



BILLING CODE: 4410-09-P

**UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

**[Docket No. 15-8]
WESLEY POPE, M.D.
DECISION AND ORDER**

On October 8, 2014, the former Deputy Assistant Administrator of the then-Office of Diversion Control, issued an Order to Show Cause to Wesley Pope, M.D. (hereinafter, Respondent), of Newcastle, Oklahoma. ALJ Ex. 1, at 1. The Show Cause Order proposed the denial of Respondent's application for a new Certificate of Registration as a practitioner in schedules II through V, on the ground that his registration would be "inconsistent with the public interest." *Id.* (citing 21 U.S.C. § 823(f)).

As support for the proposed denial, the Government alleged that "[f]rom on or about August 25, 2011 through on or about May 9, 2012, [Respondent] issued controlled substance prescriptions to [patient] B.B. in violation of Federal and Oklahoma . . . law." *Id.* The Government specifically alleged that "on each of the occasions that [Respondent] issued controlled substance prescriptions to B.B.," Respondent was "aware . . . that he presented a high risk of abuse and/or diversion of controlled substances, as evidenced by the red flags documented in his patient file, such as aberrant urine drug tests, a request for early refills, and a claim of stolen drugs." *Id.* The Government then alleged that Respondent "failed to address and, in fact, ignored these red flags, continuing to issue B.B. controlled substances [sic] prescriptions in the face of mounting evidence that he was misusing, abusing, and/or diverting the controlled substances [he was] prescribing." *Id.* The Government further alleged that "[t]he prescriptions [Respondent] issued to B.B. on each visit were below the standard of care in Oklahoma and fell outside the usual course of professional practice." *Id.* at 1-2 (citing 21 CFR

1306.04(a); Okla. Admin. Code § 435:10-7-4; *id.* § 435:70-7-11¹; Okla. Bd. of Med. Lic. & Super., *Use of Controlled Substances for the Treatment of Pain* (Mar. 10, 2005)). The Show Cause Order then alleged that on 11 different dates, Respondent issued to B.B. prescriptions for such drugs as hydrocodone/acetaminophen, Opana (oxymorphone), fentanyl patches, morphine sulfate, oxycodone/acetaminophen, and Soma (carisoprodol) which were “invalid.” *Id.* at 2-6. The Government also provided detailed factual allegations pertaining to each of the prescriptions. *Id.*

Respondent requested a hearing on the allegations. The matter was then placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ). Following pre-hearing procedures, the CALJ conducted a hearing on April 7-8, 2015 in Oklahoma City, Oklahoma. During the hearing, both parties submitted documentary evidence; the Government elicited the testimony of several witnesses and Respondent testified on his own behalf.

On July 24, 2015, the CALJ issued his Recommended Decision (cited as R.D.). Therein, the CALJ found that the allegations were sustained only with respect to five of the dates on which Respondent prescribed (and with respect to four of these dates, only sustained in part). *See* R.D. 44, 46, 62, 64, 68. While the CALJ concluded that Respondent had issued these prescriptions outside of the course of professional practice and thus violated 21 CFR 1306.04(a), *id.* at 90, he further reasoned that Respondent’s misconduct reflected “inattention to detail [and] not intentional diversion.” *Id.* at 82. He thus concluded that while the Government had made out a *prima facie* case to warrant some form of sanction, Respondent’s conduct was not sufficiently egregious to warrant denial even though he found that “Respondent was

¹ This is an apparent typographical error as there is no such provision. The parties, however, spent considerable time arguing as to whether Respondent complied with Okla. Admin. Code § 435:10-7-11, which governs the “Use of Controlled Substances for the Management of Chronic Pain.”

irresponsible in continuing to prescribe to this patient in the face of red flags of diversion, and in failing to document or even possess the ability to persuasively convey a medically-based justification for prescribing new controlled medication.” *Id.* at 92-93. And even though Respondent had failed to accept responsibility and put forward no evidence of remedial measures he had undertaken, the CALJ recommended that he be granted a new registration subject to a one-year period of probation with various conditions. *Id.*

The Government filed Exceptions to the Recommended Decision and Respondent filed a Response to the Government’s Exceptions. Thereafter, the record was forwarded to my Office for Final Agency Action.

Having considered the record in its entirety including the Recommended Decision, the Government’s Exceptions, and Respondent’s Response to the Government’s Exceptions, I agree with the CALJ’s findings and legal conclusion with respect to the first prescribing event (August 25, 2011). While I agree with the CALJ’s legal conclusions that Respondent acted outside of the usual course of professional practice when he prescribed controlled substances during the third, fourth, tenth, eleventh, and twelfth prescribing events, I hold that several of the exceptions raised by the Government are well taken and that additional relevant evidence should be considered in review of the record. Based on my consideration of the record as a whole, I, as the ultimate fact-finder, conclude that a preponderance of the evidence supports the conclusions that Respondent knowingly diverted controlled substances by issuing prescriptions in violation of 21 CFR 1306.04(a) when he prescribed various schedule II controlled substances on 11 occasions, beginning on September 22, 2011 and ending on May 9, 2012.

I further find that Respondent’s misconduct is egregious and establishes a *prima facie* case for denial. Because I also agree with the CALJ that the record reflects Respondent’s

“almost dogged determination to accept no responsibility for any of his actions” and that he “has not presented even the most modest plan for any remedial action,” R.D. 92, I conclude that his application should be denied.

The Government’s Exceptions

In its Exceptions, the Government raises multiple contentions, several of which warrant discussion prior to making factual findings. The first of these is that the CALJ erroneously concluded that the Oklahoma Medical Board’s Standards “on which the Government relied were permissive rather than mandatory.” Exceptions, at 5. Indeed, in making his legal conclusions, the CALJ repeatedly declined to give weight to the Government Expert’s testimony on material issues, reasoning that the Expert’s testimony was premised on his misunderstanding that the Board’s regulations, in particular its documentation and recordkeeping rules, were mandatory rather than permissive.

Second, the Government maintains that the CALJ erroneously held that the Government failed to provide adequate notice to Respondent of its intent to rely on the various aberrant drug tests as part of its proof that various prescriptions were issued in violation of 21 CFR 1306.04(a). With respect to this exception, the Government argues that not only did it provide adequate notice, the aberrant nature of the various urine drug screens (UDS) was litigated by consent. Exceptions, at 15-25. It also takes exception to the CALJ’s finding that several of the UDSs were not aberrant.

The CALJ’s Conclusion that the Board’s Standards Are Permissive

Throughout his Recommended Decision, the CALJ repeatedly declined to give weight to the Government Expert’s testimony that Respondent failed to conduct a medically adequate evaluation of B.B.’s pain complaint and establish medical necessity to justify the prescribing of

controlled substances. The basis of the CALJ's reasoning was that the deficiencies identified by the Expert "generally relate to a paucity of documented proof in the chart entries as to whether or how much various medical treatment considerations that he favors were considered by the Respondent in making his prescription decision." R.D. at 35. Based on his conclusion that the provisions of the Oklahoma Board's rules applicable to a physician's documentation of his evaluation of a patient and recordkeeping are "permissive" and not mandatory, the CALJ reasoned that "Respondent's alleged lack of documentation . . . is likely not as fatal to the Respondent's adherence to the standard of care in Oklahoma as the Government expert claims." R.D. 16. I disagree.

With respect to the evaluation of the patient, the Oklahoma Rule states:

A medical history and physical examination must be obtained, evaluated and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Okla. Admin. Code § 435:10-7-11(1). And with respect to medical records, the Oklahoma Rule states in relevant part that "[r]ecords should remain current" and that "[t]he physician should keep accurate and complete records." *Id.* § 435:10-7-11(6). The records are "to include . . . the medical history and physical examination (including vital signs)," "diagnostic, therapeutic and laboratory results," "evaluations, consultations and follow-up evaluations," "treatment objectives," "discussion of risks and benefits," "informed consent," "treatments," "medications (included date, type, dosage and quantity prescribed)," "instructions and agreements and periodic reviews." *Id.* In the CALJ's view, because the provisions of the Oklahoma regulation applicable to the documentation of the physician's evaluation of his patient and his recordkeeping use the

word “should” in expressing the State’s rules, the obligations they impose are “permissive.” R.D. at 16.

The CALJ, however, cited no authority from either the Board or the Oklahoma courts definitively interpreting the word “should” as used in the context of these two provisions as “permissive.” *See, e.g., id.* at 6. Indeed, the CALJ’s conclusion appears to have been based entirely on the fact that the Board’s prior version of its intractable pain rule used such words as “requires” and “must” in setting forth a practitioner’s obligations with respect to documentation and recordkeeping. *See* R.D. 87 n.147 (quoting Okla. Admin. Code § 435:10-7-11(b) (2004): “[t]his rule requires that a diagnosis be documented” and *id.* § 435:10-7-11(j): “[a]ccurate and complete records to document compliance with this section must be kept”). In the CALJ’s view, “[t]he evolution of the [regulations] demonstrate [sic] that their permissive nature represents an intentional re-direction by Oklahoma.” *Id.*

However, when the Board promulgated the current version of the rule in 2005, it simply noted that “[t]he rule is being updated based on recommendations from the Federation of State Medical Boards.” 22 Okla. Reg. 2096 (June 15, 2005); *see also* 22 Okla. Reg. 379 (Notice of Rulemaking Intent; Feb. 1, 2005). In short, the CALJ’s reliance on the Board’s decision to adopt the Federation of State Medical Board’s model rule simply proves too much.

Furthermore, although the word “should” is susceptible to different meanings, when used in the context of legal requirements, it generally does not connote “permission” but rather obligation or duty. *United States v. Anderson*, 798 F.2d 919, 924 (7th Cir. 1986) (“The common interpretation of the word ‘should’ is ‘shall’ and thus a straight –forward construction of [the Code of Judicial Conduct] reveals that it imposes a mandatory rule of conduct upon a judge.”)²;

² As the Seventh Circuit also noted, “as listed in *Roget’s Thesaurus*, [the word “should”] means ‘be obliged, must . . . have to.’ The common interpretation of the word ‘should’ is ‘shall.’” 798 F.2d at 924.

Wollschlaeger v. Farmer, 814 F.Supp.2d 1367, 1376 (S.D.Fl. 2011) (“Generally, laws that provide for disciplinary action in the cases of violations or noncompliance are mandatory, not precatory or hortatory. . . .”); *see also Bureau of Prisons v. FLRA*, 737 F.3d 779, 787 (D.C. Cir. 2013) (“‘Should’ is typically used to express an obligation or duty.”) (citing *Webster’s Third International Dictionary* 2104 (1976)); *see also Webster’s Third International Dictionary* 2104 (defining “should” as “used in auxiliary function to express duty, obligation, necessity, propriety or expediency”).

Moreover, reading the Board’s documentation and recordkeeping provisions as permissive cannot be squared with the Oklahoma Medical Practice Act. *Cf. Wollschlaeger*, 814 F.Supp.2d at 1376 (rejecting interpretation that statute which used “should” was hortatory when State law provided that violations of provision constituted grounds for disciplinary action). Under the Medical Practice Act, a physician’s “[f]ailure to maintain an office record for each patient which accurately reflects the evaluation, treatment, and medical necessity of treatment of the patient” constitutes “unprofessional conduct.” 50 Okla. Stat. Ann. § 509(18). Another provision of the Medical Practice Act states that “[a]dequate medical records to support diagnosis, procedures, treatment, or prescribed medications *must be produced and maintained.*” *Id.* § 509(20) (emphasis added). And a further provision of the Medical Practice Act makes “[p]rescribing . . . controlled substances or narcotic drugs without medical need in accordance with published standards” “unprofessional conduct.” *Id.* § 509(16).

Thus, construing the Board’s documentation and recordkeeping rules as permissive would be fundamentally inconsistent with the Medical Practice Act’s provisions on documentation and recordkeeping, which are clearly mandatory. *See Abramski v. United States*, 134 S.Ct. 2259, 2267 n.6 (2014) (“[A] court should not interpret each word in a statute with

blindness on, refusing to look at the word's function within the broader statutory context. As we have previously put the point, a 'provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.'") (quoting *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Associates, Ltd.*, 484 U.S. 365, 371 (1988)). See also *Jacobs v. New York Foundling Hosp.*, 577 F.3d 93, 99 (2d Cir. 2009).

Accordingly, the Board's Intractable Pain Rule's documentation and recordkeeping provisions are not reasonably read as being permissive.³ Indeed, in the Policy Statement it issued contemporaneously with the promulgation of the Rule, the Board provided further evidence that the documentation and recordkeeping requirements are not permissive. For example, the Board explained that "[a]ll such prescribing [of controlled substances for pain] *must* be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing *should* be based on a diagnosis and documentation of unrelieved pain." *Policy Statement*, at 2 (emphasis added). Were the CALJ's interpretation correct, what the Board required in the first sentence was then rendered permissive by the use of the word "should" in the following sentence. Indeed, if the word "should" rendered the rules permissive, a physician could prescribe controlled substances to his patient without even having formulated a diagnosis. This makes no sense and thus, the better view is that the words "must" and "should" have the same meaning: they impose mandatory obligations.

³ In a series of cases involving the State of Florida's former regulation entitled "Standards for the Use of Controlled Substances for Treatment of Pain" (Fla. Admin. Code r. 64B8-9.013 (2009)), which adopted nearly verbatim the FSMB's text (including the respective uses of the words "must" and "should") in setting that State's documentation standard with respect to the evaluation of the patient, the CALJ explained that "[c]onscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the physician's prescribing practices are 'within the usual course of professional practice.'" See, e.g., *Roni Dreszer*, 76 FR 19434, 19448-49 (2011). So too here.

In its Policy Statement, the Board also stated that it “will judge the validity of the physician’s treatment of the patient based on available documentation.” *Id.* And finally, the Board stated that it “will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation.” *Id.* It makes no sense to advise physicians that the validity of their treatment decisions will be based on documentation and recordkeeping requirements if those provisions are not requirements at all, but rather, merely hortatory and aspirational pronouncements.

Accordingly, I do not agree that the Government Expert’s testimony as to the deficiencies in Respondent’s evaluations of B.B. was based on the Expert’s mistaken understanding of the scope of the Oklahoma Board’s documentation and recordkeeping standards. Thus, while I fully agree with the CALJ that the Expert’s “testimony predictably raised no issues regarding credibility,” I disagree with the CALJ’s assertion that the Expert’s “testimony was not without its own ‘red flags.’” R.D. 18. I therefore find that this exception is well taken.

The CALJ’s Rulings that the Government Failed to Provide Adequate Notice of Its Intent to Rely on Various Urine Drug Screen Results As Probative Evidence of the Illegality of the Prescriptions

Throughout his Recommended Decision, the CALJ repeatedly declined to consider the Government’s evidence that Respondent failed to address an aberrant urine drug screen which showed that his patient B.B. was not taking a controlled substance that had been prescribed to him. *See, e.g.*, R.D. at 38-39 n.75. In the CALJ’s view, the Government did not provide adequate notice of its intent to rely on Respondent’s failure to address an aberrant June 1UDS in either the Show Cause Order or its Pre-hearing Statements with respect to multiple prescriptions. *See id.* at 38-39 (Sept. 25, 2011 Rx), 48 (Nov. 18 and Dec. 15, 2011 Rx); 51 (Jan. 19, 2012 Rx); 54 (Feb. 13, 2012 Rx), 56 (Mar. 13, 2012 Rx), 60 (April 12, 2012 Rx), 64 n.121 (April

25, 2012 Rx). As support for his rulings, the CALJ maintained that “the Agency has recently imposed an increased standard of notice on its administrative prosecutors.” *Id.* at 39 n.75 (citing *Farmacia Yani*, 80 FR 29053, 29064 n.28 (2015); *Jana Marjenhoff*, 80 FR 29067, 29068 (2015)). A review of these decisions shows, however, that the Agency has not “imposed an increased standard of notice”⁴ but simply applied the extensive body of judicial precedent that

⁴ According to the CALJ, in *Farmacia Yani*, “the Government’s notice was deemed insufficient in that although the alleged misconduct was disclosed and pursued, it did not include the correct regulation subsection in its [Show Cause Order] and prehearing statement.” R.D. 66 (citing 80 FR at 29064 n.28). This, however, misstates the case.

At issue in footnote 28 of *Farmacia Yani* was the Government’s allegation that the pharmacy had filled Suboxone prescriptions which were clearly issued for maintenance or detoxification purposes by two physicians but which did not contain the requisite identification number or good faith statement establishing that the physician was authorized to prescribe Suboxone for these purposes. See 80 FR 29063-64. As the legal basis for the allegation, the Government cited 21 CFR 1306.04 and 1306.06. The first regulation includes, *inter alia*, subsection a, which makes it illegal for a pharmacist to knowingly fill a prescription issued outside of the usual course of professional practice and which lacks a legitimate medical purpose, and subsection c, which provides, in part, that a prescription may not be issued for maintenance or detoxification treatment unless “the practitioner is in compliance with the requirements” applicable to practitioners who prescribe Suboxone for maintenance or detoxification treatment. See 21 CFR 1306.04(a) & (c); *id.* § 1301.28 (requirements for prescribing Suboxone for this purpose); see also *id.* § 1306.06 (“A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . .”).

While the Decision noted that the Government had not identified the specific subsection of 1306.04 which it alleged was violated, it did not hold that the “notice was deemed insufficient.” R.D. 66. Indeed, while the Decision rejected the Government’s contention that the pharmacist acted outside of the usual course of professional practice in violation of 1306.04(a) and 1306.06 for lack of evidence, 80 FR at 29064, and further noted that 1306.04(c) “impose[s] duties only on the issuer of [a] prescription which has been issued to provide maintenance or detoxification purposes,” *id.* at n.28, the Decision nonetheless found that the pharmacy had violated another provision of the Agency’s regulations. Specifically, the Decision found a violation based on 21 CFR 1306.05(f), which imposes “[a] corresponding liability . . . upon the pharmacist . . . who fills a prescription not prepared in the form prescribed by DEA regulations,” 21 CFR 1306.05(f), and 21 CFR 1306.05(b), which requires that such a prescription include either the prescriber’s X number or good faith statement. See 80 FR at 29064 & n.28 (citation omitted).

Indeed, notwithstanding that the Government cited the wrong provision of the regulations, the respondent’s principal did not dispute that her conduct in filling these prescriptions was a violation. See Respondent’s Proposed Findings of Fact and Conclusions of Law, at 11 (Proposed Conclusion of Law # 11: “The second violation[] relates to buprenorphine prescriptions from two physicians who were not authorized to prescribe such prescriptions because they were not Data-waived practitioners. Physicians are issued a specific registration that is distinguished with an X number, and this number[] should be on the prescription. *Farmacia Yani* dispensed 29 prescriptions in total from these two doctors that did not have an X number.”) (citations omitted). Thus, this case does not support the CALJ’s assertion that “recent Agency precedent has imposed significantly tighter notice requirements on the Government.” R.D. at 66.

The CALJ further asserted that “[i]n *Marjenhoff*, . . . the Agency refused to allow the Government to rely on noticed conduct alleged as a violation of the public interest factors because it failed to specify that the conduct would be specifically considered under factor 5.” R.D. 66 (citing 80 FR at 29068). Here again, this is a misstatement of the case.

addresses the adequacy of notice in administrative adjudication, which, as the Second Circuit has explained, “is so peculiarly fact-bound as to make every case unique.” *Pergament United Sales, Inc. v. NLRB*, 920 F.2d 130, 135 (2d Cir. 1990) (quoted in *Marjenhoff*, 80 FR at 29068); *see also Marjenhoff*, 80 FR at 29067-68 (discussing court decisions on notice in administrative adjudication); *Farmacia Yani*, 80 FR at 29059 (same).

The CALJ also held that the Government could not rely on this evidence under the doctrine of litigation by consent – even though Respondent never objected to the Expert’s testimony that the June 1 (and other tests) were aberrant and that Respondent failed to properly address the aberrant results – asserting that the Government had the duty to “timely and affirmatively raise[] . . . this theory” and failed to do so. *Id.* at 39 (citing *Odette Campbell*, 80

Apparently, the CALJ’s assertion refers to the Agency’s declination to find that the respondent’s conduct in intercepting a pharmacist’s phone calls (who questioned the validity of a prescription the respondent had created for herself by forging the signature of the purported prescriber) constituted actionable misconduct under factor five. 21 U.S.C. § 823(f)(5). This factor provides for liability based on “such other conduct which may threaten public health and safety.” *Id.*

Significantly, the Show Cause Order made no such allegation, and while the Government disclosed in its pre-hearing statement that it intended to elicit testimony from the pharmacist regarding his attempt to verify the prescription after it was rejected for payment by respondent’s insurer, at no point in the proceedings did the Government rely on the evidence other than as proof that the “[r]espondent illegally obtained hydrocodone on eleven occasions.” *See* Govt.’s Proposed Findings of Fact and Conclusion of Law, at 14 (discussing the pharmacist’s testimony as evidence that respondent “forged and filled hydrocodone prescriptions to herself using [a PA’s] DEA number. These actions constitute violations of 21 U.S.C. § 843(a)(3) [and] 21 CFR 1306.04. . .”). Moreover, in its discussion of Factor Five, the Government’s arguments were confined to arguing that the “[r]espondent has failed to accept responsibility for her actions,” that she had not “present[ed] any mitigating evidence,” and that she “has demonstrated a pattern of actions that are against the public interest by inappropriately prescribing controlled substances . . . in 2005 and forging and filling prescriptions in 2011.” *Id.* at 15-16.

Thus, contrary to the CALJ’s statement, the Government never relied on this conduct as a separate “violation of the public interest factors.” R.D. at 66. Nor could it have, as the public interest factors do not impose substantive rules of conduct but are simply “components of the public interest” that “shall be considered” in determining whether to grant an application for a registration. *Penick Corp., Inc. v. DEA*, 491 F.3d 483, 490 (D.C. Cir. 2007) (citation omitted). Most importantly, at no point did the Government assert that this conduct should also be considered as a separate act of misconduct under Factor Five.

FR 41062, 41062 n.2 (2015)). This reasoning, however, is also based on a misreading of that case.⁵

“The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.” *Pergament United Sales, Inc., v. NLRB*, 920 F.2d 130, 135 (2d Cir. 1990) (citation omitted). Thus, as the courts have long noted, “[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.” *Aloha Airlines v. Civil Aeronautics Bd.*, 598 F.2d 250, 262 (D.C. Cir. 1979) (quoted in *CBS Wholesale Distributors*, 74 FR 36746, 36749 (2009)); accord *Citizens State Bank of Marshfield v. FDIC*, 751 F.2d 209, 213 (8th Cir. 1984). Moreover, an agency “is not burdened with the obligation to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront.” *Boston Carrier, Inc. v. ICC*, 746 F.2d 1555, 1560 (D.C. Cir. 1984).

Accordingly, even where the Government fails to disclose an allegation in the Order to Show Cause, “an issue can be litigated if the Government otherwise timely notifies a [r]espondent of its intent to litigate the issue.” *CBS Wholesale*, 74 FR at 36570. Moreover, while the Agency has held that “the parameters of the hearing are determined by the prehearing statements,” consistent with numerous court decisions, it has also recognized that even where an

⁵ In *Campbell*, the ALJ noted that “the evidence indicate[d] that [the] [r]espondent did not follow adequate security procedures,” but then “declined to consider the evidence on the ground that the Government did not provide adequate notice in either the Show Cause Order or its Prehearing Statements, notwithstanding that [the] [r]espondent did not object to the testimony.” 80 FR at 41062 n.2 (other citation omitted). While the former Administrator observed that “the record arguably support[s] a finding that the issue was litigated by consent,” she did not consider the evidence because “the Government did not take exception to the ALJ’s ruling.” *Id.*

Here, by contrast, the Government has taken exception to the CALJ’s rulings that the issue has not been litigated by consent. See Gov. Exceptions, at 24-25. As for the CALJ’s assertion that the issue was “not timely” raised by the Government, given that: 1) Respondent never objected to the testimony nor argued in its post-hearing brief that it did not have fair notice that the June 1 drug screen would be at issue throughout the proceeding, and 2) the CALJ did not rule that the Government could not rely on this theory until he issued his Recommended Decision, it is unclear how the Government could have timely raised the issue until it received the Recommended Decision and filed its Exceptions.

allegation was not raised in either the Show Cause Order or the pre-hearing statements, the parties may nonetheless litigate an issue by consent. *Pergament United Sales*, 920 F.2d at 135-37; see also *Duane v. Department of Defense*, 275 F.3d 988, 995 (10th Cir. 2002) (discussing *Facet Enterprises, Inc., v. NLRB*, 907 F.2d 963, 974 (10th Cir. 1990); “we held that the defendant had constructive notice of an alternate theory of liability not described in the formal charge when the agency detailed that theory during its opening argument and at other points during the hearing and when the defendant’s conduct revealed that it understood and attempted to defend against that theory”).⁶

To be sure, “[a]n agency may not base its decision upon an issue the parties tried inadvertently. Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue.” *Yellow Freight System, Inc., v. Martin*, 954 F.2d 353, 358 (6th Cir.1992) (citation omitted).

Accordingly, where the Government’s case “focus[es] on another issue and [the] evidence of [an] uncharged violation [is] ‘at most incidental,’” the Government has not satisfied its constitutional obligation to provide a full and fair opportunity to litigate the issue and it cannot rely on the incidental issue as the basis for imposing a sanction. *Pergament*, 920 F.2d at 136 (quoting *NLRB v. Majestic Weaving Co.*, 355 F.2d 854, 861-62 (2d Cir. 1966)). However, the issue of whether an allegation “has been fully and fairly litigated [by consent] is so peculiarly fact-bound as to make every case unique.” *Id.* at 136.

⁶See also *Grider Drug #1 & Grider Drug #2*, 77 FR 44070, 44077 n.23 (2012) (holding that while the Government did not provide adequate notice of its intent to litigate an allegation in either the Show Cause Order or its pre-hearing statements, where respondents “did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it” and “fully litigated the issue,” the allegation was litigated by consent) (citing *Citizens State Bank*, 751 F.2d at 213; *Kuhn v. Civil Aeronautics Bd.*, 183 F.2d 839, 841-42 (D.C. Cir. 1950); and *Yellow Freight System, Inc., v. Martin*, 954 F.2d 353, 358 (6th Cir. 1992)).

Having reviewed the record, I find the Government's exception well taken and hold that the Government provided Respondent with adequate notice that both the aberrant nature of the June 1 drug test and his failure to address it would be at issue throughout the proceeding. Moreover, even if the Government failed to specifically reference the June 1 test by date in the Show Cause Order (and Pre-hearing Statements) with respect to several of the prescriptions, Respondent had adequate notice that it was at issue throughout the proceeding and indeed, had a full and fair opportunity to litigate the issue.

The Show Cause Order repeatedly provided notice that the aberrant nature of B.B.'s June 1 UDS and Respondent's failure to address it would be at issue in the proceeding. For example, paragraph 3 of the Show Cause order alleged that "[f]rom on or about *August 25, 2011 through on or about May 9, 2012*, [Respondent] issued controlled substance[] prescriptions to B.B. in violation of Federal . . . law." ALJ Ex. 1, at 1 (emphasis added). The Show Cause Order then alleged that Respondent was "*aware on each of the occasions that [he] issued controlled substance[] prescriptions* to B.B. that he presented a high risk of abuse and/or diversion of controlled substances, as evidenced by the red flags documented in his patient file, *such as aberrant urine drug tests.*" *Id.* (emphasis added). And the Order then alleged that Respondent "failed to address and, in fact, ignored these red flags, continuing to issue B.B controlled substance prescriptions in the face of mounting evidence that he was misusing, abusing, and/or diverting the controlled substances you were prescribing." *Id.*

In the allegations regarding the August 25, 2011 prescriptions, the Show Cause Order provided a detailed recitation of the factual basis for the allegation that the June 1, 2011 UDS was aberrant and that this "should have indicated . . . that B.B. may have been misusing/abusing the alprazolam by consuming more than he had been prescribed, or diverting it." *Id.* at 2. As for

the September 22, 2011 prescriptions, the Show Cause Order, after setting forth the factual basis for why the August 25 UDS was aberrant, proceeded to allege that Respondent “did not address with B.B. *the now second aberrant drug screen in an approximately three month period*, despite noting in the record that you had ‘extensively reviewed’ B.B.’s ‘[p]ast medical history.’” *Id.* at 3 (emphasis added). The Show Cause order then alleged that “[y]ou took no other steps to monitor B.B.’s controlled substance use, such as requiring him [to] take another drug screen *due to the two failed ones*, conducting a new [prescription monitoring report] check, or requiring him to submit to a pill count.” *Id.* (emphasis added).

In setting forth the allegations with respect to the October 6 and 20 prescriptions, the Show Cause Order alleged that “[y]ou still did not address with B.B. *the two aberrant drug screens*” and “[y]ou still had not confronted B.B. about *the two aberrant drug screens*” respectively. *Id.* at 4 (emphasis added). And with respect to the subsequent prescriptions, the Show Cause Order made multiple allegations such as that: 1) Respondent “did not take any steps to monitor [B.B.’s] controlled substance[] use despite his history of misusing, abusing, or diverting controlled substances” (Nov. 18, 2011 prescriptions); 2) “despite [B.B.’s] history of substance misuse, abuse, and/or diversion, you did not take appropriate steps to monitor his controlled substance use before issuing him these new prescriptions” (Jan. 19, 2012 prescriptions); and 3) Respondent again prescribed controlled substances “without taking appropriate steps to monitor [B.B.’s] controlled substance use despite the persistent red flags of abuse and diversion he previously presented” (Mar. 13, 2012 prescriptions).

Likewise, in its Pre-hearing Statement, the Government provided notice that “Dr. Owen [its Expert] will testify that [Respondent] should have been aware from documentation in B.B.’s file of red flags that B.B. may have been abusing or diverting controlled substances prior to

transferring his treatment to” Respondent (the period in which the June 1 UDS was obtained), as well as notice setting forth the factual basis as for why the June 1 UDS was aberrant. ALJ Ex. 5, at 10, 12-13. With respect to the September 22, 2011 prescriptions, the Pre-hearing Statement provided notice that the medical file shows that Respondent “never addressed with B.B. this now second aberrant UDS in an approximately three month period, despite noting in the record that [he] had ‘extensively reviewed’ B.B.’s past medical history” and that Respondent “took no other steps to monitor B.B.’s controlled substance use, such as requiring him to take another UDS *due to the two failed ones.*” *Id.* at 14 (emphasis added).

Moreover, with respect to the October 6 prescriptions, the Pre-hearing Statement provided notice that “Dr. Owen will testify that on this visit [Respondent] again failed to address with B.B. the two aberrant UDSs,” and with respect to the October 20, 2011 prescriptions, “the record lacks documentation that . . . he confronted B.B. *about the two aberrant UDSs.*” *Id.* at 15-16 (emphasis added). And with respect to the later prescriptions, the Pre-hearing Statement provided notice that Dr. Owen “will testify” that Respondent “also failed to take any steps to monitor B.B.’s controlled substances use despite B.B.’s history of misusing, abusing, or diverting controlled substances.” *Id.* at 16. *See also id.* at 17 (Jan. 19 prescriptions; “Dr. Owen will testify that despite the fact that this was B.B.’s first visit . . . in three months, and despite his history of substances misuse, abuse, and/or diversion, [Respondent] failed to take adequate steps to monitor B.B.’s controlled substance use before issuing him these new prescriptions”); *id.* at 19 (Mar. 13 prescriptions; providing notice that “Dr. Owen will testify” that Respondent again issued controlled substance prescriptions “without taking appropriate steps to monitor B.B.’s controlled substance use despite the persistent red flags of abuse and diversion he previously presented”).

Thus, the Show Cause Order's allegations and the Pre-Hearing Statement's disclosure of the expected testimony provided Respondent with more than adequate notice that the results of the June 1, 2011 UDS and his failure to address it would be at issue throughout the proceeding. And even if I concluded otherwise, the record is clear that the issue was litigated by consent.

Notably, during its direct examination of Dr. Owen regarding the September 22, 2011 prescriptions, the Government asked Dr. Owen the following questions:

Q: Would the aberrant urine drug test from June 1 have shown up in a review of the history?

A: Yes.

Q. Would the aberrant drug test from August 25, 2011, have shown up in the history?

A. Yes.

Q. And were those aberrant drug tests part of this medical file as you received it?

A. Yes, it [sic] was.

Q. What – how does [Respondent] address the aberrant drug tests in this 9/22 patient file note[]?

A. It's [sic] completely ignored.

Q. What steps should [Respondent] have taken regarding the aberrant drug screens?

A. He should have acknowledged their existence and then taken some corrective action.

....

Q. Does it appear that [Respondent] took any safeguard regarding the potential for diversion or abuse with the aberrant drug screens?

A. No.

Tr. 132-33.

Notably, Respondent did not object to any of this testimony. *See id.* Moreover, the Government asked similar questions of Dr. Owen regarding the later prescriptions, with no objection by Respondent. *See id.* at 136 (Oct. 6, 2011 visit; Q. "Having reviewed the patient file, can you tell me what steps [Respondent] took on this date to address the two previous aberrant urine drug tests?" A. "The previous aberrant urine drug tests are ignored and not addressed."); *id.* at 139 (Oct. 20, 2011 visit: Q. "What steps should [Respondent] have taken on this date?" A.

Respondent “[s]hould have, particularly in light of the previous aberrant drug tests . . . sought psychological counseling for this patient.”).⁷

Indeed, Respondent’s counsel raised the issue when, in Respondent’s case-in-chief, she asked him: ‘Do you recall if you looked back at the previous drug tests?’ *Id.* at 283.

Respondent answered: “I don’t recall, but I doubt I did” and “I wouldn’t expect myself to.” *Id.*

Respondent’s counsel then asked him if Dr. Schoelen had seen B.B. in June and July after the June 1 drug test, with Respondent answering “[t]hat’s correct.” *Id.* Respondent then testified that the test was reported back to his former partner, who saw B.B. on June 29 and July 26, before testifying that he would have “routinely looked at two, three different notes.” *Id.* at 284.

Subsequently, on its cross-examination of Respondent with respect to what he looked at in the chart when he took over B.B.’s care, the Government asked: “Did you see the June 1, 2011, UD[S], urine drug test?” *Id.* at 390. Respondent’s counsel raised no objection to the question and Respondent answered: “I don’t believe I did.” *Id.* While Respondent then asserted that he “assume[d]” that Dr. Schoelen “addressed every UDS,” when pressed as to whether, based on his review of the file, Dr. Schoelen had ever addressed the June 1 UDS, Respondent answered: “I didn’t review his part of the chart.” *Id.* at 390-91.

Thus, Respondent was clearly aware that his failure to address the June 1, 2011 drug test was at issue with respect to the entirety of his controlled substance prescribing to B.B. and in no

⁷See also Tr. 143 (Nov. 18 and Dec. 15, 2011 Rxs: Q. “Is there any mention anywhere about the aberrant drug tests and the results being discussed with BB?” A. “No, there’s not.”); *id.* at 147 (Jan. 19, 2102 visit and Rxs: Q. “Is there any mention of the aberrant urine drug tests from June or August in this [patient file] during this visit?” A. “There is not.”); *id.* at 154 (Feb. 13 Rxs: testimony of Dr. Owen’s that Respondent’s counseling B.B. “to take only as prescribed” after Jan. 19 drug test was not an adequate safeguard against abuse and diversion, “especially since this is the third aberrant drug test”); *id.* at 154-55 (Feb. 13 Rxs: Q. “In the face of so many aberrant drug tests, what steps – what should [Respondent] have done?”); *id.* at 158 (Mar. 13, 2012 Rxs: Q. “Are there any aberrant drug-taking behaviors here?” A. “There has [sic] been three previous.”); *id.* at 165-66 (Apr. 12, 2012 Rxs: Q. “Did he address any of the previous aberrant drug screens?” A. “He did not.”). Significantly, at no point did Respondent object to the questioning or testimony.

sense was this “an incidental issue” in the case. *Pergament United Sales*, 920 F.2d at 136 (citation omitted). He also had a full and fair opportunity to litigate the issues of whether the June 1 (as well other tests) were aberrant and whether he properly addressed them during the course of his prescribing to B.B. Accordingly, I find the Government’s exception well taken and will consider this evidence.⁸

Based on the preponderance of the evidence, I make the following findings.

FINDINGS OF FACT

Respondent is a family practice physician licensed by the Oklahoma State Board of Medical Licensure and Supervision. RX 1. Respondent graduated from the University of Oklahoma (OU) College of Medicine in 1989. Tr. 231. Thereafter, he did an internship through the OU “Tulsa/Bartlesville program” and “the last two years of his residency” in family medicine at OU in Oklahoma City. *Id.*

Respondent testified that upon completing his residency, he practiced family medicine and obstetrics for several years at several rural clinics. *Id.* at 234-35. He further explained that while working at one of the clinics, he was asked to become the medical director of a nursing home for terminal AIDS patients, which he did for approximately five years, after which he and Dr. Steve Schoelen bought a practice in Newcastle, Oklahoma which they named “Tri-City Family Medicine.” *Id.* at 235-36.⁹ Respondent practiced family medicine at Tri-City from approximately 2000 through 2012. *Id.* at 245. Respondent further testified that he was board

⁸ The Government’s remaining exceptions are discussed throughout this decision.

⁹ Respondent also testified that for approximately three years (which are not specified in the record) and during which he was still practicing at his clinic, he was also the medical director of Unicare of Oklahoma, a subsidiary of WellPoint, and that his duties involved oversight of the clinics, reviewing chart audits, and that “[w]e also were in charge of prior authorization.” Tr. 237, 240. He also testified that he sat on WellPoint’s national credentialing committee, which sat once a month for three hours and reviewed the credentials of practitioners applying to the company. *Id.* at 240. Respondent testified that he resumed working full time at Tri-City after the State cancelled its contract with Wellpoint to provide medical care to patients covered by the State’s Medicaid program. *Id.* at 242.

certified in family medicine until 2015. *Id.* at 247. Respondent testified that he could not reapply for board certification because he had not practiced family medicine for several years and does not “qualify to show them my charts . . . to qualify to take the test.” *Id.* at 248.

Respondent testified that due to the expense of malpractice insurance for his OB/GYN activities, he stopped delivering babies and focused on family medicine. *Id.* at 249. Respondent testified that he started seeing chronic pain patients around this time, but that Dr. Schoelen mostly saw these patients as he “took much more of an interest in the pain patients and pain management.” *Id.* He further testified that within days of Dr. Schoelen “telling Medicaid that he would accept chronic pain patients on Medicaid, we were overwhelmed with referrals from the emergency rooms . . . in Oklahoma City.” *Id.* at 253. According to Respondent, in response, Dr. Schoelen took continuing medical education (CME) classes and joined the American Academy of Pain Management. *Id.* The clinic also started using a pain management contract and contracted with a company for urine drug testing. *Id.* at 254.

Respondent testified that he did drug screens “every three months” and that any patient who received more than two Lortabs (hydrocodone with acetaminophen) a day would be subject to “the guidelines of our pain management contract and rules.” *Id.* at 256. Respondent further asserted that “[s]ometimes we [would] send [patients] for a second opinion” or for a “modality that we didn’t do” such as “an epidural or [a] further evaluation if something changed in their pain something changed neurologically.” *Id.* He testified that he would obtain a Prescription Monitoring Program report for “[e]very phone call for every prescription and every office visit.” *Id.* at 263. He also testified that the practice did not replace lost or stolen medications and that he had terminated a substantial number of patients over the years. *Id.* at 279-80.

The Investigation

Respondent came to the attention of the authorities on or about May 10, 2012, when police in Norman, Oklahoma found Respondent's patient B.B., a 27-year old male (RX 3, at 2), who was "semiconscious" and "appeared to be intoxicated" in a vehicle parked "in the center median of" Interstate-35. Tr. 18; RX 3, at 2. The police also found "several prescription bottles of opiate pain killers" which had been prescribed to B.B. by Respondent. RX 3, at 2-3; Tr. 18. With B.B.'s consent, the police searched his cell phone and found text messages that "indicated that [B.B.] was illegally buying and selling prescriptions drugs," as well as messages between B.B. and Respondent related to B.B.'s "medical care, prescription dosages and prescriptions to be picked up by" B.B. RX 3, at 3. In addition, the police found "numerous sexually explicit messages" that had been exchanged between Respondent's phone and B.B. *Id.*; Tr. 18. A Detective with the Norman police then contacted the Chief Investigator for the Oklahoma State Board of Medical Licensure and Supervision. Tr. 18. The Detective also notified a DEA Diversion Investigator (DI) that the police had found drugs in B.B.'s car and that the latter was a patient of Respondent; the Detective also asked the DI to attend an interview of B.B., who could not be interviewed until "the next day" because "he was too intoxicated." *Id.* at 46.

In the meantime, the Chief Investigator, who was familiar with Respondent's background because the latter "was on probation at that time for an incident that involved sexual misconduct," obtained a report from the Oklahoma Bureau of Narcotics Prescription Monitoring Program to "see any prescriptions that were prescribed by [Respondent] to" B.B. *Id.* at 18-19. The report showed that Respondent had written "numerous controlled drug prescriptions" for B.B. *Id.* at 19.

After reviewing the PMP report, the Chief Investigator notified the Board's Executive Director of his findings, *id.* at 21, who, on May 11, 2012, ordered the summary suspension of

Respondent's medical license. *Id.*; *see also* RX 3, at 3. The same day, the Chief Investigator went to Respondent's clinic to obtain B.B.'s record, interview Respondent, and serve the suspension order on him. *Id.* at 21. While Respondent was not at the clinic, the Chief Investigator spoke with him by phone and made arrangements to return on May 14 (a Monday); the Chief Investigator also took B.B.'s chart. *Id.*

On May 11, 2012, the DI and two Detectives interviewed B.B., who "confirmed that he was" Respondent's patient. *Id.* at 48. B.B. admitted that "he used the Opanas [oxymorphone]¹⁰ himself" but "denied that he snorted them." *Id.* B.B. explained that "[h]e crushed them up and put them in an energy drink, which he had in his vehicle . . . when he was found" by the police. *Id.* B.B. also told the Investigators that "[n]ot only was he a user of it, he also sold the medications." *Id.* After the interview, the DI was informed by the lead Detective that he had spoken to the Board's Chief Investigator and that the Board's Investigators were going to meet on Monday May 14 and go to Respondent's office. *Id.*

On that day, the Chief Investigator (accompanied by another Board Investigator), the DI and the lead Detective went to Respondent's clinic to interview him. *Id.* 25. During the interview, the Board's Chief Investigator confronted Respondent "with some of the sexually graphic text messages sent from his phone to the patient." RX 3, at 3. While Respondent "admitted that he may have made social comments to [B.B.]," he "would not answer any more questions without contacting his attorney."¹¹ *Id.* "At that point," the Chief Investigator asked Respondent "to allow him to examine" his phone "for text messages to" B.B. *Id.* Respondent

¹⁰ As discussed more fully below, Respondent issued B.B. prescriptions for Opana 10 mg. on multiple occasions, including on May 9, 2012 which B.B. filled the next day. GX 5, at 27.

¹¹ Subsequently, Respondent denied that he had exchanged these messages and attributed this conduct to his partner at the time, stating that he had allowed his partner to have "access to his cell phone." RX 3, at 3; *see also* Tr. 415.

stated that “his phone was not available because it had been run over with his tractor over the weekend.” *Id.* The Chief Investigator then served the Board’s suspension order on Respondent. RX 3, at 3. The DI then informed Respondent that because he did not have state authority, he could not maintain his DEA registration and asked Respondent to voluntarily surrender his registration; Respondent agreed to do so. Tr. 49; *see also* GX 1, at 1.

On September 13, 2012, the Board lifted Respondent’s suspension.¹² RX 3, at 4. On October 4, 2012, Respondent applied for a new registration. GX 1, at 2. Because Respondent’s application included a “yes” answer to the liability question which asked whether his state professional license had ever been sanctioned, the application was forwarded to the Oklahoma City field office and an investigation was opened. GX 2, at 1; Tr. 62, 65, 81.

Thereafter, a Diversion Investigator obtained a copy of B.B.’s patient file from the Board and provided it to Graves Owen, M.D., an expert in pain management, to review and determine whether Respondent lawfully issued the controlled substance prescriptions. Tr. 50-52, 55. The DI testified that he did not ask Dr. Owen to come to any specific conclusion and that Dr. Owen’s compensation was not contingent on the conclusions he drew. *Id.* at 56. At the hearing, Dr. Owen testified that he has previously testified as to the “standard of care in pain management” and that he has testified for a defendant. *Id.* at 92.

The Government’s Expert’s Testimony as to the Standards of Medical Practice Applicable to the Prescribing of Controlled Substances to Treat Pain

¹² On March 7, 2013, Respondent voluntarily submitted to the jurisdiction of the Board and agreed to the entry of an Order which found him guilty of unprofessional conduct in that he: 1) “[v]iolated any provision of the medical practice act or the rule and regulations of the Board or of an action, stipulation, or agreement of the Board in violation of 59 O.S. § 509(13) and OAC 435:10-7-4(39)”; 2) “[e]ngaged in the improper management of medical records in violation of OAC 435:10-7-4(36)”; and 3) “[w]illfully betrayed a professional secret to the detriment of the patient[,] 12 O.S. §509(3).” RX 3, at 5. The Board did not, however, make any findings as to the legitimacy of the controlled substance prescriptions Respondent issued to B.B. The Board then extended Respondent’s pre-existing probation, which was the result of a 2008 Order based on findings that he had prescribed controlled substances to a patient with whom he had a sexual relationship, “[b]eginning in or around 2001 . . . through approximately 2004.” RX 3, at 2. The Board further found that when questioned about his relationship with this patient, Respondent “lied and denied that it existed” until he was confronted “with corroborating evidence.” *Id.*

Dr. Owen obtained a Bachelor of Science in chemistry and biology from Texas State University in 1985 and a Doctor of Medicine from the University of Texas Health Science Center (Houston) in 1990. *Id.* at 89-90; GX 4, at 1-2. After obtaining his M.D., Dr. Owen did a one year internship in internal medicine followed by a three-year residency in Anesthesiology at the UT Health Science Center; he then did a one-year fellowship in Pain Management at the University of Pittsburgh's Pain Evaluation and Treatment Center. GX 4, at 1. Dr. Owen holds a Texas medical license and is board certified by the American Board of Pain Management and American Board of Anesthesiology. *Id.* at 2. He is a member of the American Pain Society, the American Academy of Pain Medicine, the American Academy of Pain Management and the Texas Pain Society. *Id.* at 7. With respect to the latter organization, Dr. Owen served on its Board of Directors from 2009 through 2012 and served as its President from 2012 through 2014. *Id.* at 8. He has also served on the Society's Legislative Committee and on its Educational Committee for multiple years. *Id.*

Dr. Owen's work experience includes more than 16 years at the Texas Pain Rehabilitation Institute (Sept. 1995 through Nov. 2011), which is an interdisciplinary pain management clinic. *Id.* at 2. Since February 2011, he has been a Peer Reviewer on Pain Medicine for the Journal of the American Academy of Pain Medicine. *Id.* He has also served as a member of the Medical Quality Review Panel and as an Arbiter on the Quality Assurance Panel of the Texas Department of Insurance, Division of Workers Compensation, Office of Medical Advisor. *Id.* He has written several articles and made more than 40 presentations on subjects related to pain management before both professional and governmental bodies, including on the use of urine drug testing in pain management. *Id.* at 4-9. The CALJ accepted Dr. Owen "as an expert in pain management in Oklahoma and Texas." Tr. 91.

While Dr. Owen is licensed to practice medicine in Texas, he testified that he had reviewed Oklahoma's guidelines and policies. *Id.* at 93. Asked what the requirements are in Oklahoma for prescribing opioid controlled substances, Dr. Owen testified: "Well, first you have to do an appropriate history and physical exam for whatever the chief complaint is. You need to get all pertinent previous medical records pertaining to this chief complaint." *Id.* at 94. As to why a physician needs to obtain the patient's medical records, Dr. Owen explained that: "You want to know what has previously been performed as far as treatment elements and what resulted from those treatments, *and you also want to look for any previous aberrant behaviors.*" *Id.* (emphasis added).

The Government then asked Dr. Owen "what else is required?" *Id.* Dr. Owen explained: "So after you do an appropriate history and physical exam, you review the pertinent medical records. You may need to do consultations. You may need to do diagnostics, whether laboratory or imaging studies, and then you formulate a treatment plan based on the analysis of this information." *Id.* at 94-95. Asked to explain "[w]hat's a treatment plan," Dr. Owen testified: "A treatment plan is what we're going to do to move this person from wherever they are to the next place, and part of the treatment plan will be dictated by your treatment goals that you need to set up to try to get that person to the next place." *Id.* at 95.

Subsequently, Dr. Owen explained that "there [are] three broad treatments in pain management: interventional, rehabilitative, and pharmaceutical. So your treatment plan would list each of these categories if you're going to use elements of those categories in your treatment plan, and it would specifically define what your treatment plan is and how you tie it to your treatment goal." *Id.* at 97. Dr. Owen further testified that while treatment goals are "tailor[ed] . . . to the individual" and would be different depending upon a patient's age, "you would

primarily focus on functional improvements.” *Id.* at 99-100. With respect to someone of working age, Dr. Owen explained that “return[ing] to work” is “the gold standard for functionality in pain management.” *Id.* at 100.

Subsequently, Dr. Owen testified that a treatment plan can involve more than one of these approaches and that it evolves over the course of treating the patient if the treatment goals are not being achieved. *Id.* at 98-99. However, a physician “certainly would have [a treatment plan] on the initial visit.” *Id.* at 99. While Dr. Owen acknowledged that a treatment plan can be “tease[d] . . . out” of the patient’s record “without necessarily a formal title” if “enough information” is documented in the record, he then explained what content the plan should contain:

Well, if it’s interventional, you would talk about what intervention you’re going to do. If it’s rehabilitative, you’d talk about physical therapy, occupational therapy or psychotherapy. If it’s pharmaceutical, you’re going to talk about the specific pharmaceutical, its dose and the frequency that you’re going to prescribe it and hopefully the indication it’s being used for.

Id. at 98-99.

Asked whether the file for a patient being prescribed opioid controlled substances would contain anything else, Dr. Owen testified that you would “have an informed consent and a pain management agreement.” *Id.* at 99. Dr. Owen then explained that “[a]n informed consent is telling the patient what the risks and benefits are of this proposed treatment and what alternative treatments exist.” *Id.*

As to why a physician treating a patient for pain would seek consultation with other specialists, Dr. Owen testified that “[t]hese are complex cases, and you can’t be an expert of everything, and you may need help in narrowing your diagnosis or help in stabilizing comorbidities that are outside of your scope of practice.” *Id.* at 100. Dr. Owen further explained

that the need to consult with particular specialists “depends on the [patient’s] chief complaint and your differential diagnosis and what you’re trying to achieve.” *Id.*

Asked by the Government if “these requirements . . . are . . . best practices,” Dr. Owen testified that “some of them can be best practices, but most of them are standard of care items.” *Id.* at 100-01. Then asked if “when you say standard of care, are they required,” Dr. Owen explained that “they’re required based on the context of the chief complaint and . . . the facts of the situation.” *Id.* at 101. When then asked “are they required by law,” Dr. Owen initially answered “no” before explaining that:

Well, I’m not a lawyer. I would say that the policies and guidelines that I was sent for Oklahoma say certain things about consultations, and the one that stood out is if somebody’s a complex pain patient with psychological or psychiatric comorbidities, they should get consultations with a pain management physician with expertise in these complex cases.

Id.

Dr. Owen testified that “comorbid psychiatric conditions” include “depression, anxiety, maladaptive coping mechanisms, such as catastrophization, fear avoidance, disability conviction, and a sense of injustice,” which are “all built on a foundation of cognitive distortions.” *Id.* at 101-02. He also testified that there are “personality disorders and a whole host of psychiatric conditions like PTSD, OCD, bipolar, schizophrenia, [and] other scenarios like that, that make it more difficult to treat” a pain patient. *Id.* at 102. Dr. Owen then explained that these conditions “might magnify [a patient’s] perception of pain and disability and, in doing so, [a patient’s] experience of suffering is aggravated or increased.” *Id.*

The CALJ then asked Dr. Owen if the reason it is important to refer a pain patient to a mental health expert is so that the patient’s “subjective complaint[] of pain” can be “properly gauged?” *Id.* at 103. Dr. Owen answered: “So that you can help understand the context of their

pain and what might be distorting and magnifying their pain and suffering experience, because suffering is defined as your ability to cope with adversity, and everybody comes with different skill sets of how they cope with adversity.” *Id.* at 103-04. While Dr. Owen then acknowledged that “[p]ain is subjective,” he further explained that “function is objective, so that’s why [a physician would] use functions as [the] primary baseline for measuring therapeutic influence.” *Id.* at 104.

The CALJ then asked Dr. Owen if “ask[ing] the patient about activities of daily living” is “one of the tools that you use?” *Id.* Dr. Owen answered “yes” and added “[t]hat’s one of the things. Return to work, and you can do more global things like sitting tolerance, walking tolerance, standing tolerance, and then site-specific areas of functionality like range of motion and other physical exam measurements.” *Id.* at 104.

Dr. Owen was then asked to describe “the steps that a practitioner would take to determine whether a patient is truly experiencing chronic pain?” *Id.* at 106. He replied:

Well, there’s no objective way to know if somebody [is] experiencing pain, so you take them for their word at it. But what you need to do is to make sure that you go through a process to ensure that they have exhausted all the medically reasonable treatments before you go to a high-risk, non-evidence-based treatment.

Id. at 107.

Dr. Owen further explained that “[h]igh-risk treatments are treatments that have a potential for bad outcomes, and there’s evidence-based and non-evidence-based treatments. There’s low-risk, medium-risk, and high-risk treatments, and you have to have some context for how you approach the problem.” *Id.* Dr. Owen then opined that “chronic opioid therapy and chronic benzodiazepine therapy” are high-risk treatments. *Id.* He also opined that chronic

opioid therapy is not an evidence-based¹³ treatment, noting that there are “no publications” supporting the use of “chronic opioid therapy” and that “[m]ost of the opioid articles have poor outcome[] metrics.” *Id.* at 108.

Asked whether it is “permissible to taken on a patient who’s already on high-risk treatment and to continue them on high-risk treatment,” Dr. Owen testified that while a physician “can do that,” the physician must “adequately document the justification for skipping steps,” *i.e.*, low-risk¹⁴ and medium risk treatments, and must “make sure that [the patient is] obtaining a clinically meaningful and objective therapeutic outcome.” *Id.* at 109. He then explained that this means that the patient is “having functional improvement that is truly measurable” and that a patient’s “subjective report is problematic.” *Id.* And later, Dr. Owen testified that even when the care of a patient is transferred from one doctor to another in the same practice, the new doctor “need[s] to make sure that any previous documentation deficiencies or standard of care violations are rectified by doing a proper evaluation.” *Id.* at 206.

Next, the CALJ asked Dr. Owen what, as a chronic pain specialist, he would look at to determine if a patient who was referred to him was being successfully treated with long-term opioid therapy. *Id.* at 109. Dr. Owen answered that he would “first go to the previous medical records to see what functionality was documented before [the patient was] started on that treatment and compare it to” the patient’s current “functionality.” *Id.* Asked by the CALJ if “those would be subjective notes,” Dr. Owen explained that “if someone is not working and now they are working, although they’re subjective notes, there is an objective measure to it” and that

¹³ Dr. Owen explained that “evidence-based studies are studies published in peer review articles that actually show positive outcomes for the treatment, and ideally these treatments are compared to some kind of either non[-] treatment or a sham treatment.” Tr. 108.

¹⁴ Dr. Owen testified that low-risk, evidence-based treatments include physical therapy, occupational therapy and cognitive behavioral therapy.

“[w]henever possible, I like information from friends or family that’s with the patient about [the patient’s] functionality and what it was like, so there’s an independent assessment.” *Id.* at 109-10. Continuing, Dr. Owen explained that there are also “various psychometric tests on functionality, [including the] Oswestry Disability Inventory and other things like that, that measure your function in somewhat objective terms.” *Id.* at 110. However, Dr. Owen acknowledged that “it all comes down to [the patient’s] self-report.” *Id.*

The CALJ then asked Dr. Owen if there are “tests that are traditionally done in the office, such as . . . range of motion and other things . . . that have an objective sense to them?” *Id.* Dr. Owen answered that while “you can measure range of motion of the various joints and spine, and you can look at muscle strength and those kinds of issues . . . they don’t always correlate to your ability to work and other more global functionality.” *Id.* Dr. Owen also explained that in evaluating the patient’s functionality, “[y]ou want to look at [the] neurological assessment. You want to look at [the] straight leg raise. You want to look at spine range of motion, and you want to ask [the patient] how far can you can walk; how long can you sit, and those kinds of functional assessments as well.” *Id.* at 111.

Next, the CALJ asked Dr. Owen if on taking over a long-term opioid therapy patient, it is “generally true that [the patient will be] continue[d] on the . . . regimen?” *Id.* In response, Dr. Owen testified that he would not continue the regimen if the patient is “not clinically improved from the results of this treatment.” *Id.* Continuing, he explained that “[a] lot of people deteriorate on chronic opioid therapy and they actually do better when they’re taken off of opioids” because they have “opioid-induced hyperalgesia.” *Id.* Dr. Owen then explained that this “is a paradoxical response in which [a patient’s] pain gets worse while [he/she is] on opioids, and when [the patient is] take[n] off of the opioids, [his/her] pain improves.” *Id.*

Dr. Owen further testified that there is a difference between addiction and dependence. *Id.* at 112. After noting that “dependency will happen to anybody over time in which an abrupt cessation of the drug will cause withdrawal symptoms,” he explained that “addiction has three [additional] elements: craving the drug, continued use despite its harms, and inability to self regulate” the use of the drug. *Id.* at 112-13. Asked how he would tell whether a patient he had “just assumed the care of” was dependent or addicted, Dr. Owen explained that an addicted patient “may have self-escalation of [his/her] drugs, and . . . run out early.” *Id.* at 113.

Dr. Owen then explained that a physician “would use urine drug testing to see if [the patient] ha[s] all the drugs that were prescribed in [his] urine.” *Id.* The physician would also look for “other aberrant drug-taking behaviors” such as “lost medicines” and use the prescription monitoring program to look for “doctor-shopping . . . or other concerning activities.” *Id.* Dr. Owen further explained that “[y]ou would, when possible, talk to the family and see how [the patient’s] behavior is” as well as “look for volatile behavior . . . with your staff.” *Id.*; *see also id.* at 117-18 (testifying that “problematic behaviors” or “red flags” include “[l]ost or stolen medications, self-escalation of . . . medications without permission, aberrant urine drugs tests, [PMP] behaviors that look problematic,” and receiving reports that a patient is selling drugs).

While Dr. Owen acknowledged that the presence of suspicious behavior by a patient does not necessarily mean the patient is abusing or diverting controlled substances, it does require that the physician take “some type of corrective action.” *Id.* at 118. As for what type of action should be taken, Dr. Owen explained that “[i]t depends on the context” and that “there’s a spectrum of corrective actions . . . you might take . . . from shortening the leash and seeing the patient more frequently, with less drugs per prescription,” to not treating with controlled substances, “to firing the patient.” *Id.* at 118-19.

Dr. Owen disputed the CALJ's suggestion that the use of urine drug screens is "pretty controversial in the pain management field," stating that "[i]t's a standard of care." *Id.* at 113. After explaining that he would set the frequency of drug testing based on a risk assessment of the patient, Dr. Owen acknowledged that the "point of care" enzyme-amino assay test is a "preliminary test" and that "[y]ou can't use the results with any confidence." *Id.* at 114-15. Dr. Owen explained, however, that "the mass spectrometry test . . . is very reliable." *Id.* at 115. Dr. Owen further testified that a physician would "want to test for common illicit substances, because you don't just want to know what you're prescribing" and would want to know if the patient is using "non-prescribed drugs or any street drugs." *Id.*

Asked how a practitioner should respond to an aberrant drug test, Dr. Owen testified that "first you need to document the presence of the aberrant . . . test. You need to document your rationale for your corrective actions. And then you explain what the corrective action is going to be." *Id.* at 119. Dr. Owen then reiterated his earlier testimony that "the corrective action" could be "seeing the patient more frequently with less drugs"; referring the patient to see an addictionologist or a psychiatrist or psychologist "with experience in addiction medicine" for a consultation; having the patient see a physical medicine specialist "to look at more functional goals"; and in severe cases, terminating treatment with controlled substances. *Id.* Dr. Owen also testified that "[t]here's no reason ever to ignore a red flag" and that a physician has a duty to resolve the red flag before prescribing. *Id.*

Returning to the issue of what constitutes an adequate medical history, Dr. Owen testified that:

. . . it's a history that's appropriate for whatever the chief complaint is, for example, low back pain. It includes a who, what, when, why, where, and type of elements that you would do in most any kind of a journalism course.

So you'd say, how did you hurt yourself; where does it hurt; does the pain radiate down an extremity; if so, how far down; does it go past the knee; where does it end up; is there any numbness or weakness associated with it. And then you would talk about what treatments have you had or what diagnostics have you had.

And you'd gather as much of that information, and you'd ask . . . how's the pain affecting you physically and psychosocially. And that's part of the Oklahoma guidelines is that you assess the person functionally, physically and psychosocially.

Id. at 115-16. Dr. Owen then testified that this information is required to be documented in the patient file, and if it is "not in the file," the assumption is that "it wasn't done." *Id.* at 116.

Continuing, Dr. Owen explained that:

. . . if you don't do a proper history and a proper physical exam, if you don't look at all the pertinent previous medical records, you can't get an accurate diagnosis. And . . . you can't draw any accurate conclusions about what is the right treatment plan. And if you don't do accurate assessments, it results in potentially dangerous treatments that aren't reasonable or medically necessary.

Id. at 117.

Asked by the CALJ to explain what a pain management contract is, Dr. Owen testified that it's "a document informing the patient what the rules of the road are." *Id.* at 120. Dr. Owen testified that the contract contains provisions that the patient "won't get drugs from anybody else . . . for th[e] condition," the patient "will only go to one pharmacy," that the patient "will use the drugs only as directed," and the patient will "submit[] to urine or blood drug testing." *Id.* Then asked by the CALJ if, in Oklahoma, the use of a pain management contract is a "best practice" or part of the "standard of care," Dr. Owen testified that it "is part of the [Oklahoma] guidelines of [the] standard of care." *Id.* Dr. Owen also testified that "when taking on a new patient," a physician "needs to have a pain management contract and informed consent." *Id.* at 121. Finally, when asked by the CALJ where "there is a difference" between the standard of care for "a pain management specialist and someone who is treating a patient . . . for pain symptoms," Dr. Owen explained that "[t]here's only one standard of care." *Id.* at 120-21.

On cross-examination, Dr. Owen was asked whether a prescriptive practice can “be within . . . legitimate medical practice and still be below the standard of care?” *Id.* at 181. In response, Dr. Owen testified that a physician “can violate the standard of care and still have a legitimate medical practice, but [cannot] be in the standard of care and have an illegitimate medical practice.” *Id.* When later asked “[w]hat goes into determining if the standard of care has been met,” Dr. Owen testified that “the standard of care is what a reasonable and prudent physician would do in the same or similar circumstances, and a reasonable, prudent physician would go to the evidence-based literature as a foundation for how to make decisions using critical thinking skills.” *Id.* at 183. When then asked “if there’s a community standard of care in Oklahoma,” Dr. Owen answered that “[t]here’s no such thing as a community standard of care anymore. It’s a national standard of care, and it’s based on our evolving body of knowledge, and as we learn new things, the standard changes.” *Id.* Dr. Owen then acknowledged that he did not know the Oklahoma Medicaid rules for when a patient can be referred. *Id.*

On further cross-examination, Dr. Owen was asked whether the Oklahoma Guideline which addresses the need for consultation with an expert in the management of patients who have a history of substance abuse or a comorbid psychiatric disorder is mandatory as he had previously testified. *Id.* at 185-86. Dr. Owen acknowledged that the provision states that these two conditions “may require” consultation. *Id.* at 186. He then added, however, that a physician “should document why [he] deviate[d] from that recommendation.” *Id.*

The Prescribing Events

The August 25, 2011 Prescriptions

B.B.’s patient file reflects that from the date of his first visit on or about April 24, 2009 up until August 25, 2011, B.B. obtained narcotic prescriptions from Dr. Schoelen, Respondent’s

partner. *See generally* GX 3; Tr. 236. While on August 25, 2011, Dr. Schoelen issued B.B. a prescription for 120 tablets of oxymorphone 10 mg, the same day, Respondent wrote B.B. prescriptions for 150 hydrocodone/acetaminophen 10/500 as well as 60 carisoprodol 350.¹⁵ GX 3, at 24.

B.B. was not seen by either Dr. Schoelen or Respondent on this day. GX 3, at 49. However, he was required to provide a urine sample, the results of which were reported by the lab on August 29, 2011.¹⁶ *Id.* at 99. While the lab results were expected with respect to the narcotics B.B. had previously been prescribed, the lab also detected the presence of nordiazepam, a metabolite of diazepam; oxazepam; and temazepam; none of these drugs had been prescribed to B.B.¹⁷ *Id.*

While the Government alleged in the Order to Show Cause that the prescriptions Respondent issued on this day were “invalid” and violated 21 CFR 1306.04(a) and made extensive factual allegations to support this conclusion, it did not elicit any testimony from its Expert as to why. Moreover, Respondent testified that this was “a nurse-only visit” and that he issued the prescriptions because “Dr. Schoelen works half [a] day” and while Schoelen had issued one of the prescriptions, “he had missed the fact that – or the nurses had missed and not

¹⁵ At the time carisoprodol was not controlled under the CSA. However, a proceeding to control the drug was then ongoing and the drug became federally controlled effective on January 11, 2012. *See Schedules of Controlled Substances, Placement of Carisoprodol Into Schedule IV*, 76 FR 77330 (final rule). However, during 2011, the drug was a controlled substance under Oklahoma law. *See* Okla. Stat. tit. 63, § 2-210 (2011)

¹⁶ On June 1, 2011, B.B. had also provided a urine sample. GX 3, at 103. This test, which was reported by the lab on June 6, 2011, yielded a negative result for alprazolam, even though B.B. was then being prescribed alprazolam by another physician. *Id.* According to a PMP report, B.B. had filled alprazolam prescriptions for a 30-day supply on both May 9 and June 6, 2011. *See id.* at 25.

¹⁷ While the lab results also noted that B.B. had tested positive for alpha-hydroxyalprazolam, a metabolite of alprazolam, and reported this result as “not expected based on prescribed medications,” B.B. had obtained a prescription for a 30-day supply of alprazolam on July 29, 2011 and filled the prescription the same day. GX 3, at 36.

written the other two medications for him.” Tr. 389. The CALJ found this testimony credible. R.D. at 31.

As the Government put forward no evidence to support the conclusion that it was outside of the usual course of professional practice for Respondent to cover for his partner, nor cites to any state rule prohibiting prescribing under this circumstance, I find that the allegation is unsupported by substantial evidence.¹⁸

The September 22, 2011 Visit and Prescriptions

On some date after August 25, 2011, the State Board suspended Dr. Schoelen’s medical license and Respondent took over the treatment of B.B., who came for an office visit on September 22, 2011. Tr. 290; GX 3, at 48.¹⁹ See GX 3, at 103; *id.* at 25. According to the progress note for the visit, B.B. had come in “for a recheck on lumbar disc disease” and also had a “left abdominal hernia as well.” *Id.* at 48. Respondent also indicated in the progress note that

¹⁸ In its Exceptions, the Government argues that the CALJ erred in finding the allegation with respect to the August 25, 2011 prescriptions not proved. See Exceptions, at 44-47. It argues that because Respondent issued the prescriptions without seeing B.B. on that date, without having seen him previously, and without reviewing the PMP, and because he testified that he reviewed only B.B.’s “medical history and the last two office visit notes” made by Dr. Schoelen, the “issuance of the two prescriptions fell far below the standard of care and outside the usual course of practice.” *Id.* at 46.

As noted above, the Government elicited no testimony from Dr. Owen as to whether Respondent’s issuance of the prescriptions was below the standard of care or outside of the usual course of professional practice. Apparently, the Government relies on subsection 1 of the Board’s chronic pain rule, see Okla. Admin. Code § 435:10-7-11(1), which requires that “[a] medical history and physical examination . . . be obtained, evaluated and documented in the medical record” in order to prescribe a controlled substance. See Exceptions, at 45 (arguing that “the OK Pain Rule sets forth the standard of care for Oklahoma prescribing controlled substances . . . for the treatment of pain”).

However, in 2014, the Board promulgated an exception to the requirement that “[t]he physician/patient relationship shall include a medically appropriate, timely-scheduled, face-to-face encounter with the patient,” which allows “providers covering the practice of another provider [to] approve refills of previously ordered medications if they have access to the medical file of the patient.” Okla. Admin. Code § 435:10-7-12(1). While this rule was not in effect when Respondent issued the prescriptions, it strains credulity to suggest that providing prescriptions under the circumstances of covering for a partner violated the standard of care two years earlier when Respondent issued the prescriptions. While the Government speculates that Dr. Schoelen “may not have issued B.B. these two prescriptions purposefully pending the results of the new UDS,” Exceptions at 46, and argues that Respondent was required to call Dr. Schoelen as a witness to corroborate his testimony, the Government ignores that it had the burden of proof on this issue.

¹⁹ According to a PMP report in B.B.’s patient file, he had filled a prescription for a 30-day supply of alprazolam on May 9, 2011. GX 3, at 25.

B.B.'s "[p]ast medical history [was] extensively reviewed and placed in [the] chart." *Id.* Respondent documented that he did a physical exam, noting, *inter alia*, "[l]umbar very painful spinal and paraspinal tenderness," a "[n]egative straight leg raise," and "[n]euro intact." *Id.* Respondent diagnosed B.B. as having "lumbar disc disease" and a hernia; his plan included having B.B. obtain an MRI, changing him from Lortab to Duragesic patches, and continuing Respondent on Opana and Soma (carisoprodol). *Id.* Respondent also documented that he had discussed the "[a]ddictive, dependence, and tolerance nature of the medicines," the "use of Duragesic," and suggested "[n]on-medicinal pain-relieving modalities." *Id.*

B.B.'s file also contains a Pain Management Treatment Plan, which includes a section bearing the caption: "Treatment Objective Evaluation." GX 3, at 28. This form lists several questions, with boxes for documenting by date, various findings which included: "Has patient achieved treatment objective?"; "Patient completed . . . updated pain scale"; "Re-review benefits and risks of using medications"; "Consider referral to another physician for second opinion or further treatment options"; "Changes to Treatment Plan"; and the "[p]hysician's initials." *Id.* For this visit, Respondent wrote "yes" as to whether B.B. had achieved the treatment objective (which was documented as "to be able to work without pain," *id.* at 29), wrote the number "3-5" in the pain scale block, and noted "yes" with respect to both whether he had re-reviewed the risks and benefits of controlled substances and considered a referral to another physician.²⁰ *Id.* at 28.

²⁰ In contrast to this document which contains a single box in which Respondent and Dr. Schoelen would write a number for B.B.'s pain (the "Patient Completed . . . updated pain scale"), B.B.'s file contains a "Patient Comfort Assessment Guide" form which B.B. completed on September 2, 2009. GX 3, at 32-33. On this form, B.B. circled various words such as "aching," "throbbing," "shooting" and "stabbing" to describe his pain which he maintained was "continuous" and at its worst in the "afternoon" and "evening." *Id.* The form also contains four instructions which directed B.B. to rate his pain on a numeric scale of 0 to 10 (with 0 being "no pain" and 10 being "[p]ain as bad as you can imagine"), at its worst, "its least," and "on average in the last month," as well as "right now." *Id.* at 32. In addition, the form asked "[w]hat makes your pain better," "what makes your pain worse," as well as "what treatments or medicines are you receiving for your pain," and it further instructed the patient to numerically rate the relief he obtained (again on a 0 for "no relief" to 10 for "complete relief" scale) from the treatment or medicine. *Id.*

Dr. Owen testified that because this was B.B.'s first visit with Respondent, Respondent should have "do[ne] a proper history and physical exam and review[ed] previous treatments and everything that typically is expected for a new patient evaluation." Tr. 131. According to Dr. Owen, this included reviewing B.B.'s patient file which included the aberrant June 1 and August 25, 2011 drug tests. *Id.* at 132.

With respect to the August 25 drug test, Dr. Owen testified that B.B. had previously received prescriptions for alprazolam, hydrocodone, Soma (carisoprodol) and oxymorphone. *Id.* at 130. As found above, each of these drugs (or its metabolites) was detected by this test. *Id.* Dr. Owen then noted, however, that there were "no prescriptions for the metabolites of diazepam, which is nordiazepam, or oxazepam or temazepam." *Id.* And he further noted that in the comment section with respect to these three drugs, the lab report stated that "[t]hese test results were not expected based on the [prescribed] medications." *Id.*

Dr. Owen testified that Respondent "completely ignored" the aberrant drug screens and "should have acknowledged their existence and then taken some type of corrective action." *Id.* at 132. Dr. Owen also testified that the patient file did not reflect that Respondent had consulted or discussed B.B. with past or current prescribers and that it did not appear that Respondent had taken any "safeguards regarding the potential" for diversion or abuse presented by the aberrant drug screens. *Id.* at 132-33.

On the form's second page, it asked "[w]hat side effects or symptoms are you having," and directed B.B. to "[c]ircle the number that best describes your experience during the past week," again using a 0 ("Barely Noticeable") to 10 ("Severe Enough to Stop Medicine") scale for 10 side effects and symptoms such as nausea, vomiting, constipation, lack of appetite, difficulty thinking and insomnia. And finally, the form directed B.B. to "[c]ircle the one number" – on a scale of 0 for "not [i]nterfer[ing]" to 10 for "[c]ompletely [i]nterfering" – which "describes how during the past week pain has interfered with" his "[g]eneral [a]ctivity," "[m]ood," "[n]ormal work," "[s]leep," "[e]njoyment of [l]ife," "[a]bility to [c]oncentrate," and "[r]elations with [o]ther [p]eople." *Id.* Of note, there is no evidence that B.B. was required to complete this form at any subsequent visit.

Dr. Owen then testified that the patient record did not justify the prescribing of controlled substances as it did not “establish medical necessity for this type of treatment.” *Id.* at 133. As the basis for his conclusion, Dr. Owen explained that:

For one, it’s a superficial evaluation that doesn’t adequately explain the chief complaint or what previous treatments have or have not been done. And there’s no evaluation of pain or function, physical or psychosocial in the documentation. There’s no evidence of a previous therapeutic benefit. There’s no medical rationale for continuing with an ineffective treatment, so there’s no justification to continue treatment with controlled substances.

Id. Dr. Owen also explained that “[t]here’s no proof that he’s exhausted conservative care before going into these high-risk treatments” and reiterated that “[t]here’s no evidence of a therapeutic benefit.” *Id.* at 134. And with respect to the aberrant drug screens, Dr. Owen testified that Respondent “could have sent this gentleman for evaluations by an addictionologist, by a psychiatrist [or psychologist] with experience in addiction medicine, and certainly looked at being much more careful and objective about how [he] measure[d] a therapeutic benefit with the controlled substances.” *Id.* Dr. Owen thus opined that the prescriptions Respondent provided at this visit were not issued in the usual course of professional practice and lacked a legitimate medical purpose. *Id.* at 133.

On cross-examination, Dr. Owen was asked if he considered Respondent’s ordering of an MRI at this visit to be “a safeguard.” *Id.* at 188. Dr. Owen initially answered “no,” before explaining that “[i]t depends [on] if you clinically need the MRI, and you only need the MRI if you’re looking for something that has potentially a surgically correctable lesion,” and that absent “a clinical finding” that suggests “an MRI is needed to confirm a lesion that’s surgically reversible . . . you don’t have medical necessity to get an MRI.” *Id.* Dr. Owen further explained that “MRIs have high false positive rates” and that “[a]bnormalities are commonly found in asymptomatic people.” *Id.* On questioning by the CALJ as to whether when a patient complains

of “a high subjective level of pain,” an MRI could “at least confirm [if] there was some objective basis for it,” Dr. Owen explained that “without a neurological finding,” it is “rarely . . . valuable to get an MRI.” *Id.* at 189. He further explained that MRIs show “abnormalities that are nonspecific” leading to “overtreatment,” and thus a physician “need[s] something more objective from a physical exam finding to get an MRI.” *Id.*

In response to a further question by the CALJ which posited whether an MRI would provide an objective basis such as “foraminal narrowing” or “spondylosis” for concluding that a patient “may be having a spine issue” and is not “making it up,” Dr. Owen explained that “foraminal stenosis or foraminal narrowing are common in asymptomatic people.” *Id.* at 190. Dr. Owen then explained that “[t]he only reason it would be important is if you have a radiculopathy you’ve identified on clinical exam . . . and that would be pain going down the leg in a dermatome distribution, typically below the knee.” *Id.* Continuing, Dr. Owen explained that there may be “numbness” and there may be “weakness associated with the isolated nerve that’s being entrapped, and you would have a positive straight leg raise.” *Id.*

Dr. Owen further noted that “almost all the exams” on B.B. “said it was negative straight leg raise” and that this is “the most sensitive physical finding for low back pain.” *Id.* Dr. Owen then explained that “a sensitive test means that if you don’t have a positive finding you don’t have that diagnosis.” *Id.* Moreover, Dr. Owen testified that even if a patient reported symptoms consistent with radiculopathy, “you’d want physical exam findings, with the most important being the straight leg raise, according to the North American Spine Society.” *Id.* at 191. Dr. Owen further explained that “if you had a negative straight leg raise, then you don’t have radiculopathy, and if you don’t have radiculopathy . . . you really don’t need to get an MRI,

because it's just going to lead to finding things that send you on a garden path of overinterpreting the diagnosis." *Id.*

Regarding B.B.'s September 22, 2011 visit and the prescriptions he issued, Respondent testified that the first thing he would do when entered the exam room is look at the Pain Management Treatment Plan (GX 3, at 28) after which he would "look[] at his previous notes."²¹ Tr. 286. According to Respondent, he would ask the patient if he had "achieved [his] objective in the pain medicine contract" and "what [the patient's] pain level is on medicine" and use "a scale of 1 to 10." *Id.* Continuing, Respondent testified that "then we [would] talk about what their medicines are and what utilization that we would use, what the risks are using the medicines . . . what our plans are, what treatment, what goal we're going to go for, and what we might need to change or initiate in the treatment, and then decide whether [to do] a urine drug screen." *Id.* at 286-87. Respondent then testified that B.B. "basically said that he had achieved his pain goal and that he was only a 3 to 5 out of 10, that he preferred that we not make any changes or any type of referral at that time, and I did a urine drug screen." *Id.* at 287. There is, however, no evidence that Respondent did a urine drug screen at this visit. See GX 3.

Respondent was then asked by his counsel if he looked back at the August 25 drug screen. Tr. 287. Respondent testified that he "would not" have discussed the results with B.B. because "[b]asically he was on all the medicines he was prescribed, and according to [the lab], if you're on one benzodiazepine, all the other benzodiazepines can appear positive within the drug

²¹ However, in discussing the August 25 prescriptions, Respondent testified that "[a]nytime I had to do anything with the chart of Dr. Schoelen's or pain management or anyone that I hadn't seen before, I would look at their last two office notes, and I'd look at their past medical history sheet on the front that's filled out by the physician . . . and then I would look at the PMP." Tr. 281.

Asked with respect to the August 25 prescriptions if he "looked back at the previous drug tests," Respondent answered: "I don't recall, but I doubt I did. . . . I wouldn't expect myself to." *Id.* at 283.

screen.” *Id.* Respondent then testified that B.B. was “on Xanax [alprazolam] by another provider, and he was also on Ambien.” *Id.* Asked how he knew that B.B. was on both drugs, Respondent testified that B.B. had listed the alprazolam on the intake form he completed at his first visit and while the Ambien was not listed “on his past medical sheet, [it] was on the PMP.” *Id.* Respondent then added that the Ambien was prescribed by B.B.’s psychiatrist. *Id.* at 289. He further maintained that when the practice “started doing pain management, we were getting multiple episodes where patients were denying that they had taken other benzodiazepines,” and when they contacted the lab, the lab told them that Xanax can cross-react and cause a positive result on the mass spectrometry for other benzodiazepines. *Id.* Thus, Respondent maintained that he did not believe this to be an aberrant drug screen. *Id.*

Respondent further testified that although he took over the care of B.B., he did not simply continue the same treatment that Dr. Schoelen provided. *Id.* at 290. Rather, he testified that based on his “education and . . . experience, especially with Lortab . . . I found it too addicting to keep people on short-acting pain medicines.” *Id.* at 291. Respondent told B.B. “that there would have to be . . . a change in his treatment, and that I would have to use a long-acting pain medicine and a short-acting only for breakthrough” pain. *Id.* While Respondent continued B.B. on carisoprodol and Opana, he took B.B. off of Lortab “and gave him a two-week trial of the Duragesic patch.” *Id.*

Respondent also maintained that B.B.’s “reported pain and his objective” were consistent with the findings on physical examination. *Id.* at 292. He also testified that he had discussed the use of Duragesic and that it, as well as morphine and Opana ER, were the “only long-acting pain medications that” the Oklahoma Medicaid program “would cover” and that Medicaid would

only pay for three prescriptions a month.²² *Id.* Respondent further maintained that he and B.B. had discussed non-medicinal pain-relieving modalities so that B.B. knew that he believed in them and that he then ordered the MRI. *Id.* at 293.

As for why he ordered the MRI, Respondent testified that it was the “[s]tandard of care in Oklahoma,” and that while “[h]e had an X – ray done in 2009 that was consistent with his finding . . . [i]f you treat chronic pain . . . patients and [are] audited by the Board or your insurance company [and] you don’t have an objective finding in the chart, such as X-rays and MRIs, you’re quite . . . the outlier.”²³ *Id.* Respondent added that he “wanted to make sure that [B.B.] was consistent with . . . [w]hat he was being treated for and what his exam [sic] and the fact that he was on a Schedule II narcotic.” *Id.* at 293. Respondent then explained that while an MRI might give a false positive, “[i]f the pain is consistent with it, it’s just one more piece of evidence that gives you a reason to believe that the patient’s legitimate and that you’re legitimately treating his condition.” *Id.* at 294. Respondent also testified that an MRI provides a baseline should his exam change at a later date. *Id.*

The October 6, 2011 Visit

On October 6, 2011, B.B. again saw Respondent. In the visit note, Respondent wrote: “Patient has been on the DURAGESIC 50 mcg and the OPANA. Now, he would like to try the Morphine. He is slowly trying to figure out the right regimen for him.” GX 3, at 47.

Respondent again noted in the chart that “[p]ast medical history extensively reviewed and placed

²² It is unclear, however, whether B.B. was on Medicaid or Medicare or both at the time of the prescription. See, GX 3, at 7 (copy of B.B.’s Medicare card and Sooner Care Medical ID card); *id.* at 8-9 (Medical Home Agreement for SoonerCare); *id.* at 10-13 (Advance Beneficiary Notices dated during 2011 through 2012 advising B.B. that “Medicare probably will not pay for” various items or services and explaining appeal rights if Medicare did not pay); *id.* at 14 (referral form for SoonerCare dated 10-14-09). See also Tr. at 192-93. Moreover, Respondent offered no testimony as to whether Medicare used the same formulary as the Oklahoma Medicaid program.

²³ A progress note for B.B.’s September 2, 2009 visit stated that an x-ray was obtained and confirmed the existence of lumbar thoracic scoliosis but that the disc spaces appear to be within normal limits. GX3, at 59. The Government did not, however, ask its Expert to address the significance of these findings.

in chart.” *Id.* With respect to the physical exam, Respondent noted: “[l]ow back paraspinal tenderness,” “[n]egative straight leg raise,” and “[n]euro intact.” *Id.* Respondent also found that B.B. “has a left abdominal wall hernia.” *Id.* Respondent listed his diagnoses as “[l]umbar disc disease” and “anxiety.”²⁴ *Id.*

At the visit, Respondent prescribed 30 tablets of Morphine Sulfate ER15 mg B.I.D. (one tablet twice per day), for a 15-day supply. GX 5, at 25. Respondent also recommended that B.B. “[w]ear a corset if at all possible” for his hernia. GX 3, at 47.

Regarding the prescription, Dr. Owen testified (in the words of Government counsel) that it is not “normal practice . . . for patients to dictate the controlled substances they’re prescribed.” Tr. 135. Asked “why not,” he explained that a physician must “safeguard the patient against addiction, and you need to do things that are medically necessary, not what patients want.” *Id.* at 135-36. Dr. Owen further testified that “it’s a yellow flag for a patient to ask for a drug specifically,” but not necessarily “a red flag” as “it could mean [the patient] had a previous experience with the drug and either found it helpful, or they’ve had previous experience from the drug from an illicit means.” *Id.* However, because Respondent did not document that he addressed “B.B.’s previous history with morphine” B.B.’s request was “elevate[d] to a red flag.” *Id.* at 136.

Asked what steps Respondent should have taken, Dr. Owen testified that “just the fact that the aberrant urine drug tests were there means that you should get some consultations, because . . . this is a complex issue, and there’s behaviors going on that you can’t quite understand without a more thorough assessment by mental health providers or addictionologists.” *Id.* at 136-37. According to Dr. Owen, this was so even if B.B. had not asked for morphine. *Id.* at 137.

²⁴ Respondent found, however, that B.B. was “[a]lert and oriented and in no apparent distress.” GX 3, at 47.

Here again, Dr. Owen testified that the medical record did not justify the prescribing of controlled substances. *Id.* He explained that:

this is a superficial evaluation that does not properly address the chief complaint of low back pain or establish medical necessity for treating with controlled substances. There's no assessment of pain, physical or psychosocial function, and therefore, there's no medical necessity to continue treatment with controlled substances, and if you don't have medical necessity, you don't have a legitimate purpose to treat.

Id. And again, Dr. Owen opined that the prescriptions “were not” issued in the usual course of professional practice and “were not” for a legitimate medical purpose. *Id.* at 137-38.

Regarding this visit, Respondent testified that B.B. had “report[ed] that his objectives were only fair” and that “[h]is pain level had gone up to a 6 out of 10 on the Duragesic.” *Id.* at 295. Respondent further testified that “[w]e again went over what the rules were and what the Medicaid and the Duragesic and what the risk benefits were. We talked about whether we needed to make a referral at that point or make any other changes.” *Id.* Respondent also testified that B.B. “had a full exam” but that “[t]he MRI was not back yet.” *Id.*

As for the statement in the progress note that B.B. “would like to try the Morphine,” GX 3, at 47, Respondent testified that B.B. “did not believe the Duragesic was sufficient and that he wanted to try one of the other medicines that was on the formulary.” Tr. 296. Respondent testified that he did not believe this to be a “red flag” in B.B.’s case because he “had made it very clear to [B.B.] what our choices were” under the Medicaid formulary and “the majority of patients are very concerned [because] Duragesic and morphine are used for dying cancer patients, and why are we putting them on medications for dying.” *Id.* Respondent then testified that he was “sure I told [B.B. that] Duragesic, morphine and Opana ER” were his options. *Id.*

The CALJ, observing that “saying the patient requested morphine . . . is kind of a remarkable note,” asked Respondent how his conversation with B.B. went. *Id.* at 298.

Respondent answered: “Probably that I didn’t like the Duragesic and you suggested that morphine was an option. Can we try the morphine this time. Probably something like that.” *Id.* at 299. Respondent added that B.B. “was not pleased . . . that we changed the Lortab and the Opana, so the fact that I made him do the Duragesic, he was not happy.” *Id.* at 300. Respondent further noted that he “did his exam” and “[i]t was still consistent that he did have left abdominal wall weakness.” *Id.* Respondent explained that “[h]is diagnosis was lumbar disc disease, anxiety, and a questionable upper respiratory infection” and that he “placed [B.B.] on antibiotics.” *Id.* As for his abdominal wall pain, Respondent discussed with B.B. “wearing a corset if at all possible” because he did not “want to confuse his . . . abdominal pain[] with his level of pain because of my change in his pain regimen.” *Id.* Respondent further explained that B.B. “would follow up . . . in two weeks” and was given only “a two week supply of his new Schedule II medicine.” *Id.* According to Respondent, “anytime [he] made a large change in [a patient’s] medications, [he] would only give a two-week” supply in the event the patient was “allergic to it,” was “going to abuse it,” or “got no pain relief whatsoever.” *Id.* at 302.

Respondent also testified that he had given B.B. a shot of Decadron, a steroid, which “sometimes” provides patients in “severe pain” with “significant relief” and is “a great indicator that [the patient’s] pain was more inflammatory than other nature.” *Id.* at 301.

The October 20, 2011 Visit

B.B. again saw Respondent on October 20, 2011. GX 3, at 46. According to the progress note, B.B. reported that “his stress [was] up,” that he had “los[t] his father, and “he [was] having a lot of grief.”²⁵ *Id.* Respondent again noted that B.B.’s “[p]ast medical history [was] extensively reviewed and placed in chart.” *Id.*

²⁵ Yet Respondent also noted that B.B. was “[a]lert and oriented and in no apparent distress.” GX 3, at 46.

As for the physical exam, Respondent noted that B.B. had “[l]ow back paraspinal and spinal tenderness” and a “[n]egative straight leg raise, but [that] lying down and sitting up cause him a lot of pain.” *Id.* He also noted “[n]euro intact.” *Id.* Respondent again diagnosed B.B. with “[l]umbar disc disease” and added a further diagnosis of “[a]cute grief.” *Id.* Respondent documented that he discussed the “[a]ddictive, dependence, and tolerance nature of the medicines as well as alternatives,” that he suggested “[n]on-medicinal pain-relieving modalities,” and that the follow-up would be either “p.r.n.” (as needed) or “three months per his pain contract.” *Id.* Respondent also issued B.B. new prescriptions for 120 Opana 10 (one tablet every 6 hours P.R.N. for breakthrough pain) and 90 Morphine Sulfate ER 15, increasing the dosing of the latter drug to one tablet in the morning and two tablets in the evening. *Id.*; *see also* GX 5, at 19, 22.

With respect to the statement in the progress note that B.B. was having a lot of stress and grief, Dr. Owen testified that this “magnifies the perception of pain and disability” and that because there were previous “aberrant behaviors going on and now . . . another stressor in [B.B.’s] life,” this “increase[d] the risk” that B.B. would “use [the] drugs to chemically cope.” Tr. 139. Dr. Owen then explained that Respondent should have “sought psychological counseling for” B.B. *Id.* Based on there being “no documentation of [Respondent] taking additional steps,” Dr. Owen concluded that he “did not” do that. *Id.* at 140.

Dr. Owen also testified that Respondent’s notation that “[n]onmedicinal pain-relieving modalities suggested” lacked sufficient detail before rhetorically asking: “What does that mean, nonmedicinal modalities suggested?” *Id.* at 209-10. Continuing, Dr. Owen explained:

First, you don’t suggest treatment. Your job as a physician is to advise the patient of what good medicine is, and good medicine would be if you haven’t done nonmedicinal pain-relieving modalities, we need a back-up, wean you off these controlled substances and try these other treatments first.

Id. at 210. Then asked what the purpose is “of providing that level of detail in a patient file,” Dr.

Owen answered:

Well, the purpose of documentation is for continuity of care. Not only continuity of care for this same provider from visit to visit but continuity of care should somebody else assume the care later on down the road or should you need to get a consultation, that the consultant can read your notes and understand what was happening with this patient at this point in time.

Id.

Regarding this visit, the CALJ asked Dr. Owen if Respondent’s notation that “[n]egative straight leg raise, but lying down and sitting up causes him a lot of pain” had “any significance?”

Id. Dr. Owen replied: “[I]t doesn’t – it’s not objective [in a] neurological kind of sense, but it definitely contributes to the idea that it’s not therapeutic on his controlled substances, because he’s having a lot of pain, lying down and sitting.” *Id.* When then asked by the CALJ, “[h]ow about the negative straight leg raise part of it?” Dr. Owen answered: “[t]hat means he cannot have a radiculopathy. There’s not likely anything surgically going on.” *Id.* at 211.

Dr. Owen again testified that the medical record did not support the prescribing of controlled substances. *Id.* at 140. He testified that: “[a]s previously discussed, there’s an inadequate evaluation going on. There’s a lack of medical necessity to continue treatment with controlled substances since there’s no therapeutic benefit. And if you don’t have medical necessity, you can’t have a legitimate medical purpose for using controlled substances.” *Id.*

Respondent testified that the “most remarkable” thing in the October 20 progress note was that B.B.’s blood pressure had gone up and that B.B. was also “wanting to know about his MRI report.”²⁶ Tr. 305. Respondent then testified as to the various entries in the October 20 note including B.B.’s report of having “lost his father” and “having a lot of grief.” *Id.*

²⁶ However, while the visit includes the handwritten notation “Question about MRI,” GX 3, at 46, B.B. did not undergo the MRI until the next day. See *id.* at 19.

According to Respondent, B.B.'s "exam was still exactly like before, with low back paraspinal and spinal tenderness, but he still had the negative straight leg raises. But laying down and sitting up still caused him a lot of pain." *Id.*

Continuing, Respondent testified that he diagnosed B.B. with acute grief and lumbar disc disease and that he increased his Morphine to two pills or 30 milligrams in the evening while keeping his Opana for breakthrough pain. *Id.* He also testified that he warned B.B. about "the addictive, dependence and tolerance natures" of the medications and "suggested that he continue using his non-pain [sic] relieving modalities." *Id.* Respondent did not, however, offer any further explanation as to what those modalities involved. Respondent then testified that he determined the follow-up would be in "three months" as he "felt like [B.B.] could really go into the three-month" schedule for being seen by him. *Id.* at 305-06. However, at this visit, Respondent did not document whether B.B. was achieving his treatment objective or that he had obtained a numeric rating from B.B. as to his pain. *See* GX 3, at 28.

On October 21, 2011, the day after this visit, B.B. had an MRI done of his lumbar spine. *Id.* at 19. The Radiologist reported his impression as follows: "Degenerative changes of the lower lumbar spine as above. Most affected level is at L5-S1 where a left paracentral disc protrusion contacts the descending S1 nerve root in the lateral recess."²⁷ *Id.* at 20.

Regarding the MRI, Dr. Owen testified that it "did not show any specific problems that would be attributable for this kind of pain complaint[], nor was it significant to cause the perceived disability that this 26-year-old gentleman considers himself" to have. Tr. 207. And

²⁷ Other findings included that L1-L2, L2-L3, and L3-L4 were all normal, as well as that the alignment of his vertebrae was normal. GX 3, at 19. At L4-L5, the MRI found a "[s]mall left paracentral disc protrusion with no significant spinal canal with mild left neural foraminal and no significant right neural foraminal stenosis." *Id.* At L5-S1, the MRI found a "[s]mall left paracentral disc protrusion measuring 8 mm in [the] AP dimension results in moderate subarticular recess narrowing, with contact of the descending S1 nerve root. There is mild left neural foraminal stenosis with no significant right neural foraminal stenosis." *Id.*

as he earlier testified in response to the CALJ's question as to whether an MRI would provide an objective basis such as "foraminal narrowing" or "spondylosis" for concluding that a patient "may be having a spine issue" and not "making it up," Dr. Owen explained that "foraminal stenosis or foraminal narrowing are common in asymptomatic people." *Id.* at 190. Dr. Owen then explained that "[t]he only reason it would be important is if you have a radiculopathy you've identified on clinical exam . . . and that would be pain going down the leg in a dermatome distribution, typically below the knee." *Id.* Continuing, Dr. Owen explained that there may be "numbness" and there may be "weakness associated with the isolated nerve that's being entrapped, and you would have a positive straight leg raise." *Id.*

The November 18, 2011 and December 15, 2011 Prescriptions

On November 18, 2011, Respondent wrote new prescriptions with the same dosing instructions for 90 Morphine Sulfate ER 15mg and 120 Opana 10 mg; each of these was for a 30-day supply. GX 5, at 17, 21; GX 3, at 23. B.B. filled the prescriptions the same day. While B.B.'s file contains photocopies of the prescriptions, it contains no documentation of a visit with either Respondent or a nurse on this date. *See generally* GX 3; Tr. 142.

Likewise, on December 15, 2011, Respondent wrote new prescriptions with the same dosing instructions for 90 Morphine Sulfate ER 15 mg and 120 Opana 10 mg, each of these being for a 30-day supply. GX 3, at 67, 90. Respondent filled these prescriptions the same day. *Id.* at 23. Here again, there is no documentation of a visit with either Respondent or a nurse on this date. *See generally* GX 3; Tr. 142.

Dr. Owen testified that "[e]specially in the context of the previous aberrant urine drug testing and the lack of any clear medical necessity or therapeutic benefit," Respondent "should have" seen B.B. in his office prior to prescribing the drugs on both dates. Tr. 142. Dr. Owen

further testified that notwithstanding that at the October 20 visit, B.B. had reported that “his stress is up” and that “he [was] having a lot of grief,” there is no notation in B.B.’s file as to how B.B. was dealing with these issues. *Id.* Dr. Owen also noted that there was no notation in the file that Respondent had discussed the results of the aberrant drugs tests with B.B. *Id.* at 143. Dr. Owen then testified that Respondent had “never” established “a medical necessity . . . to continue these treatments” and that this would require an in-office visit. *Id.*

After explaining that the aberrant drugs tests and mention of B.B.’s life stressors supported the need for psychological counselling and consultations with a psychologist or addictionologist, Dr. Owen was asked what risk was created by prescribing these drugs to B.B. without requiring an office visit. *Id.* Dr. Owen testified that “[t]he risk is that he continues to self-escalate these medications, and [is] either chemically coping or becomes – or is addicted to it.” *Id.* Dr. Owen then opined that Respondent had never established the “medical necessity” of the prescriptions he issued to B.B. on these two dates, that the prescriptions lacked a legitimate medical purpose, and that Respondent acted outside of the usual course of professional practice in issuing them. *Id.* at 144.

On cross-examination, Dr. Owen was asked whether he was aware that under DEA’s regulation which allows a physician to “issue multiple prescriptions authorizing the patient to receive . . . up to a 90-day supply of a schedule II controlled substance, provided [various] conditions are met,” “it was okay . . . to only see a patient once . . . every 90 days?” *Id.* at 195-96; *see also* 21 CFR 1306.12(b). While Dr. Owen answered “yes,” he added that a physician must have “established medical necessity and legitimate therapeutic benefit from previous documentation and [that] a patient doesn’t have a high risk of abuse.” Tr. 196. Dr. Owen then

re-iterated that B.B. “already had multiple aberrant urine drug tests before those prescriptions were issued.” *Id.*

Regarding these prescriptions, Respondent testified that he did not understand that he had to see B.B. “every 30 days” and that “[w]e saw him every 90 days.” *Id.* at 307. Respondent further testified that “[a]t the time there was debate within the state as to whether” patients “could be seen” even “every four months” and “we had chosen every three months, so we never gave more than two refills on a II or above.” *Id.* Respondent then explained that the patients “would call one to two days ahead, a lot of times to the pharmacy, and the pharmacist faxes the request.” *Id.* at 307-08. Continuing, Respondent testified that “[a] PMP would be pulled, and then the chart would be pulled. And then we would write a prescription for the person and leave it up front for them to pick up and sign for.” *Id.* at 308. Respondent further testified that the November 18 prescriptions were issued 29 days after the previous prescriptions. *Id.* at 311. Respondent did not, however, address Dr. Owen’s criticism that B.B. presented a high risk of escalating the use of the controlled substances and should have been seen prior to prescribing on each of these dates. *See id.* at 306-13.

The January 19, 2012 Visit and Prescriptions

On January 19, 2012, B.B. again saw Respondent, who reported that he had gone to the emergency room “two weeks ago with right leg swelling” but that “[h]is ultrasound was negative.” GX 3, at 45. B.B. complained of “some calf pain” and that “[h]e still feels very tight.” *Id.* Respondent also noted that B.B. “goes to a psychiatrist” and “reports severe lumbar disc disease”; he also noted that B.B. reported that “he ha[d] been exposed to someone with HPV” and “would like an exam.” *Id.* Respondent further noted that B.B.’s “[p]ast medical history [was] extensively reviewed” and “placed in chart.” *Id.*

According to Respondent's exam notes, B.B. was "[a]lert and oriented and in no apparent distress." *Id.* While other portions of the exam were normal, Respondent again documented that B.B. had "[l]ow back paraspinal tenderness," a "[n]egative straight leg raise," and "[n]euro intact." *Id.* He also documented that B.B. "has very tight right calf." *Id.* However, no mention was made of B.B.'s hernia which had been noted at previous visits. *Id.*

Respondent diagnosed B.B. with "lumbar disc disease," "exposure to infectious disease," and "[r]ight calf pain." *Id.* He further documented that he discussed the "[a]ddictive dependence, and tolerance nature of the medicines as well as alternatives," that he suggested "[n]on-medicinal pain-relieving modalities," and that the "[f]ollowup will be [in] three months." *Id.* Respondent then issued B.B. new prescriptions for Morphine Sulfate ER 15 mg and Opana 10 mg with the same dosing instructions, thus providing a 30-day supply for each drug if taken as directed. *Id.*

At this visit, B.B. was required to provide a urine drug screen. While the results were not reported until January 31, 2012, the lab reported that morphine was "not detected" and that this result was "not expected with prescribed medications." GX 3, at 97. Moreover, while the lab detected the presence of alpha-hydroxyalprazolam, a metabolite of alprazolam, the lab also detected the presence of nordiazepam, the metabolite of diazepam, as well as the presence of oxazepam, and temazepam. *Id.* With respect to the presence of the latter three drugs, the lab reported that these three results were "not expected with prescribed medications." *Id.* Of further note, the lab report bears the handwritten but undated notation: "Pt counseled to only take what is prescribed[.]" *Id.*

Dr. Owen testified that while "oxazepam can be a metabolite of several other benzodiazepines," this was an aberrant drug test because non-prescribed drugs were detected and

prescribed drugs were not detected. Tr. 150-51. As for the drugs that were detected but were not prescribed, Dr. Owen testified that B.B. was either “getting [them] from the illicit . . . market or from a friend.” *Id.* at 151. As for the morphine, which was prescribed but not detected, Dr. Owen explained that “[e]ither [B.B. was] selling it on the street or he self-escalated and ran out of his supply.” *Id.*

Regarding this visit, Dr. Owen testified that when a patient reports having gone to the emergency room, he would get the record to find out both “what the problem was,” as well as if “any additional medication [was] prescribed.” Tr. 147. However, the patient file does not contain a note from the emergency room. *Id.*; *see also* GX 3. Moreover, after observing that the visit note contains no mention that Respondent addressed either of the two prior urine screens during this visit, Dr. Owen again testified that Respondent had failed to establish medical necessity for the prescriptions “by doing a proper history and physical exam, by defining a therapeutic benefit, by explaining what previous treatments have or have not worked . . . and . . . addressing the previous aberrant urine drug tests.” *Id.* at 148. Thus, Dr. Owen opined that Respondent acted outside of the usual course of professional practice in issuing the prescriptions and that the prescriptions lacked a legitimate medical purpose. *Id.*

Regarding the prescriptions, Respondent testified that B.B. wanted refills and then testified as to what he had documented in the note. *Id.* at 313. Asked by his counsel if B.B. had “ask[ed] for anything different or call[ed] for additional drugs when he went to the ER,” Respondent testified that “[t]here was nothing on his PMP that revealed they prescribed anything,” a fact confirmed by the PMP. *Id.* at 314; GX 3, at 23.

Observing that the visit note “almost seems as if [B.B.] would be a person that’s not in pain,” the CALJ asked: “doesn’t it seem like an unremarkable set of . . . notes for such a high

amount of painkillers?” Tr. 315. Respondent answered: “He just continued to have the same pain that he had before, so I didn’t go into details on it.” *Id.* The CALJ then asked: “doesn’t it seem like kind of an unremarkable set of notes for somebody that’s on a lot of heavy medications?” *Id.* Respondent answered that he “agree[d]” and added that “I can only conjecture at this point as to what was going on, but I imagine I was more concerned about the fact he had went to the emergency room and making sure he didn’t get other medicine” and “less concentrated on his chronic pain.” *Id.* at 316. The CALJ then commented that “the notes do seem very benign” and asked “if that seemed normal to” him? *Id.* at 316-17. Respondent answered that “[i]t stands out that I didn’t make more.” *Id.* at 317. Respondent then maintained that he “was seeing 40 to 45 patients a day and dictating that night and the next morning, and so I definitely could have done a better job.” *Id.* Continuing, Respondent testified that he thought that at this visit, B.B. “wasn’t requesting any more or any change in his pain medicines” and “wasn’t reporting anything except his calf pain and his new conditions.” *Id.*

At this point, Respondent’s attorney suggested that he had noted “his lumbar disc disease and “low back paraspinal tenderness” in the visit note, prompting Respondent to state: “[t]hat’s correct. And he still had the negative straight leg raise.” *Id.* at 317-18. Respondent then conceded that his finding of a negative straight leg raise was an indicator that B.B.’s back issues were not causing radiculopathy in his legs. *Id.* at 318. However, Respondent maintained that “a negative straight leg raise doesn’t mean they [sic] don’t have significant pain when you raise their [sic] leg,” and that “if you raise their [sic] foot when they’re [sic] laying in a supine, they [sic] flinch back.” *Id.* Respondent did not, however, document this in the progress note for this visit, nor did he document as he had at the last visit that “lying down and sitting up cause [a] lot of pain.” *Compare* GX 3, at 46, with *id.* at 45.

Moreover, when the CALJ asked if “[t]his note was more saying . . . that he’s still maintaining an absence of at least an objective sign of radiculopathy,” Respondent answered: “[o]f radiculopathy, but not necessarily paraspinal or muscular-skeletal pain.” Tr. at 318-19. Upon further questioning by the CALJ as to his reason for noting the negative straight leg raise, Respondent agreed with the CALJ’s suggestion that the reason for the note was to “more or less show that things [weren’t] getting worse” and then added that “there was no change.” *Id.* at 319.

Yet, at this visit, Respondent neither documented that B.B. had achieved his treatment objective nor indicated if he had completed an update pain scale on the Treatment Plan form. *See* GX 3, at 28. Respondent did not document if B.B. was achieving his treatment objective and had completed an updated pain scale until his January 27, 2015 visit, when Respondent wrote “fair” in the block for “Has patient achieved treatment objective?” and either the number 3 or 7 in the block for “Patient Completed Updated Pain Scale” on the Treatment Plan form.²⁸ *Id.* On the same date, Respondent also wrote “no” in the block for whether he considered referring B.B. for a second opinion or further treatment options. *Id.*

According to the progress note for the January 27 visit, B.B. reported that he was “very anxious” about the price of the vaccine for HPV. GX 3, at 44. Respondent also documented that B.B.’s “[p]ast medical history [was] extensively reviewed and placed in chart and includes severe thoracic and lumbar pain.” *Id.* And in the physical exam section of the note, Respondent noted “low back paraspinal and spinal tenderness” and “[q]uestionable straight leg raise.” *Id.* He also noted “[n]euro intact.” *Id.* Respondent did not, however, prescribe any controlled substances on this date. *See id.; see also id.* at 22-23 (PMP Report).

²⁸ Indeed, the writing bears a strong semblance to the number 3 as written by Respondent in listing his registration number (BP2423440) on various prescriptions. *Compare* GX 3, at 28, *with* GX 5, at 23; *see also* GX 1, at 1.

The CALJ also asked Respondent whether he thought the Jan. 27 visit note looked “very benign” if he was “really evaluating” the “efficacy of the pain [medication] regimen” as it only referred to B.B.’s “past history” of thoracic and lumbar pain. *Id.* at 323. Respondent answered that even if he “was seeing someone for something other than their [sic] pain management and not writing prescriptions that day,” he would “acknowledge the fact that that was still underlying” and “reflect[] [that] in the note,” so that it did not “appear[] that he has no pain in between” the visits. *Id.* at 324.

The CALJ, explaining that the progress note did not “seem to discuss at all the underlying basis for the pain [medication] regimen” or the “activities of daily living or . . . function,” asked Respondent if “those [are] things that you would ordinarily include in there?” *Id.* at 324. Respondent answered that “[i]n the individual’s subjective – or the SOAP notes, a lot of times those would be neglected. With time constraints, I’m not necessarily efficient. That’s not ideal I guess is what I’d say.” *Id.* Continuing, Respondent testified: “But this patient had been disabled on Social Security and determined previously to have chronic pain and . . . objective data confirmed that. He was not doing anything to set off alarms with his PMP, doctor-shopping or changing his medications. He was stable on his medicines at that point.” *Id.* Respondent then maintained that B.B. “was one of our low-flyers” compared to other patients and because “[h]e wasn’t increasing his pain med [and] not asking for increased pain medicines . . . I guess [he] got less individualized SOAP notes.” *Id.* at 325.

Observing that the visit notes “don’t tend to deal with activities of daily living or anything where you were measuring how well the treatment objectives are being attained,” the CALJ asked Respondent how he evaluated “how well you’re doing in treating the patient with . . . pain medications?” *Id.* at 325-26. Respondent testified that:

[t]he notes could be much more well written. Much more went on in the office than what's written. And it's been pointed out here that if it's not written it didn't occur. That doesn't mean it didn't occur. It means I can't prove it. But I definitely knew what was going on in his life from each visit, and I just failed to dictate that.

Id. at 326.

Subsequently, the CALJ asked Respondent how he knew "how the meds were doing?"

Id. at 327. Respondent answered: "Pure subjective, and if they were needing more or less pain meds. That's all I --." *Id.*

The CALJ then asked Respondent if he was not asking B.B. "questions about what activities he's doing or what's better or worse or what's causing him pain, then aren't you just depending on his subjective desire for more or less pain medicine?" *Id.* Respondent replied:

Well, I was talking to him about those things and what all he did in a day, and he was not able to work. He . . . didn't have a vehicle, I don't believe. I think that was a major issue for how he got his prescriptions or not. And so he basically was stuck in the house all day, trying to figure out how to stretch or how to do his exercises at home - - he was pretty much homebound, taking care of his son.

Id.

The February 13, 2012 Prescriptions

On February 13, 2012, Respondent issued B.B. new prescriptions for both 120 Opana 10 and 90 Morphine Sulfate ER 15, with the same dosing instructions as the previous prescriptions. GX 5, at 3 & 23. As noted previously, the lab reported the results of the January 19, 2016 urine drug test on January 31, 2012, GX 3, at 97; and thus Respondent should have had the results by this date. Tr. 153. As explained previously, other than the undated notation on the Lab Report that B.B. was "counseled to only take what is prescribed," the only documentation in the progress notes for this date (which is written at the bottom of the January 27, 2012 progress note) is the following: "Zpack, Prednisone 10 mg # 28, Phenergan." GX 3, at 44.

Dr. Owen testified that there should have been an office visit “in light of the previous aberrant drug-taking behaviors and the lack of medical necessity [having been] established to treat with controlled substances.” Tr. 154. He further explained that Respondent “need[ed] to establish medical necessity and establish a therapeutic benefit, and now we have another aberrant drug test in late January.” *Id.* While he acknowledged that Respondent documented that he counseled B.B. to take only what is prescribed, Dr. Owen testified that this was not an adequate safeguard to prevent abuse or diversion, “especially since this [was] the third aberrant urine drug test.” *Id.* Asked what Respondent should have done, Dr. Owen testified that “you need to have a long discussion with the patient about the risk of addiction²⁹ and get some consultations by experts in [the] field of addiction.” *Id.* at 155. Based on the absence of any such documentation in the file, *see generally* GX 3, and that Respondent never claimed to have obtained any consultations, I find Respondent did not obtain a consultation with an expert in addiction.

Moreover, Dr. Owen again found that the patient record did not justify the prescribing of controlled substances and further noted that the “medical necessity for the prescriptions ha[d] not been established in any of the previous evaluations.” Tr. 155. He further opined that the Opana and morphine prescriptions issued on this date lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. *Id.* at 155-56.

Respondent testified that he had reviewed the drug test results and had directed his staff to pull a PMP report. *Id.* at 335. He also acknowledged having written the notation that “patient was counseled to only take what is prescribed.” *Id.* Asked by his counsel if “red flags [were] raised by these test results,” Respondent answered:

[t]he red flag that I saw – the morphine said not detected, but the oxymorphone was positive, so that was explainable. The nordiazepam, the oxazepam, and then the Xanax, the lab always said that if . . . Xanax was positive, that they could all three be

²⁹ Dr. Owen was not asked to provide details as to what specific areas would be discussed in such a conversation.

positive. The temazepam, in our practice, usually didn't show up, and temazepam is a sleeping pill called Restoril.

And so I wanted to pull the chart, and so Dr. Schoelen didn't mind his pain patients being on Restoril. I did, and so I wanted to make sure, has he been prescribed Restoril. I couldn't find it on the PMP, so I'm sure what was told was, if you have an old Restoril or some other doctor, I do consider that breaking our rules, and so you can't take it.

Id. at 335-36.

Notably, while the PMP report shows that B.B. had received a number of prescriptions for Ambien (zolpidem), it does not list any prescriptions for temazepam. GX 3, at 22-26. Nor do the progress notes during the period in which B.B. was being treated by Dr. Schoelen contain any indication that Schoelen had prescribed temazepam to B.B. *Id.* at 50-62. And Respondent offered no testimony that he ever asked B.B. from whom he obtained the Restoril, and the chart contains no documentation that he did. In any event, even if the lab had told Respondent that using alprazolam could also trigger false positives for diazepam and oxazepam, this was still an aberrational result and was, in fact, the third aberrational UDS that B.B. had provided in less than eight months.

Asked by the CALJ why he did not find the non-detection of morphine to be "an anomaly," Respondent asserted that this was because oxymorphone is a metabolite of the former. *Id.* at 336. When then asked "[w]hy wouldn't it show morphine positive then if the person's on morphine," Respondent testified "[t]hat would occur occasionally." *Id.* Respondent then speculated that B.B. "probably did not take two medications on that day. Most likely it was over the 30 days since his last prescription, but it was still in his system, that it had been taken recently." *Id.* Respondent then asserted that "[t]he same is true, the exact same thing for the carisoprodol, which is Soma. It's on the next page, page 98 [of the Exhibit], shows that

meprobamate was positive” and “the comments section says, ‘Test result is expected based on prescribed medications.’” *Id.* at 337.

It is true that meprobamate is a metabolite of carisoprodol – as noted by the lab itself on the reports. *See* GX 3, at 96-98, 100, 104; *see also* 76 FR at 77340 (carisoprodol scheduling order). Moreover, when B.B. was under Dr. Schoelen’s care and being prescribed hydrocodone, the lab reports noted that B.B. had tested positive for hydromorphone and that this drug “is a metabolite of hydrocodone,” thus rendering the test result “expected with [the] prescribed medications.” *See id.* at 99, 103, 104, 105, 106. Unexplained by Respondent is why, if oxymorphone is a metabolite of morphine, the lab did not indicate that on the reports as it did when it noted that meprobamate and hydromorphone were metabolites of carisoprodol and hydrocodone respectively. Of further note, Respondent did not testify as to his basis of knowledge for this assertion.

However, as found above, B.B. had last obtained a morphine prescription on December 15, 2011, 35 days before the January 19 visit, and if taken as directed, B.B. would have run out of his morphine five days earlier. GX 3, at 23. The Government produced no evidence as to how long morphine at this dosing would still be detectable in urine after it was last taken. Nonetheless, based on the presence of temazepam which was not prescribed, the January 19 drug test was still aberrational.

The March 13, 2012 Prescriptions

On March 13, 2012, Respondent issued B.B. new prescriptions for both 120 Opana 10 and 90 Morphine Sulfate ER 15, with the same dosing instructions as the previous prescriptions. *See* GX 5, at 10, 24. Respondent issued the prescriptions without requiring an office visit by

B.B. Tr. 156, *see generally* GX 3, at 42-62 (visit notes for B.B.). Nor is there any notation on any of the visit notes regarding Respondent's issuance of these prescriptions.³⁰

Dr. Owen testified that Respondent should have required an office before issuing these prescriptions, reiterating that the "medical necessity for" the prescriptions still had not been established. Tr. 156. Asked to again identify the deficiencies which led him to conclude that Respondent had not established medical necessity, Dr. Owen explained:

Reviewing all the pertinent previous medical records, including what previous treatments have been performed, an adequate history and physical exam, consultations as medically appropriate, establishing a clinically meaningful and objective therapeutic benefit, and addressing any aberrant drug-taking behaviors.

Id. at 157. Dr. Owen then noted that there were three previous incidents of aberrant drug-taking behaviors, and that "[t]he only treatment plan has been continuing the controlled substances without medical necessity." *Id.* at 158. And once again, Dr. Owen testified that the prescriptions lacked a legitimate medical purpose and "were not" issued in the usual course of professional practice. *Id.*

In his direct testimony, Respondent did not address his reasons for issuing the March 13 Opana and morphine prescriptions. *See* Tr. at 338-39. Instead, the questioning centered on why he wrote a prescription on March 14 for Nexium, "a stomach medicine" and a non-controlled drug ("I have no idea") after which the questioning moved on to the next set of prescriptions. *Id.*

The April 12, 2012 Visit and Prescriptions

On April 12, 2012, B.B. saw Respondent for an office visit. GX 3, at 42. According to the visit note, B.B. "report[ed] his pain has been worse," that "[h]e has run out of his medicines; he had them stolen," and that "[h]e has done fairly well." *Id.* Moreover, on the Treatment

³⁰ As found above, on the January 27, 2012 visit note, Respondent had written that on "2/13/12" he prescribed "Zpack, Prednisone 10 mg # 28, Phenergan." GX 3, at 44. The same visit note contains a further entry for "2-22-12" documenting the issuance of a prescription for 60 tablets of Soma (carisoprodol) 350 mg. *Id.*

Objective Evaluation section of the Treatment Plan, Respondent wrote “fair → yes” in the block for “Has patient achieved treatment objective?” and “6” in the block for “Patient Completed . . . updated pain scale.” *Id.* at 28.

In the visit note, Respondent wrote that B.B. “still has severe anxiety and depression” and has been “exposed to someone with HPV”; Respondent then wrote: “[h]e is also wanting to switch his medicines because he is having trouble finding the OPANA.” GX 3, at 42. Respondent also noted: “[p]ast medical history extensively reviewed and placed in chart.” *Id.*

In his exam findings, Respondent noted “[l]ow back paraspinal and spinal tenderness,” “[n]egative straight leg raise,” and “[n]euro intact.” *Id.* Respondent listed his diagnoses as “[l]umber disc disease,” “[a]nxiety and depression” and “[e]xposure to infectious disease,” although he “doubt[ed] that it was HPV.” *Id.* Respondent then changed B.B.’s medications to Opana ER (extended release) 20 mg b.i.d. (twice per day) and Percocet 10 mg (q. 12h) p.r.n. (as needed) for acute pain. *Id.*; *see also* Tr. 340. He also prescribed Soma (carisoprodol) one tablet b.i.d. GX 3, at 42.

Respondent further documented that he discussed the “[a]ddictive, dependence, and tolerance nature of the medicines, as well as alternatives.” *Id.* He noted that he “suggested” “[n]on-medicinal pain and anxiety-relieving modalities.” *Id.*

Respondent also required B.B. to undergo a urine drug screen. While the preliminary screen shows that B.B. tested positive for oxycodone (which had not been prescribed to him) and negative for opiates/morphine (which he had been prescribed), the line on the form for noting the oxycodone result includes the parenthetical “synthetic & semi-synthetic opiates” and the form contains no separate entry for oxymorphone, which is a semi-synthetic narcotic. GX 3, at 63. Notably, the Government produced no evidence as to whether a positive result for oxymorphone

would show up as positive for oxycodone or as positive for “opiates/morphine.” Moreover, Dr. Owen acknowledged that there are reliability issues with this type of test and thus, “you would send it off for a confirmatory mass spectroscopy test.” Tr. 164. However, according to Dr. Owen, the results are still valid until the confirmation shows otherwise. *Id.*

Respondent did send B.B.’s urine sample to the lab for further testing. GX 3, at 96. According to the lab report, which was reported back to Respondent on April 17, 2012, B.B. tested positive for oxymorphone, which was expected based on Respondent’s having prescribed Opana to him. *Id.* He also tested positive for meprobamate, which was expected based on Respondent’s having prescribed carisoprodol to B.B. *Id.* However, the lab further found that morphine was “not detected,” a result which was “not expected” because Respondent had prescribed morphine sulfate ER to B.B. on March 13, 2012. *Id.* Dr. Owen also noted that while “the confirmed . . . drug test [was] positive for some of these drugs,” Respondent had reported that he had run out of his medicines and that there was a “lack of documentation of what he ran out of and what he should still be on, so . . . there’s problems in interpreting this urine drug test.” Tr. 167.

Dr. Owen testified that Respondent did not address the aberrant preliminary drug screen conducted on April 12 nor any of the previous aberrant drugs tests at this visit. *Id.* at 165-66. However, as found above, on the January drug test report, Respondent did note – but without specifying the date that he did so – that he had counseled B.B. to take only what was prescribed.

The Government also asked Dr. Owen if it was noteworthy that B.B. had told Respondent that his pain was worse, that he had run out of his medicines and had them stolen. *Id.* at 159.

Dr. Owen answered:

Well, one, his pain is worse, so why is it worse? Two is he’s run out of his medications, and then he had them stolen. What is it? Did you run out of them because

you self-escalated, or were they stolen and you ran out of them? It needs clarification. But either event, self-escalation or having them stolen, is a red flag.

Id.

Dr. Owen then noted that B.B.'s pain contract stated that "lost and stolen medications will not be replaced," *id.* at 160, but acknowledged on cross-examination that Respondent had not provided an early refill of the prescriptions. *Id.* at 200. However, regarding B.B.'s report that his medications were stolen, Dr. Owen further testified that because there had "been the aberrant urine drug tests before . . . this, there is [sic] enough aberrant behaviors that" Respondent needed "to get the person to an addictionologist or a psychologist, or just stop prescribing these controlled substances since there's no evidence they're helping this gentleman." *Id.* at 212-13.

Dr. Owen also found problematic the notations in the visit note that B.B. reported that "his pain has been worse" and that "[h]e has done fairly well." *Id.* at 160. As Dr. Owen testified, the statement that "[h]e has done fairly well . . . kind of conflicts with his pain is worse and the aberrant drug-taking behavior, so that's an unreliable statement." *Id.* Dr. Owen also explained that B.B.'s having "severe anxiety and depression . . . are relative contraindications to prescribing controlled substances . . . [b]ecause it magnifies [the] perception of pain and disability." *Id.* Dr. Owen then testified that because of these conditions, Respondent should have requested a "consultation by a psychologist" but did not. *Id.* at 160-61.

Dr. Owen further testified that Respondent "did not" address B.B.'s "ongoing stress and anxiety issues," and that "[h]e did not" conduct a thorough patient history. *Id.* at 166. He then testified that Respondent had changed B.B.'s treatment plan by adding Percocet, but that Respondent "change[d] the medications without ever . . . documenting [a] medical rationale to add any new medication." *Id.* Asked by the CALJ "why would someone add Percocet," Dr.

Owen testified that it is a short-acting opioid that could be added “for break-through pain, if that’s not being controlled well.” *Id.* at 167.

With respect to Respondent’s notation that he had discussed “[a]ddictive dependency and tolerance nature of these medications as well as alternatives,” *id.* at 167, Dr. Owen noted that “there’s no real substance to that statement” as a statement of informed consent. *Id.* at 168. He then explained that the statement “[l]acks any details about what alternative treatments were discussed, and . . . B.B.’s already demonstrated several aberrant drug-taking behaviors.” *Id.* Continuing, Dr. Owen explained that “[t]he potential of addiction is very high in this individual, and I think you just can’t say something as generic as this statement and [not] have any meaningful documentation behind it.” *Id.*

Dr. Owen was also asked about entries in a PMP report in B.B.’s file which showed the controlled substance prescriptions he obtained and filled from April 12, 2011 through April 11, 2012. Tr. 170-72. The report showed that on March 14, 2012, B.B. had obtained and filled a prescription from another provider (R.H.) for 60 alprazolam 1 mg, which was a 30-day supply and that on April 6, 2012, he had obtained and filled another prescription from R.H. for 30 alprazolam 1 mg. *Id.* at 170-71. Dr. Owen testified that this was an early refill, as the March 14 prescriptions should have lasted until approximately the middle of April. *Id.* at 171. According to Dr. Owen, this “could represent [that] the person is self-escalating their medications.”³¹ *Id.*

Dr. Owen testified that Respondent should have addressed the early refills because although he did “not prescrib[e] this drug, it is a reflection of B.B.’s ability to self-regulate his

³¹ The Government attempted to make the same point with respect to the alprazolam prescriptions issued by R.H. on February 15 and March 14, 2012 and filled by B.B. the same day. Tr. 171; *see also* GX 3, at 22. However, 2012 was a leap year, and thus, the March 14 prescription was filled 28 days after the February 15 prescription, rendering it only two days early. The Government also attempted to establish that the February 15 prescription was an early refill, because B.B. had obtained a refill of alprazolam on January 20, 2012, thus rendering the February 15 prescription four days early. Tr. 171-72; *see also* GX 3, at 22-23. As for the latter prescription, according to the calendar for February 2012, February 19 was a Sunday and there is no evidence as to whether the practice was open on February 18.

controlled substance use.” *Id.* at 172. However, Dr. Owen then testified that an early refill does not necessarily mean that B.B. was abusing his medication if it was “a one-time situation.” *Id.* While Dr. Owen testified that “if you’re prescribing, you might call the treating doctor that is prescribing and get clarification. But when you have a pattern of early refills, it’s hard to explain that the office is closed for a holiday or a weekend and that justifying the medical necessity to prescribe early.” *Id.* at 172-73. However, given that the alprazolam prescription issued on February 15 was at most three days early and the March 14 prescription was at most two days early, the evidence does not establish a pattern of early refills but only a single early refill. Thus, I place no weight on Respondent’s failure to contact Dr. R.H. regarding the alprazolam refills.

Continuing, Dr. Owen reiterated his earlier testimony that the patient record was “not adequate” to establish “medical necessity” for prescribing the controlled substances on this date and that between September 22, 2011 (when he assumed the care of B.B.) and April 12, 2012, Respondent had not established medical necessity for the drugs. *Id.* at 173-74. He then opined that the prescriptions Respondent issued at this visit were issued outside of the usual course of professional practice and lacked a legitimate medical purpose. *Id.* at 174.

Regarding the April 12 visit, Respondent testified that B.B. “said he perceived [his] treatment objective was fair” and that “[t]here’s a ‘yes’ this time instead of just fair.” *Id.* at 339. Asked by his counsel if B.B. was able to work at that point, Respondent answered “[n]o” and that “[h]e ha[d] not worked any at that point.” *Id.* at 353. When then asked why he wrote “yes” there, Respondent testified that he did not recall. *Id.*

Respondent also testified that “[h]is pain had gone from a 7 in January to a 6.” *Id.* at 339. Later, he testified that “[m]y subjective said his pain was worse, but it was a 6, and my last note

said it was a 7.” *Id.* at 353. Respondent then asserted that B.B.’s pain rating “was still above the 4 to 5 [that] the Joint Commission says . . . needs to be addressed.”³² *Id.*

Respondent further testified that he had not replaced the stolen medication. *Id.* at 341. As for how B.B. had managed after his medications were stolen, Respondent testified that while “the notes don’t necessarily reflect it . . . he had a family member, and I don’t remember who it was, but someone had held some pain medicines for him, and he was trying to stretch them out to make sure that he didn’t run out.” *Id.* Continuing, Respondent asserted that B.B. did this “[b]ecause he knew how important his drug screen would be positive, and so he always kept some medicine back” by placing it in “an old bottle.” *Id.*

At this point, the CALJ interjected that he did not “understand this, because if a person says that my medicines were stolen, the medicines are going to be gone” and “they won’t have medicines to keep taking them.” *Id.* at 342. After Respondent acknowledged that he “tell[s] stories,” he explained that the more he “did pain medicine, the more [he] found out there is such a culture, everyone wanting their pain medicines . . . that many of them keep them in a separate bottle . . . for safety” and “keep a stash in a different place” from their other prescriptions. *Id.* Then asked by the CALJ if it made sense that B.B. reported that his drugs were stolen but stretched them out, Respondent answered that it did because he knew that “most of my patients keep extra pills or keep them in a different place” in their house. *Id.* at 343.

In his testimony, Respondent agreed with the CALJ that he preferred prescribing extended release drugs, and that these formulations require a patient “to keep a certain amount in [his] system so that [he] would have relief from [his] pain” and be able “to engage in the[]

³² Respondent also testified as to the contents of the visit note, largely reading into the record what the notes contained. However, he noted, *inter alia*, that B.B. had “reported subjectively . . . that his pain had been a little worse,” as well as that his straight leg raise was now negative and not “questionable” as he noted at the previous visit. *Id.* at 340.

activities of daily living.” *Id.* at 344-45. The CALJ then asked: “doesn’t it seem to you unusual that a person would be keeping some of those back?” *Id.* at 345. Respondent testified that “[i]t would have before I started doing pain management.” *Id.* Continuing, he maintained that “[i]t’s very common that [patients] keep a stash of their medicines in an old bottle or take some with them, because they are absolutely paranoid of having their medicine stolen, and it is such a common thing for drug seekers, and basically the medicines are highly sought after, even amongst their family members.” *Id.* Respondent then maintained that “[m]any of them have lockboxes in their house, where they actually have their pills. . . . And so it’s not unusual in my practice at all for patients to keep a separate container of their medicine.” *Id.*

Respondent offered no explanation as to how a patient could forgo taking extended release medication to create “a stash” while still managing his pain. In any event, Respondent offered no evidence that he even asked B.B. when the purported theft had occurred, which drugs had been stolen, and when B.B. had last taken the drugs he prescribed.

As for why he changed B.B.’s medication, Respondent testified that “Opana was very difficult to get in some of the pharmacies” as some of the pharmacies “couldn’t get it from their suppliers” and he had a policy of requiring patients to obtain their medications at a single pharmacy. *Id.* at 346-47. Respondent was then asked by his counsel: “so the Percocet took the place of what?” *Id.* at 347. Respondent answered: “I used the Opana ER, because he had had good luck with the Opana short-acting, so I swapped him and used the Opana ER” as it was on Medicaid formulary and easier to obtain because “it was very, very expensive” and “didn’t have a supply problem, because people on the street or private-pay people couldn’t pay for it.” *Id.* Respondent then explained that he “changed [B.B.] off the long morphine to Percocet . . .

[b]ecause I wanted another . . . short-acting . . . for his break-through” pain. *Id.* Respondent testified that he wrote only for a two-week supply of the medications. *Id.* at 348-49.

While Respondent acknowledged that “having chronic pain [can] lead to worse anxiety and depression” as well as that “uncontrolled anxiety or depression [can] lead[] to more pain,” *id.* at 409, he admitted that he never consulted with the mental health providers that B.B. was seeing. *Id.* at 408. Asked by the CALJ whether it was “within the standard of care” for him and B.B.’s mental health provider to have “ke[pt] treating [B.B.] without talking to each other,” Respondent answered that “[t]he mental health providers are very good about speaking to us about patients.” *Id.* at 409. Then asked by the CALJ “[h]ow about the other way around,” Respondent answered: “[i]f you felt it was necessary, you could report on information, I’m sure.” *Id.*

Continuing, the CALJ asked Respondent if “a mental health provider [is] prescribing controlled substances simultaneously with you, ordinarily will you consult with the mental health provider?” *Id.* Respondent answered:

We’ve become quite reliant on the PMPs now. Before the PMP, there was quite a bit of cross-talk, because you would get pharmacists [who] would call you and say, did you know that they’re [sic] seeing so and so, or they’re [sic] taking this, that or the other. And so there was much more of a need to try and get ahold [sic] of them. But we’ve become very reliant on the PMPs now to track that.

Id. at 409-10.

The CALJ then asked Respondent “if two practitioners are simultaneously providing controlled substances [to] the same patient, wouldn’t the two practitioners talk to each other about [that] approach?” *Id.* at 410. Respondent answered: “Absolutely. In every other field but mental health we do do that, and actually we don’t treat the same – we don’t treat with pain

medication any patient that's seeing another doctor for pain. We don't go and side talk at all.”
Id.

This answer prompted the CALJ to ask: “but with a mental health practitioner, if that practitioner is also prescribing controlled substances, you wouldn't consult with them and - - or ask anything about that patient?” *Id.* Respondent testified: “[t]hat doesn't happen very often.” *Id.* Indeed, notwithstanding that on the date of B.B.'s first visit to Respondent's clinic, he identified Wellbutrin and alprazolam as drugs which he was either then taking or had recently used, *see* GX 3, at 5; there is no evidence that Respondent (or Dr. Schoelen) ever discussed B.B.'s psychiatric issues with his mental health providers. *See generally* GX 3.

The April 25 Prescriptions

On April 25, 2012, Respondent provided B.B. with a prescription for 30 Roxicodone (oxycodone) 15 mg. GX 5, at 4. B.B.'s file contains no documentation that there was an office visit, and notwithstanding that this was a change in medication from what Respondent had prescribed at the previous visit, there is no notation in the progress notes as to why he changed the prescription. *See generally* GX 3; *see also* Tr. 174-75. Moreover, while Respondent testified that he would “routinely” make an entry in the Treatment Objective Evaluation section of the Pain Management Treatment Plan “if we were making a change in a medication,” Tr. 357, no such entry was made on this date. *See* GX 3, at 28. Nor is there any documentation in the patient file that Respondent addressed with B.B. the aberrant drug test result (the non-detection of morphine) which had been reported to him on April 17. *See generally* GX 3.

According to Dr. Owen, when adding a new drug to a patient's regimen of pain medications, a physician “would have to establish medical necessity with some type of note, using sound medical rationale.” Tr. 175. Dr. Owen further testified that making such a notation

is “a standard of care, and it’s part of the documentation guidelines that are issued across every state for the most part.” *Id.* Asked if he could think of a reason why a physician “would add a drug for the first time without seeing a patient,” Dr. Owen answered: “No. Or at least documenting the medical rationale and establishing medical necessity.” *Id.* at 176. Dr. Owen then testified that Respondent did not take appropriate steps to establish medical necessity for the prescription, reiterating his earlier testimony that Respondent had not demonstrated that conservative care had been tried and been unsuccessful, as well as that there was a “clinically meaningful and objective therapeutic benefit from the previous use of controlled substances.” *Id.* He again opined that the prescription was not issued in the usual course of professional practice and lacked a legitimate medical purpose. *Id.*

Regarding the Roxicodone prescription, Respondent asserted that he “was just doing a two-week trial, trying to figure out his dose, and at the time, most likely the patient didn’t have any punches on his card left, and Roxicodone is much cheaper than Percocet, and it’s the same medication.” *Id.* at 355. However, Respondent documented none of this in B.B.’s record. Nor did he explain why he failed to follow his routine of making an entry in the Treatment Objective Evaluation section of the Pain Management Treatment Plan given that he had changed B.B.’s medication.

As for why he did not take any action with regard to the lab’s finding that the April 12 drug test result was negative for morphine sulfate, Respondent asserted that the result was not aberrant. *Id.* at 366. In addressing this prescription, Respondent offered no further explanation as to why he deemed the result not aberrant. However, with respect to the January 19 UDS lab report, which was also negative for morphine, Respondent asserted that oxymorphone is a metabolite of morphine and thus he did not consider the negative result to be aberrant. *Id.* at

336. He asserted this notwithstanding that with respect to other drugs such as hydrocodone and carisoprodol, the lab specifically reported when it detected the presence of metabolites of these drugs, such as hydromorphone for hydrocodone and meprobamate for carisoprodol. Yet, the lab report contains no notation that oxymorphone is a metabolite of morphine. Nor did he testify as to his basis of knowledge for this claim.

Pursuant to 5 U.S.C. § 556(e), I take official notice that morphine does not metabolize into oxymorphone. See Edward J. Cone, *et al.*, *Evidence that Morphine is Metabolized to Hydromorphone But Not to Oxymorphone*, 32 J. Analytic Toxicology 319, 323 (2008) (finding, based on study of urine drug screens using liquid chromatography-tandem mass spectrometry conducted on 34 patients taking morphine exclusively for chronic pain, that while “hydromorphone was demonstrated to be a minor metabolite . . . no evidence was found that oxymorphone is a metabolite of morphine” and “that a positive urine test for oxymorphone can arise only from oxymorphone or oxycodone administration, and not from morphine or hydromorphone administration”); *id.* at 319 (characterizing as “unsubstantiated” the “claim of a new metabolic pathway leading from morphine to hydromorphone to oxymorphone”).³³

The May 9, 2012 Prescriptions

On May 9, 2012, Respondent wrote B.B. a prescription for 60 Opana ER 20 mg. GX 3, at 93; GX 5, at 27. Respondent did not require an office visit, and he made no notations in the progress notes regarding the prescription. See generally GX 3; see also Tr. 177-78. Regarding

³³ Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding – even in the final decision.” U.S. Dept. of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. § 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to show the contrary.” Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration within 20 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government; in the event Respondent files a motion, the Government shall have 20 calendar days to file a response.

the prescription, Dr. Owen again testified that Respondent “needed to establish medical necessity for continuation of controlled substances” and “did not.” *Id.* at 178.

Asked why he refilled the prescriptions,³⁴ Respondent testified that “I got a phone call that he was wanting his medicines refilled and that the [R]oxicodone had worked for him and *et cetera*, so we were converting him back into the one-month prescriptions in the Schedules IIs and going back to this three-month office visit.” Tr. 356. Respondent offered no testimony addressing Dr. Owen’s criticism that he still had not established that there was a medical necessity for prescribing controlled substances, which included the Opana. *See generally id.* at 356-57.

Asked to provide his opinion as to Respondent’s prescribing of controlled substances from September 2011 through May 9, 2012, Dr. Owen opined that Respondent did not adequately review B.B.’s medical history. *Id.* at 178. He further opined that a treatment plan that established medical necessity “would have logic behind the treatment” and would have “establish[ed] that conservative care has not been helpful and that [an] objective and clinically meaningful therapeutic benefit from the use of controlled substances has been established, if [they] ha[d] previously been used.” *Id.* Dr. Owen then testified that none of the controlled substance prescriptions Respondent issued to B.B. were issued in the usual course of professional practice and for a legitimate medical purpose. *Id.* at 178-79.

Respondent’s Evidence in Remediation

³⁴ In her questioning of Respondent, his counsel referred to a Roxicodone prescription as having been issued on May 9, 2012 and in his testimony regarding the prescriptions he wrote on that date, Respondent referred to both a Roxicodone prescription and an Opana ER 20 mg prescription. Tr. 356. While GX 5 contains a legible copy of the May 9, 2012 Opana ER prescription, *see* GX 5, at 27, it does not contain a copy of a Roxicodone prescription, and as for GX 3, the copy of the purported Roxicodone prescription is illegible. GX 3, at 93. Because the Government failed to produce any reliable evidence to show that Respondent issued a Roxicodone prescription on May 9, 2012, I do not consider whether any such prescription was issued, nor whether Respondent complied with 21 CFR 1306.04(a) when he issued it.

Respondent offered only vague testimony that he has taken “extreme CME [continuing medical education] . . . in hospice care and pain medicine” in 1995 and had done some “reading” on pain management. Tr. 235, 381. Respondent offered no further detail as to the subject matter of the CME course[s] he took. *See id.* As for his assertions that he had read articles on pain management and that he kept current with those articles, he admitted that he had not “read anything in a couple of years” and could not recall any articles he had read on pain management. *Id.* at 385-86.

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that “[t]he Attorney General may deny an application for [a practitioner’s] registration . . . if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest.” 21 U.S.C. § 823(f). 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.

“[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)).³⁵

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for denial of an application pursuant to 21 U.S.C. § 823(f) are met. 21 CFR 1301.44(d). However, once the Government has made a *prima facie* showing that issuing a new registration to the applicant would be inconsistent with the public interest, an applicant must then present sufficient mitigating evidence to show why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (citing cases)); see also *MacKay*, 664 F.3d at 817.

Having considered all of the factors, I find that the Government’s evidence with respect to Factors Two and Four satisfies its *prima facie* burden of showing that granting Respondent’s application would be inconsistent with the public interest.³⁶ I further find that Respondent has failed to produce sufficient evidence to rebut the Government’s *prima facie* case.

³⁵ 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 or the denial of an application. *MacKay*, 664 F.3d at 821.

³⁶ As to factor one, while the Oklahoma Board has taken disciplinary action against Respondent for conduct related to his prescribing to B.B., the Board has not made a recommendation to the Agency with respect to whether his application should be granted. To be sure, as a result of the Board’s restoration of his medical license without restriction of his controlled substance prescribing authority under Oklahoma law, Respondent satisfies the CSA’s prerequisite for obtaining a new practitioner’s registration. See 21 U.S.C. § 823(f)(1); see also *id.* § 802(21). (defining “the term ‘practitioner’ [to] mean[] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice”). However, the restoration of Respondent’s state authority is not dispositive of the public interest inquiry. See *Mortimer Levin*, 57 FR 8680, 8681 (1992) (“[T]he Controlled

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 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.*

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.”).

To be sure, the Agency’s case law contains some older decisions which can be read as giving more than nominal weight in the public interest determination to a State Board’s decision (not involving a recommendation to DEA) either restoring or maintaining a practitioner’s state authority to dispense controlled substances. See, e.g., *Gregory D. Owens*, 67 FR 50461, 50463 (2002) (expressing agreement with ALJ’s conclusion that the board’s placing dentist on probation instead of suspending or limiting his controlled substance authority “reflects favorably upon [his] retaining his . . . [r]egistration, and upon DEA’s granting of [his] pending renewal application”); *Vincent J. Scolaro*, 67 FR 42060, 42065 (2002) (concurring with ALJ’s “conclusion that” state board’s reinstatement of medical license “with restrictions” established that “[b]oard implicitly agrees that the [r]espondent is ready to maintain a DEA registration upon the terms set forth in” its order).

Of note, these cases cannot be squared with the Agency’s longstanding holding that “[t]he 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.” *Levin*, 57 FR at 8681. Indeed, neither of these cases even acknowledged the existence of *Levin*, let alone attempted to reconcile the weight it gave the state board’s action with *Levin*. While in other cases, the Agency has given some weight to a Board’s action in allowing a practitioner to retain his state authority even in the absence of an express recommendation, see *Tyson Quay*, 78 FR 47412, 47417 (2013), the Agency has repeatedly held that a practitioner’s retention of his/her state authority is not dispositive of the public interest inquiry. See, e.g., *Paul Weir Battershell*, 76 FR 44359, 44366 (2011) (citing *Edmund Chein*, 72 FR 6580, 6590 (2007), *pet. for rev. denied*, *Chein v. DEA*, 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that Respondent has been convicted of an offense under either federal or Oklahoma law “relating to the manufacture, distribution or dispensing of controlled substances.” 21 U.S.C. § 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay*, 75 FR 49956, 49973 (2010), *pet. for rev. denied*, *MacKay v. DEA*, 664 F.3d at 822. The Agency has therefore held that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.*

While I have considered factor five, I deem it unnecessary to make any findings.

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 March 2005, the Oklahoma Board of Medical Licensure and Supervision issued its Policy Statement on the “Use of Controlled Substances for the Treatment of Pain.” Okla. Bd. of Med. Lic. & Super., *Use of Controlled Substances for the Treatment of Pain* (Mar. 10, 2005) (hereinafter, Policy Statement). Therein, the Board explained that it:

will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacological and non-pharmacological modalities according to the judgment of the physician. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain and treatment outcomes.

. . . .

. . . The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and/or federal law is required.

The Board will judge the validity of the physician’s treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient’s pain while effectively addressing other aspect of the patient’s functioning, including physical, psychological, social and work-related factors.³⁷

Id. at 1-2.

Simultaneously with the issuance of its Policy Statement, the Board promulgated its regulation on the “[u]se of controlled substances for the management of chronic pain.” Okla.

³⁷ See also Policy Statement, at 2 (“Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician’s conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.”).

Admin. Code § 435:10-7-11. As the Board explained, its purpose was to adopt “criteria” to be used “when evaluating [a] physician’s treatment of pain, including the use of controlled substances.” *Id.* The regulation thus sets forth criteria for the “[e]valuation of the patient,” the “[t]reatment plan,” “[i]nformed consent and agreement for treatment,” “[p]eriodic review,” “[c]onsultation,” and “[m]edical records.” *Id.*

With respect to the evaluation of the patient, the Rule states:

A medical history and physical examination must be obtained, evaluated and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. § 435:10-7-11(1). As for the treatment plan, the Rule provides:

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Id. § 435:10-7-11(2).

After providing the criteria for informed consent and agreement for treatment, which states, *inter alia*, that “[t]he physician should discuss the risks and benefits of the use of controlled substances with the patient,” *id.* § 435:10-7-11(3), the Rule sets forth the criteria for the periodic review. The Rule states:

The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient’s state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician’s evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient’s decreased pain, increased level of function or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or

other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued uses of the current treatment plan and consider the use of other therapeutic modalities.

Id. § 435:10-7-11(4).

With respect to consultation, the Rule provides:

The physician should be willing to refer the patient, as necessary, for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultations with or referral to an expert in the management of such patients.

Id. § 435:10-7-11(5).

And finally, with respect to medical records, the Rule states in relevant part that “[r]ecords should remain current” and that “[t]he physician should keep accurate and complete records.” *Id.* § 435:10-7-11(6). The records are “to include . . . the medical history and physical examination,” “diagnostic, therapeutic and laboratory results,” “evaluations, consultations and follow-up evaluations,” “treatment objectives,” “discussion of risks and benefits,” “informed consent,” “treatments,” “medications (included date, type, dosage and quantity prescribed),” “instructions and agreements and periodic reviews.” *Id.*

The CALJ rejected the bulk of the Government's case, finding the allegations proven only “in part” and only with respect to the prescriptions Respondent issued on October 6 and 20, 2011 (prescribing events 3 and 4), April 12 and 25, and May 9, 2012 (prescribing events 10, 11, and 12). Even then, however, the CALJ reasoned that “[t]he errant prescribing events established by the record reveal inattention to detail, not intentional diversion,” R.D. at 82, only to subsequently conclude that “Respondent violated his responsibility . . . to ensure that he only prescribed controlled substances for a legitimate medical purpose in the course of professional

practice.” *Id.* at 90 (citing 21 CFR 1306.04(a)); *see also id.* (“[T]hese prescribing events violated Oklahoma medical regulations, fell below the prevailing medical practice standard in Oklahoma, and did not fall within the state and federal definitions of the usual course of a professional practice.” (citing Policy Statement, at 2; 21 CFR 1306.04(a))).

I conclude, however, that the Government has proved additional violations of 21 CFR 1306.04(a) beyond those found by the CALJ, and I further conclude that the evidence does not simply reflect “inattention to detail” on Respondent’s part – a finding which is legally insufficient to support the conclusion that he violated 21 CFR 1306.04(a) – but rather, that he knowingly diverted drugs to B.B. I am mindful of the various credibility findings made by the CALJ, particularly with respect to the testimony of Respondent, as well as his finding that “Dr. Owen’s expert testimony predictably raised no issues regarding credibility” but that his “testimony was not without its own ‘red flags.’” R.D. 18. For reasons explained earlier, I respectfully disagree with the CALJ’s reasons for declining to give weight to much of Dr. Owen’s testimony, including his conclusion that Dr. Owen’s testimony was based upon a misunderstanding of the nature of the Oklahoma Board’s Pain Management Regulations. And to the extent the CALJ declined to consider the evidence of various UDS results with respect to the specific prescribing events on the ground that the Government did not provide adequate notice, as explained above, I conclude that Respondent had constitutionally sufficient notice and understood that the UDS results were at issue throughout the proceeding.

The September 22, 2011 Prescriptions

The CALJ rejected the Government’s allegation that the Duragesic and Opana prescriptions issued by Respondent on this date violated 21 CFR 1306.04(a) because they were issued outside of the usual course of professional practice and lacked a legitimate medical

purpose.³⁸ As found above, Dr. Owen testified that because this was B.B.'s first visit with Respondent and Respondent was taking over his care, Respondent should have "do[ne] a proper history and physical exam," reviewed the "previous treatments" and done "everything that typically is expected for a new patient evaluation." Tr. 131. Dr. Owen testified that Respondent performed "a superficial evaluation that" did not "adequately explain the chief complaint or what previous treatments have or have not been done." *Id.* at 133.

Dr. Owen further noted that Respondent documented that B.B. had a negative straight leg raise and that this is "the most sensitive physical finding for low back pain." *Id.* at 190. He then

³⁸ The CALJ asserted that in the Show Cause Order and its Prehearing Statement, "the Government noticed a theory based in the issuance of prescriptions outside the course of a professional practice under 21 CFR 1306.04(a), not that any prescriptions were not issued for a legitimate medical purpose." R.D. 87-88. While then noting that "the Government did *sporadically* elicit testimony from its expert in this regard ([citing] Tr. 93, 123, 133-34, 137-38, 140, 144, 148, 155-56, 158, 174, 176, 179) and did espouse this theory in its closing brief," the CALJ again asserted that this theory was unavailable to the Government because it raised the issue for the first time in its post-hearing brief. *Id.* at 88 n.150 (citing *Fred Samimi*, 79 FR 18698, 18713 (2014)).

I decline to adopt this ruling for multiple reasons. First, as several federal appeals courts have recognized, there is no material difference between the phrases "usual course of professional practice" and "legitimate medical purpose," and thus the courts have sustained convictions for violating the regulation and 21 U.S.C. § 841(a)(1), notwithstanding that an indictment charged the defendant "with dispensing of a controlled substance not in the usual course of professional practice" but did not allege that the dispensing lacked a legitimate medical purpose, as well as where the jury instructions only referenced the "usual course of professional practice" and did not require the jury to find that the defendant "dispensed without a legitimate medical purpose." See *United States v. Fuchs*, 467 F.3d 889, 898-901 (5th Cir. 2006) (noting earlier decision that "appears to use the phrases . . . interchangeably").

Likewise, in *United States v. Nelson*, 383 F.3d 1227, 1230-31 (10th Cir. 2004), the Tenth Circuit found no error in a jury instruction which provided that a physician could be convicted of conspiracy under 21 U.S.C. § 846, "if it found the prescriptions were either without a legitimate purpose *or* outside the course of professional practice." As the Tenth Circuit explained, "[i]t is difficult to imagine circumstances in which a practitioner could have prescribed controlled substances within the usual course of medical practice but without a legitimate medical purpose. Similarly, it is difficult to imagine circumstances in which a practitioner could have prescribed controlled substances with a legitimate medical purpose and yet be outside the usual course of medical practice." *Id.* at 1231. See also *United States v. Kirk*, 584 F.2d, 773, 784 (6th Cir. 1978) ("[T]here is no difference in the meanings of the . . . phrase, '[i]n the usual course of professional practice' and the . . . phrase, 'legitimate medical purpose.'" (citing *United States v. Plesons*, 560 F.2d 890, 897 (8th Cir. 1977) and *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975)).

Furthermore, even if these were two distinct theories for proving a violation of 21 CFR 1306.04(a), the record supports a finding of litigation by consent. The Government did not "sporadically elicit testimony from its expert" on this issue, but rather, asked Dr. Owen whether each of the prescriptions lacked a legitimate medical purpose. Respondent did not object to any of these questions, and thus, it is clear that unlike the issue in *Samimi*, which was raised for the first time by the Government in its post-hearing brief, Dr. Owen's testimony that each of the prescriptions lacked a legitimate medical purpose was not directed at an incidental issue, but rather went to the heart of the Government's case.

explained that “a sensitive test means that if you don’t have a positive finding you don’t have that diagnosis.” *Id.* Dr. Owen also testified that there was “no evaluation of pain or function, physical or psychosocial in the documentation” and “no evidence of a previous therapeutic benefit” from the use of controlled substances,” nor “proof that [B.B. had] exhausted conservative care before going [to the] high-risk treatment[.]” of “prescribing controlled substances.” *Id.* at 134. Dr. Owen thus concluded that because “[t]here’s no medical rationale for continuing with an ineffective treatment . . . there’s no justification to continue” to prescribe controlled substances. *Id.* at 133.

Dr. Owen further testified that Respondent’s patient file contained two aberrant drug tests, the June 1, 2011 test, which did not detect alprazolam even though B.B. was obtaining the drug every 30 days, and the August 25, 2011 test, which detected the presence of nordiazepam, oxazepam, and temazepam, which the lab reported as not expected based on the prescribed medications. Dr. Owen testified that Respondent “completely ignored” the aberrant drug screens and that he “should have acknowledged their existence and . . . taken some type of corrective action.” *Id.* at 132. Dr. Owen then suggested that Respondent could have sent B.B. for an evaluation by an addictionologist or mental health professional (either a psychiatrist or psychologist) with experience in addiction medicine. *Id.* at 134. And he further testified that the patient file did not reflect that Respondent had discussed B.B. with either his current (such as the providers who were writing alprazolam prescriptions) or past prescribers (such as Dr. Schoelen). *Id.* at 132. Dr. Owen also noted that Respondent did not appear to have taken any safeguards against the potential for abuse or diversion. *Id.*

The CALJ found uncontroverted Dr. Owen’s testimony that B.B. was a new patient and thus, Respondent was required to have done everything typically expected of a physician in the

evaluation of a new patient, including a proper history and physical, reviewing previous treatments, and reviewing his patient file. R.D. at 33-34. The CALJ further found uncontroverted Dr. Owen's testimony that Respondent ignored the June 1 aberrant drug screen, that there was no evidence Respondent discussed B.B. with either his current or past prescribers, and that Respondent took no precautions against the potential for abuse or diversion. *Id.* at 34.

As for the aberrant drug tests, the CALJ asserted that "there is little doubt that the June 1 UDS is aberrant to the extent it shows that B.B. was not taking his alprazolam," and that Dr. Owen's testimony that "failing to act on this aberrant UDS fell below the prevailing standard . . . stands un rebutted [on] the record." *Id.* at 38. The CALJ, however, declined to consider this evidence, reasoning that it was not properly noticed by the Government in its pleadings with respect to this prescribing event. *Id.* at 38-39. For reasons explained previously, I disagree and find that Respondent had fair notice that the June 1 aberrant UDS was at issue throughout the proceeding.

Accordingly, I find that the June 1 drug test was aberrant and that Respondent breached the standard of care when he failed to address the test with B.B. prior to issuing the September 22, 2011 prescriptions. The CALJ, however, also rejected the Government's contention that the drug test of August 25, 2011, which showed the presence of nordiazepam, oxazepam and temazepam when these drugs had not been prescribed to B.B. by either Dr. Schoelen or his mental health professional, was also aberrant and not properly considered and addressed by Respondent prior to prescribing to B.B. R.D. at 38. While Respondent testified that he did not remember if he reviewed this UDS prior to the September 22 visit or at any point, Tr. 397, in the visit note, Respondent stated that B.B.'s "[p]ast medical history was extensively reviewed." GX 3, at 48. Moreover, Dr. Owen credibly testified as to the need to obtain "all . . . previous

medical records pertaining to [the] chief complaint” and review them to determine what previous treatments had been tried and their results, as well as “to look for any previous aberrant behaviors.” Tr. 94. And Dr. Owen further explained that “if you don’t look at all the pertinent previous medical records, you can’t get an accurate diagnosis.” *Id.* at 117. This testimony is unrefuted.

In rejecting the Government’s contention that the August 25 test was aberrant, the CALJ did not make a credibility finding as to Respondent’s testimony that he did not remember whether he reviewed the UDS at the time he was treating B.B. Nor did he make an explicit finding as to whether Respondent reviewed the UDS.

Instead, the CALJ reasoned that “Respondent credibly testified that, based on his professional opinion and his conversations with personnel at the testing lab, a patient taking any benzodiazepine may test positive for any other benzodiazepine[,] [and] [t]hus, the Respondent *did not*, and does not view the August 25 UDS as anomalous.” R.D. at 38 (emphasis added). After faulting the Government because it did not recall Dr. Owen “to rebut Respondent’s understanding about the limitations of the GC/MS,” the ALJ explained that “[t]here was nothing patently incredible about the Respondent’s recollection of his conversations with the UDS lab about the limits of its testing.” *Id.*

However, if, in fact, Respondent did not review the UDSs prior to prescribing (notwithstanding the notation that he “extensively reviewed” B.B.’s medical history), Dr. Owen’s unrefuted testimony establishes that Respondent committed a gross breach of the standard of care in failing to do so. Of note, Respondent testified that Dr. Schoelen had instituted urine drug testing as a “safeguard” after Dr. Schoelen joined the American Academy of Pain Management and attended training, and that a drug test was done “every three months” on

the clinic's "chronic pain patients." Tr. 253-55. Thus, Respondent clearly knew that B.B. had been subjected to drug testing.

Moreover, if it is the case that Respondent did not review the August 25 drug test, then it is clear that Respondent's testimony as to what he was told by the lab was not offered to show his state of mind in failing to address the aberrant test result. Rather, it was offered to prove the truth of the matter asserted – that because of cross-reactions, "a patient taking any benzodiazepine may test positive for any other benzodiazepine."

Thus, Respondent's testimony was hearsay which was uncorroborated by either the testimony of a lab employee, an expert in drug testing, or articles from scientific or medical journals. The CALJ did not, however, analyze the reliability of the hearsay statements recounted by Respondent.³⁹ See R.D. at 37-40.

Notably, in his Response to the Government's Exceptions, Respondent does not maintain that this testimony was offered for the non-hearsay purpose of showing Respondent's state of

³⁹ In multiple decisions, the Agency has made clear that the reliability of a hearsay statement should be evaluated by reference to the decisional law of the courts of appeals that would have jurisdiction over a subsequent petition for review; this includes the D.C. Circuit and the Tenth Circuit. As the D.C. Circuit has explained, "hearsay may constitute substantial evidence depending upon its probative value and reliability, considering *inter alia*, possible bias of the declarant, whether [the] statements are signed and sworn to, whether they are contradicted by direct testimony, whether the declarant is available, and whether the hearsay is corroborated." *Hoska v. Department of the Army*, 677 F.2d 131, 138 (D.C. Cir. 1982) (quoted in *Mireille Lalanne*, 78 FR 47750, 47752 (2013)). By contrast, the Tenth Circuit does not appear to have set forth a set of factors for evaluating the reliability of hearsay in administrative proceedings. See *Roach v. NTSB*, 804 F.2d 1147, 1160 (10th Cir. 1986); Cf. *Bennett v. NTSB*, 66 F.3d 1130, 1137 (10th Cir. 1995) (declining to decide if uncorroborated hearsay can constitute substantial evidence in administrative proceeding "given the existence of ample corroborative evidence-both nonhearsay and hearsay exceptions"); *Sorenson v. NTSB*, 684 F.2d 683, 686 (10th Cir. 1982) (declining to decide "whether uncorroborated hearsay can constitute substantial evidence in administrative proceedings").

Applying the *Hoska* factors, I conclude that the statement is not entitled to weight. Even assuming that the lab employee who made the statement was not biased, the statement was neither signed nor sworn to, Respondent did not identify the employee by name, and Respondent did not disclose that he intended to testify to the lab's statement in advance of the hearing notwithstanding that the CALJ's Order for Prehearing Statements directed that Respondent was "to indicate clearly each and every matter as to which he intends to introduce evidence in opposition" and the summary of each witness' testimony was "to state what the testimony will be." ALJ Ex. 4, at 2. Moreover, that Order then stated "that testimony not disclosed in the prehearing statement or pursuant to subsequent rulings is likely to be excluded at the hearing." *Id.* Given that Respondent did not disclose this testimony in advance of the hearing, I find that the declarant was not available. Moreover, as explained above, Respondent offered no other evidence to corroborate the lab's statement and the statement was contradicted in part by Respondent's testimony regarding the temazepam positive on the January 19 drug test.

mind when he failed to address the August 25 drug test with B.B. Response to Exceptions, at 4-6. Indeed, in his brief, Respondent argues only that “there is no evidence that the written test results provided by . . . the drug testing company . . . are unreliable and inadmissible or that the results themselves are unreliable.” *Id.* at 5. However, neither the August 25 nor the January 19, 2012 lab reports – each of which detected the presence of nordiazepam, oxazepam, and temazepam in addition to the metabolite of alprazolam – contain any statements to the effect that because of cross-reactions, taking alprazolam could result in a positive finding for the other three drugs. And as for Respondent’s contention that there is no evidence that the test results are unreliable, that is the very point made by the Government. *Id.*

Moreover, even were I to consider Respondent’s testimony on the issue of his state of mind – which would seem to require a finding that he did see the lab report – as ultimate factfinder, I would not give it weight. While the Agency must accord some deference to an ALJ’s findings on credibility issues where an ALJ observes the demeanor of the witness, “[t]he findings of the [ALJ] are to be considered along with the consistency and inherent probability of [the] testimony.” *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951).

Of consequence, B.B.’s January 19, 2012 drug test also detected the presence (in addition to that of alpha-hydroxyalprazolam, the metabolite of alprazolam) of nordiazepam, oxazepam, and temazepam. GX 3, at 97. Yet on this occasion, Respondent noted on the Lab Report that he had “counseled [B.B.] to only take what is prescribed.” GX 3, at 97. And in his testimony regarding the January 19 drug test results, Respondent stated that he made the notation because “[t]he nordiazepam, the oxazepam, and then the Xanax, the lab always said that if . . . Xanax [alprazolam] was positive, that they could all three be positive. The temazepam, in our practice usually didn’t show up, and temazepam is [a] sleeping pill called Restoril.” Tr. 335; *see also* GX

3, at 105 (lab report of Dec. 7, 2010 in B.B.'s file reporting presence of alpha-hydroxyalprazolam but no other benzodiazepines even though the drugs screened for included diazepam, oxazepam, and temazepam).

Respondent offered no explanation for the inconsistency between his testimony regarding why he "would not consider" the August 25 drug test to be aberrant and his testimony as to why he deemed the January 19 drug test as aberrant, even though both tests reported the presence of the same four benzodiazepines, and in particular, temazepam. Most significantly, the CALJ did not address the inconsistency between Respondent's testimony regarding the August 25 and January 19 drug tests in making his credibility finding. See R.D. at 38.

I conclude, however, that for the same reason that Respondent deemed the January 19 test to be aberrant, I reject his testimony that he does not believe the August 25 test was aberrant and find that it was. I further find that this was now the second aberrant drug test that B.B. had provided in the previous four months.

I am also unpersuaded by the CALJ's reasoning for rejecting Dr. Owen's testimony as to the adequacy of Respondent's evaluation of B.B. The CALJ reasoned that the deficiencies identified by Dr. Owen "generally relate to a paucity of documented proof in the chart entries" as to whether Respondent had adequately evaluated B.B.'s chief complaint, the treatments he had previously undergone, his physical and psychosocial function, and whether the prescribing of controlled substances provided a therapeutic benefit. R.D. at 35-36. As explained above, the CALJ declined to give weight to Dr. Owen's testimony based on the erroneous legal conclusion that the Board's documentation and recordkeeping standards are permissive and not mandatory. The CALJ apparently credited Respondent's testimony in finding that "B.B. reported pain, which was consistent with the findings of the exam the Respondent conducted on that date." *Id.* at 37.

The CALJ also gave weight to Respondent's decision to change B.B.'s medications from Lortab, a short-acting medication which Dr. Schoelen had prescribed, to Duragesic (fentanyl) patches, which are long-acting, because in his view, short-acting medications are too addicting. *Id.* And the CALJ also reasoned that Respondent "explained that he did not have B.B. undergo physical therapy because that approach had been tried without success . . . in the past." *Id.* at 38 (citing Tr. 392).

As to Respondent's claim that B.B. had undergone physical therapy for some time, Respondent admitted that this was not documented in the patient file. Tr. 392. Indeed, a review of the progress notes prepared by Dr. Schoelen finds no mention of B.B.'s having been referred to physical therapy, but rather, mentions only Dr. Schoelen's recommendations of such modalities as gentle stretching, low back strengthening exercises, heat, and low back range of motion exercises. *See* GX 3, at 51-54, 56, 59. Likewise, B.B.'s file does not contain either a copy of any referral or prescription for physical therapy, or a copy of any physical therapist's notes. Indeed, while Respondent cited to the Patient History Form in B.B.'s file (GX 3, at 34) and testified that "[i]t says that under pain management, that he was in therapy every month on his past medical history," Tr. 392, that form does not even use the words "pain management." *See* GX 3, at 34. Instead, the form contains a column with the heading of "Chronic Problems," under which the entries state: "Depression," "Anxiety" and then "Therapy every month." *Id.* Patients in physical therapy, however, typically receive treatment several times a week and not "every month." *Cf. United States v. Armstrong*, 550 F.3d 382, 389 (5th Cir. 2008) (explaining that "[j]urors have had a wide variety of their own experiences in doctors' care over their lives," and can rely on those experiences when assessing evidence as to whether a physician lawfully

prescribed controlled substances). And as noted previously, other evidence of record establishes that B.B. was seeing a psychiatrist and receiving alprazolam prescriptions on a monthly basis.

Accordingly, I do not find credible Respondent's testimony that he did not have B.B. go to physical therapy because B.B. "had been on physical therapy monthly for quite some time and didn't feel that it was of any benefit at all." Tr. 392. Here too, because Respondent's testimony is inconsistent with the evidence (and lack thereof), I decline to adopt the CALJ's apparent credibility finding as to this testimony. I further agree with Dr. Owen's assessment that Respondent failed to properly assess whether B.B. had undergone conservative treatments.

As explained above, Dr. Owen also provided extensive testimony as to the standard of care for evaluating the history of a patient's pain complaint and the effect of the pain on a patient's physical and psychosocial functioning. Tr. 116. In his testimony, Dr. Owen identified various questions that Respondent should have asked B.B. and for which Respondent's September 22 visit note contains no evidence that he did so. *See id.* ("[H]ow did you hurt yourself; where does it hurt; does the pain radiate down an extremity; if so, how far down; does it go past the knee; where does it end up; is any numbness or weaknesses associated with it?"); *see also id.* ("And then you talk about what treatments have you had or what diagnostics have you had"). And with respect to the assessment of the effect of pain on a patient's functioning, Dr. Owen, after explaining that function is the "primary baseline for measuring therapeutic influence," *id.* at 104, testified that a physician should ask a patient about his activities of daily living such as his ability to work and his ability to tolerate sitting, walking and standing. *Id.* at 106, 111. *See also* GX 3, at 33 (Patient Comfort Assessment Guide completed by B.B. on Sept. 2, 2009 which asked questions as to how pain interfered with his general activity, mood, sleep, enjoyment of life, ability to concentrate, and relations with other people). He also noted that in

evaluating functionality, a physician would perform a neurological assessment, do a straight leg raise test, and look at the range of motion of the patient's spine. *Id.* at 111.

Respondent's note for this visit is totally devoid of any documentation that he asked B.B. how he hurt himself; whether his pain radiated down his extremities and if so, how far down; if the pain went past his knee; if he had any weakness or numbness; how the pain effected various activities of daily living such as his ability to work, as well as his ability to tolerate sitting, walking and standing.⁴⁰ GX 3, at 48. Indeed, the only documentation Respondent made pertinent to B.B.'s ability to function was to note "yes" for whether he had achieved his treatment objective and the numbers "3-5" in the pain scale column. *Id.* at 28. See Okla. Admin. Code § 435:10-7-11(1) ("The medical record should document the nature and intensity of the pain, current and past treatment for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse.").

Against this evidence, Respondent testified that B.B. reported pain which was consistent with the exam he conducted at this visit. Tr. 292. He also explained that he ordered an MRI because he "wanted to make sure that" the results were "consistent with his pain," his physical exam, and "the fact that he was on a schedule II narcotic." *Id.* at 293. Respondent also testified that he did not continue B.B. on Lortab (hydrocodone/acetaminophen) and prescribed fentanyl patches (a long-acting) narcotic medication because of the risk of abuse and addiction present with short-acting medications. *Id.* at 291.

While Respondent may have palpated B.B.'s lumbar region, he offered no testimony or other evidence refuting Dr. Owen's testimony that the straight leg raise test is "the most sensitive physical finding for low back pain," and that "if you don't have a positive finding you don't have

⁴⁰ There is likewise no evidence that Respondent had B.B. complete a new Patient Comfort Assessment Guide or that he asked him as to how the pain interfered with his general activity, mood, sleep, enjoyment of life, ability to concentrate and relations with other people.

that diagnosis.” *Id.* at 190. While the CALJ acknowledged this testimony, *see* R.D. at 35 nn.68-69, he did not explain why the testimony was not entitled to weight in determining whether Respondent established medical necessity to prescribe controlled substances. As this testimony stands unrefuted, I conclude that Respondent did not establish a diagnosis.

As for Respondent’s having changed B.B.’s medication from Lortab to Fentanyl patches, even long-acting schedule II medications are susceptible to abuse. Moreover, because Respondent performed only a superficial evaluation and did not establish a diagnosis and medical necessity to prescribe controlled substances, let alone two schedule II controlled substances, this evidence is entitled to no weight.⁴¹

I further hold that Respondent’s issuance of the prescriptions for the fentanyl patches and Opana (oxymorphone) prescriptions was not merely malpractice. Rather, I conclude that the evidence supports the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed these drugs to B.B. Here, not only did Respondent do a superficial evaluation as to B.B.’s purported pain complaint, his medical history, and the effect of the pain on his ability to function, he also

⁴¹ In his discussion as to why the Government had not proved that Respondent violated 21 CFR 1306.04(a) in issuing the September 22, 2011 prescriptions, the CALJ also explained that “Dr. Owen’s views about the relative merits of an MRI versus an X-ray or some other treatment is a medical treatment dispute that falls squarely outside the bounds of DEA’s expertise and jurisdiction.” R.D. 39 (citing *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006)). However, while Dr. Owen criticized Respondent’s decision to order an MRI in response to questioning on cross-examination and by the CALJ because there was no clinical justification for doing so and MRIs lead to over-diagnosis, his opinion that Respondent did not establish medical necessity for the September 22 prescriptions was not based on Respondent’s decision to order an MRI, but rather, the inadequacy of the evaluation of B.B.’s pain complaint, the failure to address the two aberrant drug screens, the lack of a positive finding on the straight leg raise test and the failure to exhaust conservative treatments.

So too, the CALJ took issue with Dr. Owen’s testimony regarding “Respondent’s failure to make referral to other specialists.” R.D. 39. However, Dr. Owen’s opinion that Respondent did not establish medical necessity for the September 22 prescriptions was based on Respondent’s superficial evaluation of B.B.’s pain and function, Respondent’s failure to exhaust conservative treatments, and the lack of evidence of a therapeutic benefit. Tr. 133-34. While Dr. Owen did suggest that based on the two aberrant drug tests, Respondent “could have sent” B.B. to an evaluation by an addictionologist or a psychiatrist/psychologist with experience in addiction medicine, he also testified that there was a further alternative step that Respondent could have taken: he could have been “much more careful and objective [as to] how [he] measure[d] a therapeutic benefit.” *Id.* at 134. Thus, Dr. Owen’s testimony is not fairly read as saying that such a referral was mandated at this visit.

performed a cursory examination which did not support his diagnosis, *id.* at 190, and ignored the results of the two aberrant drugs tests. As for the June 1 UDS, as the CALJ noted, “Respondent never addressed the absence of [the alprazolam and] presented no explanation for his failure to react to the June 1 UDS.” R.D. 36.

Moreover, even were I to credit Respondent’s testimony that he “doubt[ed]” that he reviewed the drug tests performed by Dr. Schoelen and “wouldn’t expect [him]self to,” Tr. 283, the evidence shows that Respondent clearly knew that B.B. was a chronic pain patient who was on multiple narcotics and was subject to drug testing. Dr. Owen credibly testified as to the importance of reviewing a patient’s medical records to determine if the patient has a history of aberrant behaviors, *id.* at 94, yet Respondent maintained that he did not do so. Accordingly, I conclude that Respondent did not establish medical necessity to prescribe controlled substances and that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he issued the Opana and Duragesic prescriptions. See 21 CFR 1306.04(a).

The October 6 Prescriptions

Here again, Dr. Owen testified that the medical record did not justify the prescribing of controlled substances. Tr. 137. Dr. Owen then explained that Respondent’s evaluation of B.B. was superficial in that there was no assessment of B.B.’s pain and his physical and psychosocial functioning. Dr. Owen thus concluded that once again, Respondent had not established medical necessity to prescribe controlled substances and thus, he opined that the prescriptions “were not” issued in the usual course of professional practice and “were not” for a legitimate medical purpose. *Id.* at 137-38. Dr. Owen further explained that based on the aberrant drug tests, Respondent should have obtained consultations with mental health providers or

addictionologists. *Id.* at 137. And based on the notation in the visit note that “[n]ow, B.B. would like to try the morphine,” Dr. Owen further faulted Respondent for not properly addressing B.B.’s request to try morphine. *Id.* at 135.

Explaining that “[t]he principal issue raised by Dr. Owen and noticed by the Government” with respect to these prescriptions “centers on” this notation, the CALJ found credible Respondent’s testimony regarding B.B.’s request to try morphine, characterizing the notation as “a poorly-worded memorialization of a longer conversation wherein he got medication efficacy input from B.B. and outlined several medication options based on the existing Oklahoma Medicaid formulary.” R.D. 43. The CALJ then explained that “[t]he progress notes related to issues regarding the Respondent’s evaluation and treatment of a suspected upper respiratory ailment are likewise more consistent with a conscientious practitioner than a pill mill operator.” *Id.*

Next, while the CALJ rejected the Government’s contention that the August 25 UDS was anomalous based on “Respondent’s plausible and credible explanation,” he then found that “[t]he aberrant nature of the June 1 UDS is uncontroverted by the evidence.” *Id.* The CALJ further found that the Government had proved that “Respondent’s actions in continuing to prescribe controlled medications without acting to investigate or institute safeguards upon encountering an anomalous UDS . . . fell below the standard expected of a prudent controlled substances prescriber.” *Id.*

As explained previously, with respect to those instances in which he found violations, the CALJ simply concluded that Respondent’s actions were neglectful. However, even accepting the CALJ’s credibility finding with respect to Respondent’s testimony regarding B.B.’s request to try morphine, I find that the evidence still supports the conclusion that Respondent violated

21 CFR 1306.04(a) in issuing the prescriptions for both morphine ER and Opana (oxymorphone).

As explained in my discussion of the September 22nd prescriptions, I conclude that the August 25, 2011 UDS was anomalous. And as also discussed previously, I find that the Board's documentation and recordkeeping provisions are mandatory and thus, Dr. Owen's testimony should be given weight.

In refutation of Dr. Owen's testimony that Respondent's evaluation was inadequate, Respondent testified that B.B. reported that "his objectives were only fair" and that his pain level had increased to a six out of ten. Respondent further noted that he did "a full exam" but that "[t]he MRI was not back yet." Tr. 295.

As the CALJ noted, Respondent "admitted that this part of the patient visit went very quickly, and that a patient may not remember the treatment goal when asked this." R.D. 41 n.80. Indeed, after admitting that "that part would be very quick in my office," Respondent added that "I wouldn't ask him what he was actually doing to achieve that." Tr. 393. He also testified that he was not sure as to why, when the question was "has patient achieved treatment objective" and was, in essence, a yes or no question, and the patient may not even remember what his treatment objective was, B.B. would have answered "fair." *Id.* at 395. Given that Respondent offered no further testimony as to other questions he asked B.B. to ascertain how the pain was effecting his ability to function in various aspects of his life activities, nor maintained that he asked any other questions about B.B.'s pain level, I give weight to Dr. Owen's testimony that Respondent's evaluation of B.B.'s pain and ability to function was superficial.

Although Respondent maintained that he did a full physical exam, once again he found that B.B.'s straight leg raise was negative. As Dr. Owen testified, without a positive finding on

this test, Respondent did not have a diagnosis for lumbar disc disease. And as for the Respondent's testimony that "the MRI results were not back yet," B.B. had not even gone for the MRI as of this date.

Nor do I find persuasive the reasoning that Respondent's treatment of B.B.'s upper respiratory ailment was "more consistent" with the treatment provided by "a conscientious practitioner than a pill mill operator." R.D. 43. Putting aside that there is no evidence as to how a conscientious practitioner would treat a patient who complains of a potential upper respiratory ailment, even patients who engage in the abuse or diversion of controlled substances may seek treatment for legitimate health conditions. So too, a physician may nonetheless divert controlled substances to some patients without being a pill mill operator. Thus, even assuming that Respondent properly evaluated and treated B.B. for this condition, this has no bearing on whether he properly evaluated B.B. to determine whether he had a legitimate pain condition which warranted the prescription of controlled substances.⁴²

In sum, because I agree with Dr. Owen that Respondent still had not established medical necessity for the prescriptions and had still failed to address the two aberrant drug tests, I conclude that the prescriptions lacked a legitimate medical purpose and that Respondent acted outside of the usual course of professional practice in issuing them. 21 CFR 1306.04(a).

The October 20 Prescriptions

⁴² To be sure, the visit note also stated that B.B. had "a left abdominal wall hernia" and Respondent recommended that he "wear a corset if at all possible." GX 3, at 47. While Respondent testified that he suggested the use of a corset because he didn't want B.B. to confuse his abdominal pain with his level of pain because of his having changed B.B.'s pain regimen, here again, there is no evidence that he evaluated the cause of the hernia, how much pain it was generating, and how it was effecting B.B.'s ability to function. Tr. 300.

Notably, B.B. returned for another office visit only two weeks later. GX 3, at 46. Yet the note for the visit contains no mention of the hernia. *Id.* Nor is the hernia mentioned in the visit notes for B.B.'s later visits. *See id.* at 42, 44-45. And in his testimony, Respondent offered no explanation as to what happened to B.B.'s hernia such that it was no longer mentioned in subsequent visit notes.

At this visit, Respondent noted that B.B. reported that “his stress [was] up” and that he had “lo[st] his father” and was “having a lot of grief.” GX 3, at 46. He made similar physical exam findings as at the previous visit, again noting that B.B.’s straight leg raise was negative but that “lying down and sitting up cause him a lot of pain.” *Id.*; see also Tr. 305 (Respondent’s testimony that B.B.’s “exam was still exactly like before, with low back paraspinal and spinal tenderness, but he still had the negative straight leg raises. But lying down and sitting up still caused him a lot of pain.”). Respondent did not even obtain a numerical pain rating at this visit nor note whether B.B. was achieving his treatment objective. Respondent diagnosed B.B. as having both acute grief and lumbar disc disease.

Dr. Owen testified that B.B.’s having a lot of stress and grief would magnify B.B.’s “perception of pain and disability.” Tr. 139. He further explained that because of B.B.’s previous aberrant behaviors and the new stressors in B.B.’s life, he was at increased risk to “use [the] drugs to chemically cope” and that Respondent should have “sought psychological counselling for” him but did not do so. *Id.*

Dr. Owen also took issue with Respondent’s notation in the visit note that he suggested nonmedicinal modalities for two reasons. *Id.* at 209-10. First, he explained that “good medicine would be [that] if you haven’t done nonmedicinal pain-relieving modalities,” Respondent should have “wean[ed] [B.B.] off these controlled substances and tr[ied] these other treatments first.” *Id.* at 210. Second, he explained that the note did not provide an adequate level of detail such that any person who took over B.B.’s care or was asked to provide a consultation would be able to “understand what was happening with this patient at that point.” *Id.*

As for Respondent’s notations that the straight leg raise test was negative but that lying down and sitting up caused B.B. a lot of pain, Dr. Owen testified that these were not objective

findings in a neurological sense in that B.B. could not “have a radiculopathy” absent a positive straight leg raise test. *Id.* at 210-11. As for the pain that B.B. had lying down and sitting up, Dr. Owen testified that this contributed to the idea that the controlled substances did not provide a therapeutic benefit and thus did not warrant the continued prescribing of controlled substances. *Id.* at 210.

The CALJ declined to give weight to much of Dr. Owen’s testimony, reasoning that his “view of the level of documentation detail required in Oklahoma, as well as his description of a mandatory mental health referral requirement, is [sic] not consonant with the requirement of the Oklahoma Pain Management Regulations.” R.D. 46. With respect to Respondent’s recordkeeping, the CALJ explained that “[t]here was sufficient detail to support the proposition that the office visit that was conducted in conjunction with this prescribing event *presented efforts on the part of the Respondent to treat B.B.*” *Id.* (emphasis added). However, as he did with the October 6 prescriptions, the CALJ found that the August 25 UDS was not anomalous (based on Respondent’s uncorroborated hearsay testimony) but nonetheless found that the June 1 UDS was aberrant and that “Respondent’s continued controlled substance prescribing under these circumstances . . . fell outside the course of a professional medical practice, and fell short of his obligations as a DEA registrant to safeguard against diversion.” *Id.*

I do not read Dr. Owen’s testimony as categorically stating that the Oklahoma regulation imposes a mandatory requirement of obtaining a consultation when a patient presents with a comorbid psychiatric disorder. While Dr. Owen testified that one of the provisions in Oklahoma’s “policies and guidelines . . . that stood out is if somebody’s a complex pain patient with psychological or psychiatric comorbidities, they should get consultations with a pain management physician with expertise in these complex cases,” Tr. 101, he acknowledged that

the Board's rule used the words "may require" but that a physician "should document why [he] deviate[s] from that recommendation." *Id.* at 186.

Thus, Dr. Owen's testimony is not fairly read as asserting that Oklahoma imposes a mandatory requirement of obtaining a consultation in all instances in which a patient presents with a comorbid psychiatric disorder. Moreover, even if I agreed with the CALJ's characterization of Dr. Owen's testimony on this issue, the Board's standard is nonetheless evidence that the standard of care may require referral or consultation depending on the circumstances presented by the patient, and there is ample evidence to support Dr. Owen's conclusion that Respondent breached the standard of care when he failed to even consult with B.B.'s mental health providers.

Dr. Owen testified that patients who present with comorbid psychiatric conditions present a heightened risk of abusing controlled substances because these conditions may magnify a patient's perception of pain and disability and aggravate a patient's experience of suffering, *id.* 102-04, and Respondent agreed with Dr. Owen. *Id.* at 409 (Respondent's testimony that "having chronic pain [can] lead to worse anxiety and depression" and that "uncontrolled anxiety or depression [can] lead[] to more pain."). And throughout his testimony, Dr. Owen repeatedly noted that based on B.B.'s aberrant behavior alone, Respondent should have obtained consultations with mental health providers or addictionologists to obtain a more thorough assessment of B.B.'s behavior. Thus, Dr. Owen opined that Respondent should have sought psychological counselling for B.B. based on his presentation of suffering from greater stress and acute grief at this visit. *Id.* at 139.

To be sure, the evidence shows that B.B. was already seeing a mental health professional during this period. However, Respondent admitted that he never even consulted with the mental

health professionals who were simultaneously prescribing controlled substances to B.B., whether in response to B.B.'s report of increased stress and grief at this visit, or at any point during the course of his prescribing to B.B. *Id.* at 408. Notably, when Respondent was asked if it was within the standard of care for him and B.B.'s mental health provider to keep treating B.B. "without talking to each other," Respondent explained that "the mental health providers are very good about speaking to us about patients." *Id.* at 409. When then asked if he would ordinarily consult with a patient's mental health provider if the latter is simultaneously prescribing controlled substances, Respondent offered the unresponsive answer that "[w]e've become quite reliant on the PMP [reports] now" and that "[b]efore the PMP, there was quite a bit of cross-talk, because . . . pharmacists would call" and tell him that a patient was seeing another physician. *Id.* at 409-10. However, the PMP reports in the record show that they did not contain any medical information for B.B. other than the controlled substance prescriptions he obtained and filled and the names of the prescribers.

When then asked if two practitioners who are simultaneously prescribing controlled substances to the same patient wouldn't "talk to each other about" their joint prescribing, Respondent initially answered "absolutely." *Id.* at 410. However, notwithstanding his earlier testimony that "[t]he mental health providers are very good about speaking to us about patients," he then asserted that "[i]n every other field but mental health we do do that," and added that consulting with his patient's mental health professionals "doesn't happen very often." *Id.* In short, none of this testimony refutes Dr. Owen's testimony that a patient with a co-morbid psychiatric disorder is at a higher risk of abusing controlled substances to cope, that consultations are important to obtain a better understanding of such a patient's behavior, and that

based on the aberrant drug screens and his report of acute grief, Respondent should have consulted with either B.B.'s mental health providers or an addictionologist.

While, when considered in isolation, Respondent's failure to consult with B.B.'s mental health providers would not establish a violation of 21 CFR 1306.04(a), Dr. Owen again explained that Respondent's evaluation was "inadequate" and did not support a finding of medical necessity to continue prescribing controlled substances. *Id.* at 140. Moreover, while Respondent testified that lying down and sitting up caused B.B. a lot of pain, B.B. had been on controlled substances for more than two and a half years at this point and was receiving prescriptions for even more potent narcotics and in larger doses (morphine and oxymorphone, both schedule II drugs) and yet he had never been referred for physical therapy. Thus, as Dr. Owen explained, Respondent's findings that B.B. was having a lot of pain lying down and sitting up supported the finding that prescribing controlled substances was not providing a therapeutic benefit. *Id.* at 211.

As before, Respondent's failure to address the aberrant drug screens as well as Dr. Owen's testimony that the evaluation was inadequate, that prescribing controlled substances did not provide a therapeutic benefit, and that Respondent did not establish medical necessity to continue prescribing controlled substances, are sufficient to support a finding that Respondent violated 21 CFR 1306.04(a). Respondent's failure to consult with B.B.'s mental health providers given B.B.'s report of increased stress and grief provides additional support for this conclusion.

The November 18 and December 15, 2011 Prescriptions

On both dates, Respondent issued B.B. prescriptions for 90 Morphine Sulfate ER 15 mg and 120 Opana 10 mg without requiring that B.B. appear for an office visit with him. Dr. Owen again found that Respondent should have seen B.B. prior to issuing the prescriptions and that

Respondent still had not established medical necessity to continue to prescribe controlled substances. Tr. 142. Dr. Owen also noted that Respondent still had not addressed the aberrant drug screens. *Id.* at 143. He further observed that notwithstanding B.B.’s report of increased stress and grief at the previous visit and that B.B. presented a high risk of escalating his medications and abusing them, Respondent obviously did not discuss these issues with B.B. *Id.*

Dr. Owen acknowledged that under a DEA regulation (21 CFR 1306.12(b)), a practitioner may issue multiple prescriptions for a schedule II drug to provide up to a 90-day supply of the drug based on only seeing the patient once every 90 days. However, Dr. Owen explained that a physician who does so must have “established medical necessity and legitimate therapeutic benefit . . . and [that] a patient doesn’t have a high risk of abuse,” but that B.B. already had provided two aberrant drug screens before Respondent issued the prescriptions. *Id.* at 196.

In refutation, Respondent offered only that after the October 20 visit, he “felt like [B.B.] could really go into the three-month” and that he did not understand that he had to see B.B. “every 30 days.” *Id.* at 307. Respondent further asserted that when a patient requested a new schedule II prescription, a PMP report would be obtained, the patient’s file would be pulled, and that he would write the prescription and leave it “up front.” *Id.* at 308. Respondent did not offer any testimony refuting Dr. Owen’s testimony that B.B. presented a high risk of escalating the use of controlled substances and should have been seen prior to the issuance of the prescriptions on both dates.

The CALJ found the allegations “not sustained” with respect to both the November 18 and December 15 prescriptions. R.D. at 51. In the CALJ’s view, although the June 1 UDS was aberrant, it was not adequately noticed with respect to these two prescribing events, and as for

the August 25 UDS, “the record evidence [did] not support a finding that the . . . results [were] aberrant.” *Id.* The CALJ again rejected Dr. Owen’s testimony as to the lack of therapeutic benefit and medical necessity, on the ground that Dr. Owen’s view as to the required level of documentation “is at odds with the requirements of the Oklahoma Pain Management Regulations.” *Id.* at 48. And finally, the CALJ rejected Dr. Owen’s testimony regarding Respondent’s failure to require an office visit, reasoning that DEA’s regulation allows for the issuance of multiple prescriptions for up to a 90-day supply of a schedule II drug and that Dr. Owen’s opinion was “based on his assumptions that the chart contains insufficient documentation detail and two aberrant UDS lab results.” *Id.*

I find, however that on both dates, Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the morphine and Opana prescriptions without requiring an office visit. As previously explained, the Show Cause Order provided Respondent with fair notice that the aberrant June 1 drug test would be at issue throughout this proceeding, including with respect to the prescriptions he issued on November 18 and December 15, 2011. *See supra* discussion at 72-77. With respect to the August 25 drug test, the CALJ’s reasoning makes clear that he considered Respondent’s testimony as to what he was told by the lab to prove the truth of the matter asserted. As explained previously, his testimony is uncorroborated hearsay and thus unreliable. Moreover, Respondent’s testimony that he did not consider the positive test results for the other benzodiazepines including the temazepam positive to be aberrant is amply refuted by his testimony regarding the January 19, 2012, which he deemed aberrant.

So too, for reasons explained previously, I reject the CALJ’s interpretation of the documentation requirements imposed by the Oklahoma regulations. In any event, in his

testimony regarding his evaluation of B.B., Respondent simply read aloud what he had documented in the visit notes and in the Treatment Objective Evaluation section of the Treatment Plan (GX 3, at 28) and never identified additional measures he took to evaluate B.B.'s pain and how it affected his ability to function.⁴³ Thus, I give weight to Dr. Owen's testimony that Respondent did not establish medical necessity to continue to prescribe controlled substances.

As for the CALJ's reliance on the regulation which allows a practitioner to issue to a patient multiple schedule II prescriptions for up to a 90-day supply at one time, provided the practitioner meets certain conditions, the rationale underlying this provision does not provide a safe harbor to Respondent.⁴⁴ Of relevance here, these conditions include, *inter alia*, that: "[e]ach separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice"; and "[t]he individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse." 21 CFR 1306.12(b)(i) and (iii). As found above, based on my conclusions that the prescriptions Respondent issued at the three previous office visits were issued outside of the usual course of professional practice and lacked a legitimate medical purpose, Respondent did not meet the first condition. Moreover, based on Respondent's testimony that he did not remember whether he reviewed either the June 1 or August 25 drug test results, that he doubted that he did and "wouldn't expect [him]self to" have done so even though

⁴³ While Respondent had received the MRI results before he issued the November prescriptions, GX 3, at 20; Dr. Owen testified that the MRI "did not show any specific problems that would be attributable for this kind of pain complaint[], nor was it significant to cause the perceived disability that this 26-year-old gentleman considers himself" to have. Tr. 207. At no point in his testimony did Respondent refute Dr. Owen's review of the MRI results.

⁴⁴ As this provision contemplates the issuance of multiple prescriptions at one time provided the prescriptions "indicat[e] the earliest date on which a pharmacy may fill each prescription," it is not directly applicable here. However, as to the frequency of office visits, the regulation states that a physician "must determine . . . based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so." 21 CFR 1306.12(b)(2).

he knew his partner had instituted drug testing of the clinic's chronic pain patients (Tr. 283, 397), Respondent failed to determine whether issuing the prescriptions created an undue risk of diversion. Thus, the rationale underlying this regulation provides no basis to reject Dr. Owen's testimony that these prescriptions were issued outside of the usual course of professional practice and lacked a legitimate medical purpose. 21 CFR 1306.04(a).

The January 19, 2012 Prescriptions

On January 19, 2012, B.B. again saw Respondent. B.B. reported that he had gone to the emergency room "two weeks ago with right leg swelling" but that "[h]is ultrasound was negative"; he complained of "some calf pain" and that "[h]e still feels very tight." GX 3, at 45. Respondent also noted that B.B. "goes to a psychiatrist" and "reports severe lumbar disc disease." *Id.* In addition, Respondent documented that B.B. reported that "he ha[d] been exposed to someone with HPV" and "would like an exam." *Id.* Respondent further noted that B.B.'s "[p]ast medical history [was] extensively reviewed" and "placed in chart." *Id.*

According to Respondent's exam notes, B.B. was "[a]lert and oriented and in no apparent distress." *Id.* While other portions of the exam were normal, Respondent again documented that B.B. had "[l]ow back paraspinal tenderness," a "[n]egative straight leg raise," and "[n]euro intact." *Id.* He also documented that B.B. "has very tight right calf." *Id.* However, no mention was made of B.B.'s hernia which had been noted at previous visits. *Id.*

Respondent diagnosed B.B. with "lumbar disc disease," "exposure to infectious disease," and "[r]ight calf pain." *Id.* He further documented that he discussed the "[a]ddictive dependence, and tolerance nature of the medicines as well as alternatives," that he suggested "[n]on-medicinal pain-relieving modalities," and that the "[f]ollowup will be [in] three months." *Id.* Respondent

then issued B.B. new prescriptions for Morphine Sulfate ER 15 mg and Opana 10 mg with the same dosing instructions, thus providing a 30-day supply for each drug if taken as directed. *Id.*

Dr. Owen testified that when a patient reports having gone to the emergency room, he would get the record to find out both “what the problem was” as well as if “any additional medication [was] prescribed.” Tr. 147. B.B.’s file does not, however, contain a note from the emergency room. *Id.*; *see also* GX 3. Moreover, after observing that the visit note contains no mention that Respondent addressed either of the two prior urine screens during this visit, Dr. Owen again testified that Respondent had failed to establish medical necessity for the prescriptions “by doing a proper history and physical exam, by defining a therapeutic benefit, by explaining what previous treatments have or have not worked . . . and . . . addressing the previous aberrant urine drug tests.” *Id.* at 148. Thus, Dr. Owen opined that the Respondent acted outside of the usual course of professional practice in issuing the prescriptions and that the prescriptions lacked a legitimate medical purpose. *Id.*

In refutation of Dr. Owen’s testimony, Respondent asserted that B.B. did not report anything other than his calf pain and his new conditions (apparently a reference to his exposure to someone with HPV). *Id.* at 314, 317. He further testified that there was nothing in the PMP report that showed that B.B. had been prescribed anything during his emergency room visit. *Id.* at 314. He also acknowledged that during the physical exam, he again found that B.B. had a negative straight leg raise test and thus did not have radiculopathy but that this did not mean that B.B. did not have paraspinal or muscular skeletal pain. *Id.* at 318-19. However, in contrast to the last visit where Respondent documented that lying down and sitting up was causing B.B. a lot of pain, Respondent made no such note in the visit note. GX 3, at 45.

While Respondent agreed that his visit notes were unremarkable given the high amount of narcotics he was prescribing and asserted he could have done a better job dictating his notes (which he attributed to seeing 40 to 45 patients a day and dictating the notes), he maintained that because B.B. “just continued to have the same pain that he had before . . . I didn’t go into details on it.” Tr. 315. However, notwithstanding that he had not seen B.B. in three months, he did not document whether B.B. had achieved his treatment objective nor document a numeric pain rating. GX 3, at 28.

The CALJ rejected the Government’s contention that the controlled substance prescriptions Respondent issued at this visit violated 21 CFR 1306.04(a). Again, the CALJ concluded that the Government did not provide adequate notice regarding its reliance on the June 1 UDS and that the record does not support a finding that the August 25 UDS result was aberrant. R.D. at 51. And again, the CALJ reasoned that Dr. Owen’s view of the level of documentation required findings of therapeutic benefit and medical necessity, as well as his conclusion that Respondent did not adequately document B.B.’s visit to the emergency room and should have obtained the record of that visit, were “at odds with the requirements of the” Board’s rules. *Id.* Finally, the CALJ asserted that “Respondent’s testimony provide[s] convincing evidence that the Respondent was engaged in *bona fide* attempts to treat B.B., not act as a drug supplier. The same can be said of the evidence that the Respondent was seeing B.B. for maladies beyond his pain complaints.” *Id.*

For reasons explained previously, I find that Respondent was provided adequate notice regarding the Government’s reliance on the June 1 UDS and that the record supports a finding that the August 25 UDS was aberrant. As also explained previously, because I do not agree with the conclusion that Dr. Owen’s understanding of the Oklahoma documentation requirement is “at

odds” with the permissive nature of the State’s regulations, R.D. 51, and agree with the CALJ’s conclusion that Dr. Owen’s testimony “predictably raised no issues regarding credibility,” I give weight to Dr. Owen’s testimony that Respondent did not establish medical necessity to issue the prescriptions.

As for Dr. Owen’s criticism of Respondent for failing to obtain the emergency room record, Respondent testified that he checked the PMP and found no evidence that B.B. had been prescribed controlled substances. Moreover, even if the standard of care does require a pain management physician to obtain an ER record for his patient, it not clear how quickly that record could have been obtained on the date of this visit. Nor is it clear why, if a physician has otherwise properly evaluated his patient, his failure to obtain an ER record on that date would preclude his issuance of controlled substance prescriptions.

However, Dr. Owen provided credible testimony that when Respondent issued the January 19 prescriptions, he still did not perform an adequate evaluation of B.B.’s pain complaint by doing a proper history and physical exam, nor determined whether there was a therapeutic benefit to justify the continued prescribing of controlled substances, nor addressed the previous aberrant drugs tests. Dr. Owen’s testimony provides substantial evidence to conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued the prescriptions.

In discussing Respondent’s testimony regarding the notes he made after B.B.’s January 27 office visit (on which occasion he did not prescribe controlled substances), the CALJ stated that “Respondent noted that B.B. was on Social Security disability, and objective data had confirmed that he had chronic pain.” R.D. at 50 (citing Tr. 324). However, Respondent did not identify what the “objective data” were. See Tr. 324-25.

The CALJ also found that in the Respondent's view, B.B. had not behaved in a way that set off alarms, and was stable on his medications." R.D. at 50. However, as found previously, Respondent testified that he probably never even looked at the UDS results that were in B.B.'s chart and didn't expect that he would have done so. Yet Respondent also testified that Dr. Schoelen had instituted urine drug testing for the clinic's chronic pain patients and thus Respondent obviously knew that B.B.'s file likely contained UDS results. And the evidence also shows that Respondent did not conduct a drug test of B.B. at any of his first three visits and yet concluded that he only needed to see B.B. once every three months. Thus, to the extent Respondent claims that B.B.'s behavior did not set off alarm bells, it is because Respondent deliberately ignored relevant evidence and failed to monitor his patient.

The CALJ apparently also credited Respondent's testimony to the effect that "[m]uch more went on in the office than what's written" in the visit notes and that he "definitely knew what was going on in [B.B.'s] life from each visit, and I just failed to dictate that." Tr. 326. And the CALJ further asserted that "Respondent provided details to demonstrate that he knew his patient," R.D. 50, and apparently credited Respondent's testimony that he "was talking to [B.B] about those things and what all he did in a day, and he was not able to work." Tr. 327 (cited at R.D. 51).

Yet, on the occasion of the January 19 visit, during which he issued B.B. new prescriptions for morphine and oxymorphone, Respondent did not even document in the Treatment Objective Evaluation section on the Treatment Plan if B.B. was meeting his treatment objectives and did not obtain a pain rating. Of note, the former was typically documented with a

handwritten one-word answer of either “yes” or “fair,” and the latter was documented with a handwritten notation of a number; thus neither of these inquiries required dictation at all.⁴⁵

Moreover, when asked by the CALJ how he knew how the meds he prescribed “were doing,” Respondent replied that his evaluation was “purely subjective, and if they were needing more or less pain meds.” Only after a further question as to whether he asked objective questions in assessing how B.B. was responding to the medications did Respondent maintain that he was aware of what B.B. did all day and that he had not returned to work.

Dr. Owen provided unrefuted testimony that “return[ing] to work” is “the gold standard for functionality in pain management.” Tr. 100. Given this, it is telling that Respondent never documented whether B.B. had returned to work in the progress notes he prepared for the various visits. Moreover, given that B.B.’s treatment objective was to return to work without pain and yet B.B. never returned to work during the course of Respondent’s prescribing to him, *id.* at 353, it is hard to understand why Respondent wrote “fair” for whether B.B. was meeting his treatment objective.

As for why he did so, Respondent testified that he would ask his patients if they were meeting their treatment objective and he would write down what the patient told him. Tr. 392. However, Respondent further testified that “[a]ctually that part [of the visit] would be very quick in my office. I wouldn’t ask him what he was actually doing to achieve that.” *Id.* at 393.

Respondent “absolutely” agreed with the CALJ that he would ask his patients “[h]ave you achieved your treatment objective?” only to then acknowledge that his patients “may not” remember what their treatment objective was. Tr. 394. And while this question appears to have been directed at assessing a patient’s function, Respondent testified that the question was

⁴⁵ Indeed, on each of the dates on which Respondent made notations in this section of the chart, each of the entries was handwritten.

intended to elicit “[b]asically if they were satisfied with the care or the standard that they meet.”

Id. When then asked why B.B. would answer “fair” to what seemed to be “a yes or no question,”

Respondent testified that he was “not sure” why the answer would come out as “fair.” *Id.* at 395.

Tellingly, at another point during his testimony on this issue, Respondent explained:

They [the patients] were very well trained by the time this was here. Whenever we walked in, they knew the questions before we asked them. You know, are you meeting your objective? What’s your pain level? And do you wish to change? Do you think we should make a referral? We asked it every time, just like clockwork.

Tr. 394-95.

I disagree with the CALJ that “Respondent’s testimony provides convincing evidence that he was engaged in *bona fide* attempts to treat B.B., not act as a drug supplier.” On the issue of how he evaluated B.B.’s function, Respondent offered only the vague testimony that he “was talking to B.B about those things and what all he did in a day.” Yet Respondent never documented any such findings other than to make the nonsensical notation of “fair” for whether B.B. was achieving his treatment objective, and even at the hearing, Respondent still could not explain why he did so even though he did so on multiple occasions. As for his assessment of B.B.’s pain level, Respondent testified to only asking “what’s your pain level” – as if over the course of the preceding 90-day period, a patient’s pain level would not fluctuate depending upon the activities engaged in by the patient. While I am mindful that the CALJ’s finding was based on his credibility determination, it is noteworthy that in his decision, the CALJ did not discuss this portion of Respondent’s testimony (Tr. 392-95), which is clearly relevant and probative on the issue of the scope of his evaluation of B.B.⁴⁶

⁴⁶ While Respondent also asserted that B.B. “basically was stuck in the house all day,” that obviously was not the case when B.B. was found semiconscious and in an apparent state of intoxication in a vehicle parked on the median strip of I-35. As far as B.B.’s inability to work, the evidence shows that he was working by “illegally buying and selling prescriptions drugs.” RX 3, at 3 (stipulated findings of fact of the March 8, 2013 Board Order).

As noted previously, in its Policy Statement, the Board stated that it “will judge the validity of the physician’s treatment of the patient *based on available documentation*” and that “[t]he goal is to control the patient’s pain while effectively addressing other aspects of the patient’s functioning, including physical, psychological, social and work-related factors.” Policy Statement, at 2 (emphasis added). Given that Respondent’s documentation was confined to the two superficial notations in the Treatment Objective Evaluation section of the Treatment Plan and given the emphasis which the Board’s Policy Statement places on the available documentation in judging the validity of treatment, as well as Respondent’s testimony as to the scope of the questions he would ask, I conclude that Respondent has not refuted Dr. Owen’s testimony that he failed to adequately evaluate whether there was a medical necessity to prescribe controlled substances to B.B.

In concluding so, I am mindful that while the Board initially charged Respondent with “fail[ing] to maintain adequate medical records to support diagnosis . . . treatment or prescribed medications, in violation of 59 O.S. § 509(20),” RX 1, at 4, the Board ultimately entered into a settlement with him prior to hearing which did not include a finding that he violated this provision. There is, however, nothing unusual about prosecutors agreeing to enter settlement agreements in which they waive meritorious allegations and, as the voluntary settlement agreement offers no explanation as to why the Board did not rely on this specific allegation, I place no weight on the failure of the Board to find that Respondent violated the provision.

I am also mindful of the CALJ’s criticism that Dr. Owen is not licensed to practice in Oklahoma and has never practiced there, as well as that Dr. Owen’s “representation that the controlled substance prescribing standards in his home state of Texas are similar to, but less

restrictive than Oklahoma, is flat out wrong,” and that this diminishes the weight to be given to his testimony. R.D. 89 (citing Tr. 87, 94,105-06).

It is true that in several respects the Texas Board’s standards are more restrictive than Oklahoma’s, and thus, Dr. Owen’s testimony that Texas’s standards are less restrictive was erroneous. However, on the critical issues of the scope of the evaluation of the patient and the documentation required, as explained previously, I conclude that the Oklahoma Board’s standards on these issues are mandatory. While the Texas Board uses even more emphatic language to express the mandatory nature of these requirements, I conclude that there is no material difference between the standards of Oklahoma and Texas.

Moreover, Dr. Owen provided additional evidence to support the view that the standards of medical practice require the documentation of considerably more information than found in B.B.’s progress notes. As he explained:

the purpose of documentation is for continuity of care. Not only continuity of care for this same provider from visit to visit but continuity of care should somebody else assume the care later on down the road or should you need to get a consultation, that the consultant can read your notes and understand what was happening with this patient at this point in time.

Tr. 210.

Notably, Respondent put on no evidence showing that Oklahoma’s standard was materially different than what Dr. Owen testified to on the issue of the adequacy of the evaluation and required level of documentation. See *United States v. Joseph*, 709 F.3d 1082, 1096 (11th Cir. 2013) (upholding criminal conviction for violation 21 CFR 1306.04(a); “[e]ven if the district court should have instructed the jury to evaluate the conduct of the defendants against only a Georgia standard of medical practice, the defendants failed to offer any proof that

the Georgia standard differs at all from any national standard that the jury purportedly considered”).

Moreover, while States have the primary responsibility for the regulation of the medical profession, many of the profession’s norms were created by the profession itself. Thus, on such issues as the adequacy of a clinical evaluation for a particular pain complaint and the necessary documentation to support the prescribing of controlled substances, the standard of medical practice would not seem to vary to any material degree between States, especially between States that border each other.

Finally, unlike Respondent, Dr. Owen is board certified in pain management, is a member of multiple pain management professional organizations, including the American Academy of Pain Medicine and the American Academy of Pain Management, has practiced pain management for more than sixteen years, serves as a peer reviewer on pain medicine for the Journal of the American Academy of Pain Medicine, and has made numerous presentations on pain-management. In light of his extensive professional credentials, I conclude that even though he has not practiced in Oklahoma, I find persuasive his testimony as to the inadequacy of Respondent’s evaluations of B.B. and Respondent’s failure to establish a medical necessity for the prescriptions. I thus conclude that the January 19, 2012 Morphine and Opana prescriptions lacked a legitimate medical purpose and that Respondent acted outside of the usual course of professional practice in issuing them. 21 CFR 1306.04(a).

The February 13, 2013 Prescriptions

On this date, Respondent issued B.B. new prescriptions for 120 Opana 10 and 90 Morphine Sulfate ER 15. Moreover, by this date, Respondent likely had the results of the January 19 UDS, which showed that Morphine Sulfate was not detected and that B.B. had tested

positive for nordiazepam, oxazepam and temazepam (as well as alprazolam). On the lab report, Respondent wrote that B.B. was “counsel[led] to only take what is prescribed.” Respondent did not require that B.B. appear for an office visit.

Dr. Owen testified that Respondent should have required an office visit because of B.B.’s previous aberrant drug-taking behaviors and because Respondent still needed to establish that there was a medical necessity to prescribe controlled substances and a therapeutic benefit. Tr. 154. While Dr. Owen acknowledged Respondent’s notation that he had counseled B.B., Dr. Owen testified that this was not an adequate safeguard to prevent abuse or diversion because this was B.B.’s third aberrant drug test. *Id.* Dr. Owen further testified that Respondent “need[ed] to have a long discussion with [B.B.] about the risk of addiction” and obtain a consultation by a specialist in addiction.

In refutation, Respondent maintained that “the morphine said not detected, but the oxymorphone was positive, so that was explainable.” *Id.* at 335. And he again maintained that “the lab always said that if “the Xanax was positive,” then nordiazepam, oxazepam and Xanax “could all three be positive.” *Id.* Continuing, Respondent testified that “temazepam, in our practice, usually didn’t show up,” so he checked B.B.’s PMP report to see if he had been prescribed Restoril (the name of the legend drug) but “couldn’t find it on the PMP.” *Id.* Respondent then maintained that “Dr. Schoelen didn’t mind his pain patient being on Restoril,” but “I did, and so I wanted to make sure, has he been prescribed Restoril.” *Id.* at 335-36. Respondent then testified that he was “sure” that he told B.B. that if he had “an old Restoril or some other doctor, I do consider that breaking our rules, and so you can’t take it.” *Id.* at 336.

The CALJ again rejected the Government’s contention that Respondent violated 21 CFR 1306.04(a) when he issued the prescriptions, reasoning that “the record evidence does not

support a finding that the August 25 or January 19 UDS results are aberrant.” R.D. at 54. While the CALJ again explained that “it is beyond argument that the June 1 UDS does present an anomaly, reliance on that event [was] not adequately notice by the Government in support” of its contentions regarding these prescriptions. *Id.*

In addition, the CALJ found that Respondent “provided a thoughtful and reasoned explanation (based on his professional experience and knowledge of operating Tri-City) of why B.B. may have tested positive for temazepam despite not having been prescribed it.” *Id.* at 54-55. Taking the January 19 UDS in isolation, the CALJ explained that the Government did not “establish that the Respondent’s counseling B.B. to ‘only take what is prescribed’ fell below the standard of care in Oklahoma.” *Id.* at 55. The CALJ then rejected Dr. Owen’s testimony that Respondent should have referred B.B. to an addictionologist, explaining that “the existence of the UDS reports that are unavailable to the Government and/or unsupported by the evidence were integral to that recommendation, and their absence from a useful role in the record likewise undermines his testimony in this regards [sic].” *Id.*

However, as explained above, even though the June 1 UDS was not specifically referenced in the Show Cause Order with respect to the February 13 prescriptions, the issues of the aberrant nature of the June 1 test (as well as the August 25 test) were litigated by consent. As for the CALJ’s assertion that the record does not support a finding that the August 25 and January 19 UDS results were aberrant, Respondent’s testimony and the notation he placed on the report of the January 19 test establish that both tests were aberrant in that B.B. was taking a medication which Respondent had not prescribed to him and which was not listed on the PMP reports, including one that went back as far as August 27, 2010. Moreover, none of Dr. Schoelen’s progress notes ever mentioned that B.B. was taking Restoril or temazepam, whether

prescribed by Dr. Schoelen or another authorized prescriber. And while the CALJ noted that Respondent provided a thoughtful and reasoned explanation as to “why B.B. *may have tested positive for temazepam*,” the fact of the matter is that in his testimony, Respondent never maintained that he even asked B.B. if he had an old prescription for the drug and who prescribed it to him. Thus, B.B. may have tested positive for the drug because he was obtaining it without a prescription.

As for the CALJ’s assertion that the Government provided no evidence that Respondent’s action in counseling B.B. to take only what he was prescribed fell below the standard of care, the CALJ’s reasoning rests on the erroneous premise that this was B.B.’s first aberrant drug test. However, for reasons explained previously, it was his third aberrant test in less than eight months, and each of his last three tests produced an aberrational result.⁴⁷

In rejecting Dr. Owen’s testimony that Respondent needed to obtain a consultation, the CALJ further asserted that Oklahoma’s referral standard (which uses the language “may require”) is “permissive” and not “directive.” R.D. at 55. The provision is, however, more appropriately read as conferring a degree of discretion which must be exercised within the bounds of “sound clinical judgment,” *Policy Statement*, at 2; and which is necessarily dependent on the facts and circumstances presented by the patient.

Thus, in contrast to the CALJ, I give weight to Dr. Owen’s testimony that based on B.B.’s multiple aberrational tests, Respondent needed to obtain a consultation with a specialist in addiction. Moreover, as Respondent did not require an office visit, I also give weight to Dr.

⁴⁷ However, I do not rely on the January 19 UDS result that morphine was not detected. In contrast to the results which showed the presence of drugs which B.B. had not been prescribed, B.B. was five days past 30 days (the number of days the morphine prescription would have lasted if taken as directed), and the Government put forward no evidence that morphine would still be detectable five days later. While B.B.’s having been five days late raises other issues (such as whether he should have been going through withdrawal by January 19), the Government elicited no such testimony from Dr. Owen.

Owen's testimony that Respondent had still not established medical necessity to justify the continued prescribing of controlled substances. Accordingly, I conclude that the Opana and Morphine prescriptions lacked a legitimate medical purpose and that Respondent acted outside of the usual course of professional practice in issuing them. 21 CFR 1306.04(a).

The March 13, 2012 Prescriptions

On March 13, 2012, Respondent issued B.B. new prescriptions for both 120 Opana 10 and 90 Morphine Sulfate ER 15. *See* GX 5, at 10, 24. Respondent issued the prescriptions without requiring an office visit by B.B. Tr. 156; *see generally* GX 3, at 42-62 (visit notes for B.B.). Nor is there any notation on any of the visit notes regarding Respondent's issuance of these prescriptions.⁴⁸

Dr. Owen testified that Respondent should have required an office visit before issuing these prescriptions, reiterating that Respondent still had not established "medical necessity for" prescribing controlled substances to B.B. Tr. 155. Asked to again identify the deficiencies which led him to conclude that Respondent had not established medical necessity, Dr. Owen explained:

Reviewing all the pertinent previous medical records, including what previous treatments have been performed, an adequate history and physical exam, consultations as medically appropriate, establishing a clinically meaningful and objective therapeutic benefit, and addressing any aberrant drug-taking behaviors.

Id. at 157. Dr. Owen again noted that there were three previous incidents of aberrant drug-taking behaviors, and that "[t]he only treatment plan has been continuing the controlled substances without medical necessity." *Id.* at 158. And once again, Dr. Owen testified that the prescriptions

⁴⁸ As found above, on the January 27, 2012 visit note, Respondent had written that on "2/13/12" he prescribed "Zpack, Prednisone 10 mg # 28, Phenergan." GX 3, at 44. The same visit note contains a further entry for "2-22-12" documenting the issuance of a prescription for 60 tablets of Soma (carisoprodol) 350 mg. *Id.*

lacked a legitimate medical purpose and “were not” issued in the usual course of professional practice. *Id.*

In his direct testimony, Respondent did not address his reasons for issuing the March 13 Opana and morphine prescriptions. *See* Tr. at 338-39. Instead, the questioning centered on the issue of why he wrote a prescription on March 14 for Nexium, “a stomach medicine” and a non-controlled drug (“I have no idea”) after which the questioning moved on to the next set of prescriptions. *Id.*

Here again, the CALJ concluded that the Government’s evidence was not sufficient to sustain the allegations that Respondent violated 21 CFR 1306.04(a) in issuing the prescriptions. According to the CALJ, “there [was] no persuasive evidence to support the conclusion that the absence of an office visit by B.B., standing alone, render[ed] this prescribing event below the prevailing medical standard in Oklahoma.” R.D. at 56. Again noting that under 21 CFR 1306.12(b), which allows for the issuance of multiple schedule II prescriptions to provide up to a 90-day supply provided certain conditions are met, the CALJ concluded that “without persuasive expert or state regulatory guidance, evidence [of] the failure to conduct an in-person office visit does not establish that this prescribing event fell below the standard of care required in Oklahoma.” *Id.* And in rejecting the allegations, the CALJ further cited the purported permissive nature of the State’s documentation standard and asserted that “none of the UDS results raised by Dr. Owen in his testimony were adequately noticed by the Government regarding this prescribing event.” *Id.*

As for the CALJ’s assertion that the UDS results were not adequately noticed, in the Show Cause Order, the Government alleged with respect to these prescriptions that Respondent “once again issued [B.B.] controlled substance prescriptions . . . without taking appropriate steps

to monitor his controlled substances use despite the persistent red flags of abuse and diversion he previously presented.” ALJ Ex. 1, at 5 (¶ 3h). Even if this was not enough to provide Respondent with notice that the three UDSs would be at issue with respect to these prescriptions, Respondent did not object when the Government asked Dr. Owen: “[a]re there any aberrant drug-taking behaviors here?” and he answered: “[t]here has [sic] been three previous.” Tr. 158. I thus conclude that Respondent consented to the litigation of the issue.

As for the CALJ’s assertion that there is no persuasive evidence that standing alone, the absence of an office visit rendered these prescriptions below the prevailing medical standard, the Respondent’s prescribing without requiring an office visit does not stand alone. Rather, Dr. Owen credibly identified multiple deficiencies in Respondent’s evaluation of B.B.’s pain complaint, including his failure to perform an adequate history and physical, his failure to properly evaluate how B.B.’s pain was effecting his ability to function, his failure to determine if the controlled substances were providing a therapeutic benefit and to try conservative treatments, and his failure to address the multiple instances of aberrant behavior. Of further note, Respondent offered no evidence refuting Dr. Owen’s testimony regarding these prescriptions. I thus conclude that these prescriptions lacked a legitimate medical purpose and that Respondent acted outside of the usual course of professional practice in issuing them. 21 CFR 1306.04(a).

The April 12 Prescriptions

On April 12, 2012, B.B. saw Respondent for an office visit. GX 3, at 42. According to the visit note, B.B. “report[ed] his pain has been worse,” that “[h]e has run out of his medicines; he had them stolen,” and that “[h]e has done fairly well.” *Id.* Moreover, on the Treatment Objective Evaluation section of the Treatment Plan, Respondent wrote “fair → yes” and made an

arrow pointing to “yes” in the block for “Has patient achieved treatment objective?” and “6” in the block for “Patient Completed . . . update [sic] pain scale.” *Id.* at 28.

In the visit note, Respondent wrote that B.B. “still has severe anxiety and depression” and has been “exposed to someone with HPV”; Respondent then wrote: “[h]e is also wanting to switch his medicines because he is having trouble finding the OPANA.” *Id.* Respondent also noted: “[p]ast medical history extensively reviewed and placed in chart.” *Id.*

In his exam findings, Respondent noted “[l]ow back paraspinal and spinal tenderness,” “[n]egative straight leg raise,” and “[n]euro intact.” *Id.* Respondent listed his diagnoses as “[l]umber disc disease,” “[a]nxiety and depression” and “[e]xposure to infectious disease” although he “doubt[ed] that it was HPV.” *Id.* Respondent then changed B.B.’s medications to Opana ER (extended release) 20 mg, b.i.d. (twice per day) and Percocet 10 mg (q. 12h) p.r.n. (as needed) for acute pain. *Id.*; *see also* Tr. 340. He also prescribed Soma (carisoprodol) one tablet b.i.d. GX 3, at 42.

Respondent further documented that he discussed the “[a]ddictive, dependence, and tolerance nature of the medicines, as well as alternatives.” *Id.* He noted that he “suggested” “[n]on-medicinal pain and anxiety-relieving modalities.” *Id.*

During this visit, Respondent also required B.B. to provide a UDS. The preliminary screening found that B.B. was negative for opiates and morphine. And according to the confirmatory testing done by the lab, which was reported back to Respondent on April 17, 2012, B.B. tested positive for oxymorphone, which was expected based on Respondent’s having prescribed Opana to him. *Id.* He also tested positive for meprobamate, which was expected based on Respondent’s having prescribed carisoprodol to B.B. *Id.* However, the lab further found that morphine was “not detected,” a result which was “not expected” because Respondent

had prescribed morphine sulfate ER to B.B. on March 13, 2012. *Id.* Dr. Owen also noted that while “the confirmed . . . drug test [was] positive for some of these drugs,” Respondent had reported that he had run out of his medicines and that there was a “lack of documentation of what he ran out of and what he should still be on.” Tr. 167.

Dr. Owen found it problematic that B.B. had told Respondent that his pain was worse, that he had run out of his medicines and had them stolen. *Id.* at 159. As he explained:

Well, one, his pain is worse, so why is it worse? Two is he’s run out of his medications, and then he had them stolen. What is it? Did you run out of them because you self-escalated, or were they stolen and you ran out of them? It needs clarification. But either event, self-escalation or having them stolen, is a red flag.

Id.

Regarding B.B.’s report that his medications were stolen, Dr. Owen testified that because there had “been the aberrant urine drug tests before . . . this, there is [sic] enough aberrant behaviors that” Respondent needed “to get the person to an addictionologist or a psychologist, or just stop prescribing these controlled substances since there’s no evidence they’re helping this gentleman.” *Id.* at 212-13.

Dr. Owen also found problematic the notations in the visit note that B.B. reported that “his pain has been worse” and that “[h]e has done fairly well.” *Id.* at 160. As Dr. Owen testified, the statement that “[h]e has done fairly well . . . kind of conflicts with his pain is worse and the aberrant drug-taking behavior, so that’s an unreliable statement.” *Id.* Dr. Owen also explained that B.B.’s having “severe anxiety and depression . . . are relative contraindications to prescribing controlled substances . . . [b]ecause it magnifies [the] perception of pain and disability.” *Id.* Dr. Owen then testified that because of these conditions, Respondent should have requested a “consultation by a psychologist” but did not. *Id.* at 160-61.

Dr. Owen further testified that Respondent “did not” address B.B.’s “ongoing stress and anxiety issues” and that “[h]e did not” conduct a thorough patient history. *Id.* at 166. He then testified that Respondent had changed B.B.’s treatment plan by adding Percocet, but that Respondent “change[d] the medications without ever . . . documenting [a] medical rationale to add any new medication.” *Id.* Asked by the CALJ “why would someone add Percocet,” Dr. Owen testified that it is a short-acting opioid that could be added “for break-through pain, if that’s not being controlled well.” *Id.* at 167.

Dr. Owen reiterated his earlier testimony that the patient record was “not adequate” to establish “medical necessity” for prescribing the controlled substances on this date and that between September 22, 2011 (when he assumed the care of B.B.) and April 12, 2012, Respondent had never established medical necessity for prescribing controlled substances to B.B. *Id.* at 173-74. He then opined that the prescriptions Respondent issued at this visit were issued outside of the usual course of professional practice and lacked a legitimate medical purpose. *Id.* at 174.

The CALJ sustained the Government’s allegations only with respect to its contention that Respondent ignored the PMP data showing that B.B. was obtaining early refills of alprazolam and failed to take any action in response to this information, such as contacting the other prescribers or cautioning B.B. in response to this information. *R.D.* at 61-62. For reasons explained previously, the evidence does not support the contention that B.B. exhibited a pattern of obtaining early refills as of this visit. I also agree with the CALJ that the evidence does not support a finding that Respondent provided B.B. with an early refill of his pain medications.

However, for many of the same reasons previously discussed, the CALJ rejected the other evidence offered by the Government to prove that the prescriptions violated 21 CFR

1306.04(a). For example, the CALJ again reasoned that “the UDS results prior to the April 12 amino assay UDS” were not “adequately noticed by the Government . . . regarding this prescribing event [and] are unavailable to support its expert’s opinion here.” R.D. at 60. And the CALJ further asserted that the Government could not rely on litigation by consent because it did “not timely and affirmatively raise[]” this theory. *Id.* However, as discussed previously, paragraph 3 of the Show Cause Order provided adequate notice that various aberrant drug tests would be at issue throughout the proceeding.⁴⁹ And even if it did not, the record fully supports the conclusion that the issue was litigated by consent as, given the absence of an objection, the Government had no obligation to affirmatively raise the argument (which it did in its Exceptions) until the CALJ issued his Recommended Decision.

The CALJ also failed to give weight to Dr. Owen’s testimony that Respondent should have either referred B.B. to a specialist in addiction or spoken with his mental health professional, asserting that the Government did “not establish[] that good medical practice in Oklahoma require[d] that.” R.D. at 60. However, Dr. Owen is board-certified in pain management, a member of multiple national professional societies which focus on pain medicine and is a peer reviewer on pain medicine for the Journal of Pain Management. As previously explained, while the Oklahoma referral provision does not categorically require that a physician refer a patient to a specialist in addiction or consult with other providers, it clearly contemplates

⁴⁹ As the Show Cause Order alleged:

From on or about August 25, 2011 through on or about May 9, 2012, you issued controlled substance[] prescriptions to B.B. in violation of Federal and Oklahoma state law. You were aware on each of the occasions that you issued controlled substance[] prescriptions to B.B. that he presented a high risk of abuse and/or diversion of controlled substances, as evidenced by the red flags documented in his patient file, such as aberrant urine drug tests, a request for early refills, and a claim of stolen drugs. You failed to address and, in fact, ignored these red flags, continuing to issue B.B. controlled substance prescriptions in the face of mounting evidence that he was misusing, abusing, and/or diverting the controlled substances you were prescribing.

ALJ Ex. 1, at 1 ¶ 3.

that a physician will use sound clinical judgment in determining whether a referral or consultation is necessary. And as to whether Respondent exercised sound clinical judgment when he neither referred B.B. to an addictionologist nor consulted with his mental health providers, Respondent produced no evidence showing that the standard of care in Oklahoma is materially different from the standard in Texas or the standard that is generally recognized by pain management practitioners. *See United States v. Joseph*, 709 F.3d at 1096.

In rejecting the Government's evidence, the CALJ also explained that the Government did not establish that "good medical practice in Oklahoma require[d]" that Respondent "document[] in any specific level of detail the Respondent's discussion with B.B. about . . . [his] success on the treatment plan." R.D. at 60. Yet the Board's Regulation directs that "[t]he physician should periodically review the course of pain treatment" and "[c]ontinuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Objective evidence of improved or diminished function should be monitored" Okla. Admin. Code § 435:10-7-11(4). Moreover, another provision of the regulation requires physicians to "keep accurate and complete records to include . . . follow-up evaluations . . . [and] periodic reviews." *Id.* § 435:10-7-11(6). And the Board's Policy Statement explains that "[a]ll such prescribing must be based on clear documentation of unrelieved pain" and that "the validity of the physician's treatment of the patient" will be judged "based on available documentation." Policy Statement, at 2.

Moreover, even if the Board's rule does not mandate "any specific level of detail," Dr. Owen offered credible testimony as to why the standard of care clearly requires more

documentation than that made by Respondent. As he explained, “the purpose of documentation is for continuity of care. Not only continuity of care for this same provider from visit to visit but continuity of care should somebody else assume the care later on down the road or should you need to get a consultation, that the consultant can read your notes and understand what was happening with this patient at this point in time.” Tr. 210.

Notably, while B.B.’s treatment objective was to return to work without pain, B.B. had not returned to work as of the April 12 visit (and never did during the course of Respondent’s prescribing) and yet in the box for documenting whether he was meeting his treatment objective, Respondent wrote the words “fair” and “yes.” Yet at the hearing, Respondent did not recall why he wrote “yes,” just as he was “unsure” as to why he had written “fair” in the box at previous visits. As Respondent could not even explain why he made these entries, it is clear that no other physician who subsequently took over B.B.’s care could “understand what was happening with” B.B. at various points. So too, as Respondent could not explain the inconsistency between his having noted in B.B.’s progress note that “his pain was worse” while B.B. reported a decrease in his numeric pain rating and that “he has done fairly well,” I give weight to Dr. Owen’s testimony that Respondent’s notes fell below the standard of care.

Finally, the CALJ declined to give weight to Dr. Owen’s testimony regarding Respondent’s failure to address the aberrant immunoassay drug test result once again asserting that the Board’s regulations “contain no specific directive to mandate such a notation.” R.D. at 61. However, as the CALJ noted, “Respondent did not address this issue in his testimony” and thus, there is no dispute that he took no action other than to send the specimen in for confirmatory testing. While it is true that Dr. Owen testified that the immunoassay test has reliability problems and thus, by sending the specimen to the lab for further testing “it could not

be said that [Respondent] took no action,” what is notable is that Respondent offered no testimony that he ever asked B.B. which drugs had been purportedly stolen and when they had been stolen. Obviously, without determining and documenting what drugs had been stolen, Respondent could not evaluate whether the lab’s finding (using GC-MS testing) that B.B. had tested negative for morphine was aberrational.⁵⁰

Moreover, even crediting Respondent’s testimony regarding the notation that B.B. wanted to switch medications because he was having troubling finding immediate release Opana, his testimony regarding the limitations imposed by the Medicaid formulary, and his explanation for why he provided B.B. with Percocet, I still conclude that the Government has proved that Respondent violated 21 CFR 1306.04(a) when he issued the Opana 20 ER and Percocet 10 prescriptions at this visit. As Dr. Owen testified, Respondent still had not done a thorough patient history and evaluation of B.B.’s pain complaint; failed to properly address multiple instances of aberrant behavior including the three previous UDSs and the other red flags he presented (*i.e.*, the claims of stolen medications and having run out of them); never consulted with B.B.’s mental health providers notwithstanding Respondent’s finding that B.B. had severe anxiety and depression and that these are relative contraindications to prescribing controlled substances; never determined which drugs were stolen from B.B. or which drugs he ran out of thus rendering the UDS he obtained at this visit useless; never resolved inconsistencies in B.B.’s report of pain; and never established that the controlled substances provided a therapeutic benefit and that there was a medical necessity for the prescriptions. Also, while Dr. Owen did not specifically cite Respondent’s failure to try conservative treatments such as physical therapy

⁵⁰ While Respondent offered testimony to the effect that pain patients will maintain “a stash” of controlled substances in the event their medications are stolen, and asserted that B.B. did this as well, he offered no explanation as to how B.B. could have accumulated a stash of extended release medications (such as Morphine Sulfate ER, the drug which was not detected) while still managing pain.

when he testified regarding these two prescriptions, the evidence shows that Respondent never referred B.B. for physical therapy.

Of further note, Respondent could not explain why he made the entries of “fair” and “yes” for whether B.B. was meeting his treatment objective, when he acknowledged that B.B.’s treatment objective was to return to work but never did so. And while he essentially agreed with Dr. Owen’s testimony that a patient with depression and anxiety has a higher perception of pain and is at greater risk of self-escalating his use of controlled substances, he nonetheless maintained that while “[i]n every other field but mental health we do” consult with the patient’s other practitioners, consulting with mental health practitioners who are “also prescribing controlled substances . . . [t]hat doesn’t happen very often.” Tr. 410. I thus conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when, on this date, he issued the Opana and Percocet prescriptions to B.B. 21 CFR 1306.04(a).

The April 25 Prescriptions

On April 25, 2012, Respondent provided B.B. with a prescription for 30 Roxicodone (oxycodone) 15 mg. GX 5, at 4. B.B.’s file contains no documentation that there was an office visit, and notwithstanding that this was a change in medication from what Respondent had prescribed at the previous visit, there is no notation in the progress notes as to why he changed the prescription. *See generally* GX 3; *see also* Tr. 174-75. Moreover, while Respondent testified that he would “routinely” make an entry in the Treatment Objective Evaluation section of the Pain Management Treatment Plan “if we were making a change in a medication,” Tr. 357, no such entry was made on this date. *See* GX 3, at 28. Nor is there any documentation in the

patient file that Respondent addressed with B.B. the aberrant drug test result (the non-detection of morphine) which had been reported to him on April 17. *See generally* GX 3.

According to Dr. Owen, when adding a new drug to a patient's regimen of pain medications, a physician "would have to establish medical necessity with some type of note, using sound medical rationale." Tr. 175. Dr. Owen further testified that making such a notation is "a standard of care, and it's part of the documentation guidelines that are issued across every state for the most part." *Id.* Asked if he could think of a reason why a physician "would add a drug for the first time without seeing a patient," Dr. Owen answered: "No. Or at least documenting the medical rationale and establishing medical necessity." *Id.* at 176. Dr. Owen then testified that Respondent did not take appropriate steps to establish medical necessity for the prescription, reiterating his earlier testimony that Respondent had not demonstrated that conservative care had been tried and been unsuccessful, as well as that there was a "clinically meaningful and objective therapeutic benefit from the previous use of controlled substances." *Id.* He again opined that the prescription was not issued in the usual course of professional practice and lacked a legitimate medical purpose. *Id.*

Regarding the Roxicodone prescription, Respondent asserted that he "was just doing a two-week trial, trying to figure out his dose, and at the time, most likely the patient didn't have any punches on his card left, and Roxicodone is much cheaper than Percocet, and it's the same medication." *Id.* at 355. However, Respondent did not document any of this in B.B.'s record. Nor did he explain why he failed to follow his routine of making an entry in the Treatment Objective Evaluation section of the Pain Management Treatment Plan given that he had changed B.B.'s medication.

As for the April 12 UDS lab report, which he had obtained prior to issuing the prescription and which found that morphine was not detected and that this result was not expected based on the prescribed medications, Respondent testified that in his opinion the result was not aberrant. Respondent did not explain whether this was based on his previous claim that the oxymorphone is a metabolite of morphine or because B.B. had reported that his medications were stolen. Tr. 364-66.

As Respondent offered no testimony that he asked B.B. which of his drugs were stolen and was told that it was the morphine, B.B.'s claim of stolen drugs does not render the test non-aberrant. Moreover, the lab reports noted various instances in which the presence of various metabolites was consistent with prescribed medications and that the particular substances were metabolites of prescribed drugs but included no such notation with respect to oxymorphone and morphine. Finally, Respondent's testimony is contradicted by science and he offered no evidence which would support a finding that he had a good faith but mistaken belief that oxymorphone is a metabolite of morphine. Based on these reasons, I find that the April 12 UDS was aberrant and that Respondent knew it to be.

While the CALJ concluded that the Government could not rely on the four UDS reports, he nonetheless found that the evidence supported the Government's contention that Respondent acted outside of the usual course of professional practice in issuing the prescriptions. R.D. at 64. While the CALJ accepted Respondent's assertion that Percocet and Roxicodone are similar drugs in that they both contain oxycodone (although he noted that Roxicodone does not contain acetaminophen and contains only oxycodone), *id.* at n.119, he explained that Respondent did not merely provide a refill but was changing B.B.'s medications. *Id.* at 63-64. While the CALJ then noted Dr. Owen's opinion that the standard of care required the "establish[ment] of medical

necessity with some type of note, using sound medical rationale,” the CALJ then explained that “it is not the documentation of the medical determination that carries the day here. Rather, it is whether the evidence or record supports the Respondent’s proposition that he made such a determination; and it does not.” *Id.* at 64. And while again asserting erroneously that the Oklahoma regulation stating that “[t]he medical record . . . *should* document the presence of one or more recognized medical indications for the use of a controlled substance” is permissive, *id.* (emphasis added by CALJ), he concluded that Respondent acted outside of the usual course of professional practice because he neither documented an indication for a medication change nor could “remember it in a way that is persuasive.”⁵¹ *Id.*

While I agree with the CALJ that Respondent’s testimony was unpersuasive, I also give weight to Dr. Owen’s testimony that Respondent had not established medical necessity for prescribing controlled substances by demonstrating that conservative treatments had been tried and been unsuccessful and by establishing an “objective therapeutic benefit from the previous use of controlled substances.” Tr. 176. Moreover, Dr. Owen’s testimony as to the other reasons why the Respondent did not establish a medical necessity for the previous prescriptions likewise applies to the Roxicodone prescription issued on this date. Finally, once again B.B. provided an aberrant drug test which Respondent ignored (and could not properly evaluate). I therefore conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed Roxicodone to B.B. on this date.

The May 9, 2012 Prescriptions

⁵¹ Unexplained by the CALJ is why he did not apply the same reasoning to Respondent’s testimony that he was “unsure” as to why, on various occasions, he wrote “fair” in the block for noting whether B.B. had achieved his treatment objective as well as to why he wrote “yes” when B.B. never returned to work during the course of Respondent’s prescribing to him.

On May 9, 2012, Respondent wrote B.B. a prescription for 60 Opana ER 20 mg. GX 3, at 93; GX 5, at 27. Respondent did not require an office visit, and he made no notations in the progress notes regarding the prescription. *See generally* GX 3; *see also* Tr. 177-78. Regarding the prescription, Dr. Owen again testified that Respondent “needed to establish medical necessity for continuation of controlled substances” and “did not.” *Id.* at 178.

Asked to provide his opinion as to Respondent’s prescribing of controlled substances from September 2011 through May 9, 2012, Dr. Owen opined that Respondent did not adequately review B.B.’s medical history. *Id.* He further opined that the treatment plan “would have the logic behind the treatment” and would have “establish[ed] that conservative care has not been helpful and that [an] objective and clinically meaningful therapeutic benefit from the use of controlled substances has been established, if [they] ha[d] previously been used.” *Id.* Dr. Owen then testified that none of the controlled substance prescriptions Respondent issued to B.B. were issued in the usual course of professional practice and for a legitimate medical purpose. *Id.* at 178-79.

Asked why he refilled the prescriptions,⁵² Respondent testified that “I got a phone call that he was wanting his medicines refilled and that the [R]oxicodone had worked for him and *et cetera*, so we were converting him back into the one-month prescriptions in the Schedule IIs and

⁵² In her questioning of Respondent, Respondent’s counsel referred to a Roxicodone prescription as having been issued on May 9, 2012, and in his testimony regarding the prescriptions he wrote on that date, Respondent referred to both a Roxicodone prescription and an Opana ER 20 mg prescription. Tr. 356. While GX 5 contains a legible copy of the May 9, 2012 Opana ER prescription, *see* GX 5, at 27, it does not contain a copy of a Roxicodone prescription, and as for GX 3, the copy of the purported Roxicodone prescription is illegible. GX 3, at 93.

Moreover, at no point did the Government put in issue whether Respondent violated 21 CFR 1306.04(a) when he issued the Roxicodone prescription. The Government did not mention this prescription in the specific allegation it made in the Show Cause Order regarding the events of May 9, 2012, *see* ALJ Ex. 1, at 6 ¶ 3(j); it did not mention the prescription in its Pre-hearing Statement, *see* ALJ Ex. 5, at 21; it did not question Dr. Owen about this prescription, *see* Tr. 177-78; and even after Respondent testified about it, the Government did not argue in its post-hearing brief that Respondent issued this Roxicodone prescription in violation of 21 CFR 1306.04(a). Thus, I do not consider the prescription.

going back to this three-month office visit.” Tr. 356. Respondent offered no testimony addressing Dr. Owen’s criticism that he still had not established that there was a medical necessity for prescribing controlled substances, which included the Opana. *See generally id.* at 356-57.

The CALJ found that because he “had PMP data indicating that B.B. had previously engaged in a pattern of procuring early refills from multiple prescribers,” Respondent’s issuance of the prescription was “a breach of [his] obligation as a registrant to guard against the diversion of controlled substances.” R.D. at 67-68. The CALJ thus concluded that Respondent acted outside of the course of professional practice in issuing the Opana prescription.⁵³ *Id.* at 68.

⁵³ In his decision, the CALJ explained that “[a]lthough the Government’s pleadings do not specifically refer to the early refills in support of this prescribing event, the [Show Cause Order] alleges that the prescribing was effected ‘despite previous indications that B.B. was at risk for abuse or diversion of controlled substance[s].’” R.D. 67-68 n.124 (quoting ALJ Ex. 1, at 6). The CALJ also noted that “[t]he Government Prehearing Statement alleges that the prescription for Opana was issued ‘despite previous indications that B.B. was at risk for abuse or diversion of controlled substances[s]’” *Id.* (quoting ALJ Ex. 5, at 21). The CALJ then explained that “[t]hese broadly-worded phrases supply sufficient notice . . . to constitute sufficient notice to use the PMP early refill evidence in support of this prescribing event.” *Id.*

I am, however, left to wonder why the same reasoning did not apply to the multiple instances in which the CALJ asserted that the Government did not provide sufficient notice that it intended to rely on the various UDSs. Notably, paragraph 3 of the Show Cause Order alleged that:

[f]rom on or about August 25, 2011 through on or about May 9, 2012, you issued controlled substance[] prescriptions to B.B. in violation of Federal and Oklahoma state law. You were aware on each of the occasions that you issued controlled substance[] prescriptions to B.B. that he presented a high risk of abuse and/or diversion of controlled substances, as evidenced by the red flags documented in his patient file, such as aberrant urine drug tests. . . . You failed to address and, in fact, ignored these red flags, continuing to issue B.B. controlled substance prescriptions in the face of mounting evidence that he was misusing, abusing, and/or diverting the controlled substances you were prescribing.

ALJ Ex. 1, at 1. *See also, e.g., id.* at 3 (Sept. 22, 2011 Rxs: “you did not address with B.B. the now second aberrant drug screen in an approximately three month period” and “[y]ou took no other steps to monitor B.B.’s controlled substance use, such as requiring him [to] take another drug screen due to the two failed ones”); *id.* at 4 (Nov. 18 and Dec. 15 Rxs: alleging that “you did not take any steps to monitor [B.B.’s] controlled substances use despite his history of misusing, abusing, or diverting controlled substances”); *id.* at 5 (Mar. 13, 2012 Rxs: “you once again issued him controlled substance[] prescriptions . . . without taking appropriate steps to monitor his controlled substance use despite the persistent red flags of abuse and diversion he previously presented”).

While I agree with the CALJ that Respondent violated 21 CFR 1306.04(a) in issuing the prescription, I do so for reasons other than that B.B. had “engaged in a pattern of early refills.” As Respondent did not see B.B. on this date, I give weight to Dr. Owen’s testimony that Respondent did not establish medical necessity for the prescription (or any of the prescriptions for that matter) for the reasons he explained throughout his testimony as well as for the other reasons discussed in this Decision.

* * *

In his Recommended Decision, the CALJ alleges that the Agency “has been engaged in a deliberate winnowing of the scope of Factor 2, to the extent that . . . it now largely mirrors the considerations found in Factor 4.” R.D. 77. He further asserts that the Agency’s rejection of dicta which has appeared in various recommended decisions to the effect that Factor 2 “manifests Congress’s acknowledgement that . . . the quantitative volume in which an applicant has engaged in the dispensing of controlled substances may be [a] significant factor” in the public interest determination, *see JM Pharmacy Group, Inc.*, 80 FR 28667, 28684 (2015), is inconsistent with the plain meaning of Factor 2. R.D. 77-81.

Congress did not, however, define the term “experience” in the CSA, and as the Administrator has explained at length, the word has multiple meanings, none of which “compels the conclusion that Congress acknowledged that the quantitative volume of an applicant’s dispensing may be a significant consideration under this factor, and certainly none [of these definitions] suggests that the Agency is required to count up the number of times an applicant or registrant has dispensed controlled substances,” *JM Pharmacy Group*, 80 FR at 28667 n.1, let alone compare the number of lawful dispensings against those shown to be unlawful, as some registrants have argued. *See, e.g., Syed-Jawed Akhtar-Zaidi*, 80 FR 42961, 42967 (2015)

(arguing that physician was denied a “fair adjudication” where the Government based its case only on undercover visits but had seized 400 patient files from physician’s office and yet “failed to present any evidence . . . that the treatment of those patients failed to meet the standard of care,” as well as any evidence regarding the treatment of “over 400 additional patients” whose charts were not seized), *pet. for rev. denied*, 841 F.3d 707, 713 (6th Cir. 2016).

Notably, the CALJ does not cite to any of the sources typically invoked by the courts in cases which have held that a statute has a plain meaning.⁵⁴ See, e.g., *Williams v. Taylor*, 529 U.S. 420, 431-32 (2000) (giving statutory text its “ordinary, contemporary, common meaning” based on definitions from *Webster’s New International Dictionary* and *Black’s Law Dictionary*); *United States v. Labonte*, 520 U.S. 751, 757-58 (1997) (giving statutory text ordinary meaning by reference to same dictionaries); *Levorsen v. Octapharma Plasma, Inc.*, 828 F.3d 1227, 1231 (10th Cir. 2016) (relying on *Webster’s Third New International Dictionary* for meaning of statutory terms). And while “[t]he plainness or ambiguity of statutory language is [also] determined by reference to the . . . specific context in which that language is used, and the broader context of the statute as a whole,” *Yates v. United States*, 135 S.Ct. 1074, 1082 (2015), nothing in the context of providing factors for determining the public interest supports the notion that the term “experience” requires a consideration of the quantitative volume of an applicant’s dispensing.

⁵⁴ As the Administrator noted in *JM Pharmacy*, the word “experience” has multiple meanings. Among those most relevant in assessing its meaning as used in the context of Factor Two are: 1) the “direct observation of or participation in events as a basis for knowledge,” 2) “the fact or state of having been affected by or gained knowledge through direct observation or participation,” 3) “practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity,” and 4) “the length of such participation.” See *Merriam-Webster’s Collegiate Dictionary* 409 (10th ed. 1998); see also *The Random House Dictionary of the English Language* 681 (2d ed. 1987) (defining experience to include “the process or fact of personally observing encountering, or undergoing something,” “the observing, encountering, or undergoing of things generally as they occur in the course of time,” “knowledge or practical wisdom gained from what one has observed, encountered, or undergone”).

As previously explained, Congress enacted the public interest standard to provide DEA with additional authority to address the diversion of controlled substances because prior to the 1984 amendment of section 823(f), the Agency's authority to deny an application or revoke a registration was limited to cases in which a practitioner: 1) had materially falsified an application, 2) had been convicted of a State or Federal felony offense related to controlled substances, or 3) had his State license or registration suspended, revoked, or denied. *See* S. Rep. No. 98-225, at 266 (1983), *as reprinted in* 1984 U.S.C.C.A.N. 3182, 3448. Finding that the "[i]mproper diversion of controlled substances" was "one of the most serious aspects of the drug abuse problem," and yet "effective Federal action against practitioners ha[d] been severely inhibited by the [then] limited authority to deny or revoke practitioner registrations," *id.*, Congress concluded that "the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest." *Id.*

The Senate Report thus explained that "the bill would amend 21 U.S.C. 824(f) [sic] to expand the authority of the Attorney General to deny a practitioner's registration application." *Id.* The Report further explained that "in those cases in which registration is clearly contrary to the public interest, the amendment would allow a swift and sure response to the danger posed to the public health and safety by the registration of the practitioner in question." *Id.* at 267, *as reprinted in* 1984 U.S.C.C.A.N. at 3449. Accordingly, section 823(f) was amended to provide the Agency with authority to deny an application based upon a finding that the issuance of a registration "would be inconsistent with the public interest," upon consideration of the five public interest factors, including the experience factor. *Id.* *See also* 21 U.S.C. § 824(a)(4). Nowhere in the Report's discussion of the amendments to sections 823 and 824 is there any

support for the notion that Congress deemed the quantitative volume of a practitioner's dispensings to be a significant consideration in making findings under the experience factor.⁵⁵

Indeed, as *Krishna-Iyer* explained, because the CSA limits registration to those practitioners who possess authority under state law 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*, 459 FR at 463. Thus, in past cases, this Agency has given no more than nominal weight to a practitioner's evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion. *See, e.g., Caragine*, 63 FR at 51599 ("[T]he Government does not dispute that during Respondent's 20 years in practice he has seen over 15,000 patients. At issue in this proceeding is Respondent's controlled substance prescribing to 18 patients."); *id.* at 51600 ("[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future."); *see also Medicine Shoppe – Jonesborough*, 73 FR 364, 386 & n.56 (2008) (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render . . . flagrant violations [acts which are] 'consistent with the public interest.'"), *pet. for review denied, Medicine Shoppe-Jonesborough v. DEA*, slip. op. at 11 (6th Cir. Nov. 13, 2008).

⁵⁵ As the CALJ noted, one of the House Reports explained that "[t]he second factor shall not, of course, be construed in anyway to hinder registration of recent graduates of professional schools who may have no professional experience dispensing or conducting research with controlled substances." H. R. Rep. No. 98-835, Pt. 1, at 14. Obviously, if Factor Two's meaning was so plain, the Judiciary Committee had no need to express that it should not be construed to deny registrations to newly-licensed practitioners, most of whom can point to no volume of dispensings other than by observing a physician during clinical rotations. Thus, the Committee's direction refutes the notion that the quantitative volume of an applicant's dispensings may be a significant consideration under the factor.

As in past cases, the parties may continue to introduce evidence as to the extent of both a practitioner's lawful or unlawful dispensing activities. However, under Agency precedent, proof of a single act of intentional or knowing diversion remains sufficient to satisfy the Government's *prima facie* burden and to impose on a respondent the obligation to produce evidence to show that it can be entrusted with a registration. *See Krishna-Iyer*, 74 FR 459, 463 (2009); *see also Alan H. Olefsky*, 57 FR 928, 928-29 (1992) (revoking registration based on physician's presentation of two fraudulent prescriptions to pharmacy and noting that the respondent "refuses to accept responsibility for his actions and does not even acknowledge the criminality of his behavior").

The CALJ further alleges that on remand in *Krishna-Iyer*, the Agency failed to follow the Eleventh Circuit's unpublished decision, in which the Administrator was directed to consider 12 additional patient files as well as the "entire corpus" of the physician's controlled substance dispensing for evidence of the physician's "positive experience" in dispensing controlled substances. R.D. 79. However, the Administrator carefully reviewed those files, and noted that the files "included numerous instances in which [the physician] appear[ed] to have ignored warning signs that the patient was either abusing or diverting controlled substance"; she also made findings with respect to multiple incidents. 74 FR at 460-61 n.3. And as for the "entire corpus" of the physician's prescribing, notwithstanding the physician had not introduced any evidence as to the propriety of her prescribing to the "thousands of other patients" she had treated, the Administrator assumed that every one of those prescriptions was lawfully issued. *Id.* at 461. However, as the Administrator explained, even if those prescriptions were lawfully issued, they did not negate the Government's *prima facie* showing that the physician had knowingly diverted drugs to others. *Id.* at 462-63. And while the Administrator granted the

physician a new registration, she made clear that had the physician not acknowledged her misconduct, she would have again revoked the physician's registration. *Id.* at 463.

Not mentioned by the CALJ is that several years later, the exact same arguments were raised before the Eleventh Circuit by two different physicians and rejected without any discussion. In *Lynch v. DEA*, a physician whose registration was revoked by the Agency for unlawful prescribing,⁵⁶ argued that the Agency's Decision arbitrarily "limited its consideration of [his] experience to only ten prescriptions issued to out of state patients, the two undercover patients, and the use of a rubber stamp on nine prescriptions . . . and did not consider the evidence that he had been dispensing controlled substances for over twenty years," and thus "fail[ed] to consider the overwhelming evidence of positive experience." See Brief of Petitioner 31-32, *Lynch v. DEA*, No. 11-10207-EE (11th Cir. 2011) (citing *Krishna-Iyer, M.D., v. DEA*, 249 Fed. Appx. 159, 161 (11th Cir. 2007) (unpublished)). Notably, the Eleventh Circuit denied the physician's petition for review, holding that the revocation of the physician's registration "was not arbitrary, capricious, an abuse of discretion or contrary to law." *Lynch v. DEA*, Slip. Op. at 4 (11th Cir. May 22, 2012) (per curiam). Indeed, the Court of Appeals did not even deem the respondent's argument to warrant discussion. See *id.* at 2-4.

So too, in *McNichol v. DEA*, another physician whose registration was revoked for issuing unlawful prescriptions to four undercover officers relied on *Krishna-Iyer* to argue that the Agency's final decision was arbitrary and capricious because the investigation "failed to take into account any positive conduct on [his] part" and "intentionally ignored any evidence not specifically related to the undercover patients." Brief of Petitioner 21-23, *McNichol v. DEA*, No. 12-15292 (11th Cir. 2013) (citing *Krishna-Iyer*, 249 Fed. Appx. at 161). Of note, the Agency's Decision specifically rejected the ALJ's assertion that the Government was required to review

⁵⁶ See *Ronald Lynch*, 75 FR 78745 (2010).

the patient charts for patients other than the undercover officers and look for evidence of the physician's "positive prescribing practices" so as to "develop evidence to enlighten the administrative record." *T.J. McNichol*, 77 FR 57133, 57146 (2012). The Administrator further explained that "[h]aving garnered evidence of what it believed to be unlawful prescriptions issued to the four undercover officers, the Government was entitled to go to hearing with that evidence." *Id.*

Again, the Eleventh Circuit denied the physician's petition for review, holding that "the record supports that the administrator considered all aspects of the evidence in light of the applicable statutory factors and . . . [her] decision was not arbitrary and capricious. . . . [w]e also agree with the administrator's conclusion that [the physician's] continued registration would be inconsistent with the public interest." *McNichol v. DEA*, Slip. Op. at 4 (11th Cir. Oct. 17, 2013) (per curiam). Here again, the Court did not deem Respondent's argument to warrant discussion.

The CALJ also dismisses the published decision of the Tenth Circuit in *MacKay v. DEA*, 664 F.3d 808 (10th Cir. 2011), asserting that "the Agency's view of Factor 2 *was not a focus* of the court's decision." R.D. 80 (emphasis added). Therein, after the Agency revoked the physician's registration based on his unlawful prescribing to two patients, the physician argued on review that:

The DEA must consider the totality of the experiences a physician has, including: the interaction reflected in each of the medical charts of patients that were seized by the DEA, the "thousands of other patients . . . [and] positive experience" with dispensing controlled substances and not merely the testimony of people trying to make a case against the physician.

The DEA, in fact, flat out disregarded the substantial experience Dr. McKay has had with dispensing controlled substances. The law requires the DEA to consider evidence that reflects that the physician is not a danger to the public and delineates how the DEA must do so.

Brief of Petitioner, 13-14, *MacKay v. DEA*. Moreover, after discussing the affidavits of several patients who testified that Dr. McKay had provided medically appropriate, and in some instances, beneficial treatment for their pain, Respondent argued that “[t]he DEA decision is based only on the medical charts of a few patients out of thousands Dr. MacKay has successfully treated over the years. In fact . . . the DEA’s expert only reviewed twelve patient files and testified about even fewer.” *Id.* at 20.

Notwithstanding that the Agency’s decision was based entirely on the evidence with respect to two patients (K.R. and M.R.), *see Dewey C. MacKay*, 75 FR 49956, 49972 (2009); the Tenth Circuit rejected Respondent’s contention that the Agency had failed to consider his “positive experience” evidence. As the Court of Appeals explained:

Despite Dr. MacKay’s claim to the contrary, the Deputy Administrator considered the entire record, including the evidence in Dr. MacKay’s favor. She determined, however, that none of Dr. MacKay’s evidence negated the DEA’s *prima facie* showing that Dr. MacKay had intentionally diverted drugs to K.D. and M.R. Indeed, she found that even if Dr. MacKay had provided proper medical care to all of his other patients, that fact would not overcome the government’s evidence with regard to M.R. and K.D.

None of the evidence presented by Dr. MacKay undermines the evidence relating to M.R. and K.D. Although numerous patients and colleagues of Dr. MacKay related their positive experiences with him, none had any personal knowledge regarding his treatment of M.R. and K.D. Notably, Dr. MacKay’s medical expert . . . failed to specifically discuss and justify Dr. MacKay’s treatment of M.R. and K.D. As a result, none of Dr. MacKay’s evidence contradicts the testimony and evidence presented by the DEA relating to the knowing diversion of drugs to these two patients.

664 F.3d at 819.

The Court of Appeals then rejected McKay’s contention that the Deputy Administrator had misweighed the public interest factors. As the Court explained: “[i]n light of Dr. MacKay’s misconduct relating to factors two and four, the government made a *prima facie* showing that [his] continued registration is inconsistent with the public interest.” *Id.* (citing 75 FR at 49977).

And the Court further explained that “[a]lthough Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to K.D. and M.R. is sufficient to support her determination that his continued registration is inconsistent with the public interest.” *Id.*

The CALJ further asserts that “to the extent that the ever-widening range of activity that the Agency considers ‘positive experience’ is banned, Factor 2 analysis, in the majority of Agency cases, will largely consist of a reprise of evidence also considered under Factor 4.” R.D. 81. Continuing, the CALJ contends that “[t]he Government’s ability to introduce alleged acts of malfeasance will warrant double consideration under Factor 2 and again under Factor 4, but respondents will remain unable to demonstrate that a transgression constituted an isolated occurrence when compared with even many years of compliant practice as a registrant.” *Id.*

The CALJ is mistaken. As *JM Pharmacy* made clear, “[a]s in past cases, the parties may continue to introduce evidence as to the extent of both a practitioner’s lawful or unlawful dispensing activities.” 80 FR at 28668 n.2. Indeed, in these proceedings, the Agency will assume, without requiring the production of any evidence by a respondent, that the practitioner has lawfully issued every prescription other than those alleged by the Government to be unlawful. And contrary to the CALJ’s understanding, notwithstanding the Agency’s rejection of the notion that “the plain meaning” of Factor 2 mandates the consideration of “the quantitative volume” of a respondent’s dispensing, a respondent may still argue that his conduct was “an isolated occurrence when compared with even many years of compliant practice” or an “aberration.” R.D. 81-82.

Equally misplaced is the CALJ’s assertion that the Government’s evidence of unlawful prescribing will hence be given double consideration in the public interest determination. *Id.* at

82. While evidence of a respondent’s unlawful prescribing is clearly relevant in assessing both his/her experience in dispensing controlled substances and compliance with applicable laws related to controlled substances and thus typically discussed under both factors – indeed, because of the overlap between the factors, the Agency has long discussed both factors together – this does not mean that the prescriptions have been double weighted. *See, e.g., Albert Lepis*, 51 FR 17555, 17555-56 (1986).

As the Agency’s decision on remand in *Krishna-Iyer* explained, “[w]hether this conduct is evaluated under factor two . . . or factor four, or both [factors], is of no legal consequence. In establishing [the Government’s] *prima facie* case, the fundamental question is whether [a] [r]espondent ‘has committed such acts as would render [his] registration inconsistent with the public interest.’”⁵⁷ 74 FR at 462 (quoting 21 U.S.C. § 824(a)(4)). Moreover, as both the Agency and federal courts have recognized, findings under a single factor can support the denial of an application or the revocation of a registration. *See MacKay*, 664 F.3d at 821 (quoting *Krishna-Iyer*, 74 FR at 462).

While the Agency has explained that proof of a single act of intentional or knowing diversion remains sufficient to satisfy the Government’s *prima facie* burden and to impose on a respondent the obligation to produce evidence to show that he can be entrusted with a registration, this is not the result of double weighting the misconduct. *See Krishna-Iyer*, 74 FR at 463; *see also MacKay*, 664 F.3d at 819. Rather, it is based on the recognition that a violation of the prescription requirement (21 CFR 1306.04(a)) “strikes at the CSA’s core purpose of preventing the abuse and diversion of controlled substances.” *Samuel Mintlow*, 80 FR 3630, 3653 (2015); *accord David A. Ruben*, 78 FR 38363, 38386 (2013). Accordingly, the Agency has

⁵⁷ While *Krishna-Iyer* involved a revocation proceeding, the public interest inquiry is essentially the same where the Agency proposes the denial of an application.

held that where the Government proves that a practitioner has engaged in knowing or intentional diversion, a respondent is not entitled to be registered (or maintain an existing registration) absent a credible acceptance of responsibility.⁵⁸ As the Tenth Circuit has recognized:

. . . the DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether continued registration is in the public interest. Without Dr. MacKay's testimony, the Deputy Administrator had no evidence that Dr. McKay recognized the extent of his misconduct and was prepared to remedy his prescribing practices.

MacKay, 664 F.3d at 820 (citing *Hoxie v. DEA*, 419 F.3d 477, 483 (2005)).

Thus, contrary to the CALJ's understanding, a respondent can still argue (as he/she always could) that his/her misconduct in knowingly or intentionally diverting controlled substances was "an isolated occurrence" or an "aberration" in his/her years of otherwise compliant professional practice. However, one cannot argue that his/her conduct was "an isolated occurrence" or "an aberration" without first acknowledging that he/she has engaged in unlawful conduct.⁵⁹ And in any case, Respondent has made no such argument.

⁵⁸ In *Krishna-Iyer*, the Agency explained that "while some isolated decisions . . . may suggest that a practitioner who committed only a few acts of diversion was entitled to regain his registration even without having to accept responsibility for his misconduct, see *Anant N. Mauskar*, 63 FR 13687, 13689 (1998), the great weight of the Agency's decisions are to the contrary." 74 FR at 464. Noting that "[t]he diversion of controlled substances has become an increasingly grave threat to this nation's public health and safety," the Agency clarified its policy and explained that "[t]o the extent *Mauskar*, or any other decision of this Agency suggests otherwise, it [wa]s overruled." *Id.* at 464 n.9. Continuing, the Agency explained that because of the grave and increasing harm to public health and safety caused by the diversion of prescription controlled substances, even where the Agency's proof establishes that a practitioner has committed only a few acts of knowing or intentional diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct. *Id.* at 464.

⁵⁹ The CALJ also asserts that in *JM Pharmacy*, "the Agency determined in clear terms that it will no longer consider whether established misconduct presented an isolated piece of an applicant's record, irrespective of whether the misconduct is *intentional or otherwise*." R.D. at 82 (emphasis added). To the contrary, in *JM Pharmacy*, the Administrator denied two applications for pharmacy registrations, expressly adopting the CALJ's conclusion that the owner of the two pharmacies had "knowingly and materially falsified the applications he submitted." 80 FR at 28669; see also *id.* at 28683 (CALJ's Recommended Decision: "It is clear that the Respondents, through their common owner . . . *knew or should have known* that the answers provided to Question 2 were false, and that their . . . applications contained material falsifications. The absence of any logical basis for confusion and the past

Summary of Factors Two and Four

While Respondent put on no evidence as to the lawfulness of his controlled substance prescribing to patients other than B.B., I have assumed that every other prescription he has issued in the course of his professional career complied with 21 CFR 1306.04(a).⁶⁰ Nonetheless, as found above, Respondent issued multiple prescriptions for various schedule II narcotics outside the course of professional practice and which lacked a legitimate medical purpose. 21 CFR 1306.04(a). Moreover, the evidence in no sense shows that Respondent was merely neglectful, but rather supports a finding that Respondent acted with knowledge that B.B. was abusing and/or diverting the controlled substances he prescribed. And while the evidence of record does not support a finding that Respondent unlawfully prescribed to any other patient, it is significant that his misconduct went on for eight months and involved 19 prescriptions for schedule II narcotics alone. Thus, I conclude that Respondent has engaged in egregious misconduct which supports the denial of his registration. See *MacKay*, 75 FR at 49997; *Krishna-Iyer*, 74 FR at 463; *Olefsky*, 57 FR at 928-29.

I therefore hold that the Government has established its *prima facie* case that Respondent's registration "would be inconsistent with the public interest." 21 U.S.C. § 823(f).

SANCTION

experience of [their owner] as a registrant holder and pharmacist preponderantly support a finding that the misrepresentations were intentional, not negligent. . . . [E]ven standing alone, the denial of the Respondent's . . . applications is adequately supported on this record based on the material falsifications set forth in the filed applications.") (emphasis added); *id.* at 28689 (CALJ noting that owner's "insistence that his false response to an application query . . . was simply not credible and defeats the Respondents' efforts to meet the Government's case. The false misrepresentation[s] . . . are sufficiently egregious on their face to warrant sanction"). Thus, *JM Pharmacy* does not support the CALJ's assertion that the Agency does not consider a respondent's level of culpability in committing misconduct.

⁶⁰ This assumption may actually be more favorable to Respondent than what is warranted with respect to his experience in dispensing controlled substances. In 2008, Respondent was sanctioned by the Board for "prescribing controlled dangerous substances" over the course of a three-year period to a patient with whom he had sexual relations. RX 3, at 2.

Where, as here,⁶¹ the Government has met its *prima facie* burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest, a respondent must come forward with ““sufficient mitigating evidence”” to show why he can be entrusted with a new 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 MacKay v. DEA*, 664 F.3d at 820; *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).

Finally, the Agency has also held that “[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.” *Joseph Gaudio*, 74 FR 10083, 10094 (2009) (quoting *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 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

⁶¹ So too, 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 (2011) (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). As explained above, Respondent’s misconduct in knowingly issuing multiple prescriptions in violation of 21 CFR 1306.04(a) is egregious and supports the denial of his registration and not the issuance of a registration subject to conditions. Indeed, this is not a close call.

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”).

Even with respect to the violations which he found proven, the CALJ found that “one clear and consistent aspect of the record is the Respondent’s almost dogged determination to accept no responsibility for his actions.” R.D. 92. This holds equally true with respect to each of the controlled substance prescriptions he issued in violation of 21 CFR 1306.04(a), as other than his meager acknowledgement that his documentation on certain progress notes could have been better, Respondent has not accepted responsibility for his misconduct with respect to any of the controlled substance prescriptions he unlawfully issued to B.B. beginning on September 22, 2011 and ending on May 9, 2012. And as explained above, the evidence supports the conclusion that Respondent was not merely neglectful, but that he engaged in knowing misconduct when he issued the prescriptions. As the Tenth Circuit has recognized, Respondent’s failure to acknowledge his misconduct establishes that he is not prepared to remedy his unlawful prescribing practices. *MacKay*, 664 F.3d at 820. This alone supports the conclusion that he cannot be entrusted with a new registration.⁶²

So too, while the Agency’s interest in specific deterrence is not triggered (because I deny his application), as found above, Respondent’s misconduct is egregious and the Agency has a manifest interest in deterring similar misconduct by other practitioners. This interest would be compelling even if it was not the case that the nation was confronting an epidemic of opioid

⁶² Even if Respondent had credibly accepted responsibility for his misconduct, he has offered no evidence of any remedial training he has undertaken in controlled substance prescribing. While the CSA does not impose a time bar on a practitioner’s ability to reapply for a registration, the rules of the Agency are clear. Thus, to obtain favorable consideration of any new application, Respondent must both credibly acknowledge his misconduct in prescribing to B.B. and provide evidence of remedial training he has undertaken in the proper prescribing of controlled substances.

abuse. I therefore conclude that granting Respondent's application "would be inconsistent with the public interest." 21 U.S.C. § 823(f). Accordingly, I will deny his application.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the application of Wesley Pope, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effectively immediately.

Dated: March 16, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017-05676 Filed: 3/22/2017 8:45 am; Publication Date: 3/23/2017]