Order

Pursuant to the authority vested in me by 21 U.S.C. § 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration AS3236406, issued to Charles Szyman, D.O., be, and it hereby is, revoked. This Order is effective immediately.[4]

Dated: September 13, 2016.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Richard J. Settles, D.O.; Decision and Order

On September 9, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Richard J. Settles, D.O. (hereinafter, Respondent), of Grand Junction, Colorado. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration FS3717975, pursuant to which he is authorized to dispense controlled substances in schedules II through V, as a practitioner, at the registered address of 715 Horizon Drive, Suite 200, Grand Junction, Colorado. GX 2, at 1 (citing 21 U.S.C. 824(a)(1) and (4)). The Show Cause Order also proposed the denial of any pending application to renew or modify Respondent's registration, on the ground that his ''continued registration is inconsistent with the public interest.'' *Id.*

As grounds for the proposed actions, the Government alleged that Respondent had materially falsified his March 4, 2013 application for registration. *Id.* at 2 (21 U.S.C. 824(a)(1)). The Order also alleged that he had issued prescriptions for controlled substances without authority to do so under both Arizona and Federal law. *Id.* at 3 (citing 21 U.S.C. 824(a)(4)).

With respect to the material falsification allegation, the Government alleged that on March 4, 2013, Respondent applied for a DEA registration at a location in Chattanooga, Tennessee. *Id.* at 1. The Government alleged that Respondent provided a ''yes'' answer to the application question: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substances registration revoked, suspended, restricted, or placed on probation, or is any such action pending?'' and that ''[i]n furtherance of [his] answer,'' Respondent explained that on July 17, 2012, ''the Arizona Board of Osteopathic Examiners placed my license on a 5 year probation,'' and that as a result, ''I voluntarily surrendered my Arizona license and DEA registration as I knew I was moving to Tennessee in the next few months.'' *Id.* at 1–2.

The Government then alleged that Respondent's answer was materially false because he was ''aware of at least two . . . other state professional license actions'' when he submitted the application and failed to disclose them. *Id.* at 2. The Government alleged that these actions included a November 17, 2012 Interim Consent Order issued by the Arizona Board, which restricted Respondent's license to practice osteopathic medicine pending the Board's investigation into whether he violated its July 17, 2012 Order by prescribing controlled substances as his authority to do so had been restricted by that Order. *Id.* As for the second Board action, the Government alleged that on February 6, 2013, Respondent entered into a Stipulation and Order with the Utah Division of Occupational and Professional Licensing, in which he admitted that he had falsified a May 4, 2012 application for licensure in that State, because he failed to disclose that he was then under investigation by the Arizona Board, and that he had surrendered his Utah license to practice as an osteopath. *Id.* at 2–3 (citing 21 U.S.C. 824(a)(1), 823(f), 843(a)(4)(A)).

As for the prescribing allegations, the Government alleged that pursuant to the July 17, 2012 Arizona Board Order, Respondent was restricted from prescribing schedule I through IV controlled substances. *Id.* at 3. The Order alleged that the Board subsequently found that after the effective date of the Order, Respondent became the medical director of a hospice program and prescribed controlled substances to 10 of the program's patients. *Id.* The Order then alleged that ''[p]rescribing controlled substances without appropriate authority is contrary to Federal law.'' *Id.* at 3 (citations omitted).

Next, the Order alleged that on May 7, 2014, one day before the Tennessee State Board of Osteopathic Examination issued a Consent Order which indefinitely suspended his Tennessee license, Respondent applied to modify his registered address from Tennessee to an address in Dolores, Colorado. *Id.* at 4. The Order alleged that Respondent made several additional requests to modify his registered address, concluding with his February 18, 2015 request to change his address to a location in Grand Junction, Colorado and that the Agency approved this request on March 17, 2015. *Id.*

The Order then alleged that prior to the Agency's approval of his modification request, Respondent issued controlled substance prescriptions in Colorado, ''in violation of 21 U.S.C. 810(10),[1] 822(e), and 841(a)(1).'' *Id.* at 4 (citing, *inter alia,* 21 CFR 1301.12(a), 1301.13(a)). Specifically, the Order alleged that ''from July 2014 through February 2015, [Respondent] issued over 250 prescriptions when [he] lacked the requisite federal authority to issue prescriptions in Colorado.'' *Id.* The Order then set forth multiple instances of such prescriptions. *Id.* at 5–6. The Order further alleged that Respondent ''issued multiple prescriptions to patients within a thirty-day window, amounting to prescriptions for large dosages of highly abused controlled substances'' and set forth a dozen patients to whom he issued the prescriptions. *Id.* at 6–7.

On September 14, 2015, the Show Cause Order, which also notified Respondent of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option, was served on Respondent by certified mail, return receipt requested. GX 4, at 1. Thereafter, on October 14, 2015, Respondent, through his attorney, filed a document entitled ''Waiver of Hearing, Statement of Position on the Facts and Law'' (hereinafter ''Position Statement'') with the Office of Administrative Law Judges. *See* 21 CFR 1301.43(c); GX 5. Therein, Respondent acknowledged service of the Order to Show Cause on September 14, 2015, *see* GX 5 at 5, and explained he was waiving his right to a hearing and filing his ''Statement of Position on the Facts and Law regarding the matters alleged in the Order to Show Cause.'' GX 5, at 2.

On February 29, 2016, the Government forwarded its Request for Final Agency action, the Investigative Record, and Respondent's Position Statement. Subsequently, on March 21, 2016, the Government filed an Addendum to its Request for Final Agency Action (hereinafter, First

[4] For the same reasons which led the Wisconsin Board to summarily suspend Respondent's osteopathic license, *see supra* note 2, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

[1] There is no such provision in the CSA.

Addendum). Therein, the Government notified my Office that Respondent did not file his renewal application until February 2, 2106,[2] which was less than 45 days before the expiration date of his registration (Feb. 29, 2016). Noting that under an agency regulation, '''a registrant, who has been served with an Order to Show Cause, [must] file his renewal application at least 45 days before the expiration of his registration, in order for it to continue in effect past its expiration date and pending the issuance of a final order,''' and that Respondent had filed his renewal application less than 45 days prior to the expiration of his registration, the Government argued that Respondent's registration had expired and thus, ''the issue to be considered . . . is whether DEA should grant [his] application . . . not whether DEA should revoke Respondent's registration.'' *Id.* at 1 (quoting *Paul Weir Battershell,* 76 FR 44359, 44361 (2011) (quoting 21 CFR 1301.36(i))).

On April 28, 2016 the Government filed a second Addendum to its Request for Final Agency Action (hereinafter, Second Addendum). Therein, the Government advised that ''the Medical Board of Colorado issued an Order of Suspension which suspended Applicant's Colorado medical license, effective Friday, April 22, 2016''; the Government provided a copy of the Board's Order.[3] *Id.* at 1; *see also* Attachment (GX 27), at 1–2. The Board's Order has been made a part of the Investigative Record in this proceeding.

Respondent's Position Statement

Respondent's Position Statement raises various contentions which warrant discussion prior to my determination of the material facts in this matter. As a preliminary matter, Respondent asserts that ''in waiving his right to participate in the hearing[,] [he] did not and does not waive any rights other than his right to a hearing'' and that ''there is no authority in the regulations of the Agency to waive any other rights pertaining to the adjudication of this matter.'' GX 5, at 1.

Among other things, Respondent contends that the Administrative Law Judge is required, ''upon receipt of a waiver of hearing and statement on the matters of fact and law to determine if the statement is admissible, and if so make the statement part of the record.'' *Id.* at 3 (citing 21 CFR 1316.49). Respondent then argues that he ''is entitled to have the ALJ certify the record in this proceeding to the Administrator,'' that ''the ALJ's jurisdiction . . . does not terminate until after he certifies the record,'' that ''a termination of the proceedings that permits the Government's counsel to determine what constitutes the record is a clear violation of this regulation,'' and that ''[t]he ALJ's role and authority is not altered by the waiver of a hearing.'' *Id.* at 4 (citing 21 CFR 1316.52).

Respondent is mistaken. Under the Agency's rules, absent the filing of a request for a hearing on an Order to Show Cause, the Office of Administrative Law Judges does not acquire jurisdiction over the matter. Here, Respondent did not file a request for a hearing, and indeed, explicitly waived his right to a hearing. Accordingly, no Administrative Law Judge was designated as a presiding officer and because no hearing was held, there was no record to be certified by a member of the Office of Administrative Law Judges.

Thus, the Government, while it was required to submit Respondent's Position Statement with its filing, was otherwise entitled to determine what evidence it would submit to my Office in support of its Request for Final Agency action. Moreover, the Government has represented to me that it provided to Respondent a copy of its Request for Final Agency Action, the Exhibits, the Addendums, and the Attachment to the Second Addendum. Accordingly, as the Government has provided Respondent with all of its filings, Respondent cannot claim that it has been stripped ''of its status as a party to the proceeding.''[4] *Id.* For the same reason, I reject Respondent's assertion that a ''quagmire . . . would ensue if the proceedings were cancelled in their entirety[5] and Government Counsel were permitted to seek a final order by presenting DEA's case directly to the Administrator in *ex parte* communications.'' *Id.* at 5.

Respondent further argues that under 21 CFR 1301.43(c), I ''may not terminate the proceeding and issue [my] final order unless 'all persons entitled to a hearing *or to participate in a hearing* waive . . . their opportunity for the hearing *or to participate in the hearing.''* *Id.* (quoting 21 CFR 1301.43(e))[6] (emphasis in Respondent's Position Statement). Respondent then argues that ''DEA is entitled to participate in the hearing and . . . has counsel of record representing it,'' but ''has not waived its opportunity to participate in the hearing.'' *Id.* at 4. Respondent thus contends that ''canceling the hearing and allowing the Administrator to issue [his] final order is not authorized.'' *Id.*

Once again, Respondent is mistaken. Notwithstanding that an agency regulation applicable to hearings (21 CFR 1316.42(e)) defines the ''[t]he term *person* [to] include[] an individual, corporation, government or governmental subdivision or agency,'' when the Government initiates an Order to Show Cause proceeding, it is not a ''person entitled to a hearing'' within the meaning of 21 CFR 1301.43.[7] Indeed, this language is fairly read as encompassing only the recipient of the Show Cause Order.

For the same reason, *i.e.,* because it initiated the proceeding, when the Government initiates an Order to Show Cause proceeding, it is not a ''person entitled to participate in a hearing pursuant to § 1301.34 or § 1301.35(b).'' 21 CFR 1301.43(b). With respect to § 1301.34, this provision applies to only a narrow category of cases which are not initiated by the Government—specifically, where an applicant seeks registration to import schedule I or II controlled substances. Under this provision, the Agency is required to give notice to registered manufacturers as

[2] On the date the Show Cause Order was issued, Respondent was registered as a practitioner to handle controlled substances in schedules II–V under DEA Registration FS3717975 at the registered address of La Junta Clinic, 715 Horizon Drive, Suite 200, Grand Junction, Colorado; this registration, which was issued on March 5, 2013, was due to expire by its terms on February 29, 2016. GX 1.

[3] The Government certified that a copy of both Addendums was served on Respondent's counsel. First Addendum, at 3; Second Addendum at 2.

[4] As support for this contention, Respondent quotes 20 CFR 404.929, a regulation applicable to certain hearings conducted by ALJs on behalf of the Social Security Administration. *See* GX 5, at 4. This provision has no relevance to this proceeding.

[5] Respondent offers no explanation as to what further rights he believes he is entitled to, given that he has waived his right to a hearing and has filed his Position Statement. Nor does he explain what he believes remains of the proceeding other than the Government's submission of its Request for Final Agency Action and its evidence and my issuance of this Decision and Order.

[6] The correct regulation is 21 CFR 1301.43(e).

[7] Words take their meaning from the context in which they are used, and in this regard the language of 21 CFR 1301.43(a) is probative. It states: ''Any person entitled to a hearing pursuant to § 1301.32 or §§ 1301.34–1301.36 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause . . . file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.'' The reference provisions apply to applicants for registration whose applications the Agency is proposing to deny, and the holders of registrations whose registrations the Agency is proposing to revoke. As the provision applicable to Respondent states: ''[b]efore revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, *if requested by the registrant,* shall hold a hearing pursuant to § 1301.41.'' 21 CFR 1301.36(d) (emphasis added). Here, however, Respondent did not request a hearing but rather chose to submit a position statement in lieu thereof.

well as other applicants for registration to manufacturer the same basic substance, and upon request of such manufacturer or applicant, the Agency ''shall hold a hearing on the application.'' 21 CFR 1301.34(a). While Government does not initiate the proceeding, it may intervene in the proceeding as a ''person entitled to participate in a hearing.'' 21 CFR 1301.43(b). *See also e.g., Chattem Chemicals, Inc.,* 71 FR 9834, 9834 (2006), *pet. for rev. denied sub nom. Penick Corp, Inc.,* v. *DEA,* 491 F.3d 483, 493 (D.C. Cir. 2007); *Penick Corp., Inc.,* 68 FR 6947, 6947 (2003), *pet. for rev. denied sub nom. Noramco, Inc.,* v. *DEA,* 375 F.3d 1148, 1159 (D.C. Cir. 2004). Indeed, this is the only circumstance in which the Government can be fairly described as a ''person entitled to participate in a hearing.'' [8]

Thus, with respect to this proceeding, the Government is neither a ''person[] entitled to a hearing or to participate in a hearing,'' 21 CFR 1301.43(e), and the only person whose waiver matters for the purpose of cancelling the hearing is Respondent. Because Respondent has waived his right to a hearing, I am authorized to issue this ''final order . . . without a hearing.'' [9] *Id.*

Having reviewed the entire record, including Respondent's Statement of Position, I make the following factual findings.

FINDINGS OF FACT

Jurisdictional Facts

Respondent, a doctor of osteopathic medicine, previously held DEA Certificate of Registration FS3717975, pursuant to which he was authorized to dispense controlled substances in schedules II–V, at the address of La Junta Clinic, 1012 Belmont Ave., La Junta, Colorado. GX 1. This registration was issued on March 5, 2013, after Respondent submitted the application which is the subject of the material falsification allegations. On February 2, 2016, Respondent submitted an application to renew this registration. First Addendum, at 1. However, because Respondent had previously been served with the Show Cause Order, in order for his registration to remain valid pending this proceeding, he was required to submit his application at least 45 days before the date on which the registration was due to expire. 21 CFR 1301.36(i). Accordingly, I find that Respondent's registration expired on February 29, 2016. I further find, however, that Respondent's application remains pending in this proceeding.[10]

The Arizona and Utah Investigations of Respondent

On April 29, 2010, the mother of Respondent's patient K.K. made a complaint to the Arizona Board of Osteopathic Examiners alleging that K.K. was a heroin addict and that Respondent was prescribing drugs and quantities that ''were inappropriate [given] K.K.'s history with substance abuse.'' GX 8, at 2. The same day, the Board notified Respondent that it was initiating an investigation. *Id.* at 1.

Thereafter, Respondent was invited to attend an investigative hearing which was conducted on September 24, 2011; the hearing was continued to allow the Board to obtain additional information and conduct ''a chart review of thirty (30) patients.'' *Id.* The Board also ordered Respondent to undergo a psychological evaluation and requested that he provide additional documentation to it. *Id.*

On April 10, 2012, the Board notified Respondent ''that the Investigative Hearing would continue on May 19, 2012.'' *Id.* On that date, the Board conducted the hearing with Respondent present and represented by counsel. *Id.* Thereafter, the Board issued a decision and order which made factual findings and legal conclusions regarding Respondent's prescribing to K.K. as well as its chart review.

With respect to K.K., the Board found that she was Respondent's patient ''from March 2005 through March 2010, with a lapse in care from February 2006 to early 2009.'' *Id.* at 2. The Board found that at K.K.'s second visit, Respondent prescribed Percocet to her in quantities ranging from 120 to 180 dosage units each month as well as 90 Xanax and 30 Ambien each month. *Id.* The Board further found that ''Respondent failed to obtain prior medical records or to perform a workup on K.K. and no consultations were ordered.'' *Id.* It also found that ''[t]he majority of K.K.'s medications were obtained through Respondent's office'' and that he ''did not enter into a medication contract with [her] until May 5, 2010 for Suboxone.'' *Id.*

Continuing, the Board found that K.K. ''returned to Respondent . . . in 2009 and . . . was started on'' 90 Percocet and 90 Soma, and that ''[i]n October 2009, K.K. overdosed and was taken to the hospital.'' *Id.* The Board found that ''Respondent continued'' to provided K.K. with prescriptions each month for 120 dosage units of Percocet, 90 Xanax, and 30 Ambien until March 2010, when he increased her Percocet prescription to 180 du per month. *Id.* According to the Board, K.K. overdosed again on March 17, 2010 as well as on April 11, 2010. *Id.* at 2–3.

With respect to the chart review, the Board found that ''Respondent prescribed controlled substances to chronic pain patients'' and that ''[p]harmacy inquiries and drug screens were ignored in patients that were clearly diverting.'' *Id.* at 3. The Board further found that ''Respondent deviated from the standard of care by failing to'':

(1) ''stop prescribing controlled substances for patients that had overdosed'';
(2) ''recognize drug seeking behavior in patients'';
(3) ''request prior medical records'';
(4) ''obtain appropriate laboratory testing'';
(5) ''conduct a physical exam in at least one patient'';
(6) ''obtain consultations''; and
(7) ''follow the directions of specialist [sic] or recommendations when consultations were obtained.''

Id.

The Board thus found that ''Respondent practice[d] medicine in a manner that harmed or had potential to harm patients and fell below the community standard . . . and . . . this conduct endangered a patient or the public's health.'' *Id.* And the Board concluded that Respondent engaged in unprofessional conduct by '' '[e]ngaging in the practice of medicine in a manner that harms or may harm a patient or that the board determines falls below the community,' '' as well as that he engaged in '' '[a]ny conduct or practice

[8] 21 CFR 1301.43(b) also refers to the provisions of 1301.35(b), which allow for registered bulk manufacturers of a basic substance in schedule I or II (as well as applicants for registration to manufacture the basis substance) to ''participate in a hearing'' when the Government has issued a Show Cause Order proposing the denial of an application for registration ''to manufacture in bulk'' the same basic class and the applicant has requested a hearing. Here too, the Government is not a ''person entitled to participate in a hearing.'' Rather, it is initiator of the proceeding.

[9] The Agency's longstanding and consistent practice is that where a party waives its right to a hearing, the Government is entitled to present its evidence directly to the Administrator, who is the ultimate factfinder. *See, e.g., Cf. Reckitt & Colman, Ltd.* v. *Administrator,* 788 F.2d 22, 26 (quoting 5 U.S.C. 557(b) (''On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision . . . .'')). This practice has been followed in hundreds of cases over the years.

[10] Respondent previously held DEA Certificate of Registration BS3176105. GX 7, at 3. Pursuant to this registration, Respondent was authorized to dispense controlled substances in schedules II through V, at the registered location of 10752 North 89th Place, Suite 218, Scottsdale, Arizona 85620. GX 9, at 1. However, on July 30, 2012, Respondent surrendered this registration ''[i]n view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practice on [his] part.'' *Id.* This registration was retired the following day. GX 7, at 3.

that endangers the public's health or may reasonably be expected to do so.''' *Id.* at 4 (quoting Ariz. Rev. Stat. §§ 32–1854(6) & (38)).

Based on the above, the Board censured Respondent and ''restricted'' him ''from prescribing or recommending Schedule I, II, III or IV controlled substances for a period of two years . . . from'' the Order's effective date. The Board also restricted him from practicing pain management, imposed a civil penalty of $1,000 and placed him on probation for a period of five years, the terms of which included that he ''obey all federal, state and local laws, and rules governing the practice of medicine in the State of Arizona.'' *Id.* The Order became effective on July 17, 2012. GX 10, at 3.

As found above, on July 30, 2012, Respondent voluntarily surrendered his then DEA registration (BS3176105). Thereafter, on October 12, 2012, the Board received information form anonymous sources that Respondent ''may be prescribing controlled substances.'' GX 16, at 1. In response, the Board queried the Board of Pharmacy's Controlled Substances Prescription Monitoring Program ''for all controlled substances written or ordered by [Respondent] from June 11, 2012 through October 15, 2012.'' *Id.* The query showed that between July 17, 2012 and October 15, 2012, Respondent had issued 99 prescriptions for schedule II drugs, 23 prescriptions for schedule III drugs, and 70 prescriptions for schedule IV drugs. *Id.* at 1–2. The Board identified one patient Respondent saw at his office who received a prescription for temazepam on August 21, 2012, and 11 patients at hospices in Tuscon and Mesa to whom he either prescribed or ordered the dispensing of controlled substances, which included morphine, hydromorphone, oxycodone, lorazepam and temazepam. *Id.* at 2–6. Moreover, Respondent issued 17 controlled substance prescriptions or orders for the dispensing of controlled substances for 12 patients after he surrendered his DEA registration. *Id.*

On November 9, 2012, Respondent was interviewed by the Board and admitted ''that he had signed prescriptions for Schedule I, II, III or IV controlled substances after the Effective Date'' of the Order. GX 10, at 4. Respondent denied having ''written prescriptions for patients in his private practice'' and ''stated that he had only written or authorized prescriptions in his capacity as the . . . medical director for various hospice locations.'' [11] *Id.*

[11] Under the probationary terms of the July 17, 2012 Order, Respondent was required to hire a practice monitor. GX 10, at 4. During the November 9 interview, ''Respondent stated that he did not hire a practice monitor because he was not actively practicing in Arizona.'' *Id.*

On November 16, 2012, Respondent entered into an Interim Consent Agreement which the Board approved the following day. *Id.* at 2, 5. Respondent admitted to the findings of fact contained therein, including that he had prescribed or ordered controlled substances after the July 17, 2012 Order became effective, as well as the legal conclusion that he had engaged in unprofessional conduct by ''[v]iolating a formal order, probation or a stipulation issued by the board.'' *Id.* at 1, 4. The Board then ordered that Respondent be ''restricted from practicing medicine until the investigation'' was completed and ''he appear[ed] before the Board . . . for resolution'' of the matter. *Id.* at 4.

On May 12, 2014, Respondent entered into a Consent Agreement and Order for Voluntary Surrender of Licensee. GX 12, at 1, 5. Therein, Respondent waived his right to a hearing before the Board. *Id.* at 2. The Board found, *inter alia,* that on August 1, 2012, Respondent had ''entered into an Independent Contractor Agreement with Hospice Family Care, Inc.[,] to continue to serve as its Executive Medical Director of Hospice'' and that he had ''signed prescriptions for controlled substances for ten patients ''after the effective date of the [July 17, 2012] Board Order.'' *Id.* at 3.

While the Arizona Board's investigation was ongoing, Respondent was also the subject of disciplinary proceedings brought by the Utah Division of Occupational and Professional Licensing against his licenses to practice osteopathy and prescribe controlled substances in that State. GX 11, at 1. On February 4, 2013, Respondent entered into a Stipulation and Order with the State in which he admitted that on May 4, 2012, he had submitted an application for licensure as an osteopath and represented on the application ''that he was not currently under investigation by any licensing agency, even though [he] knew he was currently under investigation in Arizona.'' *Id.* at 3. Respondent admitted that his conduct constituted both ''unprofessional conduct as defined in Utah Code Ann. § 58–1–501(2)(a) and unlawful conduct as defined in Utah Code Ann. § 58–1–501(e).'' *Id.* Respondent agreed to surrender his licenses to practice as an osteopath and to administer and prescribe controlled substances and to not reapply for such licenses for a period of five years. *Id.* On February 6, 2013, the Division approved the Order. *Id.* at 6.

Respondent's March 2013 DEA Application, the Tennessee Board Action, and His Subsequent Address Changes

On March 4, 2013, Respondent applied for a new DEA registration at an address in Chattanooga, Tennessee. GX 6, at 2. On the application, Respondent was required to answer four liability questions. With respect to Question Two, which asked, *inter alia,* whether Respondent had ever surrendered (for cause) his DEA registration, Respondent answered ''yes.'' GX 7, at 2. After listing the incident date as ''7/17/2012'' and the incident location as ''Scottsdale, AZ,'' Respondent explained the nature of the incident as follows: ''AN ADDICTION PATIENT OF MINE ESCALATED THE USE OF HER MEDICATIONS AND ENDED UP IN THE ER. SHE WAS DISCHARGED FROM THE ER UNHARMED BUT HER MOTHER COMPLAINED TO THE ARIZONA OSTEOPATHIC BOARD OF EXAMINERS. THEY PLACED MY LICENSE ON SUSPENSION.'' *Id.* As for the ''incident result,'' Respondent explained: ''I VOLUNTARILY SURRENDERED MY ARIZONA MEDICAL LICENSE AND DEA REGISTRATION AS I NEW [sic] THAT I WAS MOVING TO TENNESSEE IN THE NEAR FUTURE.'' *Id.*

As for Question Three, it asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.* Respondent again answered ''Yes'' and listed the same incident date and location as he did in his previous answer. *Id.* As for the nature of the incident, Respondent explained: ''THE ARIZONA BOARD . . . PLACED MY LICENSE ON A 5 YEAR PROBATION.'' *Id.* He then explained the incident result as: ''I VOLUNTARILY SURRENDERED MY ARIZONA LICENSE AND DEA REGISTRATION AS I KNEW I WAS MOVING TO TENNESSE IN THE NEXT FEW MONTHS.'' *Id.* at 3.

Respondent did not disclose on the application the November 16, 2012 Interim Consent Agreement with the Arizona Board. *See id.* He also did not disclose the February 6, 2013 Stipulation and Order with the State of Utah. *Id.*

As found above, the next day, Respondent was issued a new registration which authorized him to dispense controlled substances in schedules II through V, at a location in

Chattanooga, Tennessee; this registration did not expire until February 29, 2016. Shortly thereafter, Respondent sought to change his registered address to a location in Hixson, Tennessee, which the Agency approved on April 3, 2013. GX 6, at 5.

However, on March 17, 2014, Respondent entered into a Consent Order with the Tennessee Board of Osteopathic Examination. GX 13, at 7. The Order was based on the July 17, 2012 and November 17, 2012 Arizona Orders, as well as the Utah Stipulation and Order. GX 13, at 3–4. Respondent agreed that the ''disciplinary actions in Utah and Arizona . . . constitute [sic] unprofessional conduct'' in that they involved ''[u]nprofessional, dishonorable or unethical conduct'' which, while it occurred in other States, was also grounds for discipline in Tennessee. *Id.* (citing Tenn. Code Ann. §§ 63–9–111(b)(1) & (b)(21)). Respondent further agreed to the indefinite suspension of his Tennessee license. *Id.* at 4. On May 7, 2014, the Board approved the Order. *Id.* at 6.

According to Respondent, in July 2014, he moved to Grand Junction, Colorado, where he was also licensed, and began working for Dr. Rebecca Tolby, and worked for her for 11 months. GX 5, at 11 (Resp. Position Statement). On some date which is not clear on the record,[12] Respondent sought to modify his registered location to an address in Colorado; however, the modification was not approved until April 6, 2015. GX 6, at 6 (Diversion Investigator's (DI) Declaration); *see also* GX 7, at 1 (Certification of Registration History).

In her Declaration, the DI stated that on December 1, 2014, she phoned ''Respondent regarding his lack of authority to write prescriptions in the State of Colorado'' and offered him ''the opportunity to surrender [his] DEA registration.'' GX 6, at 6. According to the DI, ''[t]hat same evening . . . Respondent attempted to modify his registered address again from Tennessee to New Mexico.'' [13] *Id.* However, Respondent subsequently changed his modification request ''back to Colorado.'' [14] *Id.*

The DI's Investigation of Respondent's Controlled Substance Prescribing in Colorado

On April 30, 2015, the DI served a Notice of Inspection on five pharmacies located in Grand Junction, Colorado seeking to obtain copies of the prescriptions written by Respondent and dispensing reports showing the prescriptions he had written ''from approximately July 2014 through February 2015.'' GX 6, at 7–8. Upon reviewing the records, the DI prepared a list by month of 89 controlled substance prescriptions (some of which provided for refills) Respondent issued from July 29, 2014 through December 1, 2014 while practicing in Grand Junction, Colorado, *id.* at 7–10; copies of the prescriptions were submitted for the record.[15] *See* GXs 14, 15, 20, 21, 22, 23, 24, 25. Moreover, the dispensing reports obtained from two of the pharmacies showed that Respondent issued additional controlled substance prescriptions even after December 1, 2014, the date on which he was told by the DI that he was not authorized to issue such prescriptions in Colorado. *See* GX 22, at 7 (report obtained from Palisade Pharmacy of Palisade, Colorado showing prescriptions for Tramadol issued to M.B. on Dec. 18, 2014 (filled on Dec. 29, 2014) and on January 26, 2015 (filled that day)); GX 25, at 7 (report obtained from Walgreens of Clifton, Colorado showing prescription for clonazepam issued to A.O. on Mar. 2, 2015 and dispensed by pharmacy on Mar. 3, 2015).

The Colorado Board Proceeding

On April 22, 2016, the Colorado Medical Board suspended Respondent's license to practice medicine pending proceedings for suspension or revocation. The suspension was based on the Board's finding that there is ''reasonable grounds to believe that Respondent was guilty of a deliberate and willful violation of the Medical Practice Act'' in that he ''authorized prescriptions for controlled substances for at least four patients . . . using another physician's DEA registration'' when he did not have an active DEA registration number. April 2016 Addendum to Government's RFAA, GX 27. As of the date of this Decision and Order, Respondent's Colorado license remains suspended. *See https://www.colorado.gov/dora/licensing/Lookup/Licensedlookup.aspx* (visited September 13, 2016).

Respondent's Position Statement

In support of his Position Statement, Respondent provided an affidavit. Therein, Respondent states that he ''take[s] full responsibility for my actions that resulted in the probation and ultimate surrender of my Arizona license'' and that he since ''learned a great deal on the proper prescribing of controlled substances.'' GX 5, at 11. He further asserts that ''I did not fully understand the scope of my initial restriction, which caused me to inadvertently violate that restriction.'' *Id.*

Respondent further asserts that ''[s]ince 2012, [he] ha[s] taken a number of steps to ensure that my prescribing practices are compliant with federal and state law'' and that in ''the past year,'' he has ''been a member of the Colorado Consortium for Prescription Drug Abuse Prevention'' and that ''[t]he program is helpful to keep abreast of the latest trends on opioid abuse and strategies for prevention.'' *Id.* at 11–12. He further states that in 2014, he attended lectures during a medical convention on the ''Tennessee Substance Abuse Epidemic'' and ''Office Based Opioid Withdrawal.'' *Id.* at 12.

In his affidavit, Respondent states that ''I have had some challenges with my state medical licenses, all of which arise from the suspension of my Arizona license.'' *Id.* He then maintains that ''I have tried to be as transparent as possible in communicating these issues to the various state medical boards and the local DEA offices that have conducted pre-registration investigations.'' *Id.* at 13.

[12] In an affidavit attached to his Position Statement, Respondent asserted that ''[w]hen I moved to Colorado in 2014, I applied to modify my DEA registration to my Colorado address.'' GX 5, at 13. Respondent did not, however, specify the date on which he applied for the modification. *Id.*

[13] Respondent also obtained an osteopathic medicine license in New Mexico in May 2012; he provided the Agency with a contact address in Albuquerque from December 2014 through February 2015, but there is no indication in the record that he practiced in New Mexico. Respondent admits that the New Mexico Board of Osteopathic Medical Examiners (NMBOME) had opened an investigation into his license but that his license had been renewed on August 19, 2015. GX 5 at 12. However, the NMBOME Web site states that Respondent's Pharmacy license expired on March 1, 2016, and that his osteopathic license expired on July 1, 2016. *See http://verification.rld.state.nm.us/Details.aspx?agency_id=l&license_id=625477.*

[14] On September 14, 2015 (the same date the Show Cause Order was served), Respondent's registered address was changed to the La Junta Clinic, 1012 Belmont Avenue, in La Junta, Colorado. GX 7, at 1.

[15] As discussed above, the Government also alleged that Respondent ''issued multiple prescriptions to patients within a thirty-day window, amounting to prescriptions for large dosages of highly-abused controlled substances.'' GX 2, at 6. As support for the allegation, the DI listed 11 patients who received additional prescriptions within 30 days of having received prescriptions from Respondent. GX 6, at 10–11. While Respondent violated federal law when he issued the prescriptions because he was not registered in Colorado, the Government did not allege that any of these prescriptions lacked a legitimate medical purpose and thus violated 21 CFR 1306.04(a) or a similar provision under Colorado law. Beyond that, in some instances the prescriptions were issued 28 days after the previous prescriptions, which hardly suggests that patients were seeking refills that were too early. While in other instances, the time between the prescriptions was only two or three weeks, the Government did not address why, given the dosing instruction, the refill was too early. I thus reject the allegation.

As for his conduct in issuing controlled substance prescriptions in Colorado when he was not registered in the State, Respondent states that he ''was unaware when I moved to Colorado that I was not able to prescribe controlled substances until the DEA actually approved the modification of my . . . registration to my new address.'' *Id.* Respondent states that he thought that he could prescribe controlled substances in Colorado ''so long as I had submitted my request for a modification.'' *Id.* Respondent then states that he ''take[s] full responsibility'' for this misconduct which was based on his ''misunderstanding of the law and not on any intentional effort to circumvent the'' CSA. *Id.* at 14.

According to Respondent, ''[a]s soon as I understood my mistake, I immediately stopped prescribing controlled substances.'' *Id.* However, as found above, the reports of Respondent's dispensings that were provided by the Palisade Pharmacy and Walgreens show that Respondent issued additional prescriptions after the DI told him on December 1, 2014 that he lacked authority to write prescriptions in Colorado.[16] I thus find that Respondent's statement is false.

Respondent further states that he ''understand[s] that the allegations in the . . . Order to Show Cause are very serious and that compliance with the DEA's regulations on prescribing controlled substances is crucial to prevent . . . diversion and abuse of controlled substances.'' *Id.* at 17. Notably, Respondent did not address the allegation that he materially falsified his March 4, 2013 application for a DEA registration. *See generally id.* at 10–17.

DISCUSSION

Pursuant to section 303(f) of the Controlled Substances Act, ''[t]he 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.'' 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination ''that the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires the consideration of the following factors:

> (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.

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman,* 567 F.3d 215, 222 (6th Cir. 2009) (quoting *Hoxie,* 419 F.3d 477, 482 (6th Cir. 2005))).[17]

Pursuant to section 304(a)(1), the Attorney General is also authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. § 824(a)(1). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. § 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See The Lawsons, Inc.,* 72 FR 74334, 74337 (2007); *Anthony D. Funches,* 64 FR 14267, 14268 (1999); *Alan R. Schankman,* 63 FR 45260 (1998); *Kuen H. Chen,* 58 FR 65401, 65402 (1993).

Thus, the allegation that Respondent materially falsified his application is properly considered in this proceeding. *See Samuel S. Jackson,* 72 FR 23848, 23852 (2007). Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *The Lawsons,* 72 FR at 74338; *cf. Bobby Watts, M.D.,* 58 FR 46995 (1993); *Shannon L. Gallentine,* 76 FR 45864, 45866 (2011).

In this matter, I conclude that there are three independent grounds for denying Respondent's pending application. First, he materially falsified his March 4, 2013 application. Second, by prescribing controlled substances in both Arizona and Colorado when he was not legally authorized to issue such prescriptions in the respective State, he violated the CSA and DEA regulations and thus has committed acts which render his registration ''inconsistent with the public interest.'' 21 U.S.C. § 823(f). Third, as a result of the Colorado Board's suspension of his osteopathic license, he lacks authority under state law to dispense controlled substances in the State in which he now seeks registration. *See id; see also id.* § 802(21).

The Material Falsification Allegation

As found above, the evidence shows that when Respondent submitted his application for a registration on or about March 5, 2013, he answered ''Yes'' to two liability questions.[18] GX 7, at 2. Question Three asked: ''Has the applicant ever surrendered for cause or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' Respondent checked the ''yes'' box and provided the following information:

> Incident Date: 07/17/2012. Incident Location: Scottsdale, AZ. Incident Nature: The Arizona Board of Osteopathic Examiners placed my license on a 5 year probation. Incident Result: I voluntarily surrendered my Arizona license and DEA registration as I knew I was moving to Tennessee in the next few months.

Id.

The Government alleges that Respondent's answer was materially false because Respondent failed to disclose the November 2012 Interim Consent Agreement he entered into with the Arizona Board and the February 2013 Stipulation and Order he entered into with the Utah Division of Occupational and Professional Licensing. Request for Final Agency Action, at 11–13. I agree with the Government that Respondent materially

[16] While Respondent offered an extensive explanation of his practice, at least as it existed prior to the Colorado Board's suspension of his medical license, which involved working in rural Colorado, the Agency has made clear that it does not consider so-called community impact evidence relevant in making the public interest determination in the case of prescribing practitioners. *See Linda Sue Cheek,* 76 FR 66972, 66972–73 (2011); *Gregory Owen,* 74 FR 36751, 36756–57 (2009).

[17] ''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).

[18] The second question asked Respondent, *inter alia,* whether he had ever surrendered his DEA registration for cause. The Government does not allege that Respondent materially falsified his application in answering this question.

falsified his application, but only with respect to his failure to disclose the November 2012 Interim Consent Agreement with Arizona.

The Supreme Court has held that ''the most common formulation'' of the concept of materiality is that ''a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed.'' *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956) (other citation omitted)) (quoted in *Samuel S. Jackson,* 72 FR 23848, 23852 (2007)); *see also United States* v. *Wells,* 519 U.S. 482, 489 (1997) (quoting *Kungys,* 485 U.S. at 770); *Arthur H. Bell,* 80 FR 50035, 50038 (2015). The Court has further explained that ''[i]t has never been the test of materiality that the misrepresentation or concealment would more likely than not have produced an erroneous decision, or even that it would more likely than not have triggered an investigation.'' *Kungys,* 485 U.S. at 771 (emphasis added). Rather, the test is ''whether the misrepresentation or concealment was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.'' *Id.* '' '[T]he ultimate finding of materiality turns on an interpretation of substantive law,' '' *id.* at 772 (int. quotations and other citation omitted), and must be shown ''by evidence that is clear, unequivocal, and convincing.'' *Id.*

Respondent's failure to disclose the Arizona Interim Consent Agreement clearly meets the standard of materiality. As found above, the Consent Agreement was based on the Board's findings that even after the Board had restricted him from prescribing controlled substances, Respondent continued to dispense controlled substances in that State and did so for nearly three months after the effective date of the Board's Order by either issuing prescriptions or ordering the dispensing of controlled substances. As the evidence shows, Respondent dispensed 99 prescriptions/orders for schedule II drugs, 23 prescriptions for schedule III drugs, and 70 prescriptions for schedule IV drugs after the effective date of the Board's Order and when he no longer held authority under state law and DEA regulations. *See* 21 CFR 1306.03(a) (requiring for a legal prescription that an individual practitioner be ''[a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and . . . [e]ither registered or exempted from registration'').

Moreover, Respondent issued multiple prescriptions or ordered the dispensing of controlled substances even after he surrendered his DEA registration on July 30, 2012.[19] *See* 21 U.S.C. 843(a)(3) (''It shall be unlawful for any person knowingly or intentionally . . . to use in the course of the . . . dispensing of a controlled substance, a registration number which is fictitious, revoked, suspended, expired, or issued to another person[.]''); *id.* § 822(a)(2) (''Every person who dispenses . . . any controlled substance, shall obtain from the Attorney General a registration . . . .''); *see also* 21 CFR 1306.03(a).

In determining whether the granting of an application is consistent with the public interest, the Agency is required to consider both ''[t]he Applicant's experience in dispensing . . . controlled substances'' and ''compliance with applicable State [and] Federal . . . laws relating to controlled substances.'' 21 U.S.C. 823(f)(2) & (4). Thus, while Respondent disclosed the July 2012 Arizona Board Order on his application, his failure to disclose the November 2012 Order was clearly ''capable of affecting'' the Agency decision to grant his application because the Order was based on the additional misconduct he committed with respect to the dispensing of controlled substances when he no longer held authority under the CSA and Arizona law. *Kungys,* 485 U.S. at 771.[20]

As noted above, in his affidavit, Respondent did not address his material falsification of the 2013 application. However, in his Position Statement, he admits (through his counsel) that he ''did not provide a complete answer to the liability question,'' but then contends that ''there was never intent . . . to withhold information from DEA, to be untruthful, and/or to omit relevant information to influence DEA's decision.'' GX 5, at 4–5.

However, the statement made by Respondent's counsel is not evidence, *see INS* v. *Phinpathya,* 464 U.S. 183, 186 n.6 (1984), and I conclude that Respondent submitted his 2013 DEA application with fraudulent intent. As explained above, the November 2012 Order, which was issued only three plus months before he submitted his application, establishes that Respondent had engaged in additional misconduct and disobeyed the Board's earlier Order as well as issued prescriptions after he surrendered his DEA registration. So too, Respondent's failure to disclose the Arizona investigation on his Utah application is probative evidence of his intent or lack of mistake in failing to disclose the November 2012 Arizona order on his DEA application. *See Arthur H. Bell,* 80 FR 50035, 50038 (2015); *cf.* Fed. R. Evid. R. 404(b)(2). Accordingly, I conclude that Respondent materially falsified his March 4, 2013 application for a DEA registration in Tennessee. This conclusion provides reason alone to deny his pending application.

The Public Interest Factors

In its Request for Final Agency Action as initially submitted, the Government argues that Factors Two, Four and Five support the denial of Respondent's application.[21] Govt. Request at 14–17. I

[19] While Respondent's loss of his state authority rendered his subsequent issuance of the prescriptions and orders unlawful under the CSA even without his having formally surrendered his DEA registration, Respondent's continued dispensing of controlled substances after he surrendered his registration begs the question of what consequences he believed were attendant to the surrender of his DEA registration. However, in his Position Statement, Respondent does not address the question.

[20] Given this finding, I need not decide whether Respondent's failure to disclose the Utah Stipulation and Order was material to the Agency's determination as to whether to grant his application for registration in Tennessee.

[21] In the Request for Final Agency Action, the Government argued that Factor One—The Recommendation of the Appropriate State Licensing Board—''neither weighs in favor nor weighs against the [denial] of Respondent's'' application for registration.'' Req. for Final Agency Action, at 14.

While Respondent held a Colorado license on the date the Government submitted its Request for Final Agency Action, the Board subsequently suspended his license to practice medicine on the ground that he authorized controlled substance prescriptions ''using another physician's DEA registration'' after his DEA registration expired. GX 27, at 1. While Respondent apparently has not had a hearing on these allegations, the fact remains that he does not currently possess authority to dispense controlled substances in Colorado, the State in which he is seeking registration.

DEA has long held that the possession of state authority to dispense controlled substances in the State in which a practitioner engages in professional practice is a prerequisite for obtaining a DEA registration in that State. *See Frederick Marsh Blanton,* 43 FR 27616, 27617 (1978) (''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.''); *see also* 21 U.S.C. § 802(21) (defining ''[t]he term 'practitioner' [to] mean[] a physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices to . . . dispense . . . a controlled substance in the course of professional practice.''); *id.* § 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.''); *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975) (''In the case of a physician, this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice.''). The Agency has further held that this rule applies even where a practitioner's state authority has been summarily suspended and the State has yet to

agree that the evidence with respect to Factor Two and Four establishes a *prima facie* case to deny Respondent's application. And having reviewed Respondent's Position Statement, I hold that he has failed to present sufficient evidence to rebut the conclusion that his ''registration would be inconsistent with the public interest.'' 21 U.S.C. § 823(f).

Factors Two and Four—the Applicant's Experience in Dispensing Controlled Substances and Compliance With State and Federal Laws Related to Controlled Substances

The Government contends that the various Arizona Board Orders establish that Respondent's experience in dispensing controlled substances and his compliance with state and federal laws related to controlled substances support the denial of his application and that the Board's factual findings and legal conclusions are entitled to preclusive effect in this proceeding. Req. for Final Agency Action, at 14–15. I agree in part.

Based on its findings that Respondent deviated from the standard of care in his treatment of K.K. as well as at least 30 patients, to include prescribing excessive controlled substances to chronic pain patients, and that he ignored pharmacy inquiries and drug screenings in patients who were clearly diverting, the Board restricted him from prescribing or recommending controlled substances for two years.[22] *Id.* at 4.

Nonetheless, after the effective date of the Order, Respondent continued to issue controlled substance prescriptions as well order the administration of controlled substances to hospice patients. These prescriptions and orders violated the CSA and DEA regulations because he lacked the requisite state authority to dispense controlled substances. 21 CFR 1306.03(a). *See also* Ariz. Rev. Stat. § 32–1854 (25). Moreover, Respondent issued at least 17 of these prescriptions and orders for administration even after he surrendered his registration. 21 U.S.C. 841(a)(1), 843(a)(3), 822(a)(2). Thus, by itself, Respondent's unauthorized dispensing of controlled substances while practicing in Arizona establishes that his registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f).

Moreover, there is additional evidence of prescribing violations that supports this conclusion. As found above, upon moving to Colorado, Respondent proceeded to issue numerous controlled substance prescriptions without being registered in that State.

Under DEA's regulation, where a registrant seeks to change his registered location, the registrant must apply to modify his registration, 21 CFR § 1301.51(a), and this regulation clearly states that a ''request for modification shall be handled in the same manner as an application for registration.'' *Id.* § 1301.51(c). Moreover, under 21 CFR 1301.13(a), ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.'' *Id.; see also Anthony E. Wicks,* 78 FR 62676, 62678 (2013). Thus, a registrant may ''not engage in any activity for which registration is required until the application . . . is granted and a . . . [r]egistration is issued.'' 21 CFR 1301.13(a). *See also Mark Koch* 79 FR 18714 (2014).

Here, the evidence shows that between July 29, 2014 and December 1, 2014, Respondent issued 89 prescriptions for controlled substances while practicing in Grand Junction, Colorado, when he did not hold a DEA registration in the State and was therefore not authorized to dispense controlled substances in the State. 21 U.S.C. 822(e) (''A separate registration shall be required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances. . . .''); 21 CFR 1301.12. Moreover, while Respondent claims that he was unaware that he could not issue controlled substance prescriptions until the Agency approved his modification request and that he stopped after he was told by the DI that he could not write prescriptions until his request was approved, the evidence shows that he issued further controlled substance prescriptions after he was told by the DI that he lacked authority to do so in Colorado.

Accordingly, I conclude that Respondent violated the CSA and DEA regulations when he prescribed controlled substances in Colorado before April 6, 2015. These findings, particularly when considered in light of the extent of the Applicant's prescribing violations in Arizona, support the conclusion that granting Applicant's application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).[23]

SANCTION

Where, as here, the Government has established grounds to deny an application, Respondent must then ''present[ ] sufficient mitigating evidence'' to show why he can be entrusted with a new registration. *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 [his] actions and demonstrate that [he] will not engage in

provide him/her with a hearing to challenge the State's action. *See Bourne Pharmacy,* 72 FR 18273, 18274 (2007).

Because Respondent's Colorado medical license has been suspended, he is no longer currently authorized to dispense controlled substances in Colorado, the State in which he seeks registration. Thus, he no longer meets the CSA's requirement that he be authorized to dispense controlled substances in the State where he is registered. This conclusion provides a further reason to deny his application.

[22] While the Government argues that the Board's findings establish that Respondent ''failed to comply with state law by deviating from the standard of care in issuing prescriptions for controlled substances,'' the Arizona Board did not find that he engaged in ''[p]rescribing, dispensing, or administering controlled substances . . . for other than therapeutic purposes.'' *See* Ariz. Rev. Stat. § 32–1854. In short, neither of the provisions the Board found Respondent to have violated make specific reference to controlled substances but are provisions generally applicable to all osteopathic physicians. As such, while Respondent's conduct involved controlled substances, the provisions he violated are not laws related to controlled substances.

Notwithstanding that the Board did not find that he prescribed ''for other than therapeutic purposes,'' the Board's findings and conclusions might well have supported an adverse finding under Factor Two because ''DEA's authority to [deny an application] is not limited to those instances in which a practitioner intentionally diverts,'' and ''[a] practitioner who ignores the warning signs that [his] patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. 824(a)(4), even if [he] is merely gullible or naïve.'' *Jayam Krishna-Iyer,* 74 FR 459, 461 n.3 (2009) (citing *Paul J. Caragine, Jr.,* 63 FR 51592 (1998)). As *Caragine* explained, even ''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial'' of an application. 63 FR at 51601. The Government did not, however, raise this theory in the Show Cause Order.

[23] As for Factor Three, there is no evidence that Applicant has been convicted of an offense ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). There are, however, a number of reasons why 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.*

As for the Government's arguments with respect to Factor Five, I consider its contentions in my discussion of the appropriate sanction.

future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (citing *Medicine Shoppe,* 73 FR 364, 387(2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Cuong Tron Tran,* 63 FR 64280, 64283 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995).[24]

So too, an Applicant's candor during the course of an investigation and subsequent proceeding is an important factor to be considered in determining whether he has accepted responsibility for the proven misconduct as well as the appropriate disposition of the matter. *See Robert F. Hunt,* 75 FR 49995, 50004 (2010); *Jeri Hassman,* 75 FR 8194, 8236 (2010); *see also Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (''Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a physician's registration is consistent with the public interest.'').

While an applicant must accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct in order to establish that its registration is consistent with the public interest, DEA has repeatedly held that these are not the only factors that are relevant in determining the appropriate disposition of the matter. *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 Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

So too, the Agency can consider the need to deter similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

Having reviewed Respondent's Position Statement, I conclude that he has failed to produce sufficient evidence to show why he should be entrusted with a new registration. With respect to his acceptance of responsibility, Respondent states only that he ''accepts full responsibility for his actions that lead [sic] to the sanctions imposed by Arizona'' and ''regrets and acknowledges that he prescribed controlled substances in Colorado while his modification request was pending.'' GX 5, at 7–8. Putting aside that the credibility of Respondent's statement cannot be tested through cross-examination because Respondent waived his right to a hearing, it is notable that Respondent does not acknowledge that he materially falsified his March 2013 application for registration in Tennessee. Respondent's failure to acknowledge his misconduct in this regard is fatal to his application.

Moreover, even with respect to his misconduct in prescribing controlled substances in Colorado, I conclude that Respondent has not adequately acknowledged his misconduct. Even putting aside that ignorance of the law is no excuse, Respondent's statement regarding his actions is less than forthcoming. As found above, Respondent asserted that ''[a]s soon as I understood my mistake, I immediately stopped prescribing controlled substances.'' Yet the evidence shows that on December 1, 2014, the DI phoned him and told him that he lacked authority to issue controlled substance prescriptions in Colorado. While this should have been the point at which he ''understood [his] mistake'' and ''immediately stopped prescribing,'' the evidence shows that Respondent issued additional controlled substance prescriptions thereafter. In short, Respondent's assertion is clearly false and I therefore also find that he has not accepted responsibility for his prescribing in Colorado when he lacked a DEA registration.

Likewise, while Respondent contends that he prescribed controlled substances in violation of the first Arizona order because he ''did not fully understand the scope of my initial restriction, which caused [him] to inadvertently violate that restriction,'' having reviewed that Order, I conclude that it was more than clear. *See* GX 8, at 4 (''IT IS HEREBY FURTHER ORDERED that [Respondent], holder of osteopathic medical License number 2686 is restricted from prescribing or recommending Schedule I, II, III, or IV controlled substances for a period of two (2) years from the effective date of this Order.''). Indeed, if Respondent did not fully understand the scope of the restriction, he had five weeks to contact the Board and clarify his understanding before the Order went into effect. Nor is Respondent's explanation credible given that he continued prescribing and issuing dispensing orders even after he surrendered his DEA registration. I thus conclude that Respondent has not credibly acknowledged his misconduct.

I also conclude that the record as a whole establishes that Respondent's misconduct was egregious given his material falsification of his March 2013 DEA application, his prescribing of controlled substances after the Arizona Board's Order became effective, and his continued prescribing in Arizona after he surrendered his DEA registration. As for his prescribing in Colorado, even were I to accept his excuse that he mistakenly believed that he could prescribe once he submitted his request for modification, his issuance of prescriptions after he was told by the DI that he lacked authority to write prescriptions in the State renders this misconduct egregious as well.

Accordingly, I find that Respondent's misconduct warrants denial of his application for this reason as well. So too, I find that the Agency's interest in deterring similar misconduct by other applicants who may contemplate materially falsifying their applications, as well as by other registrants who may choose to ignore agency regulations and prescribe when they lack authority to do so, supports the denial of his application.

Of further note, as explained in my discussion of Factor One, subsequent to the issuance of the Show Cause Order and Respondent's submission of his Position Statement, the Colorado Medical Board suspended his medical license and his license remains suspended as of the date of this Order. As a consequence, Respondent no longer holds authority under state law to dispense controlled substances in the State where he is currently registered and thus no longer meets the statutory prerequisite for obtaining and maintaining his registration. *See Frederick Marsh Blanton,* 43 FR 27616, 27617 (1978) (''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.''); *see also* 21 U.S.C. 823(f) (''The Attorney General shall register practitioners . . .

[24] This rule also applies to other grounds that support the denial of an application, such as where the Government has proven that an applicant materially falsified his application. *See Jackson,* 72 FR, at 23853.

if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.''); 21 U.S.C. 802(21) (''[t]he term 'practitioner' means a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice'').[25]

While the Show Cause Order did not assert this as a ground for denial of his application (because it occurred subsequent to the issuance of the Order), the Government did serve a copy of its Addendum which presented this development to me, on Respondent. In response to this filing, Respondent has raised no objection.[26] In any event, there are two other independent and legally sufficient bases to deny his application. Accordingly, I will deny his application.

ORDER

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

Dated: September 13, 2016.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Nanosyn, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before November 21, 2016.

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on December 18, 2015, Nanosyn, Inc., Nanoscale Combinatorial Synthesis, 3331–B Industrial Drive, Santa Rosa, California 95403 applied to be registered as a bulk manufacturer the of following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Oxymorphone	9652	II
Fentanyl	9801	II

The company is a contract manufacturer. At the request of the company's customers, it manufacturers derivatives of controlled substances in bulk form.

Dated: September 15, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Kevin L. Lowe, M.D.; Decision and Order

On May 18, 2016, Chief Administrative Law Judge John J. Mulrooney, II (CALJ), issued the attached Recommended Decision (R.D.).[1] Therein, the CALJ found that it is undisputed that Respondent is currently without authority to handle controlled substances in New York, the State in which he holds DEA Registration FL2580163. R.D. at 4. The CALJ thus granted the Government's Motion for Summary Disposition and recommended that I revoke Respondent's registration and deny any pending applications.

Neither party filed exceptions to the Recommended Decision. Having reviewed the record, I adopt the CALJ's finding that Respondent lacks state authority to handle controlled substances in New York, the State in which he is registered. ''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.'' *Frederick Marsh Blanton,* 43 FR 27616, 27617 (1978). *See also Rezik A. Saqer,* 81 FR 22122, 22124–127 (2016). Thus, once the Government establishes that an applicant for a practitioner's registration or a practitioner-registrant does not possess state authority, there are no further facts to be considered and revocation is the mandatory sanction that must be entered under the Controlled Substances Act. Accordingly, I will also adopt the CALJ's recommendation that I revoke Respondent's registration and deny any pending application to renew or modify his registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FL2580163 issued to Kevin L. Lowe, M.D., be, and it hereby is, revoked. I further order that any pending application of Kevin L. Lowe, M.D., to renew or modify the above registration, be, and it hereby is, denied. This Order is effective immediately.[2]

[25] *See also Rezik A. Saqer,* 81 FR 22122, 22125–27 (2016); *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988).

[26] DEA has previously held that ''[t]he rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence. The Government's failure to file an amended Show Cause Order alleging that Respondent's state CDS license has expired does not render the proceeding fundamentally unfair.'' *Roy E. Berkowitz,* 74 FR 36758, 36759–60 (2009); *see also Hatem M. Ataya,* 81 FR 8221, 8245 (2016) (collecting cases).

[1] All citations to the Recommended Decision are to the slip opinion issued by the CALJ.

[2] Based on Respondent's acknowledgment that he has been convicted of conspiring to unlawfully distribute controlled substances, *see* Resp.'s Hrng. Req., at 1–2, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.