ''explain that . . . he reviewed the complaints and the charts on patients 'AL, KF, and JF.' '' *Id.* Respondent further proffered that Dr. Goeta-Kreisler ''will testify that he and Respondent both agreed that the early charting was 'insufficient for another practitioner to assume continuity of the patients' care' even though the documentation met the standard of practice at the earlier time.'' *Id.*

Thereafter, the Government filed a motion in limine to exclude this evidence, arguing that ''[t]he doctrine of *res judicata* bars the relitigation of the factual findings and conclusion of law of the prior proceedings before the AMB.'' Motion in Limine to Exclude Evidence (ALJ Ex. 46, at 3). The Government argued that ''[e]ach of Respondent's proposed experts' testimony and their [sic] related documentary evidence . . . are [sic] an attempt to relitigate the factual findings and conclusions of law by the AMB,'' and therefore, ''Respondent should be precluded from presenting such evidence.'' *Id.* As support for its position, the Government cited numerous authorities, including cases of both federal and state courts and the Agency. *See id.* (citing *Misischia v. Pirie,* 60 F.3d 626, 629–30 (9th Cir. 1995); *Marie Y. v. General Star Indem. Co.,* 2 Cal. Rptr. 3d 135, 155 (Cal. Ct. App. 2003); *Robert L. Dougherty,* 76 FR 16823, 16830 (2011); *Alan H. Olefsky,* 76 FR 20025, 20031 (2011); *Christopher Henry Lister,* 75 FR 28068, 28069 (2010).

Respondent opposed the motion on multiple grounds. *See* ALJ Ex. 47. More specifically, Respondent argued: (1) That the motion was untimely, *id.* at 1–2; (2) that the AMB Orders were the result of consent agreements, which stated that his ''admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding,'' and that he ''never agreed that all of the conduct set forth in the findings was accurate,'' *id.* at 2–3; and (3) that DEA could not invoke the doctrine of *res judicata* because it was not a party to the consent agreements and was not in privity with the AMB. *Id.* at 4–5.

The ALJ denied the Government's motion for two reasons. First, noting that the Government had not filed its motion until approximately eight months after Respondent had provided notice as to its witnesses and their anticipated testimony, the ALJ held that the Government had not established good cause for the untimely filing of the motion. ALJ Ex. 48, at 2–3. Second, the ALJ held that because the Agency was not a party to the proceeding before the AMB, and the AMB did not consider the issue of whether Respondent's DEA registration should be revoked under the public interest standard, the doctrine of *res judicata* could not be invoked to bar the introduction of the proposed testimony and reports. *Id.* at 3–4. However, the ALJ further noted that his ruling was ''not intended to limit the parties from making evidentiary objections at the time the evidence is offered.'' *Id.* at 4 n.3.[2]

As for the first of the ALJ's reasons, the Agency's regulations clearly grant the ALJ authority ''to take all necessary action to avoid delay.'' 21 CFR 1316.52. Moreover, this regulation provides that the ALJ ''shall have all powers necessary to these ends, including (but not limited to) the power to . . . [r]eceive, rule on, exclude, or limit evidence.'' *Id.* § 1316.52(f). This power clearly includes the authority to set reasonable time periods for the filing of motions. Given that the Government's motion was filed eight months late, the Government's motion was clearly untimely.

However, notwithstanding that the motion was untimely, the ALJ considered it on the merits. Moreover, after the parties filed their respective prehearing statements, the ALJ clearly was aware that the Government intended to introduce the AMB Orders and that Respondent intended to challenge the validity of their findings. Indeed, on June 24, 2011, Respondent filed a motion to preclude the Government from introducing the two AMB Orders. *See* ALJ Ex. 20. Thus, even though the Government did not raise issue in its response to Respondent's motion to preclude, the ALJ was obligated (and remained so throughout the proceeding) to apply the law of the Agency. Accordingly, the ALJ should have raised, *sua sponte,* the issue of whether the findings of the AMB Orders were entitled to preclusive effect.[3] I therefore conclude that it is appropriate to consider whether the ALJ's ruling on the merits was correct.

While the ALJ correctly noted that the Agency has applied the doctrine of *res judicata* in proceedings brought under 21 U.S.C. 823 and 824, he then misapplied Agency precedent. To be sure, the application of *res judicata* itself requires that the parties in the subsequent proceeding be the same parties (or privies of the parties) in the earlier proceedings and that the proceedings involve the same claim. However, this Agency has also long held that the doctrine of collateral estoppel precludes a party from re-litigating adverse findings rendered against him in either a state board proceeding or a federal/state judicial proceeding.[4] *See*

[2] Taking the ALJ at his word, throughout the proceeding, the Government made numerous objections to the testimony of several of Respondent's witnesses (as well as the admission of several documents authored by the aforementioned physicians) asserting that various AMB findings were in error, including its findings as to what the standard of care required at the time he treated the patients who were the subject of the Board's Orders. *See* Tr. 578, 591, 596, and 603.

[3] Under Agency regulations, at the hearing, the ALJ ''shall admit only evidence that is competent [and] relevant.'' 21 CFR 1316.59(a). If, as the Government argues, such evidence was barred by the doctrine of *res judicata* (or more precisely, collateral estoppel) the admission of such evidence was a violation of the above regulation.

[4] While the Government argued that ''[t]he doctrine of *res judicata* bars the relitigation of the factual findings and conclusions of law of the prior proceedings before the AMB,'' ALJ Ex. 46, at 3, as the above passage (as well as other portions of its motion) made clear, it actually sought to invoke collateral estoppel against the Respondent. *See also id.* (quoting *Marie Y.* v. *General Star Indem. Co.,* 2 Cal. Rptr. 3d 135, 155 (Cal. Ct. App. 2003) (''When an administrative agency acts in a judicial capacity to resolve disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, its decision will collaterally estop a party to the proceeding from relitigating those issues.''). As further support for its position, the Government cited Section 29 of the *Restatement (Second) of Judgments. See id.* Notably, this section is entitled ''Issue Preclusion in Subsequent Litigation With Others.''

Continued

Robert L. Dougherty, 76 FR 16823, 16830–31 (2011); *Robert A. Leslie,* 60 FR 14004, 14005 (1995). Contrary to the ALJ's misunderstanding, the Agency was not required to be a party or privy of a party in the AMB proceedings to collaterally estop Respondent from re-litigating the findings of the AMB Orders.[5] So too, that the State Board proceeding did not involve the same claim as this proceeding (whether Respondent's registration is consistent with the public interest), does not preclude the Agency from relying on those findings of the Board which are relevant and material to the Agency's public interest determination.

While not addressed by the ALJ, Respondent argued that both of the AMB Orders were based upon consent agreements, which included the following clause:

> All admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and the Respondent. Therefore, said admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding.

ALJ Ex. 47, at 2 (quoting GX Ex. 17, at 2 (2009 AMB Order) and GX 18, at 20–21 (2010 AMB Order). Respondent argues that he ''and his counsel had to consider whether there was a reasonable basis to conclude that there was at least some evidence that would lead to a conclusion that some of the allegations made would be sustained.'' *Id.* He contends that ''[h]e bargained for and received an agreement to enter each of these consent agreements, on the basis of that recognition, on his agreement that he would indeed follow the requirements of any discipline authorized as a result of the Agreement, but that outside of the required discipline set forth, the stated findings and conclusions could not be used in a non-AMB proceeding, including a 'federal government regulatory agency proceeding[,]' such as this one.'' *Id.* at 2–3. Respondent further argues that he ''never agreed that all of the conduct set forth in the findings was accurate,'' and that both he and the AMB ''agreed that [his] concessions there were not to be given substantive weight outside of the Arizona professional proceedings.'' *Id.* at 3.

In the 2010 Order, however, Respondent also ''agree[d] not to contest the validity of the Findings of Fact and Conclusions of Law contained in the Order in any present or future administrative proceedings before the Board (or any other state agency in the State of Arizona, concerning the denial or issuance of any license or registration required by the state to engage in the practice or any business or profession.)'' GX 18, at 20. Moreover, he also ''voluntarily relinquishe[d] any rights to a hearing or judicial review in state or federal court on the matters alleged, or to challenge th[e] Order in its entirety as issued by the Board, and waive[d] any other cause of action related thereto or arising from said Order.'' *Id.* Finally, he agreed that the ''Order is a public record that will be publicly disseminated *as a formal disciplinary action of the Board* and will be reported to the National Practitioner's Data Bank and on the Board's Web site as a disciplinary action.'' *Id.* at 21 (emphasis added).

Likewise, the 2009 Order provided that ''[b]y entering into this Consent Agreement, Respondent voluntarily relinquishes any rights to a hearing or judicial review in state or federal court on the matters alleged, or to challenge this Consent Agreement in its entirety as used by the Board, and waives any other cause of action related thereto or arising from said Consent Agreement.'' GX 17, at 1. Also, the 2009 Order provided that ''[t]his Consent Agreement, or any part thereof, may be considered in any future disciplinary action against Respondent,'' and that upon its approval and signing, was ''a public record that will be publicly disseminated as a formal action of the Board'' which would be reported to the National Practitioner's Data Bank and on the AMB's Web site. *Id.* at 1–2.

Respondent does not contend that he lacked a full and fair opportunity to litigate the allegations that were the subject of the 2009 and 2010 Orders. And while both Orders were the result of consent agreements in which the findings were not actually litigated, the Supreme Court of Arizona has explained that even where a judgment has been entered by stipulation or consent, it ''may be conclusive, with respect to one or more issues, if the parties have entered an agreement manifesting such intention.'' *Chaney Building Co.,* v. *City of Tuscon,* 716 P.2d 28, 30 (Ariz. 1986) (en banc) (citing *Restatement (Second) of Judgments* § 27 comment e).[6] *See also Gilbert v. Ben-Asher,* 900 F.2d 1407, 1410 (9th Cir. 1990) (''Arizona law permits a judgment by stipulation to 'be conclusive . . . if the parties have entered an agreement manifesting such intention.''') (quoting *Chaney,* 716 P.2d at 30); *Restatement (Second) of Judgments* § 8.3.

Here, both AMB Orders constitute formal disciplinary actions of the Board; their findings and legal conclusions were the basis for the sanctions which the AMB imposed on Respondent. Most significantly, the parties agreed that Respondent could not ''contest the validity of the Findings of Fact and Conclusions of Law contained in the [2010] Order in any present or future administrative proceedings before the Board,'' as well as in a proceeding before ''any other state agency in the State of Arizona, concerning the denial or issuance of any license or registration required by the state to engage in the practice or any business or profession.'' So too, Respondent agreed that he could not challenge any portion of either Order in the state or federal courts. Thus, notwithstanding that both AMB Orders were the result of consent agreements, it is clear that the parties agreed that the findings of fact and

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While in his ruling, the ALJ noted that ''the Agency has stated that 'the doctrine of *res judicata* bars the relitigation of the findings of the [state medical board]'s final order,' '' ALJ Ex. 48 at 4 n.2 (quoting *Dougherty,* 76 FR at 16830), he then ''declined to extend this dicta [sic] to the facts in the present case for the reasons discussed above.'' *Id.* Contrary to the ALJ's understanding, the passage in *Dougherty* was not a dictum but rather a holding, as the Agency's decision relied on numerous findings of the state medical board's order in support of its finding that Respondent had committed acts which rendered his registration inconsistent with the public interest and squarely rejected the physician's attempts to relitigate the state board's findings. *See* 76 FR at 16831. As I explained:

> All of Respondent's testimony could have been, and should have been presented in the MBC proceeding. Here again, it is clear that Respondent is simply trying to relitigate the findings of the MBC proceeding. Having failed to establish that the MBC proceeding did not provide him with a full and fair opportunity to litigate these issues, the doctrine of *res judicata* precludes Respondent from relitigating them in this proceeding.

Id. Thus, contrary to the ALJ's reasoning, there was no dictum ''to extend'' but only a holding to apply; his reasons for ignoring Agency precedent reflect a fundamental misunderstanding of the differences between claim preclusion and issue preclusion.

[5] As support for his reasoning, the ALJ also cited the Agency decision in *Robert Raymond Reppy,* 76 FR 61154, 61159–60 (2011), noting that the decision ''refus[ed] to apply *res judicata* because, although a prior Agency decision was a final judgment on the merits, the respondent was not a party to the prior litigation.'' ALJ Ex 48, at 3. The ALJ ignored, however, the fundamental difference between *Reppy* and this matter, that being that the Government sought preclusion against Dr. Reppy based on findings made in a matter involving the pharmacy for which he worked, and did so notwithstanding that he was not a party to the pharmacy's proceeding. By contrast, here the Government seeks preclusion against Respondent based on findings made in a proceeding in which he was a party.

[6] Indeed, in *Chaney,* the Supreme Court of Arizona explained that even where parties stipulate to a dismissal, if the parties ''intended the . . . dismissal to be binding as to certain factual issues, and if their intention was reflected in the dismissal, we would enforce the intent of the parties and collateral estoppel would apply.'' 716 P.2d at 30 (citing James, *Consent Judgments as Collateral Estoppel,* 108 U. Pa. L. Rev. 173, 192 (1959)).

conclusions of law contained in them, were not subject to relitigation between Respondent and the Board.

As for Respondent's contention that ''the stated findings and conclusions could not be used in a non-AMB proceeding,'' ALJ Ex. 47, at 3, the 2010 Order itself expressly provided that it could be used in administrative proceedings brought by other Arizona agencies. GX 18, at 20. And as for his contention that he and the AMB agreed that his admissions were ''not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding,'' Respondent cites no authority to support the proposition that he and the State can dictate to an Agency of the United States that it cannot give the same effect to the factual findings and legal conclusions as would exist in a subsequent state administrative proceeding.[7] *Cf. Howlett* v. *Rose,* 496 U.S. 356, 371 (1990) (*citing FERC* v. *Mississippi,* 456 U.S. 742, 776 n.1 (1982) (opinion of O'Connor, J.) (''State may not discriminate against federal causes of action'')); U.S. Const. art. VI, cl. 2. Accordingly, I hold that the ALJ erred by failing to give preclusive effect to the factual findings and legal conclusions of the two AMB Orders.[8]

Findings of Fact

Respondent is the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V as a practitioner at the registered address of 2016 South 4th Avenue, Tucson, Arizona. GX 1, at 1. Respondent's registration was due to expire on April 30, 2011, *id.;* however, on March 16, 2011, Respondent submitted a renewal application. GX 2. Because Respondent has timely submitted a renewal application, I find that Respondent's registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c).

Respondent is also the holder of a license to practice allopathic medicine in the State of Arizona. GX 18, at 1. Respondent holds board certifications from the American Board of Psychiatry and Neurology, the American Board of Child and Adolescent Psychiatry, American Board of Addiction Medicine, and the American Board of Pain Medicine. Tr. 802–03.

The State Board Proceedings

The 2009 AMB Order

Respondent first came to the attention of the AMB, after DF, a Tucson area pharmacist, filed a complaint with the Board regarding Respondent's issuance of an OxyContin prescription to DK in October 2007.[9] Tr. 68–69. DF testified that he had received and filled prescriptions which Respondent had issued for OxyContin for patients who were participants in the Arizona Health Care Cost Containment System (AHCCS), the State's Medicaid Program. *Id.* at 55. DF further testified that while OxyContin was not covered by AHCCS, Respondent's prescriptions would, based on the ''quantity and strength . . . cost in the neighborhood of $2,000 per month,'' and yet the ''the patient would pay cash.'' *Id.* at 56–57. Moreover, even when DF ''offered the generic, which was significantly less money, [Respondent's] patients demanded the brand name'' OxyContin and paid cash.[10] *Id.* at 57.

As for the quantity and strength of Respondent's prescriptions, DF testified that ''some of'' them were for ''the highest milligram strength, 80 milligrams,'' with a dosing instruction to take ''multiple tablets of that strength more frequently than was substantiated in the literature.'' *Id.* Based on his ''knowledge of prescribing practices of other physicians writing the same medications,'' DF found the quantities to be ''very excessive.'' *Id.*

In October 2007, DK presented a prescription issued by Respondent for 210 tablets of OxyContin 80mg, with a dosing instruction to take one tablet up to seven times per day. *Id.* at 64. DF testified that the dosing instruction was ''totally outside of the literature and the general accepted prescribing practice for that medication,'' *id.* at 65, because OxyContin is a sustained-release product which is typically taken every twelve hours, and at most every eight hours, and taking the drug every two hours ''would lead to a blood level that could be dangerous.'' *Id.* at 76.

Accordingly, the prescription ''prompted [DF] to call the doctor's office to verify that the prescription was written correctly.'' *Id.* at 65. However, when DF called Respondent's office, the latter's office manager told him that Respondent ''refuses to speak to pharmacists.'' *Id.* at 66. DF told the office manager that he wanted to know where Respondent ''got the pharmacokinetics information that would support'' the dosing interval and that he ''was not going to fill the prescription until [he] spoke with'' Respondent. *Id.* While DF made at least two phone calls regarding the prescription, Respondent did not speak with him. *Id.* at 67.

Respondent eventually faxed a letter to DF stating that ''OxyContin 80mg per day is the patient's prescription dose. She is being monitored for plain [sic] & compliance. We will continue to prescribe as appropriate for the lowest dose, which meets her pain needs. We also expect politeness in communication.'' RX 29, at 2; Tr. 67. In response, DF hand wrote a note on the fax, which he then faxed back:

> 7 times per day is *not appropriate* by anyone's measure[.] We will no longer fill prescriptions under your name. Board of Medical Examiners and DEA will be notified. We will not help maintain an addiction. You are confusing firmness with impoliteness, and appropriate therapy with inappropriate therapy.

RX 29, at 2; Tr. 68.

Consistent with his note, DF instructed the pharmacists he supervised not to fill Respondent's prescriptions and reported the incident to the AMB. Tr. 70. Respondent then called DF; during the conversation, DF related that Respondent's office manager had stated that he refused to speak with pharmacists. *Id.* at 90. Respondent maintained that he ''never directed his

[7] Nor is it even clear why the agreement's language that ''[a]ll admissions made by Respondent are solely for final disposition of this matter'' and ''said admissions are not intended or made for any other use,'' should preclude this Agency from giving collateral estoppel effect to the Board's factual findings and legal conclusions. Notably, the Board did not agree that its factual findings and legal conclusions were not entitled to preclusive effect in other proceedings; indeed, Respondent agreed that he could not contest the validity of the Board's factual findings and legal conclusions in other Arizona administrative proceedings. Rather, the above quoted language states only that Respondent's *admissions* were not intended for use in other proceedings. Notably, in his opposition to the Government's motion, Respondent did not identify any factual findings in the two Orders which were based on his admissions.

[8] As has been made clear in several agency decisions, even where the factual findings and legal conclusions of a state board order are not subject to relitigation, a respondent is entitled to argue whether those findings and legal conclusions also establish violations of federal laws and regulations, as well as whether those violations are sufficiently egregious to support the Government's proposed sanction. So too, even where the factual findings and legal conclusions of a state board order are entitled to preclusive effect, a respondent is still entitled to put on evidence as to his/her acceptance of responsibility and remedial measures. *See Robert L. Dougherty,* 76 FR 16823, 16830 (2011).

[9] At the time of the hearing, DF had been a pharmacist for twenty-nine years and had been appointed as the Assistant Director of Pharmacy for a major grocery chain in Arizona, and was responsible for supervising 43 pharmacies. Tr. 50–51. He had also previously served for twelve years as a Pharmacy Manager for the same chain and for four years as the District Pharmacy Manager for the chain's stores in southern Arizona. *Id.* at 52.

[10] Several other pharmacists also testified to instances in which Respondent's patients presented similar OxyContin prescriptions, turned down generics, and paid large sums of cash notwithstanding that they were on AHCCS. *See* Tr. 153–54 (testimony of NB); *id.* at 180–81 (testimony of WL).

office manager to say that.'' *Id.* DF asked Respondent if it ''didn't raise a red flag with him that [patients] were paying cash and demanding the brand name and that they were on AHCCCS,'' and presumably ''could not afford $2,000.00 a month for these medications?'' *Id.* at 63. Respondent replied, ''Well how do you know their family isn't paying for it?'' *Id.* DF stated that if he was paying for a family member's prescription ''that cost that much money, I would demand that they got the generic so I wasn't spending that much money for it,'' and then asked Respondent if this didn't ''raise a big red flag to you that they're selling it on the street.'' *Id.* at 63–64. Respondent ''disregarded [DF's] concerns and really had no response to that.'' *Id.* at 64. Respondent also stated that many of his patients requested brand name drugs because generics were less effective. *Id.* at 106.

DF and Respondent also discussed the dosing instruction on DK's prescription, with Respondent telling DF that DK was taking two tablets, three times a day, and one tablet at night. *Id.* at 102. In response, DF told Respondent ''that that is not the way the prescription is written and [that] for a pharmacist to fill a prescription with directions that are not indicative of . . . the doctor's true intent . . . would be unethical and unprofessional.'' *Id.* While DF recalled discussing drug ''tolerance as a general principal,'' he further told Respondent ''the standard practice for pain control with a sustained release product . . . was to use an immediate release product to help with . . . breakthrough [pain] and not to simply increase'' the dosing of the sustained release drug. *Id.* at 103. DF also testified that Respondent asserted that the medication was providing what appeared to be adequate pain relief to DK. *Id.*

With respect to DK, the AMB conducted an investigation. GX 17, at 4. Thereafter, Respondent and the AMB entered into a consent agreement, pursuant to which he stipulated to certain findings of fact and conclusions of law. *Id.* at 1. Therein, the Board made the following findings of fact:

> 4. On November 17, 2006, DK first presented to Respondent through self-referral complaining of lower back pain and psychiatric issues. DK reported her current pain management medications as OxyContin, Oxycodone, Valium, and Paxil. DK also reported having imaging studies and x-rays done three years prior to her visit. Although Respondent requested at this first meeting and four times subsequently that DK provide him with her medical records and film, she did not comply until December, 2007. At this first visit, Respondent prescribed OxyContin and Valium at the reported doses and increased the Oxycodone dosage from the reported dosage. Subsequently, Respondent prescribed medications on a monthly basis and in December 2006, he added Wellbutrin for increasing depression. Respondent did not obtain urine drug tests to monitor compliance before June 2008, or order additional testing to identify the source of DK's pain.
>
> 5. On August 29, 2007, Respondent provided DK with early refills of OxyContin and Oxycodone, although he decreased the Oxycodone dosage.
>
> 6. On October 19, 2007, Respondent saw DK and a family member, who both insisted that DK was compliant with her treatment. Respondent then wrote DK her usual opioid prescriptions. However, later that day, Respondent received written documentation from another patient that DK was recently discharged from the care of another physician for violating a pain agreement. Respondent subsequently took appropriate measures in an attempt to prevent DK from filling the prescription he had written earlier that day.
>
> 7. Respondent later learned from the other provider that DK had tested positive for cocaine and Methadone (which was not prescribed to her). Respondent referred DK to Behavioral Health for substance abuse issues, but he continued to prescribe opiates to DK for her back pain. Further, Respondent continued to prescribe opiates to DK after he learned that she had successfully completed inpatient opioid detoxification.
>
> 8. The standard of care requires a physician to base new or continuing high dose opioid prescriptions for a self-referred, chronic pain management patient (who reports currently being prescribed high dose opioid medications) on proper indications, including previous medical records and verified previous prescriptions, and/or contact with the previous prescribing physician.
>
> 9. Respondent deviated from the standard of care by prescribing high dose opioids to DK without proper indications.
>
> 10. The standard of care when treating a chronic pain patient who has a known or suspected substance abuse problem is to utilize objective measures to monitor compliance.
>
> 11. Respondent deviated from the standard of care by failing to timely use objective measures, such as urine drug tests, to assess DK's compliance with her treatment even after he was aware of her cocaine addiction.
>
> 12. As a result of Respondent's conduct, DK might have suffered an accidental overdose resulting in respiratory depression, aspiration, brain damage, or death. In addition, Respondent's inappropriate prescribing might have . . . perpetuated DK's aberrant drug seeking and addiction.

Id. at 4–5.

Based on the above findings, the Board concluded that ''[t]he conduct and circumstances described above constitute unprofessional conduct pursuant to'' Ariz. Rev. Stat. § 32–1401(27)(q), a provision which encompasses ''[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public.'' *Id.* at 6. The Board issued Respondent a reprimand and placed him on probation for one year, subject to several conditions, including that he take 15–20 hours of Continuing Medical Education in pain management; that he pay the Board's administrative costs; and that he obey all federal, state and local laws and regulations ''governing the practice of medicine.'' *Id.* at 6–7. In addition, the conditions provided that the ''Board staff or its agents shall conduct periodic chart reviews,'' and that based on the reviews, ''the Board may retain jurisdiction to take additional disciplinary or remedial action.'' *Id.* at 6.

After entering into the 2009 agreement, Respondent requested that Dr. Bennet E. Davis, M.D., President of the Pima County Medical Society Pain Working Group review the consent agreement. RX 8, at 4. Therein, Dr. Davis took issue with several of the AMB's findings, specifically findings 8, 9, and 11.

As set forth above, in findings number 8 and 9, the AMB found that in the case of ''a self-referred, chronic pain management patient (who reports currently being prescribed high dose opioid medications),'' the standard of care requires that a physician base the prescription ''on proper indications, including previous medical records and verified previous prescriptions, and/or contact with the previous prescribing physician,'' and that Respondent failed to do so. With respect to these findings, Dr. Davis asserted that the Board was applying a standard of care which ''does not reflect the actual standard of care in the state of Arizona, nor in the community in which [Respondent] practices medicine,'' but rather a standard which ''reflects an ideal which is not achievable in reality.'' *Id.*

As for finding number 11, in which the Board found that Respondent deviated from the standard of care by failing to timely use objective measures, such as urine drug tests, to assess DK's compliance with her treatment, even after he was aware of her cocaine addiction, Dr. Davis asserted that the Board's finding ''appears to have no basis in fact.'' *Id.* Dr. Davis then opined that even ''if it did, it would not reflect actual standard of care in the community in which [Respondent] practices medicine because the use of urine screening in pain medicine is an area of some controversy and consequently wide latitude must be given to practitioners.'' *Id.*

The short answer to these contentions is that the AMB is the expert agency entrusted under Arizona law with authority to determine ''if a doctor of

medicine has engaged in unprofessional conduct or provided incompetent medical care.'' Ariz. Rev. Stat. § 32–1403(A)(2). *See also id.* § 32–1403(A) (''The primary duty of the board is to protect the public from unlawful, incompetent, unqualified, impaired, or unprofessional practitioners of allopathic medicine through licensure, regulation and rehabilitation of the profession in this state.''). Under Arizona law, eight of the Board's twelve members must ''be actively practicing medicine,'' and ''[e]ach doctor of medicine who is appointed to the board [must] have been a resident of this state and actively engaged in the practice of medicine as a licensed physician for at least the five years before appointment.'' *Id.* § 32–1402(A) and (B).

Respondent could have presented this evidence to the Board, but did not. Most significantly, to even entertain such evidence undermines fundamental values of federalism. As *Gonzales* v. *Oregon* makes clear, ''[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 279 (2006). Where, as here, a state medical board has determined that a practitioner's conduct violated the standard of care, its findings of fact and conclusions of law are not subject to relitigation before the Agency. Rather, the only question is whether those findings also establish whether a practitioner has committed acts which render his registration inconsistent with the public interest within the meaning of the CSA.

With respect to DK, Respondent testified that he recognized the AMB's criticism of his failure to get her records ''originally.'' Tr. 850–51. Indeed, other than a then-five year old MRI, which DK did not produce until more than a year after she had begun seeing Respondent and which had negative findings (*see* RX 30, at 11), Respondent did not obtain any records from DK's prior treating physicians, notwithstanding that at the first visit, Respondent noted in his evaluation that ''[h]er most recent treatment has been OxyContin 160 mg t.i.d. (three times a day) and oxycodone 30 mg two tablets, one to two times daily which she currently takes. She also takes Valium, 10mg. one p.o. at h.s.'' RX 30, at 40.[11] Respondent maintained, however, that:

> There was a dilemma in obtaining her records. We asked many times and our option—the only option I saw available to us if she would not tell us or remember who she had seen in the past, was to fire her. And I felt, as I answered before, that she was a multiple diagnosed patient and that would be to her detriment and would be poor medical care. So I decided though she could not remember or give us the name or produce records, to continue her in my care based on my original examination of her, my history I took of her and her compliance.

Tr. 851–52.[12]

Moreover, shortly after DF questioned the OxyContin 80 mg prescription (in early October 2007), Respondent was provided with a copy of a letter (dated 9–13–07) written by another physician (Dr. P.), which stated that Dr. P. had fired DK for breaking her pain contract, specifically citing DK's use of cocaine and narcotics. RX 30, at 20. Respondent noted in DK's record that the patient, who provided him with this letter, had observed that DK, who had recently stayed in the patient's residence, had ''not be[en] compliant with her medications,'' and that this was corroborated by the reporting patient's relative. *Id.* at 21.

On October 19, 2007, Respondent sent out a Fax Net [13] cancelling the narcotic prescriptions he had issued to DK earlier that day. *Id.* at 19. However, the following month, he resumed prescribing both OxyContin and oxycodone to DK. *Id.* at 46. Respondent also noted in DK's chart that his plan was ''to contact Dr. [P's] office, receive prior treatment information from [DK] and review this with prior providers, review this with [DK] before making a decision to continuing care for her. In the event, opioid medication care is not continued, she will be supported with detoxification medication and referral to appropriate treatment.''

Respondent testified that he corroborated with DK's previous physician that she had ''violated the pain contract.'' Tr. 844. However, he concluded that he ''was her physician and she obviously needed additional care.'' *Id.* According to Respondent, he told DK that ''in order to continue treatment she would have to get treatment at the Behavioral Health Center for this drug problem,'' and that he ''coordinated with Behavioral Health Center'' and ''required records back.'' *Id.* at 844–45. Respondent then maintained that they ''requested actually that I continue the care'' as DK ''continued to have pain and needed treatment for that and that was how we proceeded.'' *Id.* at 845.

Respondent then explained that he did not fire her at that point because:

> Abandoning her would have been unethical and immoral in my mind. She was—had multiple problems, including psychiatric. She had been apparently to two doctors previously. I felt that if I had fired her at that point, she would have gone looking for another doctor. She wouldn't have gotten the care she needed. And that as long as she was willing to cooperate with a restructured treatment plan and supervision, it was my responsibility to care for her.

Id. Respondent further maintained that ''[a]fter we sent her to CODAC Behavioral Health, we continued to care for her at a lower dose. Communicated with them. She came back to us several months later for several more visits.'' *Id.* at 848.

Respondent continued to prescribe OxyContin and oxycodone to D.K. Indeed, he issued prescriptions for these drugs (as well as others) on a monthly basis on multiple occasions following her commencement of treatment at CODAC Behavioral Health, up to and including in March 2008, after which he stopped prescribing OxyContin but continued prescribing oxycodone 30mg and added methadone. RX 30, at 46–47. This continued through DK's last visit, which occurred on August 27, 2008. *Id.* DK, however, had tested positive for cocaine on June 3, 2008. *Id.* at 3; Tr. 1013.[14]

[11] Respondent also noted that DK ''was previously treated with methadone, five to six years ago, and also received Percocet in the past. She has also a history of diazepam for muscle spasms.'' *See* RX 30, at 40. Respondent also noted that DK had undergone physical therapy and ''some psychiatric counseling.'' *Id.*

[12] At the first visit, Respondent prescribed DK 180 tablets of OxyContin 80 mg as well as 180 tablets of oxycodone 30 mg. RX 30, at 40. Respondent issued monthly prescriptions to DK for both drugs, increasing the quantity of OxyContin 80 mg to 210 tablets after three months; he also issued monthly prescriptions of oxycodone 30 mg, which were typically for 180 tablets. *Id.*

[13] A Fax Net is an Arizona State Board of Pharmacy form which is used by doctors and pharmacies to report such incidents as forged prescriptions, phony telephone prescriptions, doctor shopping, prescription pad thefts, and armed robberies. *See* RX 30, at 19.

[14] While Respondent acknowledged that DK was prescribed 45 dosage units of oxycodone 30 mg on June 30, 2008, Tr. 1013, he then testified that:

> [m]y progress notes only go to June 4th, so I don't know anything more than the record reflects that she was prescribed that. It may or may not have been me. My last progress note in this is June 4, 2008 and then there's one additional note, August 27, '08 which has really no record except it was a rewrite for a methadone script.

Tr. 1013. While on further questioning, Respondent again testified that he did not know whether he or another doctor wrote the script, he acknowledged that his office had continued to prescribe oxycodone to DK even after her positive test for cocaine. Tr. 1015.

Notwithstanding his testimony that on June 4, 2008, DK ''was given a three day supply of oxycodone, 40 to 60 milligrams a day, and then it was to be reduced,'' *id.* at 1014, Respondent later acknowledged that between June 4 and August 27, 2008, DK's oxycodone prescription was ''increased'' from 15–30 mg per day to thirty mg, twice a day. *Id.* at 1016. Respondent then maintained that RX 30, an exhibit he introduced into the record (and which was denominated as ''Copy of DK Medical

Continued

As set forth above, the Board found that even after Respondent had referred DK for treatment for substance abuse, he continued to prescribe opiates to her for her back pain. Moreover, the Board found that Respondent continued to prescribe opiates to DK after he learned that she had successfully completed inpatient opioid detoxification.[15]

Of note, DK's medical record contains the results of a single urine drug screen, which did not occur until June 3, 2008.[16] Yet even after this screen showed that DK tested positive for cocaine, Respondent continued to prescribe to her.

On cross-examination, Respondent testified that ''we didn't have all the perfect records.'' Tr. 1027. However, he then asserted that DK ''wouldn't tell us or couldn't tell what they were.'' *Id.* When asked if he accepted the AMB's judgment regarding his treatment of DK, Respondent testified that ''I accept that I didn't do a urine screen early on, which we would always do now.'' *Id.* at 1028. As for the AMB's findings that he failed to obtained DK's records, Respondent testified that ''I accept that I didn't get old records, which we would handle as we handled,'' *id.* whatever that means.

As for the Board's findings related to his continued prescribing to DK, even after he had referred her to substance abuse treatment and even after ''she had completed inpatient opioid detoxification treatment,'' (AMB Finding #7), Respondent testified that he did not accept the Board's finding. Tr. 1028. According to Respondent, ''they said I referred her to treatment and that was great that I followed her. She continued . . . to have pain and I did that treatment at much, much lower doses in conjunction with . . . her behavioral health center and at their request. So I think that was appropriate. But that's [sic] everybody has differences of opinions.'' *Id.*

The 2010 AMB Order

As set forth above, under the terms of the 2009 AMB order, Respondent was required ''to participate in the periodic review of his patients' charts.'' GX 18, at 14; GX 17, at 6. The Board's staff selected three charts at random and provided them to a medical consultant who reviewed them and ''found deviations from the standard of care in each case,'' as well as ''medical recordkeeping issues.'' GX 18, at 14. The 2010 AMB Order set forth extensive findings regarding three patients, JR, LP, and ML. *Id.* at 14–16.

Based on several complaints the Board received regarding his treatment and care of multiple patients, the AMB initiated additional cases. *See generally id.* at 2–17. In its 2010 Order, the AMB made extensive findings regarding Respondent's treatment of patients AL, KF, JF, DD, SS, AM, MF, ML, WO and CJ. *See id.* at 2–13, 17. Based on these findings, the AMB concluded that Respondent had engaged in unprofessional conduct, both by ''[f]ailing or refusing to maintain adequate records on a patient,'' and by engaging in ''[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public.'' *Id.* at 17 (citing Ariz. Rev. Stat. §§ 32–1401(27)(e) and (q)).[17]

JR

The Board found that Respondent treated JR for reported neck and back pain from July 2007 until September 2009. GX 18, at 14. No previous medical records were obtained prior to Respondent prescribing oxycodone, Xanax and Subutex. *Id.* Despite normal CT scans of JR's head and neck on February 18, 2008, Respondent continued to prescribe oxycodone on numerous occasions until August 2009. *Id.* Respondent changed JR's medication on several occasions without documenting his reasoning and refilled JR's medication after he reported that it had been stolen. *Id.*

According to the Board, when treating a patient for chronic pain, the standard of care requires a physician to obtain prior records pertaining to the past treatment of the patient, and to obtain any objective measures for the cause of pain. *Id.* The Board found that Respondent deviated from the standard of care because he did not obtain JR's previous medical and/or treatment records prior to prescribing opioid medication for reported chronic pain, and that he failed to obtain objective measures for the cause of JR's pain. *Id.* It further found that Respondent's conduct could result in an overdose and/or perpetuation of drug seeking behavior and addiction. *Id.*

The Board also found that Respondent's records were inadequate because they failed to document a treatment plan and reasoning for high dose opioids in a patient with a history of substance abuse, lost/stolen medications and positive drug-screen findings. *Id.* at 15. Further, his records failed to adequately document the reasoning for, and the results of, his prescribing of Adderall.[18] *Id.*

LP

The Board found that LP's chart indicated that in August 2005, Respondent began treating LP for his reported history of chronic lower back

Records in Possession of [Respondent],'' was ''apparently not'' DK's complete patient file, but rather only ''the med log'' as ''the notes aren't there that would explain in detail what was going on.'' *Id.* at 1017.

[15] According to the affidavit of Dr. Bennett Davis, Respondent's medical record for DK included ''notes from CODAC behavioral health clinic from 12–04–07 and 03–18–08.'' RX 8, at 7. Strangely, the exhibit which Respondent submitted as DK's medical record does not contain a note from CODAC dated 3–18–08. *See generally* RX 30.

[16] A letter dated 10/09/08 from Respondent's practice to another physician regarding DK's request for medical records stated that ''[s]he also tested positive for cocaine on two occasions. She was referred to Codac Behavioral Health for additional help and to our knowledge she did not complete treatment.'' RX 30, at 1. While the log of DK's prescriptions contains an entry for July 28, 2008, indicating that a urine drug screen was done on this date, DK's patient record, as submitted into evidence, contains the test results of only the June 2008 drug screen.

[17] Under Ariz. Rev. Stat. § 32–1401(2), the term '''[a]dequate records' means legible medical records, produced by hand or electronically, containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment.''

[18] Regarding JR, as well as LP, CJ, WO and JF, Respondent's Expert testified that she believed that Respondent was ''practicing with skill and safety,'' (as she had written in her June 7, 2010 letter to the AMB) in that ''[t]he dosage he prescribed for the patients initially based on their symptoms, which of course are subjective, were reasonable. When he raised the doses subsequently, he did it in a careful manner, and he didn't increase them sufficiently to risk the patient's health. So I felt that he was skillful and he was taking into consideration the safety of the patient.'' Tr. 592–93. Yet in her letter, Dr. Schneider noted ''it is difficult at times to reconstruct his reasoning because his documentation, although typical of psychiatric patients, needs to be more detailed when dealing with chronic pain patients.'' RX 4, at 1. And subsequently, Dr. Schneider testified that she ''remember[ed] that I read some of [Respondent's] records where he didn't do a physical exam on the first visit and things like that.'' *Id.* at 597. Thus, even if the Board's findings were subject to relitigation in this proceeding, Dr. Schneider's testimony provides no reason to reject the Board's findings.

Dr. Schneider also took issue with several of the AMB findings, asserting that in the case of one patient (AM), ''the consultant alleged'' that Respondent ''did not get prior imaging studies'' when ''those records were in the chart''; that in the case of MF, ''the consultant alleged that [he] did not try alternative non-opioid treatment before initiating opioid treatment,'' as well as that he did not get imaging studies when ''a CT of the thorax was in the chart''; and that ''the consultant alleged'' that he did not physically examine patient SS at the initial visit, when the results were in the chart. RX 4, at 2.

Here again, Respondent could have raised these contentions with the Board. Moreover, even if the Board's findings were subject to relitigation, the Board made findings with respect to fourteen patients. Thus, even if I were to place no weight on the Board's findings with respect to these three patients, the Board's findings were essentially unchallenged with respect to most of the other patients.

pain, DJD, musculoskeletal pain, chronic depression, PTSD, Lupus and ADD. *Id.* On the first as well as subsequent visits, Respondent prescribed OxyContin and oxycodone without obtaining past medical records. *Id.* The Board noted that objective data in the records such as x-rays were documented as normal; however, Respondent continued to treat LP with opioids and/or methadone through October 2009 without a documented treatment plan. *Id.* Respondent increased LP's medications, as well as changed them at times without documented reasoning. *Id.*

According to the Board, the standard of care when treating a patient for chronic pain requires a physician to obtain objective measures as to the cause of pain. *Id.* The Board found that Respondent deviated from the standard of care in that he continued to treat LP's reported pain with high-dose opioid medications without obtaining objective measures as to the cause of the reported pain. *Id.* The Board further found that Respondent's conduct could result in an overdose or perpetuation of drug seeking behavior and addiction. *Id.* at 16.

The Board also noted that Respondent's records were inadequate because they fail to adequately document the initial visit, treatment plan and reasoning for high dose opioids and changes in medications, in violation of Ariz. Rev. Stat. § 32–1401(2).

ML

The Board made findings pertaining to ML, a twenty-three year old male, as part of both the random chart review it conducted pursuant to the 2009 Order, as well as the case it opened following the receipt of a complaint regarding Respondent's care and treatment of him.[19] *Id.* at 9, 16.

The Board found that in October 2006, Respondent diagnosed ML with spondylolisthesis based on his reported history and that he prescribed oxycodone, but that he did not perform a facet, sacroiliac joint, myofascial pain or neural flexes examination on ML, nor did he test him for weakness or numbness. *Id.* at 9. The Board also found that Respondent did not order flexion extension films to assess spinal instability from spondylolisthesis or an MRI scan to assess for neural compression. *Id.* Moreover, in the course of its chart review, the Board found that there was an x-ray in the chart dated February 18, 2008, which stated: ''NO evidence of spondylolisthesis.'' *Id.* at 16.

The Board found that in November 2007, Respondent documented that ML had, on his own, increased the oxycodone medication. *Id.* at 9. However, there was no documentation that Respondent cautioned ML to adhere to his dosing instructions. *Id.*

The Board also found that from January through December 2007, Respondent prescribed multiple early refills of oxycodone, that he added hydrocodone to the regime in January but discontinued it in March without indication, and that from February through December 2008 Respondent prescribed multiple early refills of oxycodone.[20] *Id.* It also found that in June 2008 Respondent was notified that ML was undergoing methadone treatment at a facility; however, Respondent he did not obtain ML's medical records from that facility. *Id.*

Next, the Board found that Respondent discharged ML from opioid therapy in January 2009, but restarted opioids in March 2009, without documenting an explanation. *Id.* Moreover, the Board found that even after he was placed on probation pursuant to the 2009 Order, ''Respondent continued to prescribe high-dose opioids to ML for pain secondary to spondylolisthesis'' until September 2009. *Id.* at 16. The Board noted that during the course of Respondent's treatment of ML there was no further documentation that he performed any examinations prior to prescribing the medications, or that he obtained ML's past medical records or diagnostic studies. *Id.* at 9–10.

According to the Board, prior to initiating high dose opiate therapy, the standard of care requires a physician to perform an adequate exam for pain generators, obtain the patient's past medical records and diagnostic studies, offer the patient adjunct treatments that include non-opioid medications and physical therapy, address aberrant drug seeking behaviors, and refrain from prescribing more than one month of Schedule II prescriptions at a time. *Id.* The Board found that Respondent deviated from the standard of care because he did not perform an adequate exam prior to initiating high dose opiate therapy, did not obtain ML's past medical records and diagnostic studies, did not offer adjunct treatments, did not address ML's aberrant drug-seeking behaviors, and did not refrain from prescribing more than one month of schedule II prescriptions at a time. *Id.*

As it noted with the previously discussed patients, the Board also found that when treating a patient for chronic pain, the standard of care requires a physician to obtain objective measures as to the cause of pain. *Id.* at 16. The Board thus found that Respondent violated the standard of care by continuing to treat ML's reported pain with high-dose opioids without obtaining objective measures for the cause of his pain, and that his conduct could result in the perpetuation of ML's drug-seeking behavior/addiction or an overdose. *Id.* In addition, the Board found that there was potential for diversion or abuse of the oxycodone. *Id.* at 10.

Finally, the Board found that ''[a] physician is required to maintain adequate legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate [the] advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment.'' *Id.* at 11 (citing Ariz. Rev. Stat. § 32–1401(2)). The Board thus found that ''Respondent's records were inadequate[,] because there was no documentation that [he] performed any [neurologic] and musculoskeletal examinations prior to prescribing opioid therapy, no documentation that he cautioned ML to stay within the prescribing instructions, no documented rationale for re-starting opiates again later[,] and that [he] did not obtain ML's medical records from the treatment facility or from his previous treating physicians.'' *Id.*

During the hearing, Respondent's expert did not dispute the Board's findings with respect to Respondent's multiple early refills for ML. Tr. 675. She also did not dispute that notwithstanding that ML had tested positive for both marijuana and cocaine, as well as benzodiazepines which Respondent had not prescribed on previous visits, Respondent continued to prescribe oxycodone to him. *Id.* at 675–76. Nor did she dispute that ML

[19] This individual is not the same person as the confidential source who made undercover visits to Respondent on May 2 and June 6, 2008, and was also referred to by the initials ML.

Respondent also elicited testimony from an individual with the same initials, who testified that he was treated by Respondent for spondylolisthesis. Tr. 464–94. The testimony of this individual suggests he may well have been the same ML as discussed in the AMB's 2010 Order. *Compare* GX 18, at 9 (discussing ML's treatment at methadone facility) *with* Tr. 474, 484–8 (ML testifying about his treatment by methadone program). The record does not, however, definitively establish if the ML who testified and the ML discussed in the AMB's Order are one and the same.

[20] Here again, Respondent's Expert did not take issue this finding. Tr. 675.

had tested negative for oxycodone even though Respondent had prescribed the drug to him at the preceding visit. *Id.* at 677. While Dr. Schneider testified that there might be a valid reason why a short acting opioid might not turn up in a urine drug screen (depending upon when it was taken), she testified that the physician ''need[s] to find out when the patient took their last dose so that you can find out if there's some legitimate reasons for why they[sic] tested negative when one would have expected it to be positive.'' *Id.* at 679. And notwithstanding that the ALJ allowed Respondent to relitigate the Board's findings, Respondent offered no evidence as to whether ML had a legitimate reason for testing negative for oxycodone.[21]

CJ

Following its receipt of a complaint from a pharmacy alleging inappropriate prescribing by Respondent, the Board investigated his treatment of CJ. GX 18, at 17. The Board found that Respondent ''prescribed large amounts of opioids to . . . CJ with an inadequate treatment plan,'' and that he did so even though ''CJ had a history of testing positive for [h]eroine [sic], [o]xycodone, [m]orphine and [c]ocaine.'' *Id.* The Board also found that ''on two occasions, CJ tested positive for narcotics that were not prescribed by Respondent.'' *Id.*

According to the Board, ''[t]he standard of care is to develop an adequate treatment plan prior to prescribing opioids and to treat the patient's substance abuse problem before treating pain.'' *Id.* The Board found that Respondent violated this standard when he ''prescribed opioids to CJ without an adequate treatment plan,'' and that he ''exposed the patient to possible drug overdose and drug diversion.'' *Id.*

AL

The Board found that on November 6, 2006, AL, who was then an eighteen year old female, presented to Respondent complaining of moodiness and irritability. *Id.* at 2. Respondent diagnosed AL as having Attention Deficit Hyperactivity Disorder and prescribed Adderall (a schedule II stimulant) to her, but did not document the prescription in AL's record. *Id.* The Board found that there was no documentation that Respondent performed an adequate psychiatric evaluation, which included ordering laboratory studies; that he had obtained her past medical records, her history of alcohol or substance abuse, and her psychiatric history; or that he performed a functional assessment to support his diagnosis and prescription. *Id.* The Board also found that there was no initial treatment plan documented in the record. *Id.*

The Board further found that ''[f]rom November 2006 through February 2009, Respondent provided AL with frequent, early and escalated doses of Adderall without documenting any rationale for doing so.'' *Id.* Moreover, the Board found that ''[o]n several occasions[,] AL attempted to refill her Adderall prescription early. There was, however, no documentation that Respondent investigated or addressed AL's rationale for doing so. *Id.*

Next, the Board further found that during the course of AL's treatment, Respondent added Prozac, Cymbalta, Lorazepam, and Zoloft [22] to her medication regime but did not document his rationale for the medications or whether he discussed the risks and benefits of taking them. *Id.* There was also no documentation that he ordered any laboratory studies to support his continued prescribing of Adderall, or urine drug screens to determine whether AL was taking the medications as prescribed and/or any illicit substances. *Id.* Further, several of Respondent's progress notes were illegible. *Id.*

The Board found that the standard of care requires a psychiatrist to perform adequate psychiatric evaluations prior to commencing treatment, and that when prescribing Adderall, a physician is required to perform tests to confirm the diagnosis and the necessity of the medication, and to monitor the patient's use of the medication. *Id.* at 3. The Board thus found that Respondent deviated from the standard of care in that he did not perform an adequate psychiatric evaluation of AL, he did not perform tests to confirm his diagnosis and the necessity of medication, and he did not monitor AL's use of the medication. *Id.*

The Board further found that there was no collateral information in AL's record to support prescribing Adderall, which created a potential for misdiagnosis, addiction, abuse, misuse, overdose and diversion. *Id.* The Board also found that because no urine drug tests were performed, it was unknown whether AL was taking the medication as prescribed and/or whether she was utilizing illicit substances. *Id.*

Finally, the Board found that Respondent's records did not comply with Ariz. Rev. Stat. § 32–1401(2), because there was no documentation of the initial Adderall prescription, no documented initial treatment plan, the psychiatric evaluation was inadequate, there was no documented rationale for his prescribing of several medications, and several of his progress notes were illegible, including his use of non-standard abbreviations.[23] *Id.*

KF

The Board found that on March 25, 2008, Respondent began treating KF, a twenty-one year old female patient, who complained that she had ''difficulty finishing tasks and focusing.'' *Id.* at 4. Respondent prescribed Adderall to KF, yet ''[t]here was no documentation that [he] obtained her past medical records or ordered any laboratory tests that would qualify KF for a diagnosis to support the use of Adderall.'' *Id.* Respondent prescribed frequent early refills at several subsequent office visits without documenting any rationale for the refills. *Id.* Moreover, on November 4, 2008, Respondent increased KF's dose of Adderall from 20 mg to 30 mg, without any rationale for the prescription. *Id.* There was no documentation that Respondent ordered any laboratory studies to support his continued prescribing of the drug, or any urine drug screens to determine whether KF was taking the medications as prescribed and/or any illicit substances; also, ''several of Respondent's progress notes were illegible.'' *Id.*

The Board found that the standard of care requires a psychiatrist to perform adequate psychiatric evaluations, and that Respondent deviated from the standard of care because he did not perform an adequate psychiatric evaluation. *Id.* The Board also found that the standard of care requires a physician who prescribes Adderall ''to obtain prior medical records, perform tests to confirm the diagnosis and the necessity of the medication[,] and to monitor the patient's use of the medication.'' *Id.* The Board thus found that ''Respondent deviated from the standard of care because he did not obtain prior medical records, perform tests to confirm the diagnosis and the necessity of the medication[,] and he

[21] Nor did she dispute the Board findings that Respondent had continued to prescribe opioids to individuals with anomalous urine drug screens, such as where patients tested positive for drugs he had not prescribed or illicit street drugs, or had tested negative for drugs he had prescribed. Tr. 678–80.

[22] Of these drugs, only Lorazepam is controlled. *See* 21 CFR 1308.14(c).

[23] When asked about the Board's finding that ''Respondent provided AL with frequent early and escalated doses of Adderall,'' Respondent's Expert did not take issue with this finding. Tr. 668–69.

did not monitor KF's use of the medication.'' *Id.*

The Board also found that ''[t]here was no collateral information to support prescribing Adderall, creating a potential for misdiagnosis, addiction, abuse, misuse, overdose and diversion. Since no urine drug tests were performed it is unknown whether KF was taking the medication as prescribed and/or whether she was utilizing illicit substances.'' *Id.* at 4–5.

Finally, the Board found that Respondent's records were inadequate because he did not obtain KF's past medical records, did not document a physical examination prior to prescribing medications, did not document any rationale for the prescriptions, dosage escalations, additions of medication, that several of Respondent's progress notes were illegible, and that he used non-standard abbreviations.[24] *Id.* at 5 (citing Ariz. Rev. Stat. § 32–1401(2)).

JF

The Board found that Respondent began treating patient JF, a nineteen-year old female patient in August 2007 for chronic pain, Attention Deficit Disorder and Obsessive Compulsive Disorder. *Id.* JF reported current prescriptions of OxyContin 40 mg and oxycodone 30 mg. *Id.* There was neither a documented physical examination nor laboratory studies, and Respondent did not obtain past medical records. *Id.* Respondent, however, prescribed 90 tablets of OxyContin 40 mg, 45 tablets of oxycodone 30 mg, and Requip to her. *Id.*

The Board found that Respondent added Adderall to JF's medication regime in October 2007, without documenting any rationale for the medication. *Id.* It also noted that during the course of JF's treatment, she reported on multiple occasions damaged or stolen prescriptions, running out of medication, and that the pharmacy had refused to fill a prescription because of different handwriting. *Id.* However, Respondent continued to prescribe to her and escalated the doses of oxycodone and Adderall. *Id.* The Board further found that there was no documentation that Respondent ordered laboratory studies to support his continued prescribing of OxyContin, oxycodone, and Adderall, or that he did any urine drug screens to determine whether JF was taking the medications as prescribed and/or illicit substances. *Id.* at 5–6. In addition, there was no documentation that Respondent referred JF to a specialist for consultation. *Id.* at 6.

The Board found that that the standard of care requires a psychiatrist to perform adequate psychiatric evaluations, and that Respondent deviated from the standard of care because he did not perform an adequate psychiatric evaluation for JF. *Id.* In addition, the Board found that when a physician prescribes Adderall, the standard of care requires that he perform tests to confirm the diagnosis and the necessity of the medication and to monitor the patient's use of the medication, and that Respondent deviated from this standard because he prescribed the drug without performing tests to confirm the diagnosis and the necessity of the medication and did not monitor JF's use of the medication. *Id.*

Next, the Board found that when prescribing opioids for the treatment of chronic pain, the standard of care requires a physician to review previous diagnostic studies and interventions, assess the chronic pain complaint prior to initiating an opioid trial, appropriately monitor the patient's use of the medication, and obtain appropriate therapeutic and laboratory test results that support the diagnosis. *Id.* The Board found that Respondent deviated from the standard of care because he did not review past medical records and he did not order appropriate tests or consultations for JF. *Id.*

The Board further found that there was no collateral information to support prescribing Adderall, which created a potential for misdiagnosis, addiction, abuse, misuse, overdose and diversion, and that no urine drug tests were performed to determine whether JF was taking the medication as prescribed. *Id.* The Board also found that Respondent's medical records for JF were inadequate because he did not obtain JF's past medical records, did not document a physical examination prior to prescribing medications, did not document any rationale for prescriptions, dosage escalations, and additions of medication. *Id.* at 7. Further, it found that Respondent used non-standard abbreviations in his records. *Id.* (citing Ariz. Rev. Stat. § 32–1401(2)).

DD, SS, AM & MF

The Board found that in 2008, Respondent treated patients DD, SS, AM and MF for chronic pain. *Id.* He prescribed medications that included OxyContin and oxycodone based on the patients' reported history and complaints of chronic pain. *Id.* Yet the Board found that there was no documentation that Respondent obtained past medical records to confirm the patients' diagnoses. *Id.* Moreover, the Board found that during the course of his treatment, Respondent provided early refills and escalated the patients' doses of OxyContin and oxycodone, without documenting any rationale to support his diagnosis or prescribing. *Id.*

The Board further found that Respondent ''did not perform adequate physical examinations, obtain past medical records, or order diagnostic and laboratory studies.'' *Id.* Also, there was no documentation that Respondent referred the patients to a specialist to confirm his continued prescribing of opioids, or that he performed any urine drug screens to determine whether the patients were taking the medications as prescribed and/or illicit substances. *Id.*

The Board found that when prescribing opioids for the treatment of chronic pain, the standard of care ''requires a physician to review past diagnostic studies and interventions, assess and confirm the chronic pain complaint prior to initiating an opioid trial, appropriately monitor the patient's use of the medication, and obtain appropriate therapeutic and laboratory results that support the diagnosis. *Id.* at 8.

The Board found that Respondent deviated from the standard of care because he did not review DD's, SS's, AM's and MF's past diagnostic studies and interventions, assess and confirm their chronic pain complaints prior to initiating an opioid trial, appropriately monitor their use of the medication, and obtain appropriate therapeutic and laboratory test results that supported his diagnoses of chronic pain. *Id.* The Board further found that there was no collateral information to support prescribing opioids to DD, SS, AM and MF, thus creating the potential for misdiagnosis, addiction, abuse, misuse, overdose and diversion, and that because no urine drug tests were performed, it was unknown whether they were taking the medication as prescribed and/or whether they were utilizing illicit substances. *Id.*

Finally, the Board found that Respondent's records for patients, DD, SS, AM, and MF were inadequate because he did not obtain past medical records, did not document adequate physical examinations or laboratory and diagnostic studies prior to prescribing medications, did not obtain any diagnostic studies to support his continued prescribing of medications,

[24] Here again, Respondent's Expert did not dispute the Board's finding that Respondent provided AL with ''frequent early refills of Adderall.'' Tr. 669. She also did not ''take issue with the fact that this dose was increased.'' *Id.* at 670.

and did not document any rationale for prescriptions and dosage escalations.[25] *Id.* at 8–9 (citing Ariz. Rev. Stat. § 32–1401(2)).

WO

The Board investigated a complaint regarding Respondent's care and treatment of patient WO, a fifty-two year old male, for chronic pain syndrome. *Id.* at 11. Respondent assumed WO's care in January 2008, at which time ''WO was on [o]xycodone, [m]orphine [s]ulfate immediate release (MSIR) and Soma, which had been prescribed by his previous physician.'' *Id.*

The Board found that Respondent reviewed previous imaging studies, including a computed tomography scan of WO's pelvis and abdomen that showed healed lower right lateral rib fractures, but no other abnormalities, and a cervical spine film that showed mild hypertrophic degenerative changes in the mid-cervical spine, but no other abnormalities. *Id.* The Board found that from WO's initial visit until July 2009, Respondent continued to see WO and refill the prescriptions. *Id.* The Board found, however, that there was no documentation that he performed a neurological or musculoskeletal exam or ordered any imaging studies of WO's lumbar spine or laboratory studies, prior to continuing the treatment of WO's previous physician. *Id.*

The Board also found that from March 2008 through December 2008, Respondent increased WO's dosage of oxycodone 30 mg to six tablets per day. *Id.* at 12. Moreover, on May 30, 2008, Respondent added Morphine Sulfate (MS) Contin 30 mg for poor sleep, but subsequently increased the dose without documenting a rationale for the increase. *Id.* Yet there was no documentation that Respondent performed any physical examinations or obtained any radiologic studies to support his increased opioid prescribing. *Id.*

Next, the Board found that in February 2009, Respondent discontinued prescribing MS Contin to WO and instead prescribed six tablets per day of morphine sulfate 30 mg to him. *Id.* The Board found that Respondent simultaneously increased WO's oxycodone dose to eight tablets per day, yet did not document a rationale for the increase. *Id.*

In March 2009, Respondent performed a urine drug screen on WO; the screen was negative for oxycodone, but positive for methadone and codeine, which were not among his prescribed medications, as well as heroin. *Id.* At WO's next visit, Respondent documented that he was aware of the positive drug screens. *Id.* The Board found however, that Respondent did not adequately investigate or address the abnormal results by either referring him to an addiction medicine specialist or discontinuing the opioid prescriptions. *Id.*

The Board found that the standard of care requires a physician to perform an adequate work up of a patient prior to continuing treatment of the patient's prior treating physician, to perform an adequate physical examination, and to obtain radiologic data to support the amount of opioid medications prescribed to the patient. *Id.* The Board found that Respondent deviated from the standard of care because he did not perform an adequate work-up and that the physical examination and radiologic data did not support the amount of opioid medications he prescribed to WO. *Id.* at 12–13.

The Board also found that the standard of care requires a physician to adequately investigate or address a patient's abnormal urine drug screen. *Id.* at 13. The Board found that Respondent deviated from the standard because he did not adequately investigate or address WO's abnormal urine drug screen. *Id.*

The Board further found that Respondent allowed WO to continue a pattern of illicit substance use and opioid misuse. *Id.* The Board found that that Respondent's prescribing of 240 tablets of oxycodone per month also created a potential for misuse and diversion.[26] *Id.* Finally, the Board found that Respondent's records were inadequate because there was no documentation that he performed a neurological or musculoskeletal examination, ordered any imaging or lab studies prior to continuing the treatment, and there was no documented rational for his excessive prescribing of opioids. *Id.* (citing Ariz. Rev. Stat. § 32–1401(2)).

Summary of the 2010 Order

Based on its findings with respect to all of the patients, the Board found that Respondent committed unprofessional conduct by ''failing or refusing to maintain adequate records on a patient,'' Ariz. Rev. Stat. § 32–1401(27)(e), as well as by engaging in ''[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public,'' Ariz. Rev. Stat. § 32–1401(27)(q). GX 18, at 17. The Board issued Respondent a Decree of Censure and prohibited him ''from prescribing, administering or dispensing any opioids for a period of one year.'' *Id.* at 18. It also placed him on probation for two years; among the terms of the probation, Respondent was required ''to complete the PACE prescribing course within 6 months of the effective date of this Order'' and enter into a contract providing for quarterly chart reviews by a monitor. *Id.*

Regarding the 2010 AMB Order, Respondent testified that the Board had reviewed 45 of his patient records and had not criticized his recordkeeping other than with respect to the thirteen that were the subject of the Order. Tr. 856–58. He asserted that the reason his recordkeeping was inadequate was because his ''early training and practice was primarily in psychiatry'' where ''[t]he confidentiality of the patient is paramount,'' such that his ''[n]otes were often brief'' and hit just ''the main points'' of the patient's ''main complaint, perhaps a mental status examination, the diagnosis and the plan.'' *Id.* at 859–60. He then testified that ''the main purpose of the record was to refresh your own memory and wasn't necessarily always focused on outside review,'' *id.* at 860, but that he was now ''making every effort to make the record transparent to outside individuals, which was really not the standard of care or the practice for psychiatry.'' *Id.* at 861.

Respondent further testified that during the period in which the AMB was investigating his prescribing to D.K., he sought out assistance from other pain management physicians, studied for and took the board in Pain Medicine, read multiple textbooks and took online courses. *Id.* at 864. He also testified that he had complied with the 2010 Order's practice restriction, which prohibited him from prescribing opioids, and that the restriction had been lifted. *Id.* at 870.

As far as other measures he has undertaken since 2007, Respondent stated that his practice was now able to use the Arizona Controlled Substance Prescription Monitoring Program, that the office was now certified to do in-office urine testing and that it was doing random urine screening, that the office was using the fax alert system, and that he was now placing ''[a] very high priority'' on calls from pharmacies. *Id.*

[25] When asked about the Board's finding with respect to these four patients that ''[d]uring the course of treatment Respondent provided early refills and escalated the patient doses,'' Respondent's Expert testified that she didn't know whether or not it was appropriate for Respondent to increase the patients' doses ''because he didn't document it.'' Tr. 670–71.

[26] The Board also found that ''[t]he long-term use of Soma has the potential for habituation and misuse.'' GX 18, at 13. However, at the time, Soma (carisoprodol) was not a controlled substance under federal law.

at 870–72. Respondent also stated that he had imposed an ''internal kind of ceiling on opiate dosing,'' and that ''[w]e're not a prescribing mill.'' *Id.* 874, 877.

Regarding the second AMB Order, Respondent testified that ''there was a Board statement that no actual harm was found in any patient'' and ''no patients . . . were found to have been diverting substances.'' *Id.* at 883. He then asserted that ''[t]here was no potential addiction, which was perpetuated by my behavior, which is one of the claims.'' *Id.* When asked whether he accepted the AMB's criticism of his recordkeeping and care of his patients, Respondent testified: ''Yes. I realize this is a difficult area and that I need to keep working to improve and I have and I will.'' *Id.* at 884. Respondent then testified that ''I accept the general criticism that there needs to be improvement of my care as I can do so'' but that he did not agree with some of the specifics of the Order, as his Expert had testified. *Id.*

The Undercover Visits

The Government also introduced evidence that it sent two confidential sources (CS) into Respondent's office to obtain controlled substances; each source performed two visits and obtained controlled substances at each visit. With respect to these visits, the Government introduced the recordings (and transcripts) of each visit, and the medical record for each CS. In addition, the Government elicited testimony from a Special Agent (S/A) who was involved in conducting the visits and debriefing the CSs after the visits.

The Government did not, however, elicit testimony from an expert witness regarding whether Respondent had acted within the usual course of professional practice and with a legitimate medical purpose when he prescribed to the two CSs. Instead, it argues that the evidence shows that ''on four occasions,'' Respondent prescribed controlled substances to the CSs ''without ever conducting a physical examination,'' and that the prescriptions violated an Arizona Statute, which provides that it is '' '[u]nprofessional conduct' '' to '' '[p]rescrib[e], dispens[e], or furnish[] a prescription medication . . . to a person unless the licensee first conducts a *physical examination* of that person or has previously established a doctor-patient relationship,' '' and therefore, the prescriptions violated 21 CFR 1306.04(a). Gov. Exceptions at 3 (quoting Ariz. Rev. Stat. §§ 32–1401(27)(ss)).

With respect to RL, the evidence showed that she visited Respondent on April 9 and May 7, 2008, obtaining a prescription for 120 oxycodone 5 mg at the first visit and a prescription for 60 OxyContin 20 mg. at the second visit. *See* GXs 3 and 5. In addition, the S/A testified that during the debriefing of RL following her visit, RL said that ''she told [Respondent] where she had pain'' and that Respondent ''asked a series of questions regarding exercise, sleep, family history, basically general medical questions as to how her life is, what her occupation is, what she does, is she stressed out, does she have anxiety, things of that nature.'' Tr. 358. The S/A further testified that RL did not provide any medical records to Respondent and that RL ''said there was no physical examination.'' *Id.* at 359.

According to the transcript of the visit, RL complained of having hip pain which was caused by a fall. GX 11, at 2. Respondent asked RL a series of questions, including when she had fallen; whether her hips had been ok prior to the fall; whether she had had an x-ray or MRI, and whether the x-ray showed arthritis; whether the pain bothered her when she did various body movements and whether it went down her leg; how often she had the pain; whether it was a sharp or dull pain; whether she had any numbness; whether it impaired her ability to walk; whether it affected her ability to sleep, her appetite, her energy, and her mood; whether she had anxiety attacks; whether she drank alcohol; whether she had taken any medication for the pain and whether it had helped; whether her health was otherwise good; and whether her family had certain medical conditions. *Id.* at 3–8; 13–15; 18–22. Respondent also discussed various forms RL needed to complete, including one to describe her pain, his controlled substance contract, and a form regarding which pharmacy she was using. *Id.* at 25. Respondent then told RL that oxycodone and Percocet were ''not refillable'' and that the long-term effect of taking oxycodone could include constipation and affect her level of hormones. *Id.* at 29.

Although the transcript corroborates some of RL's hearsay statements (as related by the S/A), significantly, the transcript shows that early on in the visit, the following colloquy occurred:

> Respondent: Do you have any tenderness if, if you push on it like this?
>
> RL: Yeah.
>
> Respondent: Where does it hurt? Just when you push on it here?
>
> RL: Directly on it, yes.

Id. at 6.

While the above colloquy does not foreclose the possibility that Respondent may actually have palpated only his own hip and not RL's, the Government had the burden of proof on the issue and produced no other evidence other than the conclusory testimony of the S/A regarding RL's statement that Respondent did not perform a physical exam on her.[27]

With respect to the second CS (ML), the evidence showed that she saw Respondent on May 2, 2008 and June 6, 2008. GX 6, at 1; GX 8, at 1. At the first visit, Respondent prescribed 30 oxycodone 5 mg to ML, GX 6, at 1; at the second visit, Respondent prescribed both 30 oxycodone 5 mg and 30 morphine sulfate ER 15 mg. GX 8, at 1.

According to the S/A, during the debriefing following her first visit, ML stated ''that an evaluation was done with questions based on anxiety, sleep, her family history, [and] what her pain was. She said she had a pain in her shoulder due to her occupation.'' Tr. 373. ML also told Respondent that she had undergone gastric bypass surgery and ''how much weight she had lost.'' *Id.* The S/A further testified that ML did not provide Respondent with any medical records on this visit, and when asked what type of physical examination Respondent had performed on her during the visit, ML answered: ''[n]one.'' *Id.*

The transcript for the visit shows that after discussing her dental pain, ML complained of pain, stated that the pain was ''right here'' and that it was ''really hurting . . . a lot!'' GX 15, at 4. Respondent then asked if the pain was in the bone or ''the joint here?'' *Id.* ML stated that ''it's like a muscle type tissue or something.'' *Id.* Respondent then asked ML to ''point right there,'' ML said, ''[i]t, it hurts.'' *Id.* at 4–5. Respondent suggested that ML should ''maybe . . . get that injected'' and asked ''[w]hen did that start?'' *Id.* at 5. ML stated that she didn't remember when, or what she was doing when she started feeling the pain, and that she had to alter the position of her bra strap. *Id.*

After discussing that Respondent was also a psychiatrist, Respondent suggested that ML see his colleague, Dr. Skinner, who ''might be able to adjust that,'' and asked if the pain went down

[27] While the transcript for RL's second visit contains no indication that Respondent physically examined her, and the S/A testified that RL stated that she was not physically examined on that occasion, *see* Tr. 367, the Arizona statute does not require that a physician physically examine his patient on each occasion that he prescribes a controlled substance to her. *See* Ariz. Rev. Stat. §§ 32–1401(27)(ss)). Nor did the Government offer any evidence that under the standard of care, a physician is required to perform a physical exam on each occasion that he prescribes.

her arm. *Id.* at 5–6. ML replied in the affirmative and said it was ''hard for'' her because ''what I do is on the phone.'' *Id.* at 6. Respondent then suggested that ML use a headset so she could keep her ''head up straight,'' and asked, ''how often does that hurt you?'' *Id.* ML said the pain ''comes and goes,'' but that ''it's been about a month now that . . . it pulls.'' *Id.* Respondent then said he would see if Dr. Skinner would be available to help ML and asked ''what else is going on?'' *Id.* ML then complained that ''I get emotional'' and ''just stress out because I think people are looking at me''; ML and Respondent then discussed ML's efforts to lose weight and her having undergone a gastric bypass procedure. *Id.* at 7–9.

Next, Respondent asked ML if she was ''sleeping okay''; ML replied that she had ''a sleeping disorder'' for which she took ''some sleeping pills.'' *Id.* at 9. Thereafter, Respondent asked ML ''about [her] energy'' (with ML stating that she fatigued easily), if she was ''irritable or grouchy'' (with ML answering in the affirmative), and whether ML had anxiety or panic attacks, (with ML saying just when she hurt). *Id.* at 10. Respondent again asked ML, ''what hurts? It's, it's this area in your shoulder?'' and ML replied ''it's the shoulder, my back.'' *Id.*

Respondent then asked ML if she had depression (with ML saying she did not think so), whether she drank alcohol (ML answering ''no''), what ML took to sleep (with ML saying she had ''no idea''), whether she took any other medications (with ML apparently answering that she took a drug for blood pressure), and whether she had ''any other health problems'' (with ML answering ''no.''). *Id.* at 11–12. Following this, Respondent asked ML a series of questions about her family, including whether her parents were still alive, whether she had siblings, whether she was married and had children, as well as where she was living, and the circumstances surrounding the death of her mother. *Id.* at 12–17. Respondent then asked ML if she had ever taken medication for anxiety or depression; ML replied that she had taken Lexapro for a while and that it had helped but that she didn't have insurance and the drug was expensive. *Id.* at 17–18. ML added that the only drug she was presently taking were her ''pain pills'' and that they made her ''feel better.'' *Id.* at 18. When Respondent asked ML what she had taken in the past, the latter said that she had tried hydrocodone but was allergic to it, and that the only drug she thought she could take was oxycodone. *Id.* Respondent then asked how much oxycodone she could take; ML said she could take one a day and that the drug ''calm[ed her] down a lot,'' but that she did not know how many milligrams the pills were. *Id.* at 18–19. ML then said she was just really nervous and explained that she worked as a phone sex operator and that she had previously worked as a financial counselor at a hospital. *Id.* at 20–22.

Respondent asked ML who had previously given her pain medication; ML identified the name of a doctor and his practice. *Id.* at 22. Respondent then said he would see if Dr. Skinner was available and suggested that she might be able to ''fix'' ML's injured area and added that he would get ML some prescriptions. *Id.* at 24. Respondent then found Dr. Skinner and brought her to see ML. *Id.* at 26.

Respondent explained to Dr. Skinner that ML ''ha[d] a crook on her neck,'' which was ''like a . . . [a] little rock in there.'' *Id.* Notably, before Respondent completed this sentence, ML stated: ''That right there!'' *Id.* ML then complained that she could not move her arm very well and again said that she had to alter where she wore her bra strap. *Id.*

Dr. Skinner then observed that ML's shoulders were straight but that her ''neck [wa]s out,'' and after an unintelligible comment by Respondent, replied ''I know.'' Dr. Skinner then said that she would ''rotate it to the right . . . and then to the left.'' *Id.*at 27. ML asked if that was ''from a muscle spasm?'' *Id.* Dr. Skinner asked ML if she was ''on the phone,'' and after ML said that it was her ''job,'' Skinner stated: ''Okay, listen to me. Don't do that!'' *Id.* Respondent and Dr. Skinner then discussed with ML that she needed to get a headset or some other device so that ML could keep her head upright while she was on the phone. *Id.* at 27–28. ML then asked Dr. Skinner if she could ''feel that?'' *Id.* Dr. Skinner said ''[y]eah,'' and Respondent asked if there was something such as acupuncture'' that could be useful. *Id.* at 28–29.

Dr. Skinner then told ML not to ''resist [her] pain'' and explained that ''it's stuck because you keep your head in the wrong position'' and that ML was ''not going to be able to fix it, if [she] ke[pt] using [her] head, putting [her] head . . . that way.'' *Id.* at 29. ML said ''[a]h,'' and Dr. Skinner stated: ''Don't resist it please.'' *Id.* ML said ''[o]kay,'' and Dr. Skinner replied: ''Just accept it, until I say move. You might need to come back . . . I think it's going to take some time.'' *Id.* ML said ''now it's starting to feel a little better''; Skinner replied: ''Yeah, it does,'' and added ''but if you resist it[,] it's going to feel worse.'' *Id.* at 30.

ML then asked if ''it's more[ ] like a mental thing?'' *Id.* Dr. Skinner replied ''[e]xactly,'' and Respondent interjected: ''[w]ell, your muscles are attached to your brain[,] [y]ou know?'' *Id.* ML said ''[o]h,'' and Respondent added: ''So your . . . brain has to let it . . . .'' *Id.*

Dr. Skinner then stated: ''We got to release all that, so we can—and your neck is out of alignment. And I don't know if anything—yeah, push your head against my hand and relax.'' *Id.* After ML said ''Ah,'' Skinner said ''[o]kay,'' and added that ''we're going to have to work on it with acupuncture.'' *Id.* ML said ''okay,'' and Respondent told ML that if she made an appointment with Dr. Skinner, she would ''have it adjusted.'' *Id.* at 30–31. Respondent then asked Skinner if acupuncture would be of any use, and Skinner said that ''it helps it release it so.'' *Id.* at 31. After Respondent, Skinner, and ML discussed her weight loss, Skinner left. *Id.* at 31–32.

Respondent then told ML that he had various paperwork which had to be completed when he prescribed controlled substances, including his pain contract, a form that was sent to the patient's pharmacy, and a form on which ML was to show the location of her pain and describe it. *Id.* at 32–33. He also told ML that she was expected to participate in the meetings of a monthly support group for his pain management patients. *Id.* at 34–37.

Respondent then discussed with ML that all he was going to prescribe to her was oxycodone and asked if she had ever taken Percocet, a drug which combines oxycodone with Tylenol (acetaminophen). *Id.* at 38. ML said that she had taken Tylenol but it ''ha[d] done nothing'' for her, and after Respondent said that Percocet was a combination of the drugs, added that he would be giving ML oxycodone. *Id.* Respondent then explained that oxycodone had to be written every month. *Id.* at 39. After some small talk, the visit ended. *Id.* at 39–41.

Here again, the evidence shows that Respondent did more than simply observe ML during the course of her first visit. Rather, the evidence shows that ML was palpated during the visit.

In its Exceptions, the Government argues that ''Respondent's own expert (Dr. Schneider) testified that Respondent failed to conduct a physical examination of either [RL or ML] prior to issuing them prescriptions for controlled substances.'' Exceptions at 3. As support for the contention, the Government cites various portions of Dr. Schneider's testimony during cross-examination regarding both her review of RL's and ML's patient files and the

transcripts of the visits, as well as a May 27, 2011 letter she had written regarding Respondent's treatment of RL and ML. *Id.* In the letter, Dr. Schneider noted that she had reviewed the charts of both RL and ML, as well as the transcripts of their visits.[28] RX 23, at 1.

On cross-examination, the Government questioned Dr. Schneider about various findings that Respondent had documented in RL's record, including that her pulse was 70, that her respiration was 16, meaning that she was ''breathing at 16 times per minute,'' her hip flexion was 1 over 4 for her right hip and 3 over 4 for her left hip, and that her range of motion was fair. Tr. 635–36.

The Government then asked Dr. Schneider to point to where in the transcript Respondent had measured RL's pulse. *Id.* at 638. Dr. Schneider testified: ''I don't believe it is in there.'' *Id.* Next, the Government asked Dr. Schneider where in the transcript Respondent had measured RL's respiration. *Id.* Dr. Schneider replied: ''I believe it's not in the transcript.'' *Id.*[29]

The Government then asked Dr. Schneider to point to where in the transcript Respondent had measure RL's hip flexion; Dr. Schneider acknowledged: ''It is not in there.'' *Id.* Likewise, when asked in reference to Respondent's documentation that RL was able to do a partial squat and bend at the waist, where in the transcript this had occurred, Dr. Schneider answered that ''I probably won't be able to find it.'' *Id.* at 639.

Turning to Dr. Schneider's letter, in which she wrote that ''[o]n April 9, 2008 Dr. Ruben conducted a physical and mental exam,'' Dr. Schneider interrupted the Government counsel before the latter even asked a question, testifying:

> [Y]ou're pointing out a discrepancy, right. And assuming, unless I spend a half hour looking through these records and seeing if I can find it, the physical exam, which I may not be able to, that would suggest that I made a mistake in writing that he did a physical exam on that visit.

Id. at 640. Likewise, when asked about her having noted in her letter, that Respondent's plan included obtaining an x-ray followed by a referral to an orthopedic surgeon, Dr. Schneider could not recall where in the transcript Respondent had told RL that she would need to get an x-ray. *Id.* at 641.

Regarding his treatment of RL, Respondent testified that she was able to do a partial squat, which he determined by watching her sit down in a chair. *Id.* at 920. With regard to how he had determined RL's pulse rate, Respondent testified:

> The pulse is determined by feeling the pulsation at the wrist. It's easy to do when you shake hands. If you hold the handshake for three or four to five seconds, you can tell a pulse. If you've done it a lot, it's fairly easy to tell within about ten to [fifteen percent] of what the pulse is. Pulses are not significant if—unless they are outside a couple of standard deviations. And you can tell that very quickly. If somebody is beating at 90 it only takes you, measuring with your fingertip two or three beats. If someone is beating at 30 and they're still standing up, it doesn't take long. Maybe a couple seconds. So I always shake hands with patients. I always hold their hand. Some of them may think it's weird, but I'm taking their pulse. I'm feeling their body temperature. I'm feeling their muscular strength. . . .
>
> Now if I'm concerned about their pulse being something that I can't really think is within the normal range, I may sit down and take their pulse for 15 seconds and sit there formally with them. Or if I can't find their pulse easily. But most people you can—with some practice, you can pretty much find it. You can pretty much hold their hand and you have the pulse.

Id. at 924–25. *See also id.* at 984 (testifying in response to Government's question: ''[h]ow long would a handshake last?,'' that ''[i]f you're holding their hand it often can last the three or four second[s] needed to kind of evaluate the pulse''); *id.* at 985–86 (testifying in response to Government's question ''what's a normal pulse range for your three second handshake?,'' that ''[a]ll you need to assess, if you're experienced at assessing, is a couple of beats'' and then maintaining that ''[i]t's more the rhythm. You don't have to actually count it. You can feel. If you feel two or three beats, you can really tell what—basically within ten—we're only interested in seeing . . . if somebody is within normal range.'').

However, on further questioning as to whether he had determined R.L.'s pulse using his three-second handshake technique, Respondent testified:

> Yes. If that was how I did it. That's—I was telling you that the three second handshake is one way to do it. I may have done it another way. I may have done it some other way but I would have touched the areas that would have given me the reading on the pulse.

Id. at 987.

As for how he determined RL's rate of respiration, Respondent testified that ''[y]ou can look at you or me, particularly if they don't have covering on their upper chest as in summer. This was in May. And you can watch the respirations. You can tell the respirations again, with an observation of a very short time. You can look and watch.'' *Id.* at 926. Respondent then stated that the ''normal range for resting respirations is probably 14 to 17 or something like that,'' and that ''[i]f it's not within a normal range, then you can do more definitive testing,'' including ''count[ing] them more clearly'' and ''listen[ing] to see if their lungs are clear.'' *Id.* at 927. *See also id.* at 987–88 (''I can tell a respiratory rate just from watching a person at any point in an interview where you're in the same room with them. Just by watching if their chest is moving.'').

As for his findings that RL was ''[a]ble to do partial squat and bend at waist,'' Respondent testified that this was essentially the chair test and that when ''ladies put down their purse[,] [t]hey reach over for that[,] [t]hey reach for things[,] [a]ll that is information about their movement.'' *Id.* at 928. On cross-

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[28] In the letter, Dr. Schneider wrote with respect to RL that Respondent ''asked her about the quality of the pain, effect of exercise, what helps, diurnal course. He asked what she had tried and what medication worked. He asked about a history of alcohol or drug abuse. He obtained a social history. *He did a physical and mental exam.''* RX 23, at 1 (emphasis added). After discussing RL's second visit, Dr. Schneider asserted that ''[t]he transcripts were consistent with his chart notes,'' and that Respondent ''did a lot of things correctly, including excellent documentation, discussion with patient, asking about her past treatments for the pain problem, getting addiction history on first visit, dealing with her mental status, doing a physical exam on first visit, assessing and treating her smoking . . . , and talking with her about physical medicine options.'' *Id.*

So too with respect to M.L., Dr. Schneider wrote that Respondent ''did a lot of things correctly, including excellent documentation, discussion with the patient, asking about her alcohol use, dealing with her mental status, *doing a focused physical on first visit,* referring her for physical medicine and psychotherapy group, and documenting his thinking and his plan.'' *Id.* at 2 (emphasis added).

[29] Regarding whether a physician is required to take a patient's vital signs during a physical examination which is performed at a patient's initial visit, Dr. Schneider testified:

> That's usually done. Again, listening to heart and lungs in someone with low back pain is not really going to be all that helpful. It's just sort of a tradition to do it, let's say. So, yeah I would imagine you would get normal vital signs. And a lot of times the nurse does it, not the doctor so it doesn't even come up in the discussion on the transcript because it was done even before the doctor comes into the office. And that's actually the usual thing. That's [the] rule rather than the exception, that the medical assistant does the vital signs.

Tr. 664–65. Notably, in his testimony, Respondent did not maintain that an assistant or nurse took vital signs for him.

Moreover, while Dr. Schneider testified that observing the patient was ''part of the physical exam,'' she then acknowledged that ''[t]here are some things you need to do more directly; for example, you have to put your stethoscope on their chest and listen to their lungs and heart. You can't just look at them across the room and assess their heart function.'' *Id.* at 713. While Dr. Schneider testified that taking a pulse does not necessarily require a conversation, to do so she ''would take the patient's hand and with my fingers on their radial artery and count up how many times I feel it over a 15 second period'' and then multiply by four. *Id.* at 696.

examination, Respondent testified that he ''may not have'' asked RL to do a partial squat and ''probably would not have'' asked her to bend at her waist. *Id.* at 990. Respondent then testified that ''[a]nd if it's not here, I must have not asked it. But I gained the information through observation.'' *Id.*

And as for his finding that RL's hip flexor was ''R ¼, L ¾,'' Respondent testified that ''[f]our is a norm'' and that ''[i]t's more of an average of what was going on.'' *Id.* at 928. Continuing, Respondent explained: ''You know, I might of [sic] observed as she sat down she favored—she flexed one side more than—sat one way rath[er]—and guarded on [one] side. So that would be an estimation of that.'' *Id.* at 928–29. And regarding his finding RL's ''R hip tender with ROM [f]air,'' Respondent testified:

> Range of motion is how the hip moves. How the leg moves. You can watch that from the gait. You watch that from the movement. Tender would mean that I put my hand on her hip and may have pushed. May have said, ''is your pain here or is it[?]''

Id. at 929. Later, when asked on cross-examination whether he had actually asked RL to move her left leg so that he could observe her range of motion, Respondent, explained that:

> [o]ne of the tests I conduct is to have them walk in front of me . . . that shows me range of motion in their body. They move through the exam room. They sit. They stand. I shake their hands. I do all sorts of things that are range of motion tests.

Id. at 991.

On cross-examination, Respondent further testified that he did not do ''a more formal physical exam'' on RL, because he ''felt [he] gathered sufficient information to meet the needs for her first visit to begin to treat her and make a diagnosis and to make a basis for prescribing the limited amounts of medication that she was receiving.'' *Id.* at 982–83. Respondent then stated that he ''didn't perform more than what I did. But I told you—that's true.'' *Id.* at 983.

Likewise, with respect to M.L., the Government established that Respondent made findings in her patient record that she had a pulse of 80 beats per minute, a respiration rate of 18 breaths a minute, that she ''[h]a[s] decreased flexion and extension'' in her head, that her cranial nerves were intact, that her grip for both hands was a ⅖, and that she moved ''both arms in abduction and adduction.'' Tr. 650–52; RX 2, at 2. The Government then asked Dr. Schneider where in the transcript there was evidence that Respondent had performed these various tests. Tr. 653–56.

Dr. Schneider admitted that she did not see in the transcript where Respondent had taken M.L.'s pulse or measured her respiration. *Id.* at 653, 655. As for where Respondent had measured the extension and flexion of M.L.'s head, Dr. Schneider acknowledged that ''[i]t's not in there.'' *Id.* at 653. However, Dr. Schneider then testified ''that [it] is possible to tell from—sometimes from looking at a person.'' *Id.* Dr. Schneider also acknowledged that the transcript contained no indication that Respondent had done ''a formal'' cranial nerve examination, nor measured M.L.'s grip. *Id.* at 653–54. As for where in the transcript there was evidence that Respondent had ML move her arms, Dr. Schneider answered: ''[T]hat again, he may have seen just watching her.'' *Id.* at 654.

Next, the Government asked Dr. Schneider whether Respondent could rely on Dr. Skinner's examination of ML. More specifically, the Government asked:

> Q. Okay. And in your experience, is it acceptable to replace your own physical examination of the patient with the examination of someone else in your office?
>
> A. That's a good question and I don't have an exact answer because that doesn't often come up. I suppose if it's someone else who's skilled who is doing the physical exam that might be appropriate. I don't know.

Id. at 654–55.[30]

Next, the Government noted that in her letter, Dr. Schneider had stated that Respondent ''did a focused physical exam on the first visit of'' ML and asked Dr. Schneider ''where in the transcript does [Respondent] conduct a focused physical of [ML] on this occasion?'' [31] *Id.* at 655–56. Dr. Schneider answered: ''I don't see it.'' *Id.* at 656. And with regard to Dr. Schneider's statement in her letter that Respondent ''had excellent documentation of his treatment of'' ML, Dr. Schneider acknowledged that her definition of excellent documentation does not include documenting findings ''that were not actually discerned during the course of a visit.'' [32] *Id.*

Regarding ML, Respondent testified that he observed her gait and walking during his evaluation of her and that he did not do any formal test of her reflexes. *Id.* at 957. He further testified that he ''could see that there was some difficulty she had with movement of her head, range of motion,'' but that ''she did not have any neurological findings that I could—from a review of [her] cranial nerves.'' *Id.* at 958. Moreover, he acknowledged that he did not use any ''instruments to measure her flexion of her head,'' and that he had measured her grip by shaking her hands. *Id.* at 998–99. However, Respondent then stated that ''there may have been some other way'' he used to ''sense[] her grip strength,'' and that he ''probably . . . t[ook] her hands in [his] hands.'' *Id.* at 999.

And as for whether he had asked ML to move her arms in abduction or adduction, Respondent testified that ''I may have handed her something or in that sense made a prompt to move them or I may have just observed her in her natural moving around the room, sitting down, getting up, picking things up to do. It's possible that I handed her something purposefully to see if she could reach. Sometimes I do that.'' *Id.* at 1000. Respondent then testified that he did not know how he tested this,

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[30] In discussing the various instances in which Dr. Schneider acknowledged that the transcripts of the undercover visits contained no indication that Respondent had performed various tests or discussed various matters with the patients which he documented in the medical records, the ALJ noted Dr. Schneider's testimony that ''parts of the written transcript were unintelligible.'' R.D. 57 (citing Tr. 693–97). Dr. Schneider conceded, however, that she did not listen to the recordings. Tr. 711. Nor, apparently, did the ALJ listen to any of the recordings, as notwithstanding that they were part of the record, the R.D. contains no indication that he did so. However, my Office has listened to them and has concluded that none of the unintelligible parts are of sufficient duration to support the possibility that Respondent actually performed various tests or had various discussions which he documented in the patient records as having done but which did not appear in the transcripts.

[31] Regarding what constitutes ''a focused physical exam,'' Dr. Schneider testified:

> It's when you concentrate on one particular part of the body. So for example, if someone has back pain, you watch how they get up, you watch how they sit down, you watch how they move, you watch how they pick up something and you can get some conclusions without doing a formal one. Ideally, you'd want to do a formal one, but it is possible to gather information from observing the patient.

Tr. 664.

[32] In its Exceptions, the Government also cites to its cross-examination of Dr. Schneider regarding the statements in her letter that, at ML's second visit, Respondent performed ''a focused physical exam'' and that ML had ''said her pain had decreased to 3/10 on [the] current dose.'' Exceptions at 3–4 (citing Tr. 662–64); *see also* RX 23, at 2. When questioned about these statements in her letter, Dr. Schneider conceded that the transcript did not reflect that Respondent had done a focused physical exam, but added that ''he could have been observing her as he talked with her.'' Tr. 664. Dr. Schneider also acknowledged that the transcript contained no indication that ML had said her pain had decreased to three out of ten. *Id.* at 663. While in her letter, Dr. Schneider made no mention as to whether Respondent had tested ML's grip at the second visit, Dr. Schneider acknowledged that the transcript contained no indication that he had tested ML's grip even though he documented in the progress note having done so. *Id.* at 663; *see also* RX 2, at 1.

because he did not ''remember specifically.'' *Id.*

Regarding the scope of the examination he performed on M.L., Respondent explained that:

> The focus on this patient was not a hip. It was neck and back. So the focused examination in my focus would have been on her mobility and her movements and her functions in that area. So that would be—I'd be looking at upper extremities. That there was no wasting of her arms. I could see her, I believe from this examination, I could see her arms and movement of her arms and movement of her head and again, we talked about how we can do pulse and we can do respirations. We talked about gait. That didn't seem to be the main issue.
> *Id.* at 959.

Respondent further explained that Dr. Skinner is a naturopath ''who is very adept at diagnosing neck and shoulder injuries.'' *Id.* at 963. He testified that he ''brought her in to look at [ML] and give me a second opinion.'' *Id.* Respondent then explained that:

> She put her hands on the patient. I put my hands on the patient. We were looking for muscle spasm. We were looking for range of motion and Dr. Skinner then probably did do some kind of stretching or some kind of manipulation to see if that would relieve some of the spasm which was probably in this patient's neck.
> *Id.*[33]

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . *has committed such acts* as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4) (emphasis added). With respect to a practitioner, the Act requires the consideration of 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 manufacture, 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.
> *Id.* § 823(f).

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.'' *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 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 (quoting *Hoxie,* 419 F.3d at 482)).[34]

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. § 824(a) are met. 21 CFR 1301.44(e). However, ''once the [G]overnment establishes a prima facie case showing a practitioner has committed acts which render his registration inconsistent with the public interest, the burden shifts to the practitioner to show why his continued registration would be consistent with the public interest.'' *MacKay,* 664 F.3d at 817 (citing *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (citing cases)).

Having considered all of the factors, I agree with the ALJ's conclusion that the Government's evidence with respect to factors two (Respondent's experience in dispensing controlled substances) and four (Respondent's compliance with applicable controlled substance laws), establishes that Respondent has committed acts which render his registration inconsistent with the public interest.[35] 21 U.S.C. 824(a)(4). While I also agree with the ALJ's conclusion that Respondent has accepted responsibility for his misconduct and put forward evidence as to his remedial measures, I reject the ALJ's recommended sanction because the ALJ failed to consider the egregiousness of Respondent's misconduct and the Agency's interest in deterring others from engaging in similar acts. Accordingly, I will order that Respondent's registration be suspended for a period of one year.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an

[33] The Government also introduced an affidavit from BO, a person who, in March 2009, saw Respondent for her depression. GX 19. In her affidavit, BO related that ''[w]hile in the waiting room, I heard other patients speaking about oxycodone'' and that ''these other patients were exchanging information regarding which pharmacies had stock of certain dosages and in what quantities.'' *Id.* at 1. Even assuming that BO's affidavit bears substantial indicia of reliability (such that it could constitute substantial evidence), there is no evidence that Respondent was aware of this discussion. Moreover, while BO also related that she overheard a conversation between Respondent and an employee in which the former stated that ''a pharmaceutical representative had just informed him that he could make a lot of money if he were to dispense medications directly from his office, because [he] would get a percentage of money from each prescription filled in-house,'' even assuming that this constitutes an admission, it does not establish any wrongdoing. *Id.* at 2. Finally, while BO stated that Respondent gave her prescriptions for Ambien (zolpidem), a schedule IV controlled substance, as well as Cymbalta and Depakote, two non-controlled medications, the record does not establish that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing the Ambien. *Id.* at 2–3.

[34] In short, this is not a contest in which score is kept; 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,* 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.

[35] As for factor one, the recommendation of the state licensing authority, the ALJ found that the AMB's restoration of Respondent's authority to prescribe opioids in August 2011, ''[w]hile not dispositive . . . does weigh against a finding that Respondent's continued registration would be inconsistent with the public interest.'' R.D. at 48. Even assuming that the Board's restoration constitutes a recommendation to the Agency that Respondent's registration be continued, DEA has repeatedly held that while a practitioner's possession of state authority constitutes an essential condition for maintaining a registration, *see* 21 U.S.C. §§ 802(21) & 823(f), it '' 'is not dispositive of the public interest inquiry.' '' *George Mathew,* 75 FR 66138, 66145 (2010), *pet. for rev. denied Mathew* v. *DEA,* No. 10–73480, slip op. at 5 (9th Cir., Mar. 16, 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie,* 68 FR 15227, 15230 (2003). As the Agency has long held, ''the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Mortimer Levin,* 57 FR 8680, 8681 (1992). Thus, this factor is not dispositive either for, or against, the continuation of Respondent's registration. *Paul Weir Battershell,* 76 FR 44359, 44366 (2009) (citing *Edmund Chein,* 74 FR 6580, 6590 (2007), *pet. for rev. denied Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

Regarding factor three, there is no evidence that Respondent has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. However, as there are a number of reasons why a person may never be convicted of an offense falling under this factor, let alone be prosecuted for one, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is thus not dispositive. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011).

individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *See United States* v. *Moore,* 423 U.S. 122, 142–43 (1975); *United States* v. *Lovern,* 590 F.3d 1095, 1100–01 (10th Cir. 2009); *United States* v. *Smith,* 573 F.3d 639, 657 (8th Cir. 2009); *see also* 21 CFR 1306.04(a) (''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances'').

As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *Moore,* 423 U.S. 122, 135, 143 (1975)).

Both this Agency and the federal courts have held that ''establishing a violation of the prescription requirement 'requires proof that the practitioner's conduct went ''beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence.'' ' '' *Laurence T. McKinney,* 73 FR 43260, 43266 (2008) (quoting *United States* v. *McIver,* 470 F.3d 550, 559 (4th Cir. 2006). *See also United States* v. *Feingold,* 454 F.3d 1001, 1010 (9th Cir. 2006) (''[T]he *Moore* Court based its decision not merely on the fact that the doctor had committed malpractice, or even intentional malpractice, but rather on the fact that his actions completely betrayed any semblance of legitimate medical treatment.''); *Jack A. Danton,* 76 FR 60900, 60904 (2011) (finding violations of 21 CFR 1306.04(a), in the absence of expert testimony, ''where a physician has utterly failed to comply with multiple requirements of state law for evaluating her patients and determining whether controlled substances are medically indicated and thus has '''completely betrayed any semblance of legitimate medical treatment'''') (quoting *McKinney,* 73 FR at 43266 (quoting *Feingold,* 454 F.3d at 1010)).

However, as the Agency has held in multiple cases, ''the Agency's authority to deny an application [and] to revoke an existing registration . . . is not limited to those instances in which a practitioner intentionally diverts a controlled substance.'' *Bienvenido Tan,* 76 FR 17673, 17689 (2011) (citing *Paul J. Caragine, Jr.,* 63 FR 51592, 51601 (1998)); *see also Dewey C. MacKay,* 75 FR at 49974. As *Caragine* explained: ''[j]ust 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 or the denial of an application for a registration. 63 FR at 51601.

''Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.'' *MacKay,* 75 FR at 49974; *see also Patrick K. Chau,* 77 FR 36003, 36007 (2012). Likewise, ''[a] practitioner who ignores the warning signs that [his] patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. § 824(a)(4), even if [he] is merely gullible or naïve.'' *Jayam Krishna-Iyer,* 74 FR 459, 460 n.3 (2009); *see also Chau,* 77 FR at 36007 (holding that even if physician ''did not intentionally divert controlled substances,'' State Board Order ''identified numerous instances in which [physician] recklessly prescribed controlled substances to persons who were likely engaged in either self-abuse or diversion'' and that physician's ''repeated failure to obtain medical records for his patients, as well as to otherwise verify their treatment histories and other claims, created a substantial risk of diversion and abuse'') (citing *MacKay,* 75 FR at 49974).

In this matter, the Government alleged that Respondent violated the prescription requirement with respect to both the patients who were the subject of the AMB Orders and the undercover visitors. Notably, in his post-hearing brief, Respondent acknowledges that ''the First and Second Consent Order establish violations of Arizona State law, as explained more fully in the Orders.'' Resp's. Proposed Findings of Fact, Conclusions of Law and Argument 33. Moreover, in his post-hearing brief, Respondent states that he ''is prepared to concede that the Government established a prima facie case for revocation . . . on the basis of the portions of the Second Consent Order . . . that he did not challenge for factual insufficiency.'' *Id.* at 34. However, with respect to the first AMB Order, which involved his treatment of DK, while Respondent acknowledged that he ''should have obtained past medical records sooner'' and should have more carefully monitored her use of medication, he rejects other findings of the AMB. *Id.* at 38.

The ALJ found that ''Respondent issued controlled substance prescriptions to multiple patients referenced in the 2009 Agreement and 2010 Order for other than a legitimate medical purpose and outside the usual course of professional practice in violation of applicable state and federal law.'' ALJ at 54–55 (citing 21 CFR 1306.04(a); Ariz. Rev. Stat. § 32–1401(27)(a), (e) & (q)). Indeed, notwithstanding that the ALJ improperly allowed Respondent to challenge the Board's findings both as to historical facts regarding his treatment of the various patients and the standard of care, Respondent's evidence only addressed four of the patients. Thus, even were I to give weight to this evidence (which—like the ALJ—I do not), the Government's evidence still establishes that Respondent committed violations of the prescription requirement with respect to numerous patients, as Respondent himself concedes.

To be clear, the Board's findings with respect to many of the patients establish not simply that Respondent ''committed malpractice, or even intentional malpractice, but rather . . . that his actions completely betrayed any semblance of legitimate medical treatment,'' *Feingold,* 454 F.3d at 1010, and thus, that he intentionally or knowingly diverted controlled substances. More specifically, the AMB found that the standard of care requires that when treating a patient for chronic pain, a physician must obtain prior records for the past treatment of the pain, as well as obtain any objective measures for the cause of pain, and that Respondent failed to do so. Also, the AMB found that Respondent failed to adequately document his reasoning for prescribing high dose opioids as well as other drugs he added, as well as his treatment plan.

Moreover, even Respondent's Expert acknowledged that in various instances, Respondent failed to perform a physical examination on the first visit, notwithstanding that Arizona law clearly required that he do so. Tr. 597–98; *see also* Ariz. Rev. Stat. § 32–1401(27)(ss) (deeming it ''[u]nprofessional conduct'' to ''[p]rescrib[e], dispens[e], or furnish[] a

prescription medication . . . to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship'').

The AMB also found that Respondent violated the standard of care because he prescribed high dose opioids without performing *adequate* physical exams. For example, with respect to ML, the AMB found that Respondent diagnosed him with spondylolisthesis based on ML's report and prescribed oxycodone to him, but did not perform a facet, sacroiliac joint, myofascialpain or neural flexes examination, nor test him for weakness or numbness. The Board also found that Respondent did not order various tests such as flexion extension films or an MRI scan, and that he also failed to obtain ML's past medical records and diagnostic studies. Most significantly, the Board found in ML's chart an x-ray, dated eighteen months after Respondent diagnosed ML as having spondylolisthesis, which stated: ''no evidence of spondylolisthesis.''

Yet, notwithstanding that the x-ray contradicted his diagnosis and his failure to conduct necessary tests, the Board found that Respondent provided ML with multiple early refills of oxycodone from February through December 2008.[36] Moreover, the Board found that while in June 2008, Respondent was notified that ML was undergoing methadone treatment at a facility, he did not obtain ML's records from the facility. And while in January 2009, Respondent discharged ML from opioid therapy, two months later he resumed prescribing high does opioids without documenting an explanation. The Board also found that even after the 2009 Order placed Respondent on probation by the 2009 Order, he continued to prescribe high dose opioids to ML ''for pain secondary to spondylolisthesis until September 2009.''

In addition, Respondent's Expert acknowledged that Respondent had continued to prescribe oxycodone to ML, notwithstanding several aberrant urine drug tests. *See* Tr. 675–77. For example, ML tested positive for cocaine, as well as benzodiazepines (twice) which Respondent had not prescribed to him on previous visits. Still another time, ML tested negative for oxycodone, notwithstanding that Respondent continually prescribed the drug to ML and even provided him with numerous early refills.

As the AMB found, prior to initiating high dose opiate therapy, the standard of care requires a physician to perform an adequate exam for pain generators. Moreover, the AMB found that the standard of care requires that a physician obtain the patient's past medical records and diagnostic studies, offer the patient adjunct treatments that include non-opioid medications and physical therapy, address aberrant drug seeking behaviors and refrain from prescribing more than one month of schedule II prescriptions at a time. The Board found that Respondent deviated from the standard of care because he did not perform an adequate exam prior to initiating high dose opiate therapy, he did not obtain ML's past medical records and diagnostic studies, he did not offer adjunct treatments, he did not address ML's aberrant drug-seeking behaviors, nor did he refrain from prescribing more than one month of schedule II prescriptions at a time.[37]

While the Board also found that Respondent violated Arizona law and committed unprofessional conduct by failing to maintain adequate records, the Board's findings establish that Respondent did far more than fail to comply with recordkeeping requirements. Rather, the Board's findings establish that Respondent's prescribing of oxycodone to ML '''completely betrayed any semblance of legitimate medical treatment''' and thus violated 21 CFR 1306.04(a). *Danton,* 76 FR 60900, 60904 (2011) (quoting *McKinney,* 73 FR at 43266 (quoting *Feingold,* 454 F.3d at 1010)).

As the Supreme Court explained in *Moore* in upholding the criminal conviction of a physician for unlawfully distributing controlled substances under circumstance similar to those found by the Board:

> The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of 'professional practice.' As detailed above, he gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He . . . took no precautions against . . . misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded.

Moore, 423 U.S. at 142–43.

Likewise, the Board found that Respondent prescribed multiple controlled substances including OxyContin 40 mg, oxycodone 30 mg and Adderall to JF for conditions including chronic pain, attention deficit disorder, and obsessive compulsive disorder. While JF reported at her first visit (August 31, 2007) that her current prescriptions were OxyContin 40 mg and oxycodone 30 mg, the Board found that he did not obtain her past medical records to confirm the diagnosis and her prescriptions; he also did not document having performed a physical examination. Yet he prescribed 90 tablets of OxyContin 40 mg and 45 tablets of oxycodone 30 mg to her. Moreover, in October 2007, Respondent added Adderall, another schedule II controlled substance, to her ''medication regime without any rationale for the medication.'' GX 18, at 5.

The Board further found that on multiple occasions during the course of her treatment, JF reported that her prescriptions had been stolen or damaged, that she had run out of medication, and that a pharmacy had refused to fill a prescription because of different handwriting. Nonetheless, Respondent continued to prescribe the drugs and increased the doses of oxycodone and Adderall. As the Board found, there was no documentation that Respondent ordered any laboratory studies to support his continued prescribing of the three drugs. Nor was there any documentation that Respondent had JF undergo urine drug screens to determine if she ''was taking the medication as prescribed and/or whether she was utilizing illicit substances.'' *Id.* at 6.

With respect to his prescribing of OxyContin and oxycodone to JF for the treatment of chronic pain, the Board found that the standard of care ''requires a physician to review diagnostic studies and interventions, assess the chronic pain complaint prior to initiating an opioid trial, appropriately monitor the patient's use of the medication, and obtain appropriate therapeutic and laboratory test results that support the diagnosis.'' *Id.* The Board further found that ''Respondent deviated from the standard care because he did not review past medical records and he did not order appropriate tests or consultations for JF.'' *Id.*

As for his treatment of JF's psychiatric conditions, the Board found that

[36] The Board also found that Respondent provided multiple early refills of oxycodone to ML during the period from January through December 2007. It further found that while in November 2007, Respondent had determined that ML had self-escalated his oxycodone dosing, Respondent did not document having cautioned ML to adhere to the dosing instructions.

[37] The Board found that the standard of care when treating a patient for chronic pain is to obtain objective measures as to the cause of pain. 2010 Order, at 16. It found that Respondent violated the standard of care by continuing to treat ML's reported pain with high-dose opioids without obtaining objective measures for the cause of his pain, and that his conduct could result in the perpetuation of ML's drug-seeking behavior/addiction or an overdose. *Id.* In addition, the Board found that there was potential for diversion or abuse of the oxycodone. *Id.* at 10.

Respondent ''did not perform an adequate psychiatric evaluation'' of her and thus ''deviated from the standard of care.'' *Id.* The Board also found that Respondent deviated from the standard care because he prescribed Adderall to JF without ''perform[ing] tests to confirm the diagnosis and the necessity of the medication'' and did not monitor her ''use of the medication.'' *Id.* And because ''[t]here was no collateral information to support prescribing Adderall,'' the Board concluded that this ''creat[ed] a potential for misdiagnosis, addiction, abuse, misuse, overdose, and diversion.'' *Id.*

Finally, the Board found that Respondent's records for JF ''were inadequate because he did not obtain [her] past medical records, he did not document a physical examination prior to prescribing medications and he did not document any rationale for the prescriptions, dosage escalations, and additions of medication.'' *Id.* at 7. Here again, the Board's findings establish that Respondent's prescribing of controlled substances to JF '''completely betrayed any semblance of legitimate medical treatment''' and support the conclusion that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed schedule II opioids (OxyContin and oxycodone) and Adderall (a schedule II stimulant) to her. *See* 21 CFR 1306.04(a). Accordingly, I hold that Respondent knowingly diverted controlled substances to JF.

Of similar consequence, the Board found that Respondent prescribed both OxyContin and oxycodone to patients DD, SS, AM, and MF ''based on [their] reported history and complaints of chronic pain.'' *Id.* at 7. Here again, the Board found that ''[t]here was no documentation that Respondent obtained the patients' past medical record to confirm the diagnoses,'' that ''he did not perform adequate physical examinations,'' and that he did not ''order diagnostic and laboratory studies.'' *Id.*

The Board further found that while ''Respondent provided early refills and escalated the patients' doses of [o]xycodone and OxyContin,'' he neither ''document[ed] a rationale to support his diagnosis or [his] prescribing.'' *Id.* Nor did he ''perform[] any urine drug screens to determine whether the[se] patients were taking the medications as prescribed and/or illicit substances.'' *Id.*

Here again, the Board found that ''Respondent deviated from the standard of care because he did not review [the four patients'] past diagnostic studies and interventions, assess and confirm their chronic pain complaints prior to initiating an opioid trial, appropriately monitor their use of the medication, or obtain appropriate therapeutic and laboratory test results to support his diagnoses of chronic pain.'' *Id.* at 8. The Board further found that because ''[t]here was no collateral information to support prescribing opioids to [the four patients],'' Respondent ''creat[ed] [the] potential for misdiagnosis, addiction, abuse, misuse, overdose, and diversion.'' *Id.*

Finally, the Board found that ''Respondent's records were inadequate because he did not obtain [the four patients'] past medical records; he did not document adequate physical examinations or laboratory and diagnostic studies prior to prescribing medications; he did not obtain any diagnostic studies to support his continued prescribing of medications[;] and he did not document any rationale for [the] prescriptions and dosage escalations.'' *Id.* at 8–9. Here again, the Board's findings with respect to these four patients establish more than that Respondent failed to keep adequate records. Rather, they establish that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed OxyContin and oxycodone to DD, SS, AM, and MF.[38] 21 CFR 1306.04(a).

The Board also made findings regarding Respondent's prescribing of Adderall to two patients (AL and KF) that establish violations of the prescription requirement. Specifically, the Board found that Respondent diagnosed AL with Attention Deficit Hyperactivity Disorder and prescribed Adderall to her. GX 18, at 2. The Board found, however, that Respondent deviated from the standard of care because he did not perform an adequate psychiatric evaluation of AL. *Id.* Moreover, the Board found that there was no documentation that Respondent obtained her past medical records, her history of alcohol or substances abuse, her psychiatric history or that he ''perform[ed] a functional assessment to support the diagnosis and prescription.'' *Id.* Respondent also failed to document a treatment plan. *Id.*

The Board further found that over a twenty-seven month period, ''Respondent provided AL with frequent, early and escalated doses of Adderall'' but did not document a rationale for doing so. *Id.* And the Board found that ''on several occasions[,] AL attempted to refill her Adderall prescription early,'' yet Respondent did not document that he ''investigated or addressed AL's rationale for doing so.'' *Id.* In addition, Respondent prescribed Lorazepam, a schedule IV benzodiazepine to AL, ''without documenting a rationale for'' doing so and that he did not ''discuss[ ] the risks and benefits of taking'' the drug. *Id.* Finally, the Board found that there ''was no documentation that Respondent ordered any laboratory studies to support his continued prescribing of Adderall or any urine drug screens to determine whether AL was taking the medication as prescribed and/or illicit substances.'' *Id.*

Thus, in addition to finding that Respondent deviated from the standard of care because he failed to perform an adequate psychiatric evaluation of AL, the Board found that he committed an additional deviation ''because he did not confirm the diagnosis and the necessity of the medication and he did not monitor AL's use of the medication.'' *Id.* at 3.[39] These findings support the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed Adderall to AL. 21 CFR 1306.04(a).

Likewise, with respect to KF, the Board found that Respondent prescribed Adderall to her, yet ''[t]here was no documentation that [he] obtained her past medical record or ordered any laboratory tests that would qualify KF for a diagnosis to support the use of Adderall.'' GX 18, at 4. Moreover, the Board found that ''Respondent prescribed frequent early refills without documenting any rationale for the prescriptions,'' and that he ''increased KF's dose from 20mg to 30 mg without any rationale'' for doing so. *Id.* Also, the Board found that ''[t]here was no documentation that Respondent ordered any laboratory studies to support his

[38] Even if I were to give weight to Dr. Schneider's testimony in which she maintained that the Board's consultant made findings with respect to patients AM, MF and SS that were contradicted by the respective patient's chart, I would still adopt the Board's findings. As explained above, the AMB's findings cited multiple ways in which Respondent deviated from the standard of care, and Respondent offers no argument as to why, even if the Board's consultant may have overlooked several items, these errors would have materially affected the Board's conclusions. And here again, Respondent could have, and should have, presented Dr. Schneider's evaluation to the Board.

[39] Finally, the Board found that Respondent failed to maintain adequate records ''because there was no documentation of the initial Adderall prescription, no documented initial plan of treatment, the psychiatric evaluation was inadequate, there was no documented rationale for his prescribing of several medications, and several of his progress notes were illegible.'' GX 18, at 3.

continued prescribing of Adderall or any urine drug screens to determine whether KF was taking the medications as prescribed and/or any illicit substances.'' *Id.*

The Board thus found that ''Respondent deviated from the standard care because he did not obtain prior medical records, perform tests to confirm the diagnosis and the necessity of the medication,'' ''did not perform an adequate psychiatric evaluation for KF,'' and ''did not monitor [her] use of the medication.'' *Id.* The Board also found that because ''[t]here was not collateral information to support prescribing Adderall,'' Respondent ''created [the] potential for misdiagnosis, addiction, abuse, misuse, overdose and diversion.'' [40] *Id.* The Board's findings thus also support the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing Adderall to KF. 21 CFR 1306.04(a).

The Board also made extensive findings regarding Respondent's prescribing of schedule II opioids to WO for the latter's chronic pain over an eighteen-month period. GX 18, at 11–13. While WO had previously been treated by another physician, who prescribed to him both oxycodone and morphine sulfate, and Respondent reviewed several imaging studies, the Board found that the studies ''did not support the amount of opioid medications [Respondent] prescribed to WO.'' *Id.* at 11, 13. The Board also found that ''[t]here was no documentation that Respondent performed a neurological or musculoskeletal examination or ordered any imaging studies of WO's lumbar spine or laboratory studies prior to continuing the treatment of WO's previous treating physician.'' *Id.* at 11.

Moreover, the Board found that Respondent both increased the dose of oxycodone and added an additional drug, MS Contin, the dose of which he also ''subsequently increased,'' and yet did not document having ''performed any physical examinations or [having] obtained any radiological studies to support his increased opioid prescribing.'' *Id.* at 12. Nor did he document ''a rationale for the increase'' in the MS Contin dosing. *Id.* The Board further found that later in his treatment of WO, Respondent further increased the dose of oxycodone ''to eight tablets per day without documenting a rationale for the increase.'' *Id.*

Next, the Board found that approximately one month after the latter increase in WO's oxycodone dosage, Respondent obtained a urine drug screen from WO. *Id.* However, the results were negative for oxycodone but positive for both methadone and codeine, even though Respondent had not prescribed either of the latter two drugs. *Id.* Moreover, WO's drug screen was positive for heroin. *Id.*

While the Board found that ''Respondent documented that he was aware of the positive'' test results, it further found that ''he did not adequately investigate or address the abnormal results, which include referring WO to an addiction medicine specialist or discontinuing the opioid prescriptions.'' *Id.* The Board thus also found that ''Respondent allowed WO to continue a pattern of illicit substance use and opioid misuse.'' *Id.* at 13.

Accordingly, the Board found that Respondent ''deviated from the standard of care'' because ''he did not perform an adequate workup of WO prior to continuing the treatment of his previous treating physician,'' prescribed opioids in amounts that were not supported by ''the physical examination and radiological data,'' and ''did not adequately investigate or address WO's abnormal urine drug screens.'''' *Id.* at 12–13.[41] Here again, the Board findings support the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to WO.[42] 21 CFR 1306.04(a).

Finally, in the 2009 Order, the Board made extensive findings regarding Respondent's prescribing to DK, a self-referred patient who complained of lower back pain and psychiatric issues. GX 17, at 4. At her initial visit, DK reported that she was currently taking OxyContin 160 mg, three times per day; oxycodone 30 mg, two tablets, one to two times daily; and Valium; RX 30, at 40. She also reported that imaging studies and x-rays had been done three years earlier. *Id.* However, while at the initial visit, DK said she would provide her medical records, including these imaging studies, to Respondent, and Respondent asked her to do so on four additional visits, she did not comply for more than a year. *Id.; see also* GX 17, at 4. Regarding DK's noncompliance, Respondent testified that she either ''could not remember or give us the name [of her previous physician] or produce records.'' Tr. 851–52; *see also id.* at 1027.

Yet, notwithstanding her non-compliance, Respondent issued monthly prescriptions to DK for OxyContin 80 mg (initially for 180 tablets, but after several months, increasing to 210 tablets) and oxycodone 30 mg (typically 180 tablets). RX 30, at 40. This continued for nearly one year and until Respondent was notified that another physician had recently discharged her (in the prior month, no less) for violating her pain contract by using cocaine, as well as methadone which had not been prescribed to her. Indeed, only then did he take any action. Notably, Respondent failed to do any urine drug screens on DK from November 2006, when he first began prescribing to her, until June 3, 2008.

According to the Board, under the standard of care, a physician who ''continu[es] high dose opioid prescriptions for a self-referred, chronic pain management patient . . . who reports currently being prescribed high dose opioid medications,'' must base the prescriptions ''on proper indications, including previous medical records and verified previous prescriptions, and/or contact with the previous prescribing physician.'' GX 17, at 5. The Board thus found that ''Respondent deviated from the standard of care by prescribing high dose opioids to DK without proper indications.'' *Id.* Also, the Board found that the standard of care requires that a physician ''treating a chronic pain patient [with] known or suspected substance abuse problem . . . to utilize objective measures to monitor compliance.'' *Id.* The Board thus also found that ''Respondent deviated from the standard of care by failing to timely use objective measures, such as urine drug tests, to assess DK's compliance with her treatment even after he was aware of her cocaine addiction.'' *Id.* The deviations of the standard of care found by the Board are sufficient to support the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in

[40] Here again, the Board found that ''Respondent's records were inadequate because he did not obtain KF's past medical records, he did not document a physical examination prior to prescribing medications, he did not document any rationale for prescriptions, dosage escalations, and additions of medication.'' *Id.* at 5.

[41] The Board also found that Respondent failed to maintain adequate records ''because there was no documentation that [he] performed neurological or musculoskeletal examination or ordered any imaging or laboratory studies prior to continuing the treatment and there was no documented rationale for his excessive prescribing of opioids.'' GX 18, at 13.

[42] It is noted that the Board faulted Respondent because he did not obtain imaging studies of WO's lumbar spine. GX 18, at 11. My conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose is based on the totality of the Board's findings and the multiple deviations of the standard of care which it found.

prescribing OxyContin and oxycodone to DK.[43] *See* 21 CFR 1306.04(a).

The Undercover Patients

The ALJ concluded that the Government did not establish that the Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to RL and ML, the two undercover visitors. R.D. at 60. The Government takes exception to these findings, contending that ''[t]he evidence . . . shows that, on four occasions, Respondent prescribed controlled substances to [ML and RL] without ever conducting a physical examination,'' and thus the prescriptions were issued in violation of Ariz. Rev. Stat. § 32–1401(27)(ss), which provides that it is ''unprofessional conduct'' to prescribe ''a prescription medication . . . to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship,'' and thus also violated federal law. Exceptions at 3 (also citing 21 CFR 1306.04(a)).

As support for its contention, the Government cites the testimony of a Special Agent as to hearsay statements that were made by the two confidential sources to the effect that Respondent did not perform a physical examination on them. *Id.* (citations omitted). It also argues that ''Respondent's own expert testified that Respondent failed to conduct a physical examination of either CS1 or CS2 prior to issuing them prescriptions for controlled substances.'' *Id.* (citations omitted).

As for the hearsay statements of the confidential sources, the Government offered no evidence to support a finding that each statement is sufficiently reliable to constitute substantial evidence. *See Carlos Gonzalez,* 76 FR 63118, 63119 (2011) (citing various appellate decisions regarding factors which support a finding that hearsay statements are sufficiently reliable). And while Respondent's Expert admitted that she did not see in the transcripts of the undercover visits where Respondent had performed a physical examination at either RL or ML's first visit, as found above, I cannot ignore that the transcripts and recordings manifest that at each of the CS's first visits, either Respondent (or Dr. Skinner) palpated them in the area of their body which was the source of their purported pain complaint. Thus, the testimony of Respondent's Expert does not corroborate the hearsay statement of either RL or ML.

It may be that the physical exams Respondent performed on RL and ML were totally inadequate to validly diagnose them as having a legitimate pain condition and to support the prescribing of controlled substances. However, while Arizona law requires that a physician perform a physical exam before he initially prescribes a drug, it does not set forth what is required to constitute an adequate examination. Moreover, while Respondent's Expert repeatedly attempted to minimize his misconduct,[44] thus suggesting a less than objective portrayal on her part of Respondent's prescribing practices, even were I to reject the ALJ's credibility finding regarding her testimony that Respondent's prescribing to the two CSs was ''well within the standard of care,'' I would still reject the Government's contention because it had the burden of proving by substantial evidence that these four prescriptions violated 21 CFR 1306.04(a).[45] Here, because the transcripts clearly showed that Respondent palpated (or observed Dr. Skinner palpate[46]) the CSs, and the transcripts otherwise contain no statements by either the CSs or Respondent indicating that either CS was not a legitimate patient, expert testimony was required to show that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the two CSs. Accordingly, I reject the Government's exception and adopt the ALJ's findings with respect to the undercover patients.

Sanction

Based on his findings that Respondent acted outside of the usual course of

[43] While the Board faulted Respondent for his ''continu[ing] to prescribe opiates to DK for her back pain'' after she was referred to Behavioral Health, as well as his continued prescribing of opiates after ''he learned that she had successfully completed inpatient opioid detoxification,'' GX 17, at 5; the Board did not find that either course of conduct constituted a deviation from the standard of care. *See id.* Nor did the Government offer any expert testimony as to whether Respondent's prescribing of opiates following DK's referral to Behavioral Health or following her completion of inpatient opioid detoxification was within usual course of professional practice and lacked a legitimate medical purpose.

As for Respondent's continued prescribing to DK, notwithstanding that she purportedly could not remember the name of the physician who had previously (and likely was also continuing to prescribe to her), as well as her repeated failure to provide her medical records, the federal courts have held that knowledge can be inferred based on the ''willful blindness'' of a physician in ignoring various warning signs that a patient is either abusing or diverting drugs. *United States* v. *Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006). *See also United States* v. *Jewell,* 532 U.S. 697, 702–704 (9th Cir. 1976) (discussing deliberate ignorance instructions, noting that ''Courts of Appeals reviewing the sufficiency of evidence have approved the premise that 'knowingly' in criminal statutes is not limited to positive knowledge, but includes the state of mind of one who does not possess positive knowledge only because he consciously avoided it'').

Even if I believed that Respondent was merely naïve or gullible in his treatment of DK, which I do not, I would conclude that Respondent is so irresponsible as to raise grave doubts as to his fitness to hold a registration.

[44] For example, in her letter of May 27, 2011, Dr. Schneider, in an apparent reference to the Board's findings, characterized Respondent's problematic practices as ''past minor deficiencies.'' RX 23, at 3. Likewise, in her testimony, she asserted that the Arizona Medical Board's guidelines on using controlled substances to treat chronic pain were not even minimum standards but were aspirational and ''to educate doctors.'' Tr. 588. She further asserted that physicians were ''being judged by standards of care that are current [but] that were not the standard of care at the time that those visits took place,'' *id.* at 586, as if the standards had actually changed between the time Respondent prescribed to the patients identified in the two AMB Orders and the period during which the Board conducted its review.

So too, when asked whether the standard of care requires a physician to obtain medical records before providing the first prescription, she asserted that she did not ''think that most doctors actually get the records before providing a first prescription.'' *Id.* at 589. While she then acknowledged that it was risky if patients ''come in and what they want is super high doses, . . . it's risky to let them walk out with a prescription in the absence of any documentation that they indeed were on that dose because that could be lethal,'' she then added that ''[t]he doses we're talking about with [Respondent] were often minimal doses,'' *id.,* as if the amounts and dosages he prescribed to DK at her first visit were minimal. Finally, while Dr. Schneider noted that there were instances in which Respondent did not do a physical exam on the first visit, this, notwithstanding the requirements of Arizona law, *see* Ariz. Rev. Stat. § 32–1401(27)(ss), is, in her view, just one of the ''things that could be improved'' because Respondent ''really need[s] education.'' Tr. 598.

[45] Put another way, it was not Respondent's burden to prove that the prescriptions were lawful. Thus, in the absence of probative and reliable evidence that the prescriptions were unlawful, Respondent had no obligation to refute the charge.

[46] The Government also asked Dr. Schneider as to whether Respondent could rely upon Dr. Skinner's examination of ML. Dr. Schneider testified that she did not ''have an exact answer because that doesn't often come up. I suppose if it's someone else who's skilled who is doing the physical that might be appropriate.'' Tr. 654–55. Dr. Schneider then added that she did not know. *Id.* at 655. However, it was the Government's obligation to establish that under the standard of care, a physician cannot observe another physician examine a patient and rely on those observations as part of performing a physical exam and not Respondent's obligation to show that it is within the standard of care.

As for the Government's contention that Respondent also failed to physically examine the CSs at their second visits, the Government offered no evidence that the standard of care requires that a physician perform a physical exam at each visit at which he prescribes a controlled substance. Indeed, the statute relied on by the Government suggests the opposite, as it permits prescribing where a physician ''has previously established a doctor-patient relationship.'' Ariz. Rev. Stat. § 32–1401(27)(ss).

professional practice and lacked a legitimate medical purpose in prescribing controlled substances to numerous patients, the ALJ found that the Government had met its *prima facie* burden of showing that ''Respondent has committed acts inconsistent with the public interest between 2006 and 2009.'' R.D. at 65. However, based on his finding that Respondent had ''credibly accepted responsibility for his past misconduct and demonstrated that he has implemented various corrective measures to ensure that his medical practice is consistent with the public interest,'' *id.* at 64, the ALJ recommended that Respondent's registration should be continued subject to the condition that he comply with all terms of the AMB's 2010 Order and notify the DEA field office of any changes in the terms and conditions of the AMB's 2010 Order. *Id.* at 65–66.

Under Agency precedent, where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must ' ''present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'' ' '' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 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), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie v. DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

However, while a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2010) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

Moreover, as I have noted in several cases, '''[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.''' *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504 (2007)); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Michael S. Moore,* 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

Thus, in *Gaudio,* ''I explained that 'even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts.' '' 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504) (citing *Butz v. Glover Livestock Commission Co., Inc.,* 411 U.S. 182, 187–88 (1973)); *cf. McCarthy,* 406 F.3d at 189 (''Although general deterrence is not, by itself, sufficient justification for expulsion or suspension, we recognize that it may be considered as part of the overall remedial inquiry.''); *Paz Securities, Inc., et al.* v. *SEC,* 494 F.3d 1059, 1066 (D.C. Cir. 2007) (agreeing with *McCarthy*). In *Gaudio,* I further noted that the ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest, *see* 21 U.S.C. § 801, and the broad grant of authority conveyed in the statutory text, which authorizes the [suspension or] revocation of a registration when a registrant 'has committed such acts as would render [his] registration . . . inconsistent with the public interest,' *id.* § 824(a)(4), and [which] specifically directs the Attorney General to consider ['such other conduct which may threaten public health and safety,' *id.* § 823(f)].'' 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504).[47]

While noting that ''[a]gency precedent has recognized the significance of a registrant's remedial actions in continuing a registration,'' R.D at 63, the ALJ entirely ignored the *Southwood/Gaudio* line of authority. *See id.* at 63–65. However, as these cases make clear, even where a registrant accepts responsibility and demonstrates that he has undertaken remedial measures, in determining the appropriate sanction, the Agency can still consider the need to deter both the particular registrant, as well as others, from engaging in similar acts.

For example, in *Gaudio,* a case in which a physician was found to have recklessly dispensed controlled substances over the internet, I noted that ''even were I to ignore that Respondent has not accepted responsibility for his misconduct, and credit his testimony that he does not intend to resume his internet practice, I would still conclude that a lengthy suspension of his registration is warranted.'' 74 FR at 10095.[48] I rejected the ALJ's recommendation that I continue the physician's registration, subject only to the condition that he not prescribe controlled substances over the internet, *id.* at 10094, and instead suspended the physician's registration for a period of one year, holding that ''the ALJ's recommendation would not only 'ignore how irresponsibly [the physician] acted'; it would also signal to others that one can ignore the law . . . and yet incur no consequence for having done

[47] Unlike factors two (''[t]he applicant's experience in dispensing'') and three (''[t]he applicant's conviction record''), neither factor four (''Compliance with applicable laws related to controlled substances'') nor factor five (''Such other conduct which may threaten public health and safety'') contain the limiting words of ''[t]he applicant.'' As the Supreme Court has held, ''[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'' *Russello* v. *United States,* 464 U.S. 16, 23 (1983). Thus, the text of factors four and five suggest that these factors are not limited to assessing the applicant's compliance with applicable laws and whether he has engaged in ''such other conduct,'' but rather authorize the Agency to also consider the effect of a sanction on inducing compliance with federal law by other practitioners.

[48] I further required that as a condition of approving the physician's application to renew his registration following the completion of his suspension, the physician was required to provide a sworn statement acknowledging his wrongdoing, and that without such an acknowledgement, his application would be denied. *See* 74 FR at 10095.

so.'' *Id.* at 10095 (quoting *Southwood,* 71 FR at 36503). I also noted that ''this is not the message that should be sent to those who contemplate prescribing controlled substances in'' the same unlawful manner as had the physician. *Id.*

In *Moore,* the ALJ found that a physician had unlawfully possessed and manufactured four pounds of marijuana. 76 FR at 45867. While finding that the physician had ''demonstrate[d] an acknowledgement that his actions were illegal,'' *id.* at 45877, and had ''credibly testified that he was in compliance with the terms of his [court-imposed] probation, as well as the terms of the [o]rder of'' his state medical board, *id.* at 45876, the ALJ recommended that his registration be suspended, noting that ''the agency has an interest in both assuring that the Respondent can be entrusted with the responsibilities attendant upon a [DEA] registrant and (notwithstanding the non-punitive nature of these proceedings) . . . in deterring others from similar acts.'' *Id.* at 45877.

On review, I ''agree[d] with the ALJ that the Agency's interest in deterring similar misconduct on the part of others warrant[ed] a substantial period of outright suspension.'' *Id.* at 45868. However, I increased the length of the suspension from the ALJ's recommendation of six months to one year, noting, in part, that ''a six-month suspension [did not] sufficiently protect[ ] the Agency's interest in deterring misconduct on the part of others.'' *Id.*

It is acknowledged that Respondent largely expressed his acceptance of the AMB's concerns with various aspects of his prescribing practices.[49] Moreover, Respondent put on evidence of various improvements he had made in his prescribing practices.[50] The ALJ also noted the testimony of Dr. Schneider, to the effect that Respondent was ''doing much more careful documentation'' and ''was ordering older records and he . . . definitely changed the way he did things.'' R.D. at 64 (citing Tr. 626); *see also id.* at 64–65 (citing affidavits of two physicians regarding improvements in charting and investigation of patient backgrounds).

Yet Respondent's evidence as to his reform efforts is undercut to a significant degree by the Board's finding that, even after he had been placed on probation based on his prescribing to DK, he continued to prescribe high doses of opioids to ML without obtaining objective measures of ML's pain (and indeed, did so notwithstanding that ML's x-ray contradicted his diagnosis of spondylolisthesis).[51] GX 18, at 16. Thus, I give Respondent's evidence as to his remedial efforts substantially less weight than the ALJ did.[52]

Nor does the ALJ's recommended sanction reflect an appreciation for the egregiousness of the violations he found proved (and which I concur with). In short, proof that in issuing a prescription, a practitioner acted outside of the usual course of professional practice and lacked a legitimate medical purpose, establishes that the practitioner has engaged in an act of intentional or knowing diversion. Such conduct strikes at the CSA's core purpose of preventing the abuse and diversion of controlled substances. *See Jack A. Danton,* 76 FR 60900, 60903 (2011); *George Mathew,* 75 FR 66138 (2010). Indeed, this Agency has revoked a practitioner's registration upon proof of as few as two acts of intentional diversion and has further explained that proof of a single act of intentional diversion is sufficient to support the revocation of a registration. *See MacKay,* 75 FR at 49977 (citing *Krishna-Iyer,* 74 FR at 463 (citing *Alan H. Olefsky,* 57 FR 928, 928–29 (1992))). While Respondent's misconduct would be egregious if it had been confined to a single patient, it was not. Rather, the Board's findings establish that Respondent diverted controlled substances to at least ten patients, and that with respect to several of these patients, he did so over an extensive time period.

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[49] In support of its contention that Respondent does not accept responsibility for his misconduct, the Government contends that Respondent lacked candor in his testimony when he ''attempted to explain away the inconsistencies between [the UCs'] medical records and the recordings/transcripts of these visits by concocting a patently disingenuous story about how he conducted . . . physical examinations through silent observation and covert methods of discerning pulse, respiration, grip strength etc.'' Exceptions at 6 (citing *John Stanford Noell,* 59 FR 47359, 47362 (1994)). As found above, when confronted with the evidence that he had documented in each UC's medical record having taken their pulse while the transcript contains no indication that he had done so (at least in the typical way, *see* Tr.696), Respondent testified that he had determined the UC's pulses by shaking their hands. *Id.* at 987.

Notably, the Government does not contend that Respondent's falsification of the UCs' medical records is itself actionable misconduct which should be considered under factor five, and even if it had, falsification of a medical record (and whether there is a materiality requirement) is a question of state law. As for the Government's contention that Respondent's testimony shows that he does not accept responsibility for his misconduct in prescribing to the UCs, Respondent is not required to accept responsibility for misconduct which has not been proved on the record. Accordingly, while I conclude that Respondent's testimony as to how he took the UCs' pulses is ludicrous, I do not rely on it in setting the appropriate sanction.

[50] Respondent testified that he had read four or five textbooks, taken on-line courses, and talked with other practitioners to make improvements to his charting and that his records are now more detailed and ''transparent to outside individuals.'' Tr. 861. In addition, Respondent testified that he does not ''take patients without records if they're possible to obtain,'' and that ''[i]f a patient comes and there are no records, particularly of high dose opiates, we might give them small doses and establish a record with them ourselves.'' *Id.* at 852–53. Also, Respondent testified that he is now using the Arizona prescription monitoring program to determine whether his patients are getting controlled substances from another provider. *Id.* at 853. Finally, Respondent testified that his practice now has ''in-office urine testing'' and he does ''routine urine screenings . . . on a random basis,'' that he has given an even ''higher priority'' to pharmacy calls,'' and that ''we will often call physicians . . . that we have records on to verify if we have any questions about dosing from another physician.'' *Id.* at 872–73.

[51] The AMB's 2010 Order also identified several other patients, to whom Respondent continued to prescribe controlled substances in deviation of the standard of care, by failing to obtain prior records, obtain objective measures for the cause of pain, and address abnormal urine drug screens, and did so even after he had been placed on probation. *See* GX 18, at 11–13 (WO); *id.* at 14–15 (JR); *id.* at 15–16 (LP).

[52] In discussing Respondent's ''improvements in his prescribing practices . . . since the Board's actions,'' R.D. 60, the ALJ also cited the testimony of two patients, WR and ML (neither of whom is a medical professional), explaining that they ''credibly testified to their positive experiences in being treated by Respondent.'' R.D. at 61; *see also id.* at 62 (discussing testimony of Dr. SF that Respondent's care and treatment were ''excellent''). The term ''positive experience'' is not in the CSA, and the ALJ's conclusory discussion of WR's and ML's testimony offers little insight into what he understood the term to mean. Notably, neither patient offered testimony identifying specific changes in Respondent's prescribing practices which occurred following either of the AMB's orders. Thus, the testimony of WR and ML is not probative of the issue of whether Respondent has improved his prescribing practices.

As for Dr. SF's testimony that Respondent provided him with ''excellent'' treatment, while this Agency (as do the Federal courts) necessarily look to medical practice standards in assessing whether a physician who has prescribed controlled substances had a legitimate medical purpose and acted within the usual course of professional practice in doing so, DEA is charged with preventing the diversion of controlled substances and not with evaluating the adequacy of a physician's medical treatment. Moreover, as I have previously noted, ''[b]ecause under [the CSA], registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [his] professional career.'' *See Krishna-Iyer,* 74 FR at 463.

It is acknowledged that Dr. SF testified that Respondent took a complete history, performed a physical examination, reviewed his rules for prescribing medication, as well as subsequently helped SF taper off of his medication. Tr. 782. Yet, Dr. SF did not see Respondent until six to nine months after the AMB issued the first order, Tr. 780, and was clearly a legitimate patient. While his testimony bolsters to a degree the other evidence as to Respondent's change in his prescribing practices, it is of minimal probative value in assessing Respondent management of drug seeking patients.

Nor—not surprisingly given that the ALJ totally ignored the Agency case law—does the recommended sanction reflect an appreciation for the growing and serious problem of the diversion of prescription drugs by unscrupulous practitioners and the epidemic of prescription drug abuse.[53] Indeed, adopting the ALJ's recommendation—which simply requires Respondent to do what the State has already required him to do—would create a perverse incentive. In short, it would send the message that a practitioner can unlawfully distribute controlled substances until he/she gets caught, and as long as he/she then acknowledges wrongdoing and puts on evidence that he/she has reformed, he/she will get a slap on the wrist. This is the entirely wrong message to send to those practitioners who contemplate using their prescribing authority for illicit purposes. And even those practitioners who might fairly be described as gullible or naïve, should know that there are serious consequences if they prescribe controlled substances in a manner that does not comply with the accepted standards of professional practice.[54]

[53] *See Krishna-Iyer,* 74 FR at 463 (quoting National Center on Addiction and Substance Abuse, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* 3 (2005) [hereinafter, *Under the Counter*]). As noted in *Krishna-Iyer,* ''[t]he diversion of controlled substances has become an increasingly grave threat to this nation's public health and safety. According to The National Center on Addiction and Substance Abuse (CASA), '[t]he number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003.' '' 74 FR at 463 (quoting *Under the Counter,* at 3). CASA also found that '' '[a]pproximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000).' '' *Id.* (quoting *Under the Counter,* at 3). Finally, CASA found that '''[b]etween 1992 and 2003, there has been a . . . 140.5 percent increase in the self-reported abuse of prescription opioids,'' and in the same period, the ''abuse of controlled prescription drugs has been growing at a rate twice that of marijuana abuse, five times greater than cocaine abuse and 60 times greater than heroin abuse.'' *Id.* (quoting *Under the Counter,* at 4).

[54] As support for his recommendation, the ALJ also quoted from a letter of Dr. Schneider, in which she wrote:

The goal of regulatory agencies needs to be (and is usually claimed to be) to improve the performance of physicians when a deficiency is noted, rather than prevent them from continuing to practice, thereby wasting their training and experience. [Respondent], like many pain management doctors, developed his knowledge of pain management on the job rather than through a formal training program. This is a rapidly evolving field, and its standards are evolving. [Respondent]'s skills continue to improve. I believe that at this point he is clearly able to practice pain management with sufficient skill and safety that he should be allowed to continue to do this.

RX 23, at 2–3.

Whatever the State of Arizona has chosen, in the exercise of its sovereignty, as the goal of its Medical Board, Congress has directed this Agency to protect the public interest. *See* 21 U.S.C. §§ 823(f) and 824(a)(4). This charge necessarily contemplates not only deterring a diverter from continuing to do so, but also deterring other would be diverters from doing so. And notwithstanding Dr. Schneider's view of the appropriate goal of a state medical board, here, the AMB concluded that Respondent's prescribing of opioids was so deficient that it suspended his prescribing authority for one year.

Indeed, while in this same paragraph, Dr. Schneider characterized Respondent's prescribing practices as ''minor deficiencies,'' RX 23, at 3, the Board's findings establish that, in numerous instances, Respondent violated the standard of care by: (1) Failing to perform physical examinations; (2) failing to perform adequate psychiatric evaluations; (3) not obtaining prior records; (4) failing to perform tests to confirm diagnoses and the need for controlled substances; (5) failing to conduct urine drug screens and monitor his patients' compliance; (6) ignoring the results of drug tests which either showed that his patient was not taking drugs he prescribed or taking drugs he did not prescribe or street drugs; (7) providing early refills; (8) adding drugs to a patient's medication regime and escalating the dosing of drugs without any rationale for doing so; and (9) prescribing large doses of opioids to a patient, who purportedly could not remember the name of her previous prescriber and who repeatedly failed to comply with instructions to bring in records from prior treating physicians. These findings were in addition to the Board's findings that Respondent failed to maintain adequate records.

If these are ''minor deficiencies,'' I would like to know what, in Dr. Schneider's view, would constitute a major one. As for Dr. Schneider's suggestion that Respondent's misconduct should be excused because he ''developed his knowledge of pain management on the job rather than through a formal training program,'' on various occasions (November 1997, May 1999, and June 2003), the AMB published guidelines on the Use of Controlled Substances for the Treatment of Chronic Pain, which specifically addressed many of the problematic practices the Board identified in its review of Respondent's prescribing practices, and which ''clarif[ied] the principles of professional practice that are endorsed by the Board.'' Arizona Medical Board, *Use of Controlled Substances for the Treatment of Chronic Pain* (Substantive Policy Statement # 7).

Likewise, well before Respondent issued the prescriptions which were discussed in the AMB's orders, federal courts had issued decisions upholding convictions for violating the prescription requirement based on conduct similar to Respondent's. *See, e.g., Moore,* 423 U.S. at 142–43; *United States v. Williams,* 445 F.3d 1302, 1305 (11th Cir. 2006) (sustaining conviction for unlawful distribution noting, *inter alia,* expert's testimony that physician ''wrote prescriptions for patients on whom he performed no or very minimal physical examination,'' ''wrote prescriptions for patients whose toxicology screens . . . showed that they were not taking the prescribed drugs and were instead taking illegal drugs,'' and ''he frequently refilled prescriptions early and replaced 'lost' drugs''); *United States v. Tran Trong Cuong,* 18 F.3d 1132, 1139 (4th Cir. 1994) (sustaining conviction for unlawful distribution noting, *inter alia,* that ''[m]ost of the patients were given very superficial physical examinations and even after months of the same complaints of pain and the same prescriptions of drugs, they were not given more complete examinations, nor were they subjected to x-rays or blood analysis or referred to specialists in an effort to identify and correct the cause of the pain'').

Certainly, those who undertake to practice in a highly regulated profession cannot reasonably claim ignorance of the laws, regulations and standards applicable to the practice of their profession. *Cf. United States* v. *Southern Union Co.,* 630 F.3d 17, 31 (1st Cir. 2010). Finally, given that Respondent testified that he read four or five textbooks to improve his understanding of applicable standards, one must wonder why he did not read these textbooks when he decided to commence treating patients for chronic pain.

I therefore reject the ALJ's recommended sanction that Respondent's registration be continued subject only to the condition that he comply with the AMB's order (and notify the Agency of any changes to the order). Instead, while I will order that Respondent's renewal application be granted, I will further order that his registration then be suspended for a period of one year.

Moreover, as Respondent suggested in his post-hearing brief, the Agency ''may wish to impose requirements of continued monitoring of his files and perhaps keeping a separate log for all medications.'' Resp. Prop. Findings of Fact, Conclusions of Law and Argument, at 43. Accordingly, upon Respondent's completion of his suspension, the following conditions shall be imposed on his registration.

1. Respondent shall keep a log of all controlled substance prescriptions he issues. Said log shall be maintained in chronological order, and shall list each patient by name, and include the name of the drug prescribed, the number of refills authorized, the strength of the dosage unit, the quantity, and the dosing instruction. Not later than ten days following the end of each month, Respondent shall provide the local DEA field office with a complete copy of the log for the preceding month.

2. Respondent shall agree to continued monitoring of his patient files, with the costs of said monitoring to be borne by him. Said monitor shall be board certified in pain management and licensed by the Arizona Medical Board. DEA retains final authority to accept or reject the selection of said monitor. Said monitor shall review no less than twenty patient files each quarter, which shall be selected by the monitor; the monitor's selection of any patient file may not be challenged by Respondent. Respondent shall agree to fully cooperate with the monitor.

3. Respondent shall further consent to unannounced inspections of his registered location and to waive his right to require DEA personnel to obtain an administrative inspection warrant prior to conducting an inspection.

4. These conditions shall remain in effect for a period of two years following the completion of Respondent's suspension. Said condition shall

thereupon terminate upon Respondent's completion of the two year period without violating any of the above terms. The violation of any of the above terms shall, however, subject, Respondent's registration to an Order of Immediate Suspension.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that the application of David A. Ruben, M.D., to renew his Certificate of Registration as a practitioner, be, and it hereby is, granted subject to the conditions set forth above. I further order that Respondent's Certificate of Registration be, and it hereby is, suspended for a period of one year to begin thirty days from the date of publication of this Order in the **Federal Register**. This Order is effectively immediately.

Dated: June 18, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–15266 Filed 6–25–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2006–0040]

SGS North America, Inc. (Formerly SGS U.S. Testing Company, Inc.)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice announces the application of SGS North America, Inc., for expansion of its recognition as a Nationally Recognized Testing Laboratory by the addition of one test site and the removal of one test site. This notice presents the Agency's preliminary finding to grant this request. This notice also announces a voluntary modification of the NRTL scope of recognition of SGS North America, Inc., and formally reflects the name change from SGS U.S. Testing Company, Inc. This preliminary finding does not constitute an interim or temporary approval of this application.

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before July 11, 2013.

ADDRESSES: Submit comments by any of the following methods:

1. *Electronically:* Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

2. *Facsimile:* If submissions, including attachments, are not longer than 10 pages, commenters may fax them to the OSHA Docket Office at (202) 693–1648.

3. *Regular or express mail, hand delivery, or messenger (courier) service:* Submit a copy of comments and any attachments to the OSHA Docket Office, Docket No. OSHA–2007–0039, Technical Data Center, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2350 (TDY number: (877) 889–5627). Note that security procedures may result in significant delays in receiving comments and other written materials by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express delivery, hand delivery, or messenger service. The hours of operation for the OSHA Docket Office are 8:15 a.m.–4:45 p.m., e.t.

4. *Instructions:* All submissions must include the Agency name and the OSHA docket number (OSHA–2006–0040). OSHA will place all submissions, including any personal information provided, in the public docket without revision, and these submissions will be available online at *http://www.regulations.gov.*

5. *Docket:* To read or download submissions or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

6. *Extension of comment period:* Submit requests for an extension of the comment period on or before July 11, 2013 to the Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: David W. Johnson, Director, Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210, or phone (202) 693–1973.

SUPPLEMENTARY INFORMATION:

I. Notice of Expansion Application

The Occupational Safety and Health Administration (OSHA) is providing notice that SGS North America, Inc. (SGS) is applying for expansion of its current recognition as a Nationally Recognized Testing Laboratory (NRTL). SGS's expansion request covers the addition of one additional test site. SGS's also requests the removal of one test site from its NRTL scope of recognition. SGS informed OSHA of a change in name from SGS U.S. Testing Company, Inc. to SGS North America, Inc. (see Exhibit 1: SGS Application). This notice reflects that change. OSHA's current scope of recognition for SGS is available at *http://www.osha.gov/dts/otpca/nrtl/sgs.html.*

OSHA recognition of an NRTL signifies that the organization meets the legal requirements specified in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition, and is not a delegation or grant of government authority. As a result of recognition, employers may use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The Agency processes applications by an NRTL for initial recognition, or for an expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth modifications of the NRTL's scope of recognition. OSHA maintains an informational Web page for each NRTL that details the NRTL's scope of recognition. These pages are available from the OSHA Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

Each NRTL's scope of recognition has three elements. The first element is the type of products the NRTL may test, with each type specified by its applicable test standard. The second element identifies the recognized site(s)