hereby is, denied. This Order is effectively immediately.

Dated: May 1, 2015.

Michele M. Leonhart,

Administrator.

Brian Bayly, Esq., for the Government.
Marc S. Murphy, Esq., and Michael Denbow, Esq., for the Respondent.

Order Granting the Government's Motion for Summary Disposition and Findings of Fact, Conclusions of Law, and Recommended Decision of the Administrative Law Judge

Administrative Law Judge Christopher B. McNeil. On January 29, 2015, the Deputy Assistant Administrator of the Drug Enforcement Administration issued an Order to Show Cause as to why the DEA should not revoke DEA Certificate of Registration Number FP2719245 issued to Sharad C. Patel, M.D., the Respondent in this matter. The Order seeks to revoke Respondent's registration pursuant to 21 U.S.C. 824(a)(3) and 823(f), and to deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. 823(f). As grounds for denial, the Government alleges that Respondent is ''without authority to handle controlled substances in Kentucky, the state in which [Respondent is] registered with the DEA.''

On February 20, 2015, the DEA's Office of Administrative Law Judges received Respondent's written request for a hearing, which is dated February 19, 2015. Respondent states that his medical license is ''temporarily suspended'' by the state's medical board and that he plans to challenge the suspension in an upcoming state administrative hearing scheduled for May 18, 2015.

On February 23, 2015 this Office issued an Order for Briefing on Allegations Concerning Respondent's Lack of State Authority. In the Order, I mandated that the Government provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances and if appropriate file a motion for summary disposition no later than 2:00 p.m. Eastern Standard Time (EST) on March 2, 2015. On March 2, 2015, the Government timely submitted a brief in support of the allegation regarding state authority and filed a Motion for Summary Disposition. According to the Government's brief, the Board of Medical Licensure of the Commonwealth of Kentucky issued an Emergency Order of Suspension suspending Respondent's license to practice medicine, effective November 24, 2014. The Government attached the emergency order pertaining to Respondent to the Motion for Summary Disposition. Based on this suspension, the Government moved for a summary disposition of these proceedings.

In my Order for Briefing on Allegations Concerning Respondent's Lack of State Authority, I also provided Respondent the opportunity to respond to the Government's allegations with a brief due not later than 2:00 p.m. EST on March 9, 2015. As of today, no brief was received and therefore the Government's Motion for Summary Disposition will stand unopposed. In Respondent's Request for Hearing, Respondent admits that his license is temporary suspended. Respondent further states that he expects to prevail before the medical board at an upcoming hearing on May 18, 2015. Finally he notes that his DEA Certificate of Registration will expire by its own terms on March 31, 2015, and alleges that he is prohibited from applying for his DEA certificate until the Kentucky medical board acts upon his suspension.

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's DEA Certificate of Registration must be revoked because Respondent does not have a medical license issued by the state in which he practices — a fact which Respondent does not deny. Under DEA precedent, a practitioner's DEA Certificate of Registration for controlled substances must be summarily revoked if the applicant is not authorized to handle controlled substances in the state in which he maintains his DEA registration.[1] Pursuant to 21 U.S.C. 823(f), only a ''practitioner'' may receive a DEA registration. Under 21 U.S.C. 802(21), a ''practitioner'' must be ''licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]'' Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to maintain a practitioner's registration if that practitioner is not authorized to dispense controlled substances.[2] As noted by the Government in its Motion for Summary Disposition, Respondent's concern regarding the impending expiration of his DEA registration is unfounded. Under 21 CFR 1301.36(i), incorrectly cited by the Government as 21 CFR 1306.36(i), the existing registration of an applicant for reregistration will be automatically extended until the Administrator issues her order if the applicant applies for reregistration.[3]

As detailed above, only a ''practitioner'' may receive a DEA registration. Therefore, I will recommend the revocation of Respondent's DEA registration.

[1] *See* 21 U.S.C. 801(21), 823(f), 824(a)(3); *see also House of Medicine,* 79 FR 4959, 4961 (DEA Jan. 30, 2014); *Deanwood Pharmacy,* 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.,* 77 FR 67669–02 (DEA Nov. 13, 2012); *Alan H. Olefsky, M.D.,* 72 FR 42127–01 (DEA Aug. 1, 2007); *Layfe Robert Anthony, M.D.,* 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA–C,* 64 FR 15811–02 (DEA Apr. 1, 1999); *Shahid Musud Siddiqui, M.D.,* 61 FR 14818–02 (DEA April 4, 1996); *Michael D. Lawton, M.D.,* 59 FR 17792–01 (DEA Apr. 14, 1994); *Abraham A. Chaplan, M.D.,* 57 FR 55280–03 (DEA Nov. 24, 1992). *See also Bio Diagnosis Int'l,* 78 FR 39327–03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other ''practitioners'' in the context of summary disposition analysis).

[2] *See Abraham A. Chaplan, M.D.,* 57 FR 55280–03, 55280 (DEA Nov. 24, 1992), and cases cited therein. In *Chaplan,* DEA Administrator Robert C. Bonner adopts the ALJ's opinion that ''the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances.'' *Id.*

[3] *See also Ronald J. Riegel,* D.V.M., 63 FR 67132–01, 67132 (DEA Dec. 4, 1998).

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a ''practitioner'' as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which he seeks to practice with a DEA Certificate of Registration. I find no other material facts at issue. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I recommended that Respondent's DEA Certificate of Registration should be REVOKED and any pending application for the renewal or modification of the same should be DENIED.

Dated: March 11, 2015.

Christopher B. McNeil,

Administrative Law Judge.

[FR Doc. 2015–12025 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–34]

Annicol Marrocco, M.D.; Decision and Order

On May 17, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Annicol Marrocco, M.D., (hereinafter, Respondent), of Mahwah, New Jersey. ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration BM8059102, which authorized her to dispense controlled substances in schedules II through V, at the registered address of Olean General Hospital, 515 Main Street, Olean, New York 14760, on the ground that her ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order specifically alleged that between January 2008 and August 2009, Respondent issued approximately twenty-one prescriptions to S.C. for oxycodone, a schedule II controlled substance, ''outside the usual course of professional practice and for other than a legitimate medical purpose.'' *Id.* (citing 21 U.S.C. 841(a) and 21 CFR 1306.04(a)). The Show Cause Order further alleged that Respondent failed to maintain medical records supporting the prescriptions, in violation of Florida law; that she was in a personal relationship with S.C.; and that she ''did not examine S.C. except to

listen to his heart and lungs.'' *Id.* at 1–2, 4–5 (citing Fla. Admin Rule 64B8–9.003 and 64B8–9.013).

Next, the Show Cause Order alleged that Respondent had failed to both date and include S.C.'s address on multiple prescriptions, in violation of 21 CFR 1306.05(a). *Id.* at 2. The Show Cause Order then alleged that Respondent had violated DEA regulations that, while allowing a practitioner to issue multiple prescriptions for a schedule II controlled substance, limit the quantity of the prescriptions to a 90-day supply, require that a prescription include the earliest date on which it can be filled, and require that each prescription be issued for a legitimate medical purpose. *Id.* at 2–4 (citing 21 CFR 1306.12(b)(1)).

Next, the Show Cause Order alleged that Respondent ''violated Federal law on at least forty-nine occasions'' by issuing controlled substance prescriptions while practicing as a contract emergency room physician at the Northern Navajo Medical Center in Shiprock, New Mexico, while being registered in New York. *Id.* at 5. The Government further alleged that ''[i]ssuing controlled substance prescriptions in one state under a DEA registration issued for another state is a violation of 21 U.S.C. 822(e) . . . which require[s] separate registrations for separate locations.'' *Id.* (also citing 21 CFR 1301.12(a) & (b)(3)). The Government also alleged that Respondent knowingly and willfully violated these provisions, alleging that ''DEA personnel informed you and your attorney that to move your DEA registration to New Mexico you must first be properly licensed to practice medicine in New Mexico'' and that she ''ha[s] never held a New Mexico medical license.'' *Id.* Finally, the Show Cause Order alleged that Respondent ''no longer maintain[s] a medical practice at [her] registered address'' and that she violated DEA regulations by ''[f]ail[ing] to keep [her] registered address current with the'' Agency. *Id.* (citing 21 CFR 1301.51).

Respondent timely requested a hearing on the allegations; the matter was then placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Christopher B. McNeil (hereinafter, ALJ). ALJ Ex. 2. Following pre-hearing procedures, the ALJ conducted a hearing on August 21 and September 11, 2013, at which both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact and conclusions of law.

On November 12, 2013, the ALJ issued his Recommended Decision. Therein, the ALJ found that the Government had established a *prima facie* case that Respondent's continued registration would be inconsistent with the public interest and that she had failed to rebut the Government's showing. R.D. at 75. The ALJ thus recommended that Respondent's registration be revoked. *Id.*

With respect to factor one—the recommendation of the state licensing authority—the ALJ found that ''Respondent has a history of substantial and material disciplinary action taken by the medical licensing boards of three states'' and that the boards of Florida and New York have ''permanently limit[ed] [her] authority to prescribe controlled substances.'' *Id.* at 72. The ALJ thus concluded that ''maintaining Respondent's unrestricted DEA registration would be inconsistent with the public interest.'' *Id.*

With respect to factor two—Respondent's experience in dispensing controlled substances—the ALJ found ''that despite eighteen years of experience as an emergency medicine physician, Respondent lacked the experience necessary to identify and appropriately respond to drug-seeking behavior.'' *Id.* The ALJ also found that Respondent ''lacked the experience necessary to appreciate the need to contact the DEA when questions arose regarding the need for in-state certification after she relocated her principal place of business or professional practice from New York to New Mexico.'' *Id.* The ALJ thus found that factor two supports a finding that Respondent's continued registration is ''inconsistent with the public interest.'' *Id.*

As for factor four—compliance with applicable laws related to controlled substances—the ALJ found that Respondent violated 21 CFR 1306.04(a) by issuing multiple prescriptions for schedule II controlled substances, including OxyContin and oxycodone to S.C., while in a personal relationship with him, and that she acted outside the usual course of professional practice in issuing the prescriptions and lacked a legitimate medical purpose. R.D. 69–70. The ALJ further found that: (1) Respondent issued the prescriptions ''without maintaining medical records or justifying the prescriptions in violation of 21 CFR 1306.04(a)''; (2) Respondent issued OxyContin prescriptions, which were undated, in violation of 21 CFR 1306.05(a); (3) Respondent issued OxyContin prescriptions, which ''lacked the patient's address, in violation of 21 CFR 1306.05(a)''; (4) Respondent issued multiple prescriptions for schedule II controlled substances which lacked ''the earlier date on which'' the prescription could be filled, in violation of 1306.12(b)(1); and (5) Respondent violated the State of Florida's ''Standards for the Use of Controlled Substances for the Treatment of Pain,'' as well as the State's regulation regarding the adequacy of medical records. *Id.* at 73.

The ALJ further concluded that ''[i]ssuing controlled substance prescriptions in one state under a DEA registration issued for practice in another state is a violation of 21 U.S.C. 822(e) and 21 CFR 1301.12(a) and (b)(3).'' *Id.* at 74. While noting that an Agency regulation exempts an official of various federal agencies and the armed forces from these requirements, the ALJ found that because Respondent was a contract-physician she was not exempt under the regulation. *Id.* Based on his finding that ''[b]etween December 28, 2012 and June 8, 2013, Respondent issued prescriptions for controlled substances from her principal place of business or professional practice in Shiprock, New Mexico,'' while ''using the DEA registration that was issued to her for her practice in New York,'' the ALJ concluded that Respondent violated these provisions. *Id.* The ALJ thus found that factor four supports a finding that Respondent's continued registration ''would be inconsistent with the public interest.'' *Id.*

The ALJ further found that factor five—such other conduct which may threaten public health and safety—supports the conclusion that Respondent's continued registration ''would be inconsistent with the public interest.'' *Id.* at 74–75. As support for his conclusion, the ALJ found that Respondent lacked ''candor with the'' Agency, that she ''willful[ly] fail[ed] to determine her obligations when relocating from New York to New Mexico,'' and that she ''refus[ed] to cooperate with the [Agency's] inquiry regarding liability issues in her renewal application.'' *Id.* at 75.

Finally, the ALJ found that Respondent ''failed to affirmatively acknowledge specific acts of improper prescribing,'' as well as that she had ''failed to establish by credible and substantial evidence effective steps taken in remediation as would warrant a sanction other than revocation.'' *Id.* The ALJ thus found that ''the Government has established cause to revoke Respondent's . . . registration.'' *Id.*

Both parties filed exceptions to the ALJ's Recommended Decision. Having

considered the record in its entirety, including the parties' exceptions, I conclude that the Government has established that granting Respondent's application would be inconsistent with the public interest and that Respondent has failed to rebut the Government's *prima facie* case. Accordingly, I will adopt the ALJ's recommendation that I deny any pending application for a new registration. I make the following factual findings.

Findings

Respondent's Licensure Status, the State Board Actions, and Registration Status

Respondent is a board-certified physician in emergency medicine. *See* RX A, at 2. Respondent completed her residency in emergency medicine in 1998 and since then has worked at hospitals in New Jersey, Pennsylvania, New York, Florida, and New Mexico. *Id.* at 1–2. While Respondent holds an active license in New York, Florida, and Pennsylvania, she has been disciplined by the medical boards of each of these States, based on her prescribing of controlled substances to S.C., with whom she had a personal relationship while she was practicing in Florida. *See* GX 9, 11, 12, 13.

In the Settlement Agreement she entered into with the Florida Board, ''Respondent neither admit[ted] nor denie[d] the allegations of fact contained in the [Board's] Administrative Complaint.'' GX 8, at 2. However, she did ''admit[] that the facts alleged in the Administrative Complaint, if proven,[1] would constitute violations of Chapter 458, Florida Statutes, as alleged in the Administrative Complaint.'' *Id.*

More specifically, the State alleged that ''Respondent failed to meet the prevailing standard of care in regard to Patient S.C. in one or more of the following ways.'' GX 7, at 9. The State alleged that Respondent ''fail[ed] to adequately assess and/or diagnose Patient S.C. with chronic pain,'' ''fail[ed] to appropriately treat . . . S.C.,'' ''fail[ed] to use alternative treatment methods,'' ''prescrib[ed] S.C. an inappropriate and/or excessive quantity of [R]oxicodone, oxycodone, and/or OxyContin,'' ''fail[ed] to obtain laboratory results and/or diagnostic scans to collaborate [sic] or monitor S.C.'s condition,'' and ''fail[ed] to properly monitor and/or follow up on . . . S.C.'s condition.'' *Id.* at 9–10 (citing Fla. Stat. § 458.331(1)(t)).

The State further alleged that ''Respondent prescribed [R]oxycodone, oxycodone, and/or OxyContin to Patient S.C., in an inappropriate manner and/or in excessive quantities, which is outside the course of Respondent's professional practice.'' *Id.* at 11–12. The State thus alleged that Respondent violated Florida law ''by prescribing controlled substances other than in the course of her professional practice.'' *Id.* at 12 (citing Fla. Stat. § 458.331(1)(q)). Finally, the State alleged that Respondent violated Florida law by ''fail[ing] to maintain complete medical records that justify the course of treatment [that she] provided to . . . S.C.'' *Id.* at 10; *see also id.* at 11 (citing Fla. Stat. § 458.331(1)(m)).

Pursuant to the Settlement Agreement she entered into with Florida, Respondent received a letter of concern, was fined $5,000, and was required to reimburse the Florida Department of Health's costs of investigating and prosecuting the matter in an amount between $5,587.55 and $6,587.55. GX 8, at 2–3. Respondent was also required to perform 25 hours of community service, as well as to attend ten (10) hours of Continuing Medical Education (CME) in ''Appropriate Prescribing Practices'' and two (2) hours of CME in ''Proper Medical Record Keeping.'' *Id.* at 4–5. Finally, the Board prohibited Respondent from ''prescrib[ing] controlled substances to persons with whom [she] is in a personal, familial or non-familial, relationship.'' GX 8, at 2–5.[2]

As of the hearing, Respondent was working as a contract physician at the Northern Navajo Medical Center, a facility of the Indian Health Service (IHS), which is located in Shiprock, New Mexico; Respondent has worked at this hospital since August 2012. RX A, at 1; Tr. 163. Respondent is not licensed to practice medicine by the State of New Mexico. RX A, at 2.

Respondent also held DEA Certificate Registration BM8059102, pursuant to which she was authorized to dispense controlled substances in schedules II through V, at the registered location of Olean General Hospital, 515 Main St., Olean, New York 14760. GX 20, at 1. This registration had an expiration date of January 31, 2015. *Id.*

On December 31, 2014, Respondent applied for a renewal of this registration and sought to change her registered location to the Northern Navajo Medical Center, P.O. Box 160, Highway 491 North, Shiprock, New Mexico. *See* Government's Notice of Respondent's Filing of Renew Application and Change of Address Request, at 6–8. Thereafter, on January 23, 2015, Respondent submitted a letter seeking to change her registered location to Doctors Express Urgent Care, 1444 W. Passyunk Ave, Philadelphia, PA. *Id.* at 8.

However, at the time Respondent submitted her renewal application, the Agency had issued the Order to Show Cause. A DEA regulation applicable to an applicant who has been served with an Order to Show Cause provides:

> In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

21 CFR 1301.36(i).

Respondent did not file her renewal application more than 45 days before her registration was due to expire and thus her registration was not automatically extended pending the issuance of this Decision and Final Order. Based on my review of the record in this matter, I further conclude that the extension of her registration would be ''inconsistent with the public health and safety.'' *Id.* Accordingly, I hold that her registration expired on January 31, 2015. *See Ralph J. Chambers,* 79 FR 4962 (2014) (citing *Paul H. Volkman,* 73 FR 30630, 30641 (2008)). However, I conclude that her application remains pending before the Agency. *See id.*

The Allegations That Respondent Unlawfully Prescribed Controlled Substances to S.C.

Between February 2007 and August 2009, Respondent worked as an ER physician at the Physicians Regional Medical Center in Naples, Florida. RX A, at 1. According to Respondent, in August 2007, she met S.C., a budding reality TV star, when he came to the ER

[1] These allegations largely track what the Government alleged and I find proved in this matter. *See* GX 7, at 1–7.

[2] Based on the Florida Board's action, New York State Board for Professional Medical Conduct imposed a ''Censure and Reprimand,'' prohibited her from prescribing to persons with whom she is in a relationship, placed her on probation for three years, and fined her $1500. GX 11. Also, based on the actions of the Florida and New York Boards, the Pennsylvania State Board of Medicine imposed a $5000 civil penalty on her. GX 13.

with a broken hand and she treated him by splinting his hand and prescribing Percocet to him.[3] Tr. 207–08. A week or two later, Respondent was told by an x-ray technician that S.C. worked for Ticket Master and that he was hosting a fund-raising event at a local coffee shop. *Id.* at 211. Respondent went to the coffee shop to see if she could get tickets from S.C for an upcoming football game. *Id.* Thereafter, Respondent and S.C. entered into a personal relationship. *Id.*

Respondent did not prescribe any controlled substances to S.C. until January 18, 2008, when she wrote him a prescription for 90 tablets of oxycodone 30mg. GX 1, at 1. Respondent did not recall exactly where she wrote the prescription (this having occurred at either her home or S.C.'s) but acknowledged that it was not at either of the hospitals (both of which were located in Fort Myers, Florida) which were listed on the prescription form she used. Tr. 213. When asked whether she performed a physical exam on this occasion, Respondent testified:

> I conducted a physical exam. I don't know if it was on that specific date, but prior to me issuing this prescription, I had gotten to know him very well, and I learned more about his chronic pain syndrome, and he was a smoker. So, I did, I had listened to his heart and lungs many times before.[4]

[3] Over the Government's objection, the ALJ allowed Respondent to testify by telephone from her lawyer's office, rather than in person or by appearing at a DEA facility which has Video-Teleconferencing (VTC) capability. Gov. Exceptions, at 2–6. The Government took exception to this ruling.

While the Government makes no claim that Respondent's counsels acted improperly at any time during her testimony, it is manifest that where a witness is allowed to testify by telephone, notes could be passed to the witness during the testimony without the ALJ or Government Counsel ever being aware of this. So too, the use of telephone testimony raises a greater risk that during breaks in the proceeding, the witness could discuss her testimony with others.

I find the Government's exception to be well taken. This is not to say that every witness must testify either in person or by VTC. However, a respondent will invariably be a highly important, if not the most important witness in a proceeding, and thus, under no circumstance is it proper to allow a respondent to testify by telephone. As for other witnesses, with the exception of a witness who testifies only as to the authentication or foundation of proposed exhibits, the taking of testimony by telephone is disfavored and may be used only upon a showing that exceptional circumstances exist and that the failure to obtain a witness's testimony will result in a denial of due process.

[4] At several other points in her testimony, Respondent described the physical exam as listening to S.C.'s heart and lungs, and made no reference to any other tests she did. For example, when asked ''How often did you perform a physical examination of S.C. in the course of issuing prescriptions to him?,'' she answered:

> I can't say for certain, but I did listen—like I said, I mean, he was a smoker, so I did listen to his . . . heart and lungs, which is one of the main exams on a physical, on a regular basis, because I usually had my stethoscope with me, and you know, whenever I saw him, I just did a general, you know—was able to generally assess his overall health and well-being, just from interacting with him and speaking to his family.

Tr. 244–45. Notably, only after Respondent was asked by the Government if she specifically examined S.C.'s back and neck did she assert that she palpated him ''along the spine and surrounding areas.'' *Id.* at 263.

Id. When then asked by the Government if subsequent to the August 2007 ER visit, she ''had met with him in a clinical capacity prior to'' issuing the January 18 prescription, Respondent answered:

> I don't understand what you mean, clinical capacity. We developed a friendship, and we . . . were involved in a relationship, at that time. So, you know, I had gotten to know him personally. I knew his family, and you know, we had discussed a lot of his medical conditions, I had discussed with him and his family.

Id.

When then asked where she had conducted her physical examinations of S.C., Respondent stated ''[e]ither by my home or his home.'' *Id.* 215. When asked how she had assessed his pain level, Respondent testified: ''Just by asking him and just seeing how his overall well-being was.'' *Id.* at 215–16. Respondent then asserted that S.C. had told her that ''he was in excruciating pain. He couldn't function without being on his pain medicine.'' *Id.* at 216. Respondent admitted, however, that she did not create ''any formal records'' for the prescriptions. *Id.* Nor did she create a written treatment plan for S.C. *Id.* at 218. She further admitted that she did not order any additional tests, because she was ''work[ing] outside [the] emergency department'' and that ''that was already conducted by his pain management specialist.'' *Id.* at 232–33.

When then asked what was the medical purpose of the prescription, Respondent testified that S.C. ''was in a pain management clinic, up until about November or December of 2007, and he was transitioning. He said he lost his medical insurance. He was trying to find a new treating physician for his chronic pain.'' *Id.* at 216. According to Respondent, S.C. told her that he had back fractures and neck injuries from doing acting stunts and motorcycle racing. *Id.* at 246.

Respondent further explained that S.C. was ''starting to do a lot of traveling at that time'' as he was auditioning for various ''acting jobs,'' and that he asked her if she could help him out until he could get insurance and ''see another provider.'' *Id.* at 216–17; 234. According to Respondent, she looked at the labels of the prescriptions S.C. had received from the pain management specialist who had previously treated him and ''then copied the prescription off the bottles.'' *Id.* at 217. Respondent further denied having made a diagnosis of chronic pain, stating that ''that was established already'' by S.C.'s ''prior physician[].'' *Id.* at 229.

While Respondent admitted that she ''was not familiar with treating chronic pain,'' she did not contact the pain management doctor who had previously treated S.C., explaining that S.C. had told her that ''he was no longer involved with his care, and he did not wish to . . . see that physician any longer.'' *Id.* at 218–19. Respondent explained that she relied on what S.C. and his family had told her, as well as some of his medical records, although she did not look through all of his records. *Id.*

When then asked how she knew that his prior physician would have continued S.C. on controlled substances, Respondent answered that ''[w]hen you're on controlled substances you just don't stop . . . you have to go through either a weaning process or—that's why it requires a specialist to . . . continue treating once you're up to a certain number of high dose pain medication.'' *Id.* at 234–35. She also claimed that his family told her that S.C. did not have a history of substance abuse. *Id.* at 232. Respondent acknowledged that it ''was [her] error'' to accept S.C.'s word instead of contacting his prior physician. *Id.* at 219. She further maintained that she trusted S.C., that ''his family backed up his story,'' and that she had ''no reason to believe at the time'' that she ''was being deceived.'' *Id.* at 220. She also stated that she was in ''a very good friendship'' with S.C. and that over time, she ''lost the physician/patient relationship'' and ''was not objective.'' *Id.*

On or about February 7, 2008, Respondent wrote S.C. three undated prescriptions for OxyContin 80mg.[5] *See* GX 1, at 3, 5, and 7. The prescriptions, which authorized the dispensing of 100 dosage units q12h, 200 dosage units q8h, and 100 dosage units q8h, all lacked S.C.'s address. *See id.* Moreover, none of the prescriptions listed ''the earliest date on which'' it could be filled as required by 21 CFR 1306.12(b)(1)(ii). *See id.* Based on Respondent's dosing

[5] The prescriptions were written on the prescription forms of the Physicians Regional Medical Center and were sequentially numbered from 007424 through 007426. GX 1, at 3–7. While the prescriptions were undated, the evidence shows that prescription number 007425 for 200 OxyContin 80mg. was filled on February 7, 2008. *Id.* at 4.

instructions, the prescriptions provided S.C. with 149 days' supply of the drug.

The evidence further shows that S.C. filled the prescription for 200 tablets at a cost of $2,328.00. *Id.* at 4. Yet Respondent repeatedly claimed that she ''was trying to offer a short-term, fix for his situation'' because ''[h]e was short on money,'' Tr. 236, even though he was working at a local radio station. *Id.* at 238–39. Respondent further claimed that S.C. had told her that an office visit with a pain management specialist cost ''about $400 or $500'' not counting the cost of any prescriptions, and that she trusted what he told her. *Id.* at 239. She also claimed that she was unfamiliar with the cost of various drugs. *Id.* at 237.

Regarding the OxyContin 80mg prescriptions, Respondent stated that she had ''probably not'' physically examined S.C. ''because [she] had done it in the past.'' Tr. 231. Respondent then claimed that she had assessed S.C.'s pain level by ''his appearance and how he would tell me he was feeling.'' *Id.* Respondent did not create a record for the prescriptions. *Id.* at 231–32.

Notwithstanding the quantity of drugs provided by these prescriptions, on or about March 10, 2008,[6] Respondent issued S.C. three more prescriptions, each of which was for 450 oxycodone 30mg, with a dosing instruction to take up to 15 tablets per day ''as needed for pain.'' GX 1, at 9, 11, and 13. As before, the prescriptions were not dated, did not include S.C.'s address, and lacked the earliest date on which they could be filled.[7] *Id.* The evidence further shows that S.C. filled each of the prescriptions on March 10, 2008, and paid $280.74 for each one. *Id.* at 10, 12, and 14.

Here again, Respondent could not state ''for certain'' that she performed a physical exam on S.C. when she issued these prescriptions. Tr. 244. However, Respondent testified that she issued the prescriptions at S.C.'s home because ''this was when he was getting ready to go to Los Angeles for his acting job.'' *Id.* at 245. She also testified that she assessed S.C.'s pain level by ''[j]ust interacting with him, asking how he was feeling,'' and by S.C. letting her know whether he ''was having a good day or a bad day.'' *Id.* at 245–46.

As for why she did not date the prescriptions and include S.C.'s address, Respondent testified that:

> I know I was very distracted when I would write the prescriptions, because it was either at his home or my home, and he had a three-year-old child. It was usually—it was usually at his home.
>
> He had a three-year-old, or a four-year-old, at the time. There were two dogs, a monkey in the house. There was a loud . . . his father was hard of hearing, so . . . the TV was on very loud, and it was a very distracting environment. I don't . . . you know, I cannot explain exactly why the date wasn't on them, because I know that the date needs to be on them. So, I can just . . . go back in my mind and know that it was very distracting.

Tr. 222. Later in her testimony, Respondent explained that S.C. had two German Shepherds, and that there was also a mutt (which he apparently did not own) that was allowed to come into the house. *Id.* at 340. And then there was the monkey, which according to Respondent, was ''three or four feet'' tall and ''dangerous,'' but was nonetheless allowed to run free in the house. *Id.* at 340–41.

As for why she had written the three oxycodone 30mg prescriptions which were filled on March 10, Respondent offered the following testimony:

> I'm just trying to recall, because also, on multiple times, I was told the prescriptions were either lost or destroyed by the animals in the house, by the monkey . . . the monkey was . . . he would take the pill bottle, open it, and throw it in the pool, or you know, various different times . . . I was told that they were lost or stolen or left behind at the different hotels he was staying at.
>
> I just can't—you know, it's unclear, which set of prescriptions it may have occurred with, but it happened on numerous occasions, which is why there is [sic] a number of prescriptions.

Id. at 240–41. Respondent further maintained that S.C.'s stories regarding the monkey were believable because he ''would try to rip up my clothes and my shoes and he would take anything and just try to shred it.'' *Id.* at 341.

As a further reason for why she wrote the multiple prescriptions, Respondent explained that there were occasions in which S.C. would call and tell her that the pharmacy was either ''out of stock for a particular brand name or particular dosage.'' *Id.* at 241; *see also id.* at 245 (''this was around the time where he told me the prescriptions were being destroyed or lost or left at one pharmacy or another, because they weren't in stock'').

At this point, S.C. apparently left the area and went off to pursue his acting career. Tr. 227. As for why she had issued the multiple OxyContin prescriptions, Respondent testified that S.C. had told her that he was going to be in Los Angeles for ''three to six months'' to film a show for MTV and ''he wanted to make sure he didn't run out of pain medication while he was there.'' *Id.* She also testified that she was unaware that she could write ''do not fill until a certain date'' on the prescriptions. *Id.*

Following his appearance on the MTV show and his return to Florida (sometime around October 2008), S.C. was ''getting a lot of opportunities to travel, to do commercials, to do auditions,'' and contracts. *Id.* at 249. According to Respondent, S.C. asked her if she could continue to help him out ''because he was doing a lot of travelling'' and it was hard for him to find ''a physician in a different state.'' *Id.* Respondent agreed to do so and resumed prescribing to him. In her testimony, Respondent did not explain why given S.C.'s success, he could not afford health insurance and find a pain management specialist.

On January 20, 2009, Respondent resumed prescribing to S.C., issuing him a prescription for 40 Roxicodone 30mg, with a dosing instruction of TID or one tablet, three times a day. GX 1, at 15. Between February 3 and March 6, 2009, Respondent issued S.C. the following prescriptions, all of which had a dosing instruction of TID, or one tablet three times a day:

Date	Drug and quantity
2/3/09	90 Roxicodone 30mg.
2/3/09	90 Roxicodone 30mg.
2/9/09	90 Roxicodone 30mg.
2/9/09	90 Roxicodone 30mg.
2/9/09	90 Roxicodone 30mg.
2/10/09	90 Roxicodone 30mg.
2/10/09	90 Roxicodone 30mg.
2/10/09	90 Roxicodone 30mg.
2/20/09	90 Roxicodone 30mg.
2/20/09	90 Roxicodone 30mg.
3/6/09	90 Roxicodone 30mg.
3/6/09	280 Roxicodone 15mg.

See GX 1, at 17–35.

Based on Respondent's dosing instruction of TID, a single oxycodone 30mg prescription would have provided S.C. with a thirty-day supply; thus, a single prescription issued on February 3rd, should have lasted him through March 5th.[8] However, the prescriptions Respondent wrote S.C. between February 3 and March 6 authorized the dispensing of 990 tablets of oxycodone 30mg, an eleven-month supply; the prescription for 280 oxycodone 15mg

[6] Here again, the prescriptions were written on the forms of the Physicians Regional Medical Center and were numbered 009325, 009326, and 009329. GX 1, at 9, 11, and 13.

[7] If the drugs were actually taken at fifteen tablets per day, the prescriptions would have provided an additional 90 days' supply.

[8] It is acknowledged that the pharmacy which filled one of the February 3, 2009 prescriptions dispensed only 54 tablets on that date. GX 1, at 17–18. However, even if S.C. was unable to obtain the remaining 46 tablets from the pharmacy within 72 hours as required by DEA's regulation, *see* 21 CFR 1306.13(a), Respondent did not explain why it was necessary to write S.C. a second prescription on that date for a full 90 tablets.

provided S.C. with more than another 1.5 month's supply of the drug.

As for why Respondent issued multiple prescriptions on February 3, 2009, Respondent testified that ''that they were not in stock at the particular pharmacy that he initially went to,'' so S.C. ''called me or told me that he had left the prescription [and] needed a new one, so he could bring it to whatever other pharmacy he was using.'' Tr. 251. However, the evidence shows only that the pharmacy partially filled the prescription in the amount of 54 tablets. GX 1, at 17. Respondent then asserted that she ''never realized that [the prescriptions] were being filled'' and that she ''thought they were either being destroyed'' or ''not being filled at all.'' *Id.* at 251–52. However, Respondent never called any of the pharmacies S.C. used and ''never got word from the pharmacist that they were being filled.'' *Id.* at 252; *see also id.* at 241 (''I was never phoned by any of these pharmacists, telling me that these prescriptions were being filled. I had no idea, because I did not have any records of the number of prescriptions I wrote.'').

Respondent then testified that she did not find S.C.'s claim suspicious because in the ER, ''there were multiple times where patients would'' complain that a pharmacy would not have a particular narcotic or dosage. *Id.* at 252. When asked why the pharmacies would not have just returned the prescriptions to S.C. if the drug was out of stock, Respondent testified that she thought ''that is how they operated down there'' and added that she ''was new to the State.'' *Id.* at 253. However, Respondent has been licensed in Florida since August 2004 and had worked there since at least December 2004.[9] RX A, at 1–2. Respondent could not recall whether she had ever had another patient ask for a replacement prescription claiming that a pharmacist had said a drug was out of stock and yet kept the prescription. *Id.* at 254–55.

Regarding the February 3, 2009 prescriptions, Respondent again could not recall if she had done a physical examination. *Id.* at 255. While Respondent claimed that she had assessed S.C.'s pain level in the same manner as before, she admitted that she did not create a medical record or a written treatment plan. *Id.* at 255–56. Nor could she specifically recall if, on this occasion, she had discussed the risks and benefits of using controlled substances. *Id.* at 256.

As for why she issued three prescriptions on February 9, 2009 instead of a single prescription for 270 tablets, Respondent answered that ''[t]he particular pharmacy . . . didn't have that quantity in stock'' so she split the prescriptions. *Id.* at 260–61. Again, Respondent could not recall if she had conducted a physical exam on S.C. on this date, *id.* at 262, and acknowledged that she did not create a medical record for these prescriptions or a written treatment plan. *Id.* at 264. She claimed, however, that she had assessed his pain level in the same manner as before, and that she had discussed the risks and benefits of using controlled substances on this occasion. *Id.* at 265, 273. Respondent further testified that she used the same approach in assessing S.C.'s need for oxycodone for all of the prescriptions (other than the one she wrote during his ER visit). *Id.* at 274.

Moreover, when asked why she had issued these three prescriptions given that she had issued two similar prescriptions only six days earlier, Respondent testified that she believed that S.C. had begun having seizures and was becoming forgetful. *Id.* at 266. Continuing, Respondent testified that: ''I believe he was—he may have been having seizures, which I found out in May, when I went over [to] his house . . . and he was acting confused . . . and he was in a post-seizure state . . . and I . . . told [his] mom that he was having seizures.'' *Id.* at 266–67. However, Respondent then testified that ''this was actually in—it was around May.'' *Id.* at 267.[10] Still later in her testimony, Respondent explained that ''it was my understanding that he was being truthful and they were truly lost or misplaced or destroyed or left at the pharmacist and never filled. *Id.* at 274.

The evidence shows that the two February 3 prescriptions were filled on February 3 and 5, and that three February 9 prescriptions were filled on February 9, 11, and 16. GX 1, at 18, 19, 21, 23, and 25. So too, the evidence shows that the three prescriptions Respondent wrote on February 10, were filled on February 13, 14, and 17; the two prescriptions she wrote on February 20, were filled on February 21 and 25; and the two prescriptions she wrote on March 6, were filled on March 6 and 9. *See id.* at 26–35.

On questioning by her counsel, Respondent testified that she did not become aware that S.C. had been arrested for doctor-shopping ''until after the case was already over.'' Tr. 348–49. On further questioning by her counsel, and inconsistent with her earlier testimony that the last prescription she wrote for S.C. was in August 2009, *id.* at 267, Respondent denied having written S.C. any more prescriptions ''after the last emergency room visit.'' *Id.* at 349. Yet the evidence shows that S.C.'s last ER visit was on July 3, 2009, *see* GX 15, and the evidence further shows that on July 31, 2009, Respondent issued S.C. a prescription for 30 Roxicodone 15mg. GX 1, at 36.

The evidence further showed that Respondent and S.C. drove to a Publix pharmacy where the prescription was filled. Tr. 97–98. Respondent remained in the car while S.C. went in to the store to fill the prescription. *Id.* at 98. According to the pharmacist, ''S.C. was very chatty and used a lot of small talk'' about being on a reality TV show ''as if he was trying to distract'' her. *Id.* at 97, 105. After the pharmacist handed the filled prescription to S.C., he ''eagerly took the prescription . . . and quickly headed to the back of the store.'' *Id.* at 97. Finding S.C.'s behavior suspicious, the pharmacist called the hospital ER to verify the prescription and was told that Respondent was under investigation and was asked to fax the prescription to the ER and to call the sheriff. *Id.* at 101. The pharmacist then asked an assistant store manager to go into the bathroom and check on S.C. GX 6.

While the pharmacist was still on the phone, S.C. reappeared at the pharmacy counter and asked if there was a problem with the prescription. Tr. 98. The pharmacist told S.C. that she ''need[ed] to clarify the prescription and'' asked him if she could have it back; S.C. complied. *Id.* The pharmacist then counted the tablets and found that two were missing. *Id.* S.C. then told the pharmacist that ''if there are any questions regarding this prescription the doctor is my girlfriend and she is out in the car.'' *Id.*

The pharmacist then proceeded to the parking lot and found Respondent in a car; the pharmacist asked Respondent for her driver's license, and after determining that it was Respondent, asked if she had written the prescription. *Id.* Respondent ''said 'yes.''' *Id.* The pharmacist then returned to the pharmacy and found that ''S.C. was still there''; S.C. ''was very anxious and ask[ed] if he was going to be arrested.'' *Id.* The pharmacist went back inside the pharmacy, called the ER again and verified that Respondent was still employed there. Id. at 98–99. After being told that she was, the pharmacist gave the prescription back to S.C. and called the sheriff. *Id.* at 99.

[9] Prior to working in Naples, Respondent worked at a hospital in Fort Myers. RX A, at 1–2.

[10] The evidence shows that S.C. was hospitalized for seizures on two occasions, May 28, 2009, and July 3, 2009. *See* GX 15 & 16.

Respondent testified that she still believes that the prescriptions she issued S.C. were within the usual course of professional practice and for a legitimate medical purpose. *Id.* at 277. However, Respondent then stated that ''[i]n hindsight . . . my judgment was impaired because of the relationship I had with the individual,'' the prescriptions ''were not within . . . the standards of my medical practice.'' *Id.* Yet Respondent later asserted that she ''was definitely manipulated and taken advantage of. I was victimized.'' *Id.* at 350.

Respondent also testified that at the time she wrote the prescriptions she believed they were ''medically necessary'' because there was a ''prior diagnosis of chronic pain.'' *Id.* And when asked whether, ''[s]itting here today, knowing what you do today, do you still believe that they were medically necessary at the time?'' Respondent answered: ''[y]es.'' *Id.*

Respondent did acknowledge that she violated Florida's regulations by failing to ''keep proper documentation of each visit.'' *Id.* at 351. She then maintained that through the continuing medical education course she was required to take under the Florida Board's Order, ''I realize that will never happen again.'' *Id.*[11]

[11] During its examination of Respondent, the Government asked her if her attorney had spoken ''with a DEA representative about whether [she] needed to obtain a DEA registration in New Mexico.'' Tr. 199. Respondent's counsel objected, asserting that this was a privileged communication and the ALJ sustained the objection. *Id.; see also* R.D. at 39 (''I sustained [Respondent's] objection to the question, finding that the response was likely to call for the disclosure of information protected by the attorney client privilege. I continue to believe the sought-after response would likely have called for [Respondent] to disclose what Mr. Leider [her attorney] did or did not tell her in the course of his representation of her.'').

Notably, in his Recommended Decision, the ALJ did not cite a single case to support his ruling and I conclude that his ruling was erroneous. ''The privilege 'protects only those disclosures necessary to obtain informed legal advice which might not have been made absent the privilege.' '' *In re Walsh,* 623 F.2d 489,494 (7th Cir. 1980) (quoting *Fisher* v. *United States,* 425 U.S. 391, 403 (1976)). Moreover, '''when an attorney conveys to his client facts acquired from other persons or sources, those facts are not privileged.' '' *See In re Sealed Case,* 737 F.2d 94, 100 (D.C. Cir. 1984)) (quoting *Brinton* v. *Department of State,* 636 F.2d 600, 604 (D.C. Cir. 1980) (footnote omitted)). Because the question did not ask Respondent to disclose what facts she had communicated to her lawyer or the legal advice she received from her lawyer, the ALJ erred in barring the testimony. *See United States* v. *DeFazio,* 899 F.2d 626, 635 (7th Cir. 1990) (holding that where attorney ''testified only to what [an] IRS agent said to him, and that he later relayed those statements to [defendant,] [t]he content of this testimony is unprivileged because it did not reveal, either directly or implicitly, legal advice given [defendant] or any client confidences'').

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied ''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. § 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)).[12]

In this matter, I have considered all of the factors and conclude that the Government's evidence with respect to factors two (Respondent's experience in dispensing controlled substances), four (Respondent's compliance with applicable laws related to controlled substances), and five (such other conduct) establishes that she ''*has committed such acts* as would render [her] registration under section 823 of this title inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). While I do not adopt the ALJ findings that Respondent violated federal law by issuing prescriptions while working as a contract physician at the Northern Navajo Medical Center without being registered in New Mexico, I find that Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescriptions to S.C. Notwithstanding her claim that her conduct in prescribing to S.C. is an aberration, I find it to be egregious. And based on her insistence that even now, she still believes these prescriptions were legitimate, I conclude that Respondent has failed to produce sufficient evidence to demonstrate why she should be entrusted with a registration.[13]

[12] ''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.

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

To effectuate the dual goals of conquering drug abuse and controlling both the legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except

[13] I acknowledge that Respondent remains licensed in various States, including Pennsylvania, the State where she seeks registration and therefore meets the CSA's prerequisite for holding a practitioner's registration in that State. *See* 21 U.S.C. 823(f) (''The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'').

However, the possession of state authority '''is not dispositive of the public interest inquiry.''' *George Mathew,* 75 FR 66138, 66145 (2010), *pet. for rev. denied Mathew* v. *DEA,* No. 10–73480, slip op. at 5 (9th Cir., Mar. 16, 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009). As the Agency has long held, ''the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Mortimer Levin,* 57 FR 8680, 8681 (1992). Accordingly, this factor is not dispositive either for, or against, the granting of Respondent's applications. *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 for factor three, there is no evidence that Respondent has been convicted of an offense ''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 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 808 (10th Cir. 2011). 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.*

in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of the closed regulatory system, a controlled substance may only be dispensed upon a lawful prescription issued by a practitioner. *Carlos Gonzalez, M.D.,* 76 FR 63118, 63141 (2011).

Fundamental to the CSA's scheme is the Agency's longstanding regulation, which states that ''[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). This regulation further provides that ''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 relating to controlled substances.'' *Id.*

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 *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)); *United States* v. *Alerre,* 430 F.3d 681, 691 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006) (stating that the prescription requirement likewise stands as a proscription against doctors acting not ''as a healer[,] but as a seller of wares'').

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Paul H. Volkman,* 73 FR 30629, 30642 (2008), *pet. for rev. denied,* 567 F.3d 215, 223–24 (6th Cir. 2009); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR at 30642.

In Florida, a physician is barred from ''prescribing, dispensing, administering, mixing, or otherwise preparing . . . any controlled substance, other than in the course of the physician's professional practice.'' Fla. Stat. § 458.331(q). The statute further explains that ''prescribing, dispensing . . . or otherwise preparing . . . controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice.'' *Id.; see also* Fla. Stat. § 893.05(1) (''A practitioner, in good faith and in the course of his or her professional practice only, may prescribe . . . a controlled substance[.]'').

As found above, while Respondent neither admitted nor denied the factual allegations of the Administrative Complaint which was filed against her by the Florida Board, she did admit that if those facts were proven, they would establish violations of the Florida Statutes as alleged in the Complaint, including not only that she failed to meet the prevailing standard of care, but also that she prescribed controlled substances other than in the course of her professional practice. *See* GX 8, at 2 (citing Fla. Stat. Chap. 458). In this proceeding, the material facts set forth in the Board's complaint have been proven.

Moreover, under the Florida Board of Medicine's then-existing Standards for the Use of Controlled Substances for the Treatment of Pain:

> A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatment for pain, underlying or coexisting disease 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.

Fla. Admin R. 64B8–9.013(3)(a).[14]

The State's Standards also required a physician ''to keep accurate and complete records to include, but not be limited to: 1. [t]he medical history and physical examination, including history of drug abuse or dependence, as appropriate; 2. [d]iagnostic, therapeutic, and laboratory results; 3. [e]valuations and consultations; 4. [t]reatment objectives; 5. [d]iscussion of risks and benefits; 6.[t]reatments; 7. [m]edications (including date, type, dosage, and quantity prescribed); 8. [i]nstructions and agreements; and 9. [p]eriodic reviews.'' *Id.* at 64B8–9.013(f).

While Respondent asserted that she did a physical examination and that she knew ''about [S.C.'s] chronic pain syndrome'' from talking to both him and his parents, Tr. 214, the fact remains that she failed to document and maintain any medical records to support the prescriptions. Indeed, she specifically denied having diagnosed S.C. as having chronic pain, asserting that the diagnosis ''was established already'' by S.C.'s ''prior physician,'' *id.* at 229, and that she wrote the prescriptions by ''cop[ying] the prescription off the bottles'' S.C. showed her. *Id.* at 217. Yet, notwithstanding that those prescriptions were legally required to contain the name of the prescribing physician, *see* 21 CFR 1306.14(a), and no claim is made that they did not, Respondent never called S.C.'s prior physician.[15]

When then asked how she knew if Respondent's prior physician would have continued S.C. on narcotic controlled substances, Respondent replied that ''[w]hen you're on controlled substances you just don't stop . . . you have to go through either a weaning process—that's why it requires a specialist to . . . continue treating once you're up to a certain number of high dose pain medication.'' Tr. 234–35. Unexplained by Respondent is why she wrote S.C. prescriptions totaling 400 dosage units of OxyContin 80mg, given her testimony that a patient who is on a ''high dose [of] pain medication,'' ''requires a specialist,'' *id.,* which she is not, as well as her admission that she ''was not familiar with treating chronic pain.'' *Id.* at 218.

Moreover, Respondent repeatedly provided S.C. with prescriptions which enabled him to obtain schedule II controlled substances including OxyContin 80mg and oxycodone 30mg, drugs which are among the most highly abused and diverted controlled substances, in quantities which greatly exceeded both her own dosing instructions and DEA regulations. As found above, on or about February 7, 2008, Respondent issued S.C. prescriptions for 400 dosage units of OxyContin 80mg. Putting aside that Respondent wrote two different dosing instructions on the three prescriptions

[14] This version of the Standards was promulgated in 1999, amended in both 2002 and 2003, and remained in effect until a new version of the Standards was promulgated in 2010.

[15] Respondent also testified that she looked at S.C.'s medical records. Thus, she clearly had available to her information as to Respondent's prior physician. While Respondent testified that S.C. was no longer seeing this physician because ''he lost his medical insurance,'' *id.* at 216, as well as that ''he did not wish to . . . see that physician any longer,'' *id.* at 219, because she never called the physician, she had no idea if S.C. had told her the truth or if his prior physician had discharged him.

(one prescription calling for one tablet every 12 hours, the other two calling for one tablet every eight hours), these dosing instructions provided S.C. with more than a 149-day supply of the drug.[16] However, under DEA regulations, Respondent could lawfully prescribe a maximum of a 90-day supply. *See* 21 CFR 1306.12(b)(1).

Notwithstanding that she had written the three OxyContin prescriptions only one month earlier and that if Respondent took the drugs in accordance with her dosing instructions, he would have had at least a four-month supply of the drug remaining, on or about March 10, 2008, Respondent wrote S.C. three more prescriptions. Each of these prescriptions authorized the dispensing of 450 dosage units of oxycodone 30mg, and, with a dosing instruction of up to 15 tablets or 450 milligrams per day, provided S.C. with an additional thirty-day supply. By comparison, the OxyContin prescriptions provided a daily dose of 160 or 240mg per day.

Assuming S.C. took the full fifteen tablets per day, the three March 10, 2008 prescriptions provided S.C. with an additional 90-day supply of oxycodone. Thus, based on her own dosing instructions, the February and March 2008 prescriptions provided S.C. with nearly an eight-month supply of oxycodone.

As for why she issued these six prescriptions, Respondent offered multiple explanations. First, regarding the OxyContin prescriptions, Respondent testified that S.C. had told her he was going to be in Los Angeles for three to six months filming a show for MTV and did not want to run out of medication. Tr. 227. Second, she asserted that S.C. told her that the monkey ''would take the pill bottle, open it, and throw it in the pool.'' *Id.* at 240–41. Third, she claimed that S.C required additional prescriptions because the pharmacy was either out of stock of the particular brand or dosage, or that he left the prescription at the pharmacy. *Id.* at 241 & 245.

None of these explanations provides a persuasive justification that mitigates her misconduct. As for the first one, surely the Los Angeles area has an ample supply of pain management specialists who could have treated S.C. were he to run out of medication. Moreover, even if S.C. was a legitimate patient, given her testimony that patients on high doses of narcotics require a specialist to continue their treatment, Respondent's decision to provide S.C. with an eight-month supply of oxycodone when she had no ability to supervise his medication use—not that that ever appeared to be a concern to her—reflects a stunning disregard for her obligations as a prescriber of controlled substances. *See Gonzales,* 546 U.S. at 274 (''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse'').

As for the explanation that S.C. told her that he needed additional prescriptions because the pharmacies were out of either the branded medication (such as OxyContin) or the particular dosage strength, or that he left the prescription at the pharmacy, Respondent never called any of the pharmacies to verify S.C.'s claims. Tr. 241 & 252. Moreover, even if the pharmacies S.C. used were out of OxyContin, Respondent offered no explanation as to why, in a one-month period, she increased S.C.'s daily dose of oxycodone from either 160 or 240mgs per day (depending upon which prescription she wrote) to 450mgs per day.

Then there is Respondent's testimony that she believed S.C. when he told her that his pet monkey was opening his pill bottles and throwing the drugs in the pool. While Respondent initially offered this far-fetched story to explain why she had written the three undated oxycodone 30mg prescriptions, all of which were filled on the same date (March 10, 2008) and bore serial numbers suggesting they were all written in close temporal proximity, she offered no testimony to the effect that she had asked to see the pill bottles to determine if the prescriptions had actually been filled. Moreover, Respondent eventually backtracked on this testimony, explaining that it was ''unclear[] which set of prescriptions it may have occurred with.'' Tr. 241. Accordingly, I find this testimony incredible.

Respondent further violated DEA regulations because she failed to date the three March 2008 prescriptions and include S.C.'s address on them. *See* 21 CFR 1306.05(a) (''All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient . . . .''). As for why she did not date the prescriptions and include S.C.'s address on them, Respondent offered the ludicrous explanation that because of a young child, the dogs, the monkey, and S.C.'s hard-of-hearing father (who required that the volume on the TV be ''very loud''), ''it was a very distracting environment.'' Tr. 222. Yet somehow Respondent was able to include on the prescriptions the drug name, the dosage strength, the quantity, a dosing instruction, as well as her DEA number, printed name and signature. In short, I do not find her testimony credible as to why the prescriptions were undated.

While Respondent apparently ceased her prescribing to S.C. while he was in Los Angeles, she resumed prescribing to him in January 2009, notwithstanding that with his opportunities and the ''contracts he was getting,'' S.C. presumably could have afforded to see a pain management specialist. Tr. 249. As found above, between February 3 and March 6, 2009, Respondent issued S.C. eleven prescriptions for 90 Roxicodone (oxycodone) 30mg. Moreover, on several dates, Respondent issued S.C. two or more prescriptions.

Based on her dosing instruction of one tablet, three times per day, the prescriptions authorized the dispensing of 990 tablets of oxycodone 30mg, or an eleven-month supply of the drug. Moreover, on March 6, Respondent issued S.C. a prescription for 280 Roxicodone 15 mg (also with a dosing instruction of one tablet, three times per day). Thus, between February 3 and March 6, 2009, Respondent's prescriptions provided S.C. with more than a one-year supply of oxycodone if he actually took the drugs as directed.

As for why she issued S.C. the two February 3 prescriptions, Respondent testified that S.C. had called her and told her that the pharmacy he initially went to was out of stock and that he left the prescription there. Once again, Respondent merely accepted S.C.'s story, which was only partially true, and did not call the pharmacy.

While Respondent maintained that she did not find this suspicious because some of her ER patients had complained that a pharmacy would not have a particular drug, she could not recall if she had ever had another patient claim that he/she needed a new prescription because the pharmacist had kept it. When then asked why the pharmacist would not have simply returned the prescription to S.C., Respondent

[16] This calculation was based on Respondent's actual dosing instructions for each prescription. These three prescriptions would have provided a 200-day supply of the drug had I calculated this figure using a dosing instruction of one tablet every twelve hours for all three prescriptions, which is consistent with the manufacturer's prescribing instructions. *See Physician's Desk Reference* 2707 (61st ed. 2007) (''It is most appropriate to increase the q12h dose, not the dosing frequency. There is no clinical information on dosing intervals shorter than q12h.''); *see also id.* (''The intent of the titration period is to establish a patient-specific q12h dose that will maintain adequate analgesia with acceptable side effects for as long as pain relief is necessary.'').

asserted that was ''how they operated down there'' and that she ''was new to the State,'' even though she had worked in Florida for more than four years at that point. Yet the evidence shows that every single prescription she issued to S.C. in this period was filled, *see* GX 1, at 17–35, and while the first February 3 prescription was only partially filled (with the pharmacy dispensing 54 tablets), even if the pharmacy could not fill the remaining portion of the prescription within 72 hours, *see* 21 CFR 1306.13(a), there was no need for Respondent to issue him a second prescription for a full 90 tablets.

As for why she then issued S.C. three more prescriptions just six days later (on Feb. 9), Respondent initially claimed that S.C. had begun having seizures and was becoming forgetful, but then acknowledged that this did not happen until three months later. Other than in her earlier ludicrous testimony that the monkey was throwing S.C.'s drugs in the pool or that Respondent was leaving the drugs in his hotel room, or the drugs had been stolen—none of which was documented in a medical record because she maintained none on S.C.—Respondent failed to address why she issued S.C. three more prescriptions the next day. So too, Respondent failed to address why she wrote the multiple prescriptions on February 20 and March 6.

In her testimony, Respondent maintained ''that over time'' she ''lost the physician/patient relationship.'' Tr. 220. To the contrary, the evidence suggests that the only time she prescribed to S.C. pursuant to a valid doctor-patient relationship was in August 2007, when she treated him for his broken hand in the ER. Her testimony as to whether she performed physical examinations of S.C. was exceedingly vague and changed, both as to the dates she performed these exams and the scope of the exams. Indeed, she explicitly denied having even made a diagnosis, *id.* at 229, claiming that S.C.'s prior physician had done that, and yet she proceeded to provide him with prescriptions for more than 1750 tablets of two of the most highly abused prescription narcotics (400 OxyContin 80mg and 1350 oxycodone 30mg) without even calling S.C.'s prior physician. She also offered no explanation for the inconsistency between the dosing instructions on the various OxyContin prescriptions or for increasing S.C.'s daily dose of oxycodone from 240mgs (per the OxyContin prescriptions) to 450mgs per day (per the oxycodone 30 prescriptions) only one month later. Moreover, she provided the first set of prescriptions with full knowledge that S.C. was going off to California for several months and that she would have no ability to monitor him. And she failed to create any medical records and a written treatment plan.

As for the 2009 prescriptions, notwithstanding that she had not ''treated'' S.C. in nearly ten months, she could not recall if she had done a physical exam. Moreover, within a one-month period, she provided him with more than a one-year supply of oxycodone based on her own dosing instructions. As for her testimony that she believed the various excuses S.C. offered for why he needed additional prescriptions, and did so even when the excuse was patently absurd, the ALJ did not find this credible. Nor do I. And here again, she failed to create any medical records and a written treatment plan.

I therefore conclude that with the exception of the Percocet prescription she wrote when she treated S.C. in the ER, Respondent repeatedly acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed oxycodone (including OxyContin) to him. *See* 21 CFR 1306.04(a). While Respondent contends ''that her actions were not for personal gain,'' Resp. Post-Hrng. Br. at 36, to sustain a violation, the Government was not required to prove that she provided the prescriptions in exchange for either money or to obtain S.C.'s affection. In sum, I conclude that Respondent knowingly diverted controlled substances when she prescribed to S.C.

I also conclude that Respondent violated Agency regulations requiring that she: (1) Date the prescriptions as of the date of their issuance, 21 CFR 1306.05(a); (2) include S.C.'s address on the prescriptions, *see id.* ; (3) where issuing multiple prescriptions for schedule II drugs, not prescribe more than a 90-day supply, 21 CFR 1306.12(b)(1); and (4) where issuing multiple prescriptions, ''provide[] written instructions on each prescription . . . indicating the earliest date on which a pharmacy may fill each prescription. *Id.* 1306.12(b)(ii). She also violated Florida law and regulations by failing to create medical records.

Respondent nonetheless argues that she ''has had a long career in emergency medicine and has had no instances of malpractice or disciplinary action prior to the instant case.'' Resp. Exceptions, at 11. She further contends that ''[t]he events surrounding her relationship with S.C. and her treatment of his purported medical conditions represent an aberrant set of circumstances that are unlikely to ever be repeated.'' *Id.*

It is acknowledged that except for the matters at issue here, Respondent has practiced medicine as an ER physician for approximately sixteen years and dispensed controlled substances without incident. It also acknowledged that two of her co-workers wrote letters attesting to her ability as a clinician. *See* RX P & R.

I nonetheless reject her contention that her misconduct is an aberration. As the evidence shows, Respondent engaged in two separate bouts of unlawful prescribing. Indeed, while her prescribings to S.C. in the February–March 2008 time period were egregious (providing him with 1750 tablets of highly abused schedule II narcotics), in January 2009, she resumed prescribing to him, providing him with more than another 1,000 pills of this highly abused narcotic in a one-month period. Moreover, notwithstanding her admitted lack of familiarity with treating chronic pain, and that while S.C. was in LA, she had months to reflect on her prescribing practices with respect to him as well as to familiarize herself with Florida's standards for using controlled substances to treat pain, Respondent resumed prescribing to S.C. a highly abused narcotic in unlawful quantities, *see* 21 CFR 1306.12(b)(1), that also greatly exceeded what was medically necessary according to her own dosing instructions.

I therefore find that the Government's evidence with respect to factors two and four establishes that Respondent has committed such acts as to render her ''registration inconsistent with the public interest.'' [17] I further find that

[17] While I have considered the allegation that Respondent violated the CSA by issuing prescriptions while working at the Northern Navajo Medical Center without being licensed by New Mexico and registered with DEA in that State, I decline to rule on the allegation because several material issues have not been adequately addressed. While the Government elicited testimony from a registration program specialist to the effect that in order for Respondent to obtain a registration in New Mexico, she was required to obtain a New Mexico medical license, it is unclear whether New Mexico has authority to require a federal contract physician to be licensed in the State if she works solely at an IHS facility. The limited case law suggests to the contrary. *See Taylor* v. *United States,* 821 F.2d 1428, 1431 (9th Cir. 1987) (noting that under the Supremacy Clause, a State ''lacks power to require licensing of federal health care providers and physicians'' and that ''[t]he United States has . . . essentially deemed [an] Army [h]ospital and its staff fit to provide health care services''); *United States* v. *Composite State Bd. of Medical Examiners,* 656 F.2d 131, 135 n.4 (5th Cir. 1981) (citing *Sperry* v. *Florida ex rel. Florida Bar,* 373 U.S. 379 (1963)). *Cf.* 25 U.S.C. 1621t (''Licensed health professionals employed by a tribal health program shall be exempt, if licensed in any State, from the licensing requirements of the State in which the tribal health

Respondent's misconduct was egregious and makes out a *prima facie* case for denying her application.

Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

The ALJ also found that Respondent engaged in actionable misconduct under this factor. More specifically, the ALJ found, *inter alia,* that: (1) Respondent lacked candor in her testimony regarding her prescribings to S.C.; and (2) she failed to cooperate with DEA Investigators who were investigating her 2012 renewal application. R.D. at 63–66. Of these, I conclude that only the first finding is supported by substantial evidence.

As for the second contention, the evidence showed that during the course of investigating her renewal application, Agency Investigators went to a hospital at which Respondent was then working and asked to speak to her about the ''yes'' answer she had provided to one of the liability questions on the application. Tr. 388. Respondent declined to answer any questions without an attorney being present. *Id.* While the Investigators then explained ''this was not a criminal investigation'' and that it ''was purely regulatory in scope'' as it involved the Florida Board matter, Respondent again refused ''to discuss the matter.'' *Id.* at 390. The DI then testified that he was never able to complete his interview of Respondent. *Id.* at 391; 398.

Based on this evidence, the ALJ found that Respondent ''flatly refused to answer [the DI's] questions to resolve the liability issues she noted on her renewal application in the absence of an attorney, and made no attempt to arrange a subsequent meeting with [the DI], with or without counsel.'' R.D. at 65–66. The ALJ thus reasoned that ''Respondent's failure to cooperate . . . suggests a substantial and willful disregard for her duty to comply with DEA directives as a regulated entity'' and ''[t]his conduct threatens public health and safety.'' *Id.* at 66.

I find the ALJ's reasoning unpersuasive. Respondent was entitled to consult with her attorney before answering the DI's questions and had no obligation to agree to an interview without her attorney being present. Moreover, the DI offered no testimony to the effect that he made any further attempt to interview her, let alone that she rebuffed a further interview request or that she agreed to an interview and then failed to follow through. Accordingly, I reject the ALJ's finding and conclusion as unsupported by substantial evidence.

However, I agree with the ALJ's legal conclusion that Respondent lacked candor in her testimony. More specifically, as ultimate factfinder, *see* 5 U.S.C. 557(b), I do not find credible her testimony that she did not know ''exactly why'' she did not include the date and S.C.'s address on the OxyContin 80mg and Oxycodone 30mg prescriptions other than that S.C.'s house was a ''very distracting'' environment. Tr. 222. As found above, notwithstanding her assertion, Respondent was not so distracted that she failed to include on the prescriptions such required information as the name of the drug, its dosage strength, the quantity, and her signature. *Id.*

Nor do I find credible her testimony that she palpated S.C.'s back and neck as part of the physical exams she claimed to have performed. *Id.* at 263. As found above, at several earlier points in her testimony, Respondent described the physical exam she performed as listening to S.C.'s heart and lungs, making no mention of having palpated any part of S.C. *See id.* at 214 & 244–45. Indeed, she asserted that she palpated S.C.'s back and neck only after the Government specifically asked her if she did. *Id.* at 263.

Finally, I do not find credible Respondent's testimony that she wrote the multiple oxycodone 30mg prescriptions because she *actually believed* S.C.'s claim that the monkey had taken the pill bottle, managed to open it, and then threw the medication in the pool. *Id.* at 240–41, 341.

Accordingly, I find that substantial evidence supports a finding that Respondent lacked candor when she testified in this proceeding. *See Hoxie* v. *DEA,* 419 F.3d 477, 483 (''Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.''). Thus, I conclude that the record supports a finding that Respondent lacked candor when she testified in this proceeding and that she has committed such other conduct which may threaten public health and safety. 21 U.S.C. 823(f)(5).

Sanction

Under Agency precedent, where, as here, ''the Government has proved that [an applicant] has committed acts inconsistent with the public interest, the [applicant] must '' 'present sufficient mitigating evidence to assure the Administrator that [she] can be entrusted with the responsibility carried by such a registration.' '' '' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where [an applicant] has committed acts inconsistent with the public interest, the [applicant] must accept responsibility for [her] actions and demonstrate that [she] will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

So too, in making the public interest determination, ''this Agency places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt,* 75 FR 49995, 50004 (2010) (citing *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR 74334, 74338 (2007) (quoting *Hoxie,* 419 F.3d at 483 (''Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.'')).

Moreover, while an applicant must accept responsibility and demonstrate that she will not engage in future misconduct in order to establish that her registration is consistent with the public

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program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act.''). However, this determination is not within the Agency's authority.

Moreover, the Government does not address whether a physician is nonetheless required to obtain a registration specific to an IHS facility if the State lacks authority to require a physician to obtain a license in that State, or whether a physician who does not possess a license in the State where the facility is located and is not required to possess such a license, can nonetheless obtain a registration for that location.

Because I find that the Government has otherwise proved that Respondent's continued registration is inconsistent with public interest and that she has failed to produce sufficient evidence to rebut this conclusion, I decline to remand the matter or issue a briefing order. On this record, I decline to adopt the ALJ's conclusions of law (# 8, 9, and 10) that Respondent violated federal law because she issued prescriptions while practicing at the Northern Navajo Medical Center without being registered in New Mexico and that she is not exempt from registration in that State. *See* R.D. 74. I also decline to adopt the ALJ's finding that Respondent's ''decision to rely exclusively on representations made to her by her future employers constitutes a willful and reckless disregard for her duty to inquire of the DEA regarding the need for re-registration and in-state licensure,'' R.D. at 64, and that this is actionable misconduct under factor five. *Id.*

interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of an applicant'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 Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

Moreover, as I have noted in several cases, '' '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be revoked' '' or an application should be denied. *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504 (2007)); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Michael S. Moore,* 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36504). *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'').[18]

In his decision, the ALJ acknowledged that Respondent produced some evidence of remedial measures she has undertaken. R.D. at 68. More specifically, the evidence shows that Respondent completed a four-day course in controlled substance management and a two-day course in medical record keeping. RXs F & I.

However, based on Respondent's testimony, the ALJ also found that ''it is far from clear that the courses have brought about changes in [her] that would support continued DEA registration.'' R.D. at 68. As the ALJ explained, ''[e]ven now, Respondent would attribute her action to being victimized by . . . SC's conduct, while averring that she believed, at the time, that her prescription practice was compliant with DEA regulations.'' *Id.* The ALJ thus concluded that ''Respondent has [not] admitted to the full extent of her . . . misconduct.'' *Id.*

Respondent takes exception to the ALJ's conclusion that she has failed to accept responsibility for her misconduct, contending that this ''is contradicted by the facts in the record.'' Exceptions, at 2. Respondent argues that she ''readily admitted to losing the physician-patient relationship when treating S.C.'' and that she ''also admitted that she violated Florida law and standards of practice when she treated S.C. without creating a medical record, [a] written treatment plan, etc.'' *Id.* at 3–4.

It is acknowledged that at various points in her testimony, Respondent admitted to several professional failings. For example, she admitted that it was her error to accept S.C.'s word rather than call his prior physician. She also testified that she ''lost the physician/patient relationship'' and ''was not objective.'' Still later, she testified that ''[i]n hindsight . . . my judgment was impaired because of the relationship I had with the individual'' and that the prescriptions ''were not within . . . the standards of my medical practice.'' And she also admitted that she violated Florida's regulations by failing to ''keep proper documentation.''

While this testimony would have supported a finding that Respondent has accepted responsibility for her misconduct, at other points, she offered testimony that substantially undermines this conclusion. Notwithstanding her earlier admission that she lost the doctor/patient relationship (not that she ever had one outside of S.C.'s ER visit), she then testified that ''I was definitely manipulated and taken advantage of. I was victimized.'' Tr. 350. Respondent's statement is simply irreconcilable with the obligations imposed on a physician who is entrusted with the authority to prescribe controlled substances.

So too, notwithstanding her testimony that the prescriptions ''were not within . . . the standards of my medical practice'' and her having taken a course in controlled substance management, Respondent testified that she still believes she issued the prescriptions for a legitimate medical purpose. Tr. 277. Still later in her testimony—and after maintaining that she was victimized by S.C.—she again testified that knowing what she knows today, she still believes that the prescriptions were medically necessary. *Id.* at 277–78.

In short, this suggests that Respondent has learned nothing from the various state board proceedings, the course she took in controlled substance management, or this Proceeding. Accordingly, I have no confidence that she will refrain from similar acts were she to become love struck with a drug abuser or diverter in the future. Her equivocal testimony provides substantial evidence to support a finding that she does not accept responsibility for her misconduct.

As explained above, notwithstanding her contention that her prescribing to S.C. is an aberration, I find that her misconduct was egregious. Moreover, as found above, Respondent lacked candor in her testimony. Accordingly, I conclude that denial of her application is necessary to protect the public interest.

Order

Pursuant to the authority vested in me by 21 U.S. C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Annicol Marrocco, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective June 18, 2015.

Dated: May 4, 2015.

Michele M. Leonhart,

Administrator.

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

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