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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11-22]

KENNETH HAROLD BULL, M.D.
DECISION AND ORDER

On December 14, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Kenneth Harold Bull, M.D. (Respondent), of Albuquerque, New Mexico. ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V as a practitioner, on the ground that because of actions taken by the New Mexico Medical Board, Respondent was without authority to handle controlled substances in New Mexico, the State in which he holds his DEA registration. Id.; see also 21 U.S.C. § 824(a)(3).

Respondent timely requested a hearing. ALJ Ex. 2. The matter was placed on the docket of the DEA Office of Administrative Law Judges (ALJ) and assigned to ALJ Wing, who, on January 19, 2011, issued an Order for Prehearing Statements. ALJ Ex. 3. The next day, the Government moved to stay the proceeding and for summary disposition; its motion was based on the New Mexico Medical Board's (hereinafter, Board) issuance, on October 1, 2010, of an order which summarily suspended Respondent's state medical license "[u]ntil further [o]rder of the Board." ALJ Ex. 4 (Appendix A).

On January 25, 2011, Respondent opposed the motion, arguing that the Board's hearing was scheduled for February 11, 2011 and that the Government "will not be prejudiced by this

short delay." ALJ Ex. 5. On February 9, 2011, the ALJ issued his ruling on the motion, "conclud[ing] that further delay in ruling on the Government's motion for summary disposition is not warranted." ALJ Ex. 6, at 4. Because Respondent did not dispute that he "is presently without state authority to handle controlled substances," the ALJ granted the Government's motion and recommended that his registration be revoked. Id. at 4-5. On March 18, 2011, the ALJ forwarded the record to this Office for Final Agency Action. ALJ Ex. 7.

On May 9, 2011, the State Board issued an order, which authorizes Respondent to "continue to practice medicine in psychiatry," but prohibits him "from treating patients with chronic pain." ALJ Ex. 8 (Appendix A, at 13). The State order also prohibits him from "prescrib[ing] narcotics, including but not limited to, all opioid analgesics, including buprenorphine and all synthetic opioid analgesics." Id.

Because the sole basis for the issuance of a final order was no longer in existence, on May 26, 2011, the Government filed with my Office an unopposed motion to remand. ALJ Ex. 8, at 2, 4. Therein, the Government stated that it "intends to seek to amend the current Order to Show Cause and will seek the revocation of the Respondent's DEA Certificate of Registration on the basis that the Respondent's registration is inconsistent with the public interest." Id. at 2. The Government also stated that it "will allege that the DEA investigation revealed that the Respondent would ask his patients to return their unused drugs, which included controlled substances, and that the Respondent would re-distribute these drugs to other patients as samples." Id. at 2-3. The Government also stated that "Respondent told the DEA that he did not maintain a log of the returned drugs, . . . that he had no record-keeping for this illegal activity, that he did not keep any drug inventories, and that he did not keep a dispensing record of the re-

dispensed drugs given to his other patients." Id. at 3. On June 28, 2011, I issued an order granting the Government's motion. ALJ Ex. 9.

Thereafter, additional prehearing procedures were conducted during which both parties submitted prehearing statements; the Government also submitted a supplemental prehearing statement. The Government did not, however, file an amended show cause order.

In its Prehearing Statement, the Government stated the issues as: 1) "[w]hether the DEA should revoke the registration of [Respondent], pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f)," and 2) "[w]hether the DEA should revoke the registration of the Respondent pursuant to 21 U.S.C. § 824(a)(3) and deny any pending applications for renewal or modification of the registration, pursuant to 21 U.S.C. § 823(f), based on the Respondent's restricted/limited state authority to practice medicine or handle controlled substances in the State of New Mexico, the state in which the Respondent is registered with the DEA." ALJ Ex. 11, at 2.

In its Prehearing Statement, the Government further discussed the proposed testimony of two witnesses, an Agency Investigator (hereinafter, DI) and Respondent. Id. at 3. With respect to the DI, the Government stated that she would "testify that the DEA investigation revealed that the Respondent would ask his patients to return their unused drugs, which included controlled substances, and that the Respondent would re-distribute these drugs to his other patients as samples." Id. at 3-4. The Government also stated that the DI would testify that "Respondent told the DEA that he did not maintain a log of the returned drugs, that he did not pay his patients for the returned drugs, that he had no record-keeping for this illegal activity, that he did not keep any drug inventories, and that he did not keep a dispensing record of the re-dispensed drugs that he gave to his other patients." Id. at 4. Moreover, the Government stated that the DI would

testify that Respondent "told the DEA that he received samples from pharmaceutical companies[,] which included controlled substances[,] but that he did not keep invoices of the controlled substance samples that he received." Id. at 4-5.

With respect to the second issue, the Government stated that the DI would testify that the State Board "issued a Decision and Order dated May 9, 2011 which reinstated the Respondent's license to practice medicine and state authority to handle controlled substances for an indefinite term of probation which includes terms, conditions, and restrictions imposed by the Board." Id. at 6. The Government also stated that the DI would testify that on August 15, 2011, the Board issued an Amended Decision and Order, which stated that Respondent "may not prescribe narcotics, including but not limited to, all opioid analgesics, including buprenorphine and all synthetic opioid analgesics, as defined by the [New Mexico] Controlled Substances Act." Id. The Government then contended that "Respondent currently has limited/restricted state authority to handle controlled substances in the State of New Mexico, the state in which the Respondent is registered with the DEA" and that his "registration is not a restricted registration and includes the authority to handle all controlled substances in Schedules II through V which is different from and inconsistent with the Respondent's limited/restricted state authority to handle controlled substances." Id.[1]

As for Respondent's proposed testimony, the Government stated that Respondent would testify "he is currently on an indefinite term of probation with the Board which included terms, conditions, and restrictions," and "that he is not authorized by the State of New Mexico to handle all controlled substances in Schedules II through V." Id. at 9. The Government also stated that Respondent would "testify that he asked his patients to return their unused drugs which included

[1] The Government also stated that the DI would testify as to the inventory of various controlled substances which were found at Respondent's office during a November 16, 2009 inspection. ALJ Ex. 11, at 6-8.

controlled substances and that he would re-distribute these drugs to his other patients as samples." Id. Finally, the Government stated that Respondent would "testify that he did not maintain any log for the returned drugs, that he did not pay the patients for the returned drugs, that he had no record-keeping for this illegal activity, that he did not keep any drug inventories, and that he did not keep a dispensing record of the re-dispensed drugs given to his other patients." Id.

In its Supplemental Prehearing Statement, the Government provided notice that it also intended to elicit testimony from a former State Drug Inspector (hereinafter, SDI) for the New Mexico State Board of Pharmacy. ALJ Ex. 14, at 3. The Government stated that the SDI would testify regarding a complaint the Pharmacy Board received alleging that Respondent would take "returned medications from patients and re-dispens[e] these same medications to different patients," and that on November 16, 2009, he accompanied DEA DIs on an inspection of Respondent's office. Id. The Government also stated that the SDI would "testify that [Respondent] told him that he received returned medications from patients and re-dispensed these medications to different patients, that he kept no records of these transactions, and that he denied using any of the controlled substances himself." Id. In addition, the Government stated that Respondent "admitted that he kept medication samples in his medical office which he dispensed to his patients and that he dispensed samples of Lyrica, Lunesta, and Ambien without the annual inventory required by state law and without a biennial inventory required by federal law and that [Respondent] admitted that he did not know that these medication samples were controlled substances." Id.

Finally, in its Supplemental Prehearing Statement, the Government noted that the DI would testify that during the November 16, 2009 inspection, nine empty prescription vials were

seized. Id. at 4. The Government further stated that the DI would testify "that the seized controlled substances were not only prescribed by [Respondent] but were prescribed by several . . . physicians." Id.

On November 15, 2011, the ALJ conducted a hearing in Tucson, Arizona, at which both parties elicited testimony and submitted documentary evidence. ALJ Recommended Decision (hereinafter R.D.), at 5. Thereafter, both parties filed briefs containing their proposed factual findings, legal conclusions and argument. Id.

On January 6, 2012, the ALJ issued his R.D. Id. at 1. Therein, the ALJ made findings with respect to each of the five public interest factors. See 21 U.S.C. § 823(f). With respect to factor one – the recommendation of the state licensing board – the ALJ noted that the State Board had placed Respondent on probation based on "findings pertaining to both Respondent's prescribing practices, as well as his record-keeping practices." R.D. at 16. While noting that "Respondent is not entirely precluded from prescribing controlled substances in New Mexico," the ALJ reasoned that "the detailed findings and opinions contained within the Medical Board's order are consistent with the evidence of record, and weigh in favor of a finding that Respondent's continued registration would be inconsistent with the public interest." Id. at 17. (citation omitted).

With respect to factors two and four – Respondent's experience in dispensing controlled substances and compliance with applicable laws related to controlled substances – the ALJ first addressed the Government's argument that Respondent "improperly act[ed] as a pharmacist without a DEA registration . . . by retrieving controlled substances from patients and re-distributing them to other patients." Id. at 18. The ALJ rejected the Government's contention, finding that while "Respondent admitted that he retrieved controlled substances that had already

been dispensed to patients, the Government failed to prove by a preponderance of the evidence that Respondent re-distributed those controlled substances to other patients." Id. at 19.

Next, the ALJ addressed whether Respondent violated federal and state record-keeping requirements. Id. at 19-22. The ALJ specifically found "that Respondent did not maintain a log of the controlled substances that he retrieved from patients," that he did not "maintain any records pertaining to the controlled substance samples that he received from the pharmaceutical companies," and "failed to keep any drug inventories or dispensing records for the controlled substances that he had on hand or that he dispensed to patients." Id. at 21. The ALJ also found Respondent's testimony that he documented his dispensing of medication in the patient charts to not be credible, noting the DI's testimony that he "never provided the patient charts," that he "claimed to maintain these records in the patient charts [only] after she informed him that he was in violation of . . . federal regulations," and that Respondent "testified that he was unaware of his obligations to maintain records under state and federal law." Id. Finally, the ALJ found that Respondent did not maintain any records of either his receipt or dispensing of Suboxone and Subutex, and again noted that Respondent provided incredible testimony that he documented the dispensings in the patient charts and "would have shown the . . . charts to the DIs or [SDI] if they had asked to see" them. Id. at 22. The ALJ thus found that Respondent's "lack of knowledge of his obligations under the law weighs in favor of a finding that [his] continued registration is contrary to the public interest." Id.

Finally, the ALJ discussed whether Respondent's prescribing practices violated the CSA's requirement that a prescription be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Id. at 22 (quoting 21 CFR 1306.04(a)). The ALJ noted the State Board's findings, that with respect to five

patients, Respondent had committed "'unprofessional or dishonorable conduct'" by engaging in "'injudicious prescribing, administering or dispensing of a drug or medicine.'" Id. at 23 (quoting N.M. Stat. Ann. §§ 61-6-15(A) and 61-6-15(D)(26)). Faulting Respondent for his "failure to address the specific findings pertaining to his prescribing practices of the five patients," and notwithstanding that this was "not a central issue of the Government's case," the ALJ found "that the Government has demonstrated that Respondent has issued prescriptions outside of the usual course of professional practice in violation of federal and state law." Id. at 24. The ALJ thus concluded that factors two and four "weigh heavily in favor of a finding that Respondent's continued registration would be inconsistent with the public interest." Id.

Finally, with respect to factor five – such other conduct which may threaten public health and safety – the ALJ found that "Respondent's acceptance of responsibility was somewhat mixed, but when considering the record as a whole, [he] has failed to demonstrate that he has accepted responsibility for [his] past misconduct and that he will not engage in future misconduct." Id. at 25. The ALJ acknowledged that Respondent admitted both that "he failed to maintain adequate records as required by state and federal regulations" and "that he retrieved medications from patients and sometimes re-dispensed the non-controlled medications to other patients." Id. However, the ALJ also noted Respondent's testimony (which he found incredible) that Respondent had "always indicated" in his charts the medications he had given his patients, his testimony that he did not log samples of several controlled substances that he received from pharmaceutical company representatives because the representatives never told him that the drugs were controlled substances, as well as his testimony that "he does not agree with the Medical Board's findings pertaining to his prescribing practices." Id. at 25-26.

The ALJ ultimately concluded that the Government had made out a prima facie case for revoking Respondent's registration under factors one, two, four, and five, and that Respondent had failed to rebut the Government's case because he failed "to accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct." Id. at 26-27. The ALJ thus recommended that Respondent's registration be revoked and that any pending application be denied. Id. at 27.

Respondent filed exceptions to the ALJ's R.D. Thereafter, the record was forwarded to this Office for Final Agency Action.

Having considered the record in its entirety, I adopt the ALJ's finding that Respondent violated federal law by failing to keep proper records of the controlled substances he received, as well as his finding that the Government failed to prove that he redistributed the controlled substances he received from his patients. However, I reject the ALJ's findings that Respondent violated the CSA's prescription requirement (21 CFR 1306.04(a)) with respect to the five patients listed in the State Board's order because the Government never provided notice that it intended to raise the issue of whether the Board's findings also establish a violation of federal law. Because the issue was never properly raised, the ALJ committed further error by requiring Respondent to acknowledge wrongdoing with respect to his prescribing to these patients. With respect to the misconduct which was fairly at issue, I find that Respondent has accepted responsibility. However, I also find his misconduct to be sufficiently egregious to warrant a period of outright suspension. In addition, based on the restrictions imposed by the State Board on his controlled substance prescribing authority, I conclude that federal law requires that his DEA registration be similarly restricted. I make the following findings of fact.

FINDINGS of FACT

Respondent is a psychiatrist licensed by the New Mexico Board; as of the date of the hearing, he has practiced medicine for thirty-seven years, during which he has been the chief of psychiatry or medical director of psychiatric services at nearly every hospital in the Albuquerque area. Tr. 129-30. In addition, he has received a fellowship from the American Psychiatric Association and served as President of the New Mexico Psychiatric Association. Id. at 130. Respondent testified – without refutation – that he has "a reputation for treating particularly difficult or complex psychiatric conditions." Id. at 131.

On August 9, 2010, the Board issued Respondent a Notice of Contemplated Action against his medical license, and on October 1, 2010, the Board filed an Amended Notice of Contemplated Action and also issued a Summary Suspension Order, which suspended his medical license pending a hearing which was held on some date not clear on the record.

On May 9, 2011, the Board issued its Decision and Order. GX 5, at 1. Therein, the Board found that Respondent committed "unprofessional or dishonorable conduct" by engaging in "injudicious prescribing, administering, or dispensing of a drug or medicine" with respect to five patients. Id. at 13 (citing N.M. Stat. § 61-6-15(D)(26)). In addition, the Board found that Respondent had failed to maintain accurate, complete, and legible medical records. Id. (citing N.M. Stat. § 61-6-15(D)(33)). Based on these findings, the Board placed Respondent on probation. Id.

Respondent is also the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V, including narcotic controlled substances, as a practitioner. GX 1. In addition, Respondent is authorized to treat up to 100 patients for opiate addiction with Suboxone and Subutex under the Drug Addiction Treatment

Act of 2000, Pub. L. 106-310, title XXXV, 114 Stat. 122 (codified at 21 U.S.C. § 823(g)(2)). See id. While Respondent's registration was due to expire on July 31, 2010, on June 4, 2010, he filed a renewal application. Id. at 2. Because Respondent filed a timely renewal application, his registration remains in effect pending the issuance of this Decision and Order. See 5 U.S.C. § 557; 21 CFR 1301.36(i).

The DEA Investigation

On August 10, 2009, the New Mexico Board of Pharmacy received information from Presbyterian Health Plan Quality Management, a health insurer, that a consumer had alleged that Respondent "was accepting medications from patients that had already been dispensed to them" and that he was asking "patients to return medications to him so that he could . . . re-dispense them." Tr. 26-27. The matter was assigned to one of the Board's SDIs, who contacted the local DEA Office and asked if the DIs wanted to accompany him on a visit to Respondent's office. Id. at 29. The DIs agreed, and on November 16, 2009, the SDI, accompanied by several DIs, went to Respondent's office. Id. at 30.

Upon their arrival, Respondent agreed to meet with the Investigators, and the SDI informed him of the reason for the visit and presented him with a Notice of Inspection and a Consent to Audit, which Respondent signed. Id. at 31, 65. According to the Investigators, Respondent was cooperative during the visit. Id. at 31; see also id. at 66 (testimony of DI). Respondent admitted that he took back medications from patients and stated that he did so "to prevent patients from accumulating medications to prevent any possible self-destructive behavior and for compassionate purposes because some of the[] medications are very expensive." Id. at 32-33; see also id. at 67. Respondent, however, denied that he was personally taking or diverting any of the controlled substances. Id. at 45-46. He also denied that he re-dispensed any of the

controlled substances he had obtained, and the SDI testified that he had no evidence to the contrary. Id. at 46.

In response to Respondent's explanation of his conduct, the DI explained that "once a prescription is filled for an end-user it's outside of the cycle of distribution and [that he could not] obtain that from a patient." Id. at 67. The DI further told Respondent that this was a "violation of" federal regulations and that if his concern was that his patients could not have large quantities of controlled substances because they would engage in "self-destructive behavior," he could either "procure controlled substances himself and then dispense smaller quantities . . . that he wanted a patient to have," or "he could write more frequent prescriptions for those patients." Id. at 68. Respondent replied that "he did not like either of those options and . . . that he believed" that writing multiple prescriptions "would be an insurance nightmare" for his patients. Id. at 69.

The Investigators then asked to see where Respondent kept the medications. Id. at 33-35. Respondent took them to "a little side room" which had shelves; on the shelves were boxes containing prescription vials that were labeled with the names of the pharmacy, patient, and drug, as well as dosing instructions. Id. at 33-35. According to the SDI, Respondent's name was on more than half of the vials, however, he did not determine the respective number of the vials which Respondent and other physicians had prescribed. Id. at 35. Moreover, the SDI did not recall finding any controlled substances in this room. Id. at 34. However, the DI testified that the room contained controlled substance samples, id. at 76; the samples were for drugs such as Ambien, Lunesta, and Lyrica. Id. at 36.

The Investigators were also taken to a different room which was like an office. Id. at 36, 77. According to the SDI, the drug samples were kept in this room and "were in a cabinet that . .

. had the ability to be locked," but the SDI did not "recall it being locked when [the Investigators] were there." Id. at 36-37; but see id. at 76 (testimony of DI that the samples were located in the other room). However, according to the DI, the cabinet was closed and Respondent used a key to open it. Id. at 77. The cabinet contained both controlled and non-controlled drugs. Id. at 78; see also id. at 37. According to the DI, the room had shelving on which both controlled and non-controlled substances were stored. Id. at 78. The Investigators also found nine empty prescription vials on the shelves, id. at 79; three of the vials contained labels which indicated that they had once contained either Lorazepam or Flurazepam, both of which are schedule IV depressants. Id. at 87. The labels on two of the vials indicated that the drugs had not been prescribed by Respondent. Id. at 88. However, the DI did not ask Respondent if the vials had contained controlled substances when he obtained them from his patients and admitted that she did not know whether the vials contained any controlled substances when he took possession of them. Id. at 113-14.

The Investigators then interviewed Respondent. Id. at 38. The SDI asked him if he kept receipt records for the drugs he received from his patients; Respondent "said he did not." Id.; see also id. at 80 (testimony of DI that when she asked Respondent for a log of the returned drugs, he did not have one). The SDI then asked Respondent if he kept receipt records for the drug samples; Respondent "said he did not keep receipt records or a log." Id. at 38; see also id. at 77 (testimony of DI). Moreover, Respondent did not keep "any dispensing records for the re-dispensed drugs . . . and did not produce any [patient] charts that showed that he dispensed these." Id. at 38-39. Nor did Respondent offer to show the Investigators any patient charts which contained dispensing information. Id. at 39. However, on cross-examination, the SDI did not recall if he had asked Respondent to provide the patient charts. Id. at 47. Also, Respondent

did not have a controlled substance inventory. Id. at 40. Finally, while Respondent was providing maintenance and/or detoxification treatment to patients, he did not maintain a log of the Suboxone/Subutex that he dispensed to his patients, and with the exception of a shipment of Suboxone that arrived during the inspection, he did not have invoices for the Suboxone/Subutex which he received.[2] Id. at 70-71, 81; see also GX 8.

According to the SDI, during the interview, Respondent stated that he was "unaware" that Ambien, Lunesta, and Lyrica "were controlled substances." Tr. 40. However, according to the DI, she only spoke to Respondent about the Lyrica samples, telling him that it was a schedule V controlled substance, which he was unaware of. Id. at 80. He also said that he was unaware that he was required to keep records of the drugs he received and dispensed. Id. at 49. Respondent then promised to keep the required records going forward. Id. at 49-50; but see id. at 121 (testimony of DI that Respondent did not say that he would comply with the regulations going forward).[3] Moreover, Respondent told the Investigators that "he did not redistribute controlled substances." Id. at 80.

During cross-examination, the DI acknowledged that she had not interviewed any of Respondent's patients. Id. at 102-03. She also acknowledged that she did not ask to see any of Respondent's patient charts. Id. at 103. However, the DI testified that Respondent had initially stated that he did not maintain any documentation of his dispensing of controlled substances and

[2] While this line of questioning was directed at "what type of records are required to be kept for someone who prescribes, administers or dispenses [Suboxone or Subutex] for maintenance or detoxification" purposes, and the DI initially answered that Respondent was required to keep dispensing records, she also testified that Respondent "stated he did not keep the invoices of the procurement." Tr. 70.

[3] Following the Medical Board's suspension of Respondent's medical license, the DI returned to Respondent's office in an unsuccessful attempt to obtain the surrender of his DEA registration. Tr. 89. She did not, however, inspect any of his records to determine whether he was in compliance with state and federal record keeping requirements. Id.

did not state that he documented the dispensings in the patient records until after being told that he was required to document his dispensings. Id. at 104.

At the conclusion of the visit, the SDI seized all of the non-controlled drugs that had been returned by Respondent's patients, as well as the non-controlled drug samples that were past their expiration date; the DEA Investigators seized all of the controlled substances except for the drug samples. Id. at 40-41; 82-84; 86-87. The controlled substances seized included schedule II drugs such as Fentanyl (5 patches), Adderall XR (38 capsules), amphetamine (25 tablets), d-amphetamine 5mg (28 tablets), methadone 10mg (79 tablets), methylin 5mg (30 tablets), oxycodone 5mg (26 tablets), oxycodone/apap 5/325mg (20 tablets), oxycodone 30mg (34 tablets), oxycodone er 40mg (26 tablets), OxyContin 80mg (60 tablets), and oxycodone oral suspension 20mg/20ml (3 bottles). GX 16, at 1-2. The drugs also included the schedule III drugs hydrocodone/apap 10/500mg (16 tablets) and Suboxone (267 tablets); the schedule IV drugs zolpidem (27 tablets), Provigil (modafinil) (4 tablets), and nine different benzodiazepines totaling more than 500 tablets; and finally the schedule V drugs diphenoxylate hcl/atropine sulfate (290 tablets) and Lyrica (119 capsules). Moreover, at least seven of the vials contained controlled substances which were prescribed by other physicians. See GX 10 at 13-14 (pt. SL, prescriber Dr. KS, drug oxazepam); id. at 19-22 (pt. DC, prescriber Dr. JL, two prescriptions for liquid oxycodone); id. at 23-24 (pt. SA, prescriber Dr. AW, drug methylphenidate hcl); id. at 55-56 (pt. DC, prescriber Dr. JL, drug methadone hcl); id. at 57-58 (pt. GN, prescriber Dr. ZH, drug oxycodone); id. at 87-88 (pt. KC, prescriber Dr. CS, drug triazolam).

Respondent's Evidence

Respondent testified on his own behalf. Respondent acknowledged that he accepted medications from his patients, stating he did so because it helped him "feel more secure about

treating patients that were potentially dangerous to themselves." Tr. 141. He also denied "ask[ing] patients to bring in their medications . . . so that [he] could redistribute those drugs to other patients." Id.

Regarding the manner in which the drugs were stored, Respondent denied that any controlled substances were stored in the cardboard boxes. Tr. 142-43. Respondent stated that he kept the controlled substances that his patients returned to him because he "felt bad about putting them down the toilet" and that he kept them "in a locked cabinet," id. at 143, which is consistent with the testimony of the SDI. He also maintained that he "never" re-distributed controlled substances to patients[4] and denied using any of the controlled substances that were given to him by his patients. Id.; see also id. at 149, 152. And on cross-examination, he further denied that he was acting as a pharmacy. Id. at 187.

Respondent admitted that he "did not keep" a log of the return medications and claimed that he "did not" know that he was required to do so under state or federal law. Id. at 145. He further testified he was no longer accepting either controlled or non-controlled drugs from his patients and that he had stopped doing so after the DEA visit. Id. at 146. He also testified that he keeps a log of any samples he receives from drug companies. Id.

Respondent testified, however, that he "always indicated" in the patient charts the medications and amounts that he had given his patients. Id. Moreover, Respondent testified that neither the SDI nor the DI had asked to see any patient charts and neither had ever subpoenaed any of the charts. Id. at 147. He stated that if they had asked to review the patient charts, he would have allowed them to do so. Id. He further maintained that he documented his dispensing

[4] Respondent admitted that "on very rare occasions," he re-dispensed non-controlled drugs to patients who were "clearly indigent" and "needed the medication, either because they were in a crisis mode or because they would go through withdrawal symptoms." Tr. 144. He further denied receiving any payment from the patients to whom he provided these drugs. Id. at 145.

of Suboxone in the patient charts and that he would have shown these charts to the SDI and DI if they had asked to see them. Id. at 148-49.

Regarding whether he knew that various drugs samples were controlled substances, Respondent testified that none of the drug company representatives "ever stated that these are controlled substances and that logs have to be kept." Id. at 154. He further testified that representatives for Ambien had "indoctrinated" doctors that the drug was "preferable . . . to the benzodiazepine sedatives . . . and it was a lower risk kind of medication" and "non-addictive." Id. Respondent thus "just assumed that they were not . . . controlled substances." Id. However, Respondent testified that he "[v]ery definitely" now knows that the drugs are controlled substances. Id. Moreover, on cross-examination, Respondent testified that "[t]here was never any mention made by either the drug reps or the drug companies that I was supposed to be doing some logging of these medications." Id. at 182. While maintaining that it was part of the drug companies' and their representatives' responsibility to educate him that the drugs were controlled substances, Respondent then explained that "I'm not saying that I'm not - shouldn't take some responsibility for it, because of course, I do take responsibility for it." Id.

Respondent also testified that in response to the State Medical Board's order, he has "endeavored to do a better job" of charting. Id. at 155-56. Moreover, Respondent stated that he "believe[s] that he has been in compliance with state and federal regulations since the November 2009 inspection and will continue to comply in the future. Id. at 158. He also stated that he is remorseful for his previous lack of compliance. Id. at 159. However, he maintained that notwithstanding his thirty-seven years of medical practice, he was unaware that the New Mexico

Controlled Substances Act imposed mandatory recordkeeping requirements for controlled substances.[5] Id. at 169.

On cross-examination, the Government asked Respondent why the Medical Board had suspended his license. Id. at 161. According to Respondent, two complaints had been filed against him, one by the wife of a patient who was "going through some conflict with her husband" and complained about his "treatment of her husband"; the other complaint was filed by a mother and daughter who he had expelled from his practice. Id. Respondent then stated that during the course of the investigation, two of his patients overdosed and thus "the Board understandably was worried and summarily suspended [his] license." Id. at 161-62.

Regarding the two patients who overdosed, Respondent testified that one of the patients had allegedly attempted suicide, but later recounted his statement. Id. at 162. Moreover, Respondent asserted that toxicology testing was not performed on the patient. Id. at 190. As for the second patient who overdosed, Respondent testified that he believed that the patient "was depressed about a breakup with a girlfriend and . . . deliberately took an overdose." Id. at 162. However, according to Respondent, the medications found in the patient's body were "mostly from another physician that he was also getting medications from," and that this doctor had "lost his license because of medication issues." Id. Respondent maintained that this patient did not

[5] On cross-examination, the Government asked Respondent "what record keeping requirements" for controlled substances he was "now familiar with?" Tr. 179. Respondent answered that he did not know what the Government was asking and that "[t]hat's a pretty broad question." Id. at 180. The Government then asked: "what records are you keeping for controlled substances at this time?" Id. Respondent replied: "Are you asking in terms of things that are coming from my office or are you talking about in terms of prescriptions that patients go to fill? What are you – I'm not certain what you're asking?" Id. The Government responded: "Well, you're the doctor. You would know what you would be prescribing and dispensing so you would know what records need to be kept. I can't answer your question." Id. Respondent replied: "Well, I'm not certain if you're talking about medication that I dispense, or medications that I prescribe. Which are you asking?" Id. The Government then stated: "Records for anything to do with controlled substances that you dispense or prescribe." Id. Respondent answered: "Well, the initial documentation is in the patient's chart and to my knowledge that's all that's required. For medications that I would dispense that I had, i.e., samples of Ambien or Lunesta, Lyrica, whatever, that I have a log of, in terms of the medications that have been received and then as they're dispensed." Id. at 180-81.

tell him that he was seeing another physician. Id. at 190. Moreover, Respondent testified that he "take[s] [it] seriously when a patient is dishonest" regarding his use of medications. Id. at 191.

The Government also questioned Respondent as to whether the Medical Board's suspension was based in part on his failure to "conform to record keeping that the Board mandated[.]" Id. at 165. Respondent replied that "[t]he Board does not mandate specific medical record keeping to my knowledge, per se. There was a question as to whether . . . it was easy to interpret my records or not." Id. The Government then asked Respondent whether his records were "legible and easy to interpret[.]" Id. Respondent acknowledged that "[t]here was some difficulty with the size of the records" because they "had been reduced by the Xeroxing method and my writing is small" and he used "a lot of arrows, ups and downs kind of notations, to indicate changes in medications." Id. at 165-66. Respondent then admitted that "at some level it was difficult for an individual not familiar with my records to interpret them." Id. at 166. However, he further testified that he had changed his documentation of patients' histories to make it "a little bit more understandable" and "more of a form rather than just written notes," and that he had also expanded the level of detail in the patients' progress notes. Id. at 192. He also stated that he was "trying" to improve his handwriting. Id. at 193.

Finally, the Government asked Respondent if the Medical Board's prohibition on his being allowed to practice pain management was based on his "over prescribing [of] pain medication." Id. at 166. Respondent answered that while "that was their interpretation . . . I'm not sure that I agree with that." Id. However, Respondent then explained that he is "fully obliged to abide by their decisions and their recommendations." Id. Moreover, Respondent testified that he was no longer dispensing Suboxone and Subutex. Id. at 189.

DISCUSSION

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

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

Id. § 823(f).

"These 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)).[6]

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

Factor One – The Recommendation of the State Licensing Board

The evidence shows that the New Mexico Medical Board has not made a recommendation in this matter. However, because the Controlled Substances Act makes the possession of authority under state law to dispense controlled substances a requirement for both obtaining and maintaining a practitioner's registration, see 21 U.S.C. §§ 802(21) & 823(f), DEA has interpreted factor one more broadly and thus considers disciplinary actions taken by a state board as relevant in the public interest determination when they result in a loss of state authority, or are based on findings establishing that a registrant diverted controlled substances (whether acting intentionally, recklessly or merely negligently), failed to maintain effective controls against diversion, or otherwise failed to comply with laws and/or regulations related to controlled substances.

[6] "In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." Jayam Krishna-Iyer, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. MacKay, 664 F.3d at 821.

Here, the evidence shows that on October 1, 2010, the New Mexico Board of Medicine summarily suspended Respondent's state medical license. GX 4. The evidence also shows that on May 9, 2011, the Board, following a hearing, found that Respondent committed "unprofessional or dishonorable conduct" in that he engaged in the "injudicious prescribing of drugs" and "fail[ed] to maintain timely, accurate, legible and complete medical records." GX 5, at 13.

Notwithstanding these findings, the Board re-instated Respondent's medical license to allow him to practice psychiatry. Id. However, the Board prohibited him from practicing pain management and from prescribing "narcotics, including but not limited to, all opioid analgesics, including buprenorphine and all synthetic opioid analgesics." Id.

Under the CSA, a practitioner's registration grants authority to dispense a controlled substance, which by definition "means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner." 21 U.S.C. § 802(10) (emphasis added). Likewise, the CSA defines the "[t]he term 'practitioner' [to] mean[] a physician . . . 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." Id. § 802(21). Finally, as stated above, under the CSA, a practitioner's possession of federal authority to dispense controlled substances is premised on his possession of authority under state law to do so. See also id. § 823(f) ("The Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."). Thus, to the extent a practitioner is not authorized under state law to dispense certain categories or schedules of controlled substances, he can no longer lawfully dispense them under federal law. Accordingly, where a state board takes such action, at a minimum, a

practitioner's CSA registration must be limited to authorize the dispensing of only those controlled substances, which he can lawfully dispense under state law.

Factors Two and Four – Respondent's Experience In Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

With respect to these factors, the ALJ rejected, as unsupported by substantial evidence, the Government's contentions that: 1) Respondent acted as a pharmacy without being registered to do so; and 2) he re-dispensed the controlled substances he obtained from his patients. ALJ at 18-19. The ALJ found, however, that Respondent violated various federal and state controlled substance recordkeeping requirements by failing to: 1) take inventories of the drugs he had on hand and keep a record of such, 2) maintain records of the drugs he received, and 3) document his dispensings of controlled substances. Id. at 19-22. Moreover, based on the Medical Board's Decision and Order, which found that Respondent had engaged in "injudicious prescribing . . . of a drug," id. at 23, the ALJ further found "that the Government has demonstrated that Respondent has issued prescriptions outside of the usual course of professional practice in violation of federal and state law." Id. at 24. I adopt the ALJ's conclusion that the Government has not proved that Respondent either acted as an unregistered pharmacy or re-dispensed controlled substances, as well as his conclusion that he violated various recordkeeping requirements. However, I reject his conclusion that Respondent violated federal law by issuing prescriptions outside of the usual course of professional practice.

The Allegations of Acting as an Unregistered Pharmacy and Re-Dispensing Controlled Substances

As noted above, in its Prehearing Statement, the Government alleged that Respondent "ask[ed] his patients to return their unused drugs, which included controlled substances, and that Respondent would re-distribute these drugs to his other patients as samples." ALJ Ex. 11, at 3.

Yet the SDI, who was a witness for the Government, testified that while Respondent acknowledged that he took back both controlled and non-controlled drugs from his patients, he denied that he ever re-dispensed any controlled substances to his patients. Tr. 46, 80. Respondent likewise denied having ever re-dispensed controlled substances to his patients. Id. at 143. Moreover, the SDI acknowledged that he had no evidence to refute Respondent's statement. Id. at 46. The ALJ thus found credible Respondent's denial of the allegation that he re-dispensed controlled substances.[7] R.D. at 12.

The Government nonetheless argues that the empty prescription vials, three of which bore labels indicating they had previously held controlled substances, "shows that the controlled substances were re-dispensed to his patients because there is no reasonable, practical, or valid explanation as to why anyone would take back empty medication vials." Gov. Br. 26. The Government, however, offered no proof that the vials contained controlled substances at the time Respondent acquired possession of them. In short, the Government's evidence merely creates a suspicion that the vials contained controlled substances, which were subsequently re-dispensed. As such, the Government's evidence does not constitute substantial evidence and is manifestly insufficient to support rejecting the ALJ's finding. See NLRB v. Columbian Enameling & Stamping Co., 306 U.S. 292, 300 (1939). This conclusion likewise puts to rest the Government's contention that Respondent acted as an unregistered pharmacy.

The Government further argues that Respondent illegally possessed the controlled substances that were "returned . . . from his patients." Gov. Br. 21. On point here, the CSA provides that "[i]t shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid

[7] Respondent also denied that he was personally using the controlled substances. Here again, there is absolutely no evidence to refute his testimony.

prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter." 21 U.S.C. § 844(a). The CSA created a closed system of distribution which generally contemplates that a controlled substance can only be lawfully acquired from a registrant; in the case of a practitioner, the Act generally allows a registered practitioner to obtain a controlled substance only from a registrant who is authorized to distribute a controlled substance. Moreover, while an Agency regulation provides that "[a]ny person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he/she obtained it[,]" 21 CFR 1307.12(a), this regulation does not authorize a practitioner to acquire a controlled substance which has been dispensed to his patient by another practitioner. Nor, by its plain language, does the regulation even allow a practitioner to acquire a controlled substance which the practitioner dispensed through his own prescription.

The record contains evidence of at least seven instances in which Respondent obtained possession of controlled substances which had been prescribed by another physician. See GX 10, at 13-14 (pt. SL, prescriber Dr. KS, drug oxazepam); id. at 19-22 (pt. DC, prescriber Dr. JL, two prescriptions for liquid oxycodone); id. at 23-24 (pt. SA, prescriber Dr. AW, drug methylphenidate hcl); id. at 55-56 (pt. DC, prescriber Dr. JL, drug methadone hcl); id. at 57-58 (pt. GN, prescriber Dr. ZH, drug oxycodone); id. at 87-88 (pt. KC, prescriber Dr. CS, drug triazolam). This evidence is sufficient to establish that Respondent unlawfully possessed controlled substances. 21 U.S.C. § 844(a).

The Allegations That Respondent Failed to Maintain Required Records

The evidence further shows that Respondent violated numerous recordkeeping requirements. Indeed, notwithstanding that he has been practicing medicine for nearly four

decades and a DEA registrant for much (if not all) of this time, see GX 1, at 2, Tr. 129; Respondent testified that he was unaware of the various recordkeeping requirements imposed by both the CSA and New Mexico law. Tr. 169.

Under the CSA, Respondent was required to take an initial inventory of the controlled substances he had on hand "as soon" as he "first engage[d]" in the dispensing of controlled substances, and "every second year thereafter, make a complete and accurate record of all stocks thereof on hand." 21 U.S.C. § 827(a)(1). Respondent was also required to "maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold delivered, or otherwise disposed of by him." Id. § 827(a)(3).

Respondent did not, however, have an inventory of the controlled substances he had on hand at the time of the November 2009 inspection. Nor did he maintain a record of the controlled substances he received from either his patients or from the manufacturers/distributors who provided him with samples. He also did not have a dispensing log for the controlled substance samples he dispensed to his patients.

Finally, Respondent was required to maintain a record of his prescribing of controlled substances "in the course of maintenance or detoxification treatment of an individual." Id. § 827(c)(1)(A); 21 CFR 1304.03(c). While Respondent was providing maintenance and/or detoxification treatment to patients, he did not maintain a log of the Suboxone/Subutex he dispensed to them. Tr. 70-73. Rather, Respondent testified that he documented his dispensing of these drugs in the patient records and neither the SDI nor the DI testified that they asked to see his charts. Id. at 47, 103. However, here again, with the exception of a single patient who was obtaining Suboxone through a patient assistance program which shipped the drug to Respondent,

the Government did not establish that Respondent was engaged in the direct dispensing of Suboxone/Subutex.

As his basis for finding Respondent's testimony not credible, the ALJ cited testimony to the effect "that Respondent never provided the patient charts" to the Investigators and that he claimed that he documented the dispensing in the charts only after being informed "that he was in violation of the federal regulations." R.D. at 21. The ALJ thus reasoned that "[t]he delayed timing of Respondent's uncorroborated revelation that all his record-keeping was located in patient charts is plainly incredible, particularly given other credible testimony of record that Respondent was unaware of any record-keeping requirements for controlled substances for over thirty-five years." Id. at 21-22.

Respondent's lack of awareness of controlled substance recordkeeping requirements aside, I reject the ALJ's finding because physicians routinely document the prescriptions they write in their patient charts. As for "[t]he delayed timing" of his response, id. at 21, the ALJ ignored that where a physician merely prescribes Suboxone, DEA regulations only require that a record of the prescription be kept and do not mandate what form it must be in. Accordingly, a physician can comply with federal law by: 1) keeping a copy of the prescription, 2) keeping a logbook of the prescriptions he issued, or 3) by noting the prescription in the patient's chart. Thus, that Respondent did not immediately explain that he was documenting the prescriptions in the patient chart (whether by making a copy of it or noting it), can easily be explained by the fact that he did not understand how he could demonstrate his compliance with the regulation. His lack of understanding does not, however, establish that he was not in compliance.

As for the ALJ's observation that Respondent "never provided the patient charts," id., neither of the Government's witnesses conclusively testified that they actually asked for them.

Tr. 47 (SDI's testimony that he did not recall if he had asked Respondent to provide the charts); id. at 103 (DI's testimony that she did not ask to see any of the charts). And ultimately, it is the Government which bore the burden of proving Respondent's non-compliance and not Respondent's to prove he was compliant.

Accordingly, I reject this allegation as unsupported by substantial evidence. However, as explained above, I do find that Respondent violated the CSA and DEA regulations by: 1) failing to maintain the required inventories, 2) failing to retain records of the controlled substances he received from both patients and the drug samples he received from distributors/manufacturers, and 3) failing to document his dispensing of controlled substance samples.

The ALJ's Findings That Respondent Violated 21 CFR 1306.04(a)

As explained above, the State Board made extensive findings regarding Respondent's prescribing of controlled substances to five patients, and concluded that he had engaged in the "injudicious prescribing of drugs" and thus committed "unprofessional or dishonorable conduct." GX 5, at 13 (citing N.M. Stat. Ann. § 61-6-15(D)(26)). Based on these findings, and notwithstanding his acknowledgment that this was "not a central issue of the Government's case," the ALJ found that Respondent "issued prescriptions outside of the usual course of professional practice in violation of federal and state law." R.D. at 24; see also id. at 22 (quoting 21 CFR 1306.04(a)). I reject the ALJ's finding.

It is certainly true – if not an understatement – to say that Respondents' prescribing to the five patients was "not a central issue of the Government's case." Indeed, the Government never properly put this conduct in issue at all. As explained above, following the remand, and notwithstanding its representation that it intended to file an amended show cause order, the Government did not do so. And while it is settled (and has been upheld by various federal courts

of appeals) that Due Process is satisfied provided the Government, through its prehearing statements, provides adequate notice that it intends to litigate an issue, at no point in its pleadings did the Government state that it was alleging that Respondent violated 21 CFR 1306.04(a) and intended to use the State Board's order as proof. Rather, in its prehearing statements, the Government merely stated that it intended to put on evidence that the Board had restricted his state authority to handle controlled substances and that his DEA "registration is not a restricted registration and includes the authority to handle all controlled substances in Schedules II through V which is different from and inconsistent with the Respondent's limited/restricted state authority to handle controlled substances." ALJ Ex. 11, at 6; see also id. at 9 (noting Respondent would testify that "he is currently on an indefinite term of probation with the Board" and "that he is not authorized by the State of New Mexico to handle all controlled substances in Schedules II through V").

Moreover, even in its post-hearing brief, the Government never argued that Respondent's prescribing to the five patients identified in the Board's Order establishes that he violated 21 CFR 1306.04(a), which prohibits the issuance of prescriptions without a legitimate medical purpose and outside of the usual course of professional practice. See Gov. Br. 21-32. Indeed, the only reference to the Board's findings contained in the Government's brief is the statement that "[t]he Board's findings of fact and disciplinary actions are included in Government exhibits two, three, four, five, and eleven . . . and show the history of discipline imposed on [Respondent] by the Board." Id. at 19-20.

In its brief, the Government also notes Respondent's testimony, in which he referred to the State Board's suspension as his "sabbatical," to argue that he "accepts no responsibility whatsoever for his bad medical practices because he believes that the state suspension of his

medical license is a sabbatical as opposed to a mandatory suspension that was imposed . . . because of his bad medical practices." Id. at 20. However, here again, the Government does not argue that Respondent's "bad medical practices" also constituted violations of 21 CFR 1306.04(a). Thus, there is also no basis to conclude that the issue was litigated by consent.[8] See CBS Wholesale Distributors, 74 FR 36746, 36750 (2009) ("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 a basis for imposing a sanction") (quoting Pergament United Sales, Inc., v. NLRB, 920 F.2d 130, 136 (2d Cir. 1990) (quoting NLRB v. Majestic Weaving Co., 355 F.2d 854, 861-62 (2d Cir. 1966))). See also Yellow Freight System, Inc., v. Martin, 954 F.2d 353, 358 (6th Cir.1992) ("An 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.") (citation omitted). In short, given that the

[8] It is acknowledged that during her cross-examination of the SDI, Respondent's counsel asked him whether he had any evidence that Respondent had harmed or injured any of his patients or diverted drugs. See Tr. 45-46. However, the questions posed by Respondent's counsel to the SDI were directed at the allegations that gave rise to the Pharmacy Board's (and not the Medical Board's) investigation and the evidence the SDI obtained in the course of the former's investigation. See id.

Subsequently, after the SDI testified in essence that he had no knowledge as to whether the Medical Board investigated Respondent because he had harmed patients or diverted medications, the Government moved into evidence various board orders, arguing that they were relevant because they address "the issue that counsel brought up with [the SDI], were any patients harmed, were any patients injured, was there any diversion," and "[t]his specifically goes to [Respondent's] activities along those lines and has become relevant through [the] questioning" of the SDI. Tr. 92. Not only did Respondent's counsel object to the admission of most of these exhibits, I conclude that because her questioning of the SDI was limited to asking him about the basis for the Pharmacy Board's investigation and its findings, this did not make the Medical Board's findings relevant and does not excuse the Government from its obligation to provide notice. And I further conclude that the limited questioning undertaken by Respondent's counsel on these issues does not establish that Respondent consented to litigate the issue of whether the Medical Board's findings establish that he violated 21 CFR 1306.04(a).

Government neither alleged, nor argued that Respondent's prescribing to the five patients identified in the Board's order violated 21 CFR 1306.04(a), the ALJ erred in holding that he violated the regulation.[9]

Summary of Factors Two and Four

As explained above, I find that Respondent unlawfully possessed controlled substances which he obtained from his patients. I also find that Respondent failed to maintain required records. I thus conclude that the Government has satisfied its prima facie burden of showing that Respondent has committed acts that render his registration inconsistent with the public interest. 21 U.S.C. § 824(a)(4).

SANCTION

Where the Government has met its prima facie burden of showing that a registrant has committed acts which render his registration inconsistent with the public interest, the burden then

[9] Even if the Government had properly raised the allegation, I would nonetheless reject the ALJ's conclusion. While a violation of the standards of professional practice may constitute evidence that a practitioner has also acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing a controlled substance, the federal courts have made clear that proof of intentional or knowing diversion requires more than proof that a practitioner committed civil negligence. See United States v. McIver, 470 F.3d 550, 559 (4th Cir. 2006) (quoted in Laurence T. McKinney, 73 FR 43260, 43266 (2008) (the offense of unlawful distribution requires proof that the practitioner's conduct went "'beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence'")); see also McIver, 470 F.3d at 559 ("the scope of unlawful conduct under [21 U.S.C.] § 841(a)(1) [requires proof that a physician] used his authority to prescribe controlled substances . . . not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or some other illegitimate purposes, such as his own personal profit"); 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.").

Here, while the State Board found that Respondent had engaged in the "injudicious prescribing" of drugs and thus committed "unprofessional or dishonorable conduct" in violation of N.M. Stat. Ann. § 61-6-15(D)(26), notably, the Board did not find that Respondent had engaged in "the prescribing, administering or dispensing of narcotic, stimulant or hypnotic drugs for other than accepted therapeutic purposes." N.M. Stat. Ann. § 61-6-15(D)(17). Given the existence of the latter standard, it is clear that the State's "injudicious prescribing" standard is not equivalent to the standard imposed under 21 CFR 1306.04(a). Accordingly, the State Board's ultimate finding does not support the ALJ's conclusion that Respondent violated the CSA's prescription requirement.

While it may be that the State Board's findings establish reckless or negligent conduct in the handling of controlled substances, which is a basis to revoke a registration under Agency precedent, see Paul J. Caragine, 63 FR 51592, 51601 (1998); here again, the Government made no such allegation. The conduct therefore cannot support the ALJ's proposed sanction.

shifts to the applicant to "present sufficient mitigating evidence" to show why he can be entrusted with a registration. Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008) (quoting Samuel S. Jackson, 72 FR 23848, 23853 (2007) (quoting Leo R. Miller, 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' ALRA Labs, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." Medicine Shoppe, 73 FR at 387; see also Jackson, 72 FR at 23853; John H. Kennedy, 71 FR 35705, 35709 (2006); Cuong Tron Tran, 63 FR 64280, 64283 (1998); Prince George Daniels, 60 FR 62884, 62887 (1995); 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).

Here, although the ALJ noted that "Respondent's acceptance of responsibility was somewhat mixed," he nonetheless concluded that "when considering the record as a whole, [he] has failed to demonstrate that he will not engage in future misconduct." R.D. at 25. I reject the ALJ's conclusion because contrary to his statement, he did not consider the record as a whole, but rather, ignored relevant evidence to the contrary. And he further erred when he required Respondent to accept responsibility for conduct which the Government never properly put at issue.

For example, with respect to the recordkeeping violations, the ALJ noted that Respondent admitted that he had failed to keep required records. Id. (citing Tr. 169). However, the ALJ apparently concluded that Respondent had not provided adequate assurance that he would comply in the future, noting that when asked by the Government to state what recordkeeping

requirements he was now familiar with "for anything to do with controlled substances that you dispense or prescribe," he answered: "[t]he initial document is in the patient's chart and to my knowledge that all that's required." Id. (quoting Tr. 180). The ALJ, however, ignored the rest of Respondent's answer to this question: "For medications that I would dispense that I had, i.e., samples of Ambien or Lunesta, Lyrica, whatever, that I have a log of, in terms of the medications that have been received and then as they're dispensed." Tr. 180-81. Respondent thus acknowledged his obligation to keep a record of his dispensings.

Moreover, the ALJ entirely ignored Respondent's testimony that following the November 2009 inspection he had stopped accepting drugs from his patients. See Tr. 146. The ALJ also ignored Respondent's testimony that he was now keeping a log of any samples he received from drug companies. See id.

Next, although it is not clearly stated in his recommended decision, the ALJ apparently found that Respondent lacked candor, based on his finding not credible, Respondent's testimony that he documented the medications he was providing his patients in their charts. R.D. at 25. Because for reasons explained above, I reject the ALJ's credibility finding, I conclude that his testimony on this issue does not establish that he lacks candor.

The ALJ then noted that "Respondent also admitted that he was unaware that Ambien, Lunesta and Lyrica are controlled substances, but appeared to blame the pharmaceutical companies for failing to inform him." Id. (citing Tr. 181-82). While this aspect of Respondent's testimony - which he offered to justify his failure to maintain the records for these drugs - does not impress, the ALJ once again ignored the rest of his testimony, in which he stated: "I'm not saying that I . . . shouldn't take some responsibility for it, because of course, I do take responsibility for it." Id. at 182 (emphasis added). Moreover, it is undisputed that following the

November 2009 inspection, Respondent commenced maintaining a log of the controlled substances he received.

Finally, the ALJ cited Respondent's testimony regarding the Medical Board's findings, including his testimony to the effect that while he acknowledges his obligation to comply with the Board's order, "he does not agree with the Medical Board's findings pertaining to his prescribing practices." R.D. at 26 (citing Tr. 166). However, because as explained above, the Government failed to raise the issue, Respondent was not obligated to address it in the proceeding.

As for what was properly at issue in the proceeding, Respondent has substantially complied with the requirement that he accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct. However, even where a registrant satisfies this obligation, in fashioning an appropriate sanction, the Agency is still entitled to consider the egregiousness of the proven misconduct and its deterrence interests. See Joseph Gaudio, 74 FR 10083, 10095 (2009); see also Paul Weir Battershell, 76 FR 44359, 44368-69 (2011); Roni Dreszer, 76 FR 19434, 19435 (2011); Mark DeLalama, 76 FR 20011, 20020 (2011); Janet L. Thornton, 73 FR 50354, 50356 (2008).

Given the unrefuted evidence that he acted out of a benign motivation, I place little weight on Respondent's unlawful conduct in obtaining possession of the controlled substances from his patients. Respondent's recordkeeping violations are, however, a different matter. Indeed, I find it remarkable - and inexcusable - that Respondent was unaware of both the CSA's and the State's recordkeeping requirements. "Recordkeeping is one of the CSA's central features" for maintaining accountability of the distribution and dispensing of controlled substances; "a registrant's accurate and diligent adherence to this obligation is absolutely

essential to protect against the diversion of controlled substances." Paul H. Volkman, 73 FR 30630, 30644 (2008).

It should be obvious to anyone that the lawful handling of controlled substances is a highly regulated activity, and having voluntarily chosen to become a registrant, Respondent cannot reasonably claim ignorance of the legal requirements applicable to his controlled substance activities. See United States v. Southern Union Co., 630 F.3d 17, 31 (1st Cir. 2010). The recordkeeping requirements at issue here have been part of federal law since the enactment of the CSA in 1971. Surely, at some point during the thirty-seven years of his medical career, and preferably before he first started handling controlled substances, Respondent should have familiarized himself with the CSA and DEA regulations.

By themselves, recordkeeping violations can support the revocation of a registration. See Volkman, 73 FR at 30644. Here, however, the scope of the proven violations is limited, given that there is no evidence that he dispensed any of the controlled substances he obtained from his patients and that the other evidence in the case suggests that his dispensing activity was limited in scope. So too, while Respondent did not maintain an inventory of the controlled substances he had on hand, the quantities found during the inspection were limited. I thus conclude that Respondent's recordkeeping violations do not warrant revocation but are nonetheless sufficiently egregious to warrant the suspension of his registration.

Moreover, pursuant to the Medical Board's order, Respondent no longer holds authority under state law to prescribe "narcotics, including but not limited to, all opioid analgesics, including buprenorphine and all synthetic opioid analgesics." GX 5, at 13. As explained in the discussion of factor one, under the CSA, the Board's revocation of his authority to prescribe these drugs likewise mandates that the same restriction be imposed on his DEA registration.

Therefore, his registration will be restricted to bar him from prescribing the aforementioned drugs and his Identification Number as a DATA-Waiver physician must also be revoked.

Accordingly, I will order that Respondent's application to renew his new registration be granted subject to the following conditions:

1) Effective on the date on which Respondent's registration is renewed, his registration shall be suspended for period of six months.
2) Respondent's registration shall be restricted to authorize the dispensing of only non-narcotic controlled substances.
3) Respondent's Identification Number as a DATA-Waiver physician shall be revoked.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that the application of Kenneth Harold Bull, M.D., to renew his DEA Certificate of Registration as a practitioner be, and it hereby is, granted subject to the condition that he be authorized to dispense only non-narcotic controlled substances. I also order that the Identification Number as a DATA-Waiver physician issued to Kenneth Harold Bull, M.D., be, and it hereby is, revoked. I further order that upon the effective date of this Order, the DEA Certificate of Registration issued to Kenneth Harold Bull, M.D., be, and it hereby is, suspended for a period of six months. This Order is effective [**INSERT DATE THIRTY DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

Dated: September 22, 2013

Michele M. Leonhart
Administrator

[FR Doc. 2013-24695 Filed 10/21/2013 at 8:45 am; Publication Date: 10/22/2013]