

status confounds logic. Stated differently, the level of care exercised on Dr. Aguilar's scrips was the same as every other controlled substance scrip issued during the relevant period. The Agency has revoked based on as few as two acts of intentional diversion, and it held that one such act can be sufficient. *MacKay*, 75 FR at 4997; *Krishna-Iyer*, 74 FR at 463. While the dispensing acts proven on this record may not have been intentional, there were certainly well more than one or two.

Similarly, that the Respondents argue (without specific figures) that they have made "minimal" pecuniary gain due to their lack of care helps their respective causes not at all. A reduced profit margin is no more persuasive evidence in the context of a registrant pharmacy as it would be in the case of a street dealer in illicit drugs. The focus is on maintaining a closed regulatory system that protects the public from the unlawful distribution of controlled substances. *Gonzales*, 545 U.S. at 13. A registrant's voluntary decision to abandon the most basic of its registrant obligations should not result in any profit. Further, as is true with the Respondents' argument regarding the relative percentage of scrips that can be attributed to Dr. Aguilar, in an environment where no serious COR checking was employed, there is no basis in reason for evaluating the money Moro-Perez's pharmacies made from prescriptions authorized by Dr. Aguilar as compared to those by other practitioners. Who knows which of the issuing prescribers were actually registered? Hence, that the "pecuniary benefits gained" from dispensing controlled substances on Dr. Aguilar's scrips "is minimal"¹⁰² means nothing and mitigates nothing.

As discussed in detail, *supra*, the Respondents argument that they turned down "many" of Dr. Aguilar's prescriptions they thought to be illegitimate actually exacerbates the pharmacies' positions. Turning down "many" prescriptions from Dr. Aguilar that pharmacists determined to be illegitimate should have caused increased circumspection about dispensing on Aguilar's scrips. Instead, even by their own account, the pharmacies identified Dr. Aguilar as a problematic prescriber, never checked his COR status, and kept dispensing many of the prescriptions he authorized.

In their closing brief, the Respondents ask that, in making its decision on the COR applications, the Agency consider that "[t]here are . . . more than 40 employees among two pharmacies whose welfare depend on their jobs at the pharmacies [and that in] small towns like San Sebastian and Moca in Puerto Rico, this means a lot." ALJ Ex. 24, at 21 (internal transcript citations omitted). Even setting aside for a moment Moro-Perez's testimony that controlled substances account for only 10–15% of the prescription medications dispensed at each of the Respondent pharmacies,¹⁰³ any blame for the lost jobs must properly be laid at the feet of the Respondents themselves, and Moro-Perez in particular. It is settled Agency

precedent that normal hardships to the practitioner, and even the surrounding community, which are attendant upon the denial of a registration, are not a relevant consideration in determining whether status as a COR registrant is in the public interest within the meaning of the CSA. *Cheek*, 76 FR at 66972–73; *Owens*, 74 FR at 36757; *Abbadessa*, 74 FR at 10078.

Finally, insofar as the Respondents point to the fact that the Government's theory of the case and its evidence have never relied on the absence of a legitimate medical purpose (LMP) for any of the scrips in question, it is certainly true that the Agency has looked at the LMP issue where prescriptions were issued by a prescriber who lacked proper authorization. *Kam*, 78 FR at 62698. However, that the Government has advanced no LMP evidence does not mitigate the evidence that was received regarding the Respondents' breach in their respective duties of due care in ensuring that controlled substance prescriptions were authorized by a practitioner with a valid COR.

Regarding the material false misrepresentations intentionally placed into the COR applications, Moro-Perez doggedly adhered to his illogical position that he was reasonable in representing on the COR applications that neither pharmacy had ever surrendered a registration for cause. By Moro-Perez's intractable logic, the dismissal of an indictment against him (not either pharmacy) that occurred after the for-cause surrender of Best Pharma's COR, but before the for-cause surrender of Farmacia Nueva's COR, rendered both surrenders no longer "for cause." Moro-Perez is an experienced COR holder and an educated, veteran pharmacist. His insistence that his false response to an application query regarding whether each pharmacy had ever surrendered a COR for cause was some sort of reasonable misunderstanding is simply not credible and defeats the Respondents' efforts to meet the Government's case. The false misrepresentation regarding the errant denial of the Respondents' prior surrenders for cause are sufficiently egregious on their face to warrant sanction, and the denial of the Respondents' applications here serve the Agency's interest in deterring false statements on the applications that it depends upon in its decisionmaking.

The Respondents have, thus, failed to rebut the Government's *prima facie* case regarding either material falsification of their applications or a balancing of the public interest factors. Further, consideration of the egregiousness of the offenses, coupled with the Agency's interest in both specific deterrence regarding these pharmacies, and general deterrence among the regulated community, supports the denial of both COR applications. Accordingly, the Respondents' respective applications for DEA Certificates of Registration should be DENIED.

Dated: October 24, 2013.
s/JOHN J. MULROONEY, II,
Chief Administrative Law Judge.

[FR Doc. 2015–12043 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14–27]

Maryanne Phillips-Elias, M.D.; Decision and Order

On October 23, 2014, Administrative Law Judge (ALJ) Christopher McNeil issued the attached Recommended Decision. Therein, the ALJ found that it was undisputed that Respondent's Nevada Controlled Substance Registration had been revoked and that she does not possess authority to dispense controlled substances in Nevada, the State in which she holds her DEA registration. R.D. at 6; *see also id.* at 2. The ALJ thus concluded that Respondent is no longer a practitioner within the meaning of the Controlled Substances Act and is therefore not entitled to be registered. He therefore recommended that I "deny Respondent's application for a DEA Certificate of Registration." R.D. at 9.

There is, however, no evidence that an application is currently pending before the Agency. Rather, the Government seeks the revocation of Respondent's registration, which does not expire until March 31, 2017, and authorizes her to dispense controlled substances in schedules II through V, at registered premises located in Henderson, Nevada. Order to Show Cause, at 1.

Pursuant to 21 U.S.C. 824(a)(3), "[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has had [her] State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." This Agency has further held that notwithstanding that this provision grants the Agency authority to suspend or revoke a registration, other provisions of the Controlled Substances Act "make plain that a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances." *James L. Hooper*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, *Hooper v. Holder*, 481 F. App'x 826 (4th Cir. 2012).

These provisions include section 102(21), which defines the term "practitioner" to "mean[] a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which [s]he practices . . . to distribute, dispense, [or] administer . . . a

¹⁰² ALJ Ex. 24, at 21.

¹⁰³ Tr. 244–45.

controlled substance in the course of professional practice.” 21 U.S.C. 802(21), as well as section 303(f), which directs that “[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 [s]he practices.” *Id.* § 823(f). Based on these provisions, the Agency has long held that revocation is warranted even where a state order has summarily suspended a practitioner’s controlled substances authority and the state agency’s order remains subject to challenge in either administrative or judicial proceedings.¹ See *Gary Alfred Shearer*, 78 FR 19009 (2013); *Carmencita E. Gallora*, 60 FR 47967 (1995).

Respondent argues that she “should be given a hearing to present evidence to refute the legitimacy of the revocation” of her state registration by the Nevada Pharmacy Board. Respondent’s Reply to the Govt.’s Mot. for Summary Judgment, at 2. According to Respondent, the Nevada Board’s Order is invalid “because the Board never identified the specific grounds for which [her] license should be revoked in Nevada.” *Id.* at 3.

Respondent thus seeks to collaterally attack the Nevada Board’s Order. However, “DEA has repeatedly held that a registrant cannot collaterally attack the results of a state criminal or administrative proceeding in a proceeding brought under section 304 [21 U.S.C. 824] of the CSA.” *Calvin Ramsey*, 76 FR 20034, 20036 (2011) (quoting *Hicham K. Riba*, 73 FR 75773, 75774 (2008) (other citations omitted)); see also *Shahid Musud Siddiqui*, 61 FR 14818 (1996); *Robert A. Leslie*, 60 FR 14004 (1995). Respondent must therefore seek relief from the State Board’s Order in those administrative and judicial forums provided by the State. Her various contentions as to the validity of the Nevada Pharmacy Board’s order are therefore not material to this Agency’s resolution of whether she is entitled to maintain her DEA registration.

As for her argument that the Agency’s use of summary disposition to revoke her DEA registration has denied her “fundamental fairness” because DEA

regulations provide that she is entitled to a hearing, Resp. Reply at 3; “summary judgment has been used for more than 100 years to resolve legal ‘actions in which there is no genuine issue as to any material fact’ and has never been deemed to violate Due Process.” *Ramsey*, 76 FR at 20036 (citing Fed. R. Civ. P. 56 (Advisory Committee Notes—1937 Adoption) and *Codd v. Velger*, 429 U.S. 624, 627 (1977)). Respondent was provided with the opportunity to dispute the material fact which is dispositive of the Government’s allegation that she lacks authority to dispense controlled substances in the State in which she is registered and therefore cannot remain registered. I thus reject her contention that the use of summary disposition denied her fundamental fairness.

Accordingly, for reasons explained above and with the caveat that there is no application pending before the Agency, I adopt the ALJ’s factual finding that Respondent’s Nevada controlled substance registration has been revoked and therefore she does not possess authority under Nevada law to dispense controlled substances. I further adopt the ALJ’s legal conclusion that Respondent is no longer a practitioner within the meaning of the CSA and is therefore not entitled to be registered. However, because there is no application currently pending before the Agency, I do not adopt those portions of his opinion which discuss whether Respondent’s application should be granted or denied, including his Recommendation that I deny her application. Instead, for reasons explained above, I will order that Respondent’s registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 28 CFR 0.100(b) I order that DEA Certificate of Registration FP2501648 issued to Maryanne Phillips-Elias be, and it hereby is, revoked. This Order is effectively immediately.

Dated: May 1, 2015

Michele M. Leonhart,
Administrator.

Brian Bayly, Esq., for the Government.

Michael Khouri, Esq., and *Ashley K. Kagasoff, Esq.*, for the Respondent.

RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Nature of the Case and Procedural History

Administrative Law Judge Christopher B. McNeil. Maryanne Phillips-Elias, M.D., the respondent in this case, is registered with the DEA as a practitioner in Schedules II through V under Drug Enforcement Administration (DEA) certificate registration number FP2501648 at 9065 S. Peco Rd., Ste. 250, Henderson, NV 89074.¹ The registration number expires by its own terms on March 31, 2017.²

On September 17, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause as to why the DEA should not revoke her current certificate of registration, deny any applications for renewal or modification, and deny any application for any other DEA registration pursuant to 21 U.S.C. 823(f) and 21 U.S.C. 824(a)(3).³ As grounds for revocation, the Government alleges that Respondent does not have authority to handle controlled substances in Nevada, the State in which Respondent is registered with the DEA.⁴

On September 26, 2014, Respondent, through her Attorneys, Ashley K. Kagasoff, Esq., and Michael Khouri, Esq., filed a timely request for hearing.⁵ Respondent does not dispute that her controlled substance registration was revoked by the Nevada State Board of Pharmacy.⁶ Instead, Respondent asserts that the Nevada State Board of Pharmacy acted on grounds that did not warrant discipline and that the Board’s decision was arbitrary.⁷ Respondent has a writ, *Maryanne Phillips v. Nevada State Board of Pharmacy*,⁸ pending in the First Judicial Court of Carson City County, Nevada to set aside the decision to revoke Respondent’s registration.⁹ Respondent asks me to delay any hearing until the writ is resolved.¹⁰ Alternatively, if the delay is not granted, Respondent expresses her wish to continue with the hearing as planned.¹¹

¹ Order to Show Cause dated Sept. 17, 2014 at 1.

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ Respondent’s Request for Hearing dated Sept. 23, 2014 at 1, received by DEA Sept. 26, 2014.

⁶ *Id.*

⁷ *Id.*

⁸ Case No. 14–OC–00064.

⁹ Respondent’s Request for Hearing at 1.

¹⁰ *Id.*

¹¹ *Id.*

¹ I thus also reject Respondent’s contention that because she “has not acted [in a manner] inconsistent with [the] public interest as laid out in” section 823(f), “DEA has discretion to carve out an exception in this case” to the CSA’s requirement that she possess state authority to hold a DEA registration. Resp. Reply, at 4. As explained above, this is a requirement imposed by statute which DEA has no authority to waive.

I received the Government's Motion for Summary Judgment on October 8, 2014, with proof of service upon Respondent, accompanied by supporting documentation.¹² In my Order of September 30, 2014, I directed the Government to provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances.¹³ The factual premise relied upon by the Government in support of its motion is that Respondent does not have a controlled substance registration issued by the Nevada State Board of Pharmacy, the state in which Respondent is registered.¹⁴ Additionally, in the same Order, I provided Respondent the opportunity to respond to the Government's Motion for Summary Judgment.¹⁵ That response was due seven business days after service of the Government's motion on opposing parties.¹⁶ On October 17, 2014, I received Respondent's timely response.¹⁷ The Government exercised its right to reply to the response and submitted a reply on October 22, 2014.¹⁸ Drawing from the motion and briefs submitted, I find as follows:

Issue

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's application must be summarily denied because Respondent does not have a controlled substance registration issued by the state in which she intends to practice.¹⁹ 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 she maintains DEA

registration.²⁰ Unless from the pleadings now before me there is a material issue regarding Respondent's authority to handle controlled substances in Nevada, the application must be denied summarily, without a hearing.

Respondent's Contentions

In Respondent's Reply to the Motion for Summary Judgment, Respondent never disputes the Government's contention that she is not currently licensed by the State of Nevada to dispense controlled substances.²¹ Instead, Respondent asserts three legal arguments. Respondent's first legal argument is that Respondent should be given a hearing to present evidence to refute the legitimacy of the revocation.²² Respondent states her belief that the matter should be determined following the resolution of Respondent's writ and that the Nevada State Board of Pharmacy relied on insufficient grounds to revoke her state controlled substance registration.²³ Respondent's second argument is that she has been denied fundamental fairness by the DEA.²⁴ Respondent writes that "it does not make any sense that Respondent is given the right to a hearing only to get denied one, once the request is made."²⁵ Finally, Respondent asserts that the DEA has discretion to do what is in the best interest of promoting the public interest.²⁶ After stating the five public interest factors provided by 21 U.S.C. 823(f), Respondent declares that allowing her to retain her license is not inconsistent with the public interest.²⁷

Scope of Authority

On September 17, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause proposing to deny the application

pursuant to 21 U.S.C. 824(a)(3) and 21 U.S.C. 823(f).²⁸

Respondent believes that she should be given a hearing to present evidence to refute the legitimacy of the revocation following the resolution of Respondent's writ to demonstrate that the Nevada State Board of Pharmacy relied on insufficient grounds to revoke her state controlled substance registration.²⁹ However, the case before me is presented under a grant of authority to recommend that the Administrator either continue or revoke Respondent's Certificate of Registration for controlled substances. Pursuant to 21 U.S.C. 823(f), the DEA may grant such an application only to a "practitioner." 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 grant a registration to a practitioner if that practitioner is not authorized to dispense controlled substances.³⁰

The fact that Respondent is currently in the process of appealing what she views as an unjust decision of the Nevada State Board of Pharmacy does not change this outcome. As the Government notes, the assertion that she might prevail in overturning the Board's revocation order is "highly speculative."³¹ Even if Respondent was very likely to succeed on appeal, summary disposition is still appropriate. As the Government notes in its Reply in Support of its Motion for Summary Judgment, "[a]ll that matters is that Respondent lacks state authority to dispense or distribute controlled substances."³² Under no circumstances is the DEA authorized to provide a doctor, such as Respondent, the ability to dispense controlled substances when the doctor does not possess their state controlled substance registration. This limitation is not without meaning. In the first subchapter of the Controlled Substances Act (CSA), 21 U.S.C. 801,

¹² Government's Motion for Summary Judgment dated Oct. 7, 2014 at 1–18, received by DEA Oct. 8, 2014.

¹³ Order for Briefing on Allegations Concerning Respondent's Lack of State Authority dated Sept. 30, 2014 at 1.

¹⁴ Government's Motion for Summary Judgment at 1–3.

¹⁵ Order for Briefing on Allegations Concerning Respondent's Lack of State Authority at 2.

¹⁶ *Id.*

¹⁷ Respondent Maryanne Phillips-Elias, M.D. Reply to the Government's Motion for Summary Judgment and Declaration of Ashley K. Kagasoff in Support Thereof dated Oct. 16, 2014 at 1. Note that the fax was received at 6:00pm E.D.T. on October 16, 2014. As the document was received after normal business hours, the document is treated as if it was received on October 17, 2014. Regardless, the response was timely received.

¹⁸ Government's Reply in Support of its Motion for Summary Judgment dated Oct. 22, 2014 at 1.

¹⁹ Government's Motion for Summary Judgment at 1–2.

²⁰ See 21 U.S.C. 801(21), 823(f), 824(a)(3); see also *House of Medicine*, 79 FR 4959, 4961 (DEA 2014); *Deanwood Pharmacy*, 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.*, 77 FR 67669–02 (DEA November 13, 2012); *Alan H. Olefsky, M.D.*, 72 FR 42127–01 (DEA August 1, 2007); *Layfe Robert Anthony, M.D.*, 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA-C*, 64 FR 15811–02 (DEA April 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 April 14, 1994); *Abraham A. Chaplan, M.D.*, 57 FR 55280–03 (DEA November 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).

²¹ Reply to the Government's Motion for Summary Judgment at 2.

²² *Id.*

²³ *Id.* at 2–3.

²⁴ *Id.* at 3.

²⁵ *Id.*

²⁶ *Id.* at 4.

²⁷ *Id.*

²⁸ Order to Show Cause at 1.

²⁹ Reply to the Government's Motion for Summary Judgment at 2–3.

³⁰ See *Abraham A. Chaplan, M.D.*, 57 FR 55280–03, 55280 (DEA November 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.*

³¹ Government's Motion for Summary Judgment at 3.

³² Government's Reply in Support of its Motion for Summary Judgment at 2.

Congress acknowledged that controlled substances when utilized improperly “have a substantial and detrimental effect on the health and general welfare of the American people.”³³ Mandating that a practitioner possess state authority before providing a practitioner the privilege to handle controlled substances lowers the risk of diversion by illegitimate or unqualified practitioners.

Respondent also alleges that she has been denied fundamental fairness by the DEA.³⁴ Specifically, Respondent cites that fact that the Government’s Order to Show Cause provides her notice of the opportunity of a hearing to show cause why the DEA should not revoke her DEA certificate of registration, but later denies her a hearing.³⁵ Although Respondent may believe it is unfair that the DEA denies her a hearing after issuing an Order to Show Cause, Respondent has failed to show that any disputed material fact is involved regarding her state controlled substance registration. If Respondent through her Reply to Government’s Motion for Summary Judgment demonstrated that there was a dispute as to the material fact of whether her state controlled substance registration was revoked, I would not have dismissed this case without a comprehensive hearing. However, the inability for the DEA to grant Respondent a DEA certificate of registration without a valid state controlled substance registration prevents further consideration of this matter.

Respondent’s final argument is that the DEA has discretion to act in the public interest to not revoke Respondent’s federal certificate of registration.³⁶ In her Reply to Government’s Motion for Summary Judgment, Respondent correctly notes that to determine whether a DEA certificate of registration is in the public interest, a DEA ALJ must consider the factors enumerated under 21 U.S.C. 823(f).³⁷ Respondent proceeds to apply the factors to her specific situation to make the argument that she should not

lose her DEA certificate of registration.³⁸ Quoting the Declaration of Ashley Kagasoff,³⁹ Respondent cites statements such as that she has never been convicted of a federal or state crime to support the notion that not revoking her DEA COR is consistent with the public interest.⁴⁰ Such statements made by Respondent are unpersuasive. If Respondent is successful in her writ and her state license to dispense controlled substances is restored, she is welcome to immediately apply for a new DEA certificate of registration. If Respondent’s application for a new registration is opposed by the DEA and Respondent exercises her right to a hearing, it is at that time—not before that time—that a DEA ALJ will hear evidence from both Respondent and the Government as to whether the registration is consistent with the public interest.

Facts

Given this body of law, the material fact here, indeed the sole fact of consequence, is whether Respondent is authorized by the State of Nevada to dispense controlled substances. Where, as here, no material fact is in dispute, there is no need for an evidentiary hearing and summary disposition is appropriate.⁴¹ The sole question of fact before me can be addressed, and has been addressed, by the pleadings submitted to me by the parties. Our record includes no dispute regarding the Government’s contention that the authority of Dr. Phillips-Elias to dispense controlled substances in Nevada was revoked by the Nevada State Board of Pharmacy on June 13, 2014.⁴² The reasons for the revocation are not material, given the statutory language set forth above.

Analysis, Findings of Fact and Conclusions of Law

In determining whether to grant the Government’s Motion for Summary Disposition, I am required to apply the principle of law that holds such a motion may be granted in an administrative proceeding if no material question of fact exists:

It is settled law that when no fact question is involved or the facts are

³⁸ Reply to the Government’s Motion for Summary Judgment at 4–5.

³⁹ See Declaration of Ashley K. Kagasoff in Support Thereof.

⁴⁰ Reply to the Government’s Motion for Summary Judgment at 4.

⁴¹ See *Michael G. Dolin, M.D.*, 65 FR 5661 (DEA February 4, 2000); see also *Philip E. Kirk, M.D.*, 48 FR 32887 (DEA July 19, 1983), *aff’d sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984).

⁴² Order to Show Cause at 1.

agreed, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., is not obligatory—even though a pertinent statute prescribes a hearing. In such situations, the rationale is that Congress does not intend administrative agencies to perform meaningless tasks (citations omitted).⁴³

In this context, I am further guided by prior decisions before the DEA involving certificate holders who lacked licenses to distribute or dispense controlled substances. On the issue of whether an evidentiary hearing is required, “it is well settled that when there is no question of material fact involved, there is no need for a plenary, administrative hearing.”⁴⁴ Under this guidance, the Government’s motion must be sustained unless a material fact question has been presented.

The sole determinative fact now before me is that Respondent lacks a Nevada controlled substance registration. In order for a doctor to receive a DEA registration authorizing her to dispense controlled substances under 21 U.S.C. 823(f), she must meet the definition of “practitioner” as found in the Controlled Substances Act.⁴⁵ Such a person must be “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.”⁴⁶ Delegating to the Attorney General the authority to determine who may or may not be registered to perform these duties, Congress permitted such registration only to “practitioners” as defined by the Controlled Substances Act.⁴⁷

As cited by the Government in its Motion for Summary Judgment, there is substantial authority both through agency precedent and through decisions of courts in review of that precedent, holding that a doctor’s DEA controlled substance registration is dependent upon the doctor having a state license to dispense controlled substances.⁴⁸ Under the doctrine before me, the Government meets its burden of

⁴³ *NLRB v. International Assoc. of Bridge*, 549 F.2d 634, 638 (9th Cir. 1977) (quoting *United States v. Consolidated Mines & Smelting Co., Ltd.*, 455 F.2d 432, 453 (9th Cir. 1971)).

⁴⁴ See *Michael G. Dolin, M.D.*, 65 FR 5661 (DEA February 4, 2000); *Jesus R. Juarez, M.D.*, 62 FR 14945 (DEA March 28, 1997); see also *Philip E. Kirk, M.D.*, 48 FR 32887 (DEA July 19, 1983), *aff’d sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984).

⁴⁵ 21 U.S.C. 802(21).

⁴⁶ *Id.*

⁴⁷ 21 U.S.C. 823(f).

⁴⁸ Government’s Motion for Summary Judgment at 1–3 and cases cited therein.

³³ Controlled Substances Act, 21 U.S.C. 801(1), 1970.

³⁴ Reply to the Government’s Motion for Summary Judgment at 3. Respondent’s allegation does not directly allege a violation of her constitutional right to due process. Respondent’s failure to make a conspicuous claim regarding due process has led to a waiver of this constitutional claim. However, if Respondent chooses to submit exceptions to this order referencing her constitutional right to due process, she may succeed in preserving the issue for appeal.

³⁵ *Id.* at 3; Order to Show Cause at 1.

³⁶ Reply to the Government’s Motion for Summary Judgment at 4–5.

³⁷ *Id.* at 4. See also 21 U.S.C. 823(f).

establishing grounds to deny an application for registration upon sufficient proof establishing the applicant does not possess a state controlled substance registration. That proof is in the record before me, and it warrants the summary revocation of Respondent's DEA Certificate of Registration.

I am mindful of the arguments raised by Respondent in her Reply to the Government's Motion for Summary Judgment, including the fact that Respondent is currently appealing the revocation of her state controlled substance registration.⁴⁹ These difficulties do not, however, change the fact that without a state controlled substance registration, Respondent is not a "practitioner" and cannot be granted a Certificate of Registration.

Some care should be taken to assure the parties that the actions taken in this administrative proceeding conform to constitutional requirements. I have examined the parties' contentions with an eye towards ensuring all tenets of due process have been adhered to. There is, however, no authority for me to evaluate the facts that underlie Respondent's contentions. In the proceedings now before me, the only material question was answered by Respondent in her Request for Hearing. Further, while the Order to Show Cause sets forth a non-exhaustive summary of facts and law relevant to a determination that granting this application would be inconsistent with the public interest under 21 U.S.C. 823(f), the conclusion, order and recommendation that follow are based solely on a finding that Respondent is not a "practitioner" as that term is defined by 21 U.S.C. 802(21), and I make no finding regarding whether granting this application would or would not be inconsistent with the public interest.

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 she seeks to operate under a DEA Certificate of Registration. I find no other material facts at issue, for the reasons set forth in the Government's Motion for Summary Disposition.

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 **RECOMMEND** the Administrator **DENY** Respondent's application for a DEA Certificate of Registration.

Dated: October 23, 2014.
Christopher B. McNeil,
Administrative Law Judge.
[FR Doc. 2015-12023 Filed 5-18-15; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15-13]

Sharad C. Patel, M.D.; Decision and Order

On March 11, 2015, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision (cited as R.D.). Thereafter, on April 1, Respondent filed a pleading entitled as "Objections to Findings of Fact, Conclusions of Law, and Recommended Decision of the Administrative Law Judge (hereinafter, Resp. Objections). Therein, Respondent objected to the entry of the ALJ's Recommended Decision, on the ground that "he was never properly, or sufficiently, served with the [Government's] initial motion" for summary disposition and therefore "did not respond to the . . . [m]otion . . . because he was unaware of any such motion until the ALJ's Order granting such motion." Objections, at 1.

Respondent argues that in his request for hearing, his attorneys provided both a mailing address and email address for receiving the "notices to be sent pursuant to the proceeding." 21 CFR 1316.47(a); Objections at 1. Respondent did not, however, provide a fax number. *Id.* at 2.

Thereafter, Respondent received the ALJ's Order for Briefing on Allegations Concerning Respondent's Lack of State Authority" by First Class Mail. *Id.* The ALJ's Order specified the date (Mar. 2, 2015) by which the Government was to provide its evidence and arguments (as well as its motion for summary disposition) in support of its contention that Respondent does not possess "state authority to handle controlled substances," as well as the date by which Respondent was to file his response (Mar. 9) to any such motion. *Id.*

On March 2, the Government filed its Motion for Summary Disposition with the Office of Administrative Law Judges. Motion for Summ. Disp., at 1. In the Certificate of Service, the Government represented that it had served the Motion by facsimile, but not by first class mail or email.¹ *Id.* at 4. In its Objections, Respondent asserts that he "did not respond to the DEA Motion for Summary Disposition because he was unaware of any such motion until the ALJ's Order granting such motion." Objections, at 1.

As stated above, on March 11, the ALJ issued his Recommended Decision. Therein, the ALJ noted that the Government had attached a copy of the Emergency Order of Suspension issued by the Kentucky Board of Medical Licensure; the Order, which was issued on November 24, 2014, suspended Respondent's Kentucky medical license "effectively immediately upon its receipt." Mot. For Supp. Disp., Attachment 1, at 18.

In his Recommended Decision, the ALJ noted that Respondent had not filed a response to the Government's motion. R.D. at 2. However, the ALJ also noted that in his hearing request, Respondent had "admit[ted] that his license is temporary [sic] suspended" but that "he expects to prevail before the medical board at an upcoming hearing on May 18, 2015." *Id.* at 3. As explained in his decision, the ALJ found that there was no dispute that Respondent "is not authorized to handle controlled substances in the State in which he maintains his registration" and is therefore not a practitioner within the meaning of the Controlled Substances Act. *Id.* The ALJ thus recommended that Respondent's registration be revoked and that any pending application be denied.

Thereafter, the ALJ forwarded the record to me, noting in his letter that Respondent's objections were not timely filed. Letter from ALJ to Administrator (Apr. 7, 2015), at 2. The ALJ also provided a copy of a Transmission Verification Report showing that the Recommended Decision was successfully faxed to Respondent's

¹ Respondent's contention regarding the inadequacy of service is not without merit. Of note, Respondent did not consent to the service of pleadings by facsimile and the ALJ's Order for Briefing on Allegation Concerning Respondent's Lack of State Authority did not authorize service of pleadings in this manner. Moreover, while the use of electronic means has the advantage of faster service—at least where the transmission is successful—a hard copy should still be sent by mail, courier, or third party commercial carrier unless the serving party contacts the other party and affirmatively determines that the entire document was received.

⁴⁹ Reply to the Government's Motion for Summary Judgment at 2-3.