

BILLING CODE: 4410-09-P

DEPARTMENT OF JUSTICE Drug Enforcement Administration

[Docket No. 18-32] Narciso A. Reyes, M.D.; Decision and Order

On April 19, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Narciso A. Reyes, M.D. (hereinafter, Respondent), of Luquillo, Puerto Rico. Order to Show Cause (hereinafter, OSC), at 1. The Show Cause Order proposes the revocation of Respondent's DEA Certificate of Registration on the grounds that he materially falsified applications he submitted to DEA and that he has been excluded from participation in a program pursuant to 42 U.S.C. § 1320a-7(a). *Id.* (citing 21 U.S.C. § 824(a)(1) and (5)). It also proposes the denial of "any applications for renewal or modification of such registration and any applications for any other DEA registration." OSC, at 1 (citing 21 U.S.C. § 824(a)(1) and (5)).

Regarding jurisdiction, the Show Cause Order alleges that Respondent holds DEA Certificate of Registration No. FR4900305 at the registered address of Calle Fernandez Garcia 306, Luquillo, Puerto Rico 00773, with a mailing address of P.O. Box 247, Luquillo, PR 00773. OSC, at 2. This registration, the OSC alleges, authorizes Respondent to dispense controlled substances in schedules II through V as a practitioner. *Id.* The Show Cause Order alleges that this registration expires on April 30, 2020. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleges that, on October 20, 2009, the U.S. Department of Health and Human Services, Office of Inspector General (hereinafter, HHS/OIG), mandatorily excluded Respondent from participating in all Federal health care programs due to his conviction in U.S. District Court for conspiracy to

commit health care fraud. *Id.* at 2 (citing 42 U.S.C. § 1320a-7(a)(1)). According to the OSC, Respondent's "mandatory exclusion from Medicare, Medicaid and all Federal health care programs warrants revocation of . . . [his] registration." OSC, at 2 (citing 21 U.S.C. § 824(a)(5)).

The Show Cause Order further alleges that Respondent provided false answers to two "yes" or "no" liability questions when he applied for a DEA registration on October 16, 2014 and when he filed a renewal application on April 17, 2017. OSC, at 2-3. Specifically, the Show Cause Order alleges that Respondent twice answered that he had never been excluded from participation in a Medicare or state health care program when, in fact, he had been. *Id.* at 2-3. The Show Cause Order also alleges that Respondent twice answered that he had never surrendered (for cause) a Federal controlled substance registration when, in fact, he had. *Id.* at 3. According to the OSC, Respondent's answers to these liability questions are "material falsifications" that warrant revocation of his registration. *Id.*

The Show Cause Order notifies Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 3-4 (citing 21 C.F.R. § 1301.43). The Show Cause Order also notifies Respondent of the opportunity to submit a corrective action plan. OSC, at 4-5 (citing 21 U.S.C. § 824(c)(2)(C)).

Respondent timely requested a hearing on May 21, 2018. Hearing Request, at 1. In his Hearing Request, Respondent states that, "It was not my intention to fail to declare a material fact in the request for renewal. . . . I do not master the English language well and this may have

¹ Attached to the Government's Notice of Service of Order to Show Cause is a DEA-12 (Receipt for Cash or Other Items) that, according to the Government's allegations, Respondent executed when the Government served the OSC on April 23, 2018. Respondent did challenge the Government's service-related allegations. Thus, I find that Respondent's Hearing Request was timely since it was filed within 30 days of service of the OSC. 21 C.F.R. § 1301.43(a).

contributed to these errors." *Id.* He also states in his Hearing Request that, "My inclusion of the word N in the renewal request was in my estimate to indicate that it did not apply since I had reached an agreement with the US Attorney's Office in Puerto Rico. Clearly my mistake." *Id.*

The Office of Administrative Law Judges (hereinafter, OALJ) put the matter on the docket and assigned it to Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ). I adopt the following statement of procedural history from the ALJ's Order Granting the Government's Motion for Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision dated June 22, 2018 (hereinafter, R.D.).

On May 31, 2018, the Government filed a Motion for Summary Disposition ("Government's Motion"). The Government's Motion argued that there is no issue of material fact in this case to warrant an adversarial hearing. The Government's Motion further requested that I summarily dispose of this matter without a hearing and recommend to the Acting Administrator that . . . [Respondent's] DEA registration be revoked. On the same day, I issued an Order affording . . . [Respondent] the opportunity to respond to the Government's Motion by June 14, 2018. I explained that if . . . [Respondent] disagreed with any of the Government's statements of undisputed material facts as outlined in its motion for summary disposition, he should provide copies of documentary evidence refuting the Government's statement(s). I further directed . . . [Respondent] to identify the material fact(s) which justify an evidentiary hearing in this case. . . . [Respondent] failed to respond to the Government's Motion by the deadline on June 14, 2018.

On June 15, 2018, the day after . . . [Respondent's] Response was due, chambers staff emailed . . . [Respondent's] counsel notifying him that the OALJ had not received a response from him and asking whether he intended to submit a late filing. . . . [Respondent's] counsel replied by email on June 17, 2018, with the following statement: "There are no allegations on behalf of . . . [Respondent]. The documents are self [e]xplanatory."

Then, on June 21, 2018, the OALJ received a filing from . . . [Respondent's] counsel titled "Statement of Narciso A. Reyes, M.D." The filing states that . . . [Respondent] "will not make any statement regarding this administrative action" and that "[t]he issue is hereby submitted for final ruling."

R.D., at 2-3, 7.

The ALJ correctly concluded that Respondent's choice not to refute, challenge, or even address any of the Government's reliable and probative evidence and legal arguments "strongly indicates that he no longer wishes to proceed to hearing." *Id.* at 10. After analyzing the Government's evidence and legal argument, the ALJ granted the Government's Motion for Summary Disposition and recommended that I revoke Respondent's registration and deny any pending applications for renewal or modification. *Id.* at 10, 18.

By letter dated July 16, 2018, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions and that the time period to do so had expired.

I issue this Decision and Order based on the entire record before me. 21 C.F.R. § 1301.43(e). I make the following findings of fact.

FINDINGS OF FACT

Respondent's Criminal Conviction and Ensuing Mandatory Exclusion

On November 3, 2008, Respondent pled guilty in Federal District Court to one count of conspiracy to commit health care fraud. Government's Motion, GE-2 (Plea Agreement, United States v. Reyes Carrillo, No. 08-cr-168 (D. P.R. Nov. 3, 2008)), at 1. According to the facts submitted by the Assistant United States Attorney and explicitly adopted by Respondent, Respondent signed blank or previously completed false Certificates of Medical Necessity for durable medical equipment for Medicare beneficiaries whom he had never seen. *Id.* at 9. The Federal District Judge entered judgment against Respondent on March 13, 2009. Government's Motion, GE-3 (Judgment, United States v. Reyes Carrillo, No. 08-cr-168-03 (D. P.R. March 13, 2009)), at 1.

Based on Respondent's conviction for conspiracy to commit health care fraud, the HHS/OIG notified Respondent of his mandatory exclusion from participation in any capacity in Medicare, Medicaid, and all Federal health care programs for the minimum statutory period of five years effective October 20, 2009. Government's Motion, GE-4 (HHS/OIG Exclusion Letter), at 1 (citing 42 U.S.C. § 1320a-7(a)); Government's Motion, GE-5 (HHS/OIG Exclusions Search Results: Verify), at 1. The HHS/OIG Exclusion Letter advised Respondent that reinstatement of eligibility to participate in these programs is not automatic. Government's Motion, GE-4, at 2. Respondent is still excluded from participation in these programs. Government's Motion, GE-5, at 1.

Respondent's DEA Registration History and Current Registration Status

On January 31, 2013, Respondent voluntarily surrendered for cause DEA registration No. BR3465944. Government's Motion, GE-8 (Respondent's DEA-104 Voluntary Surrender of Controlled Substances Privileges), at 1; Government's Motion, GE-9 (Certification of Registration History), at 1. Neither the DEA-104 nor any other evidence in the record explains the context of this voluntary surrender. DEA retired registration No. BR3465944 on February 4, 2013. Government's Motion, GE-9, at 1.

On October 16, 2014, Respondent submitted an application for a new DEA registration.

Government's Motion, GE-10 (Respondent's DEA Form 224 submitted on October 16, 2014), at

1. The application Respondent completed includes "yes" or "no" liability questions that an applicant must answer to advance to the next page of the online DEA application. Government's Motion, GE-1 (Certification of Registration Status), at 2; Government's Motion, GE-10, at 1.

The first liability question that Respondent answered on his online DEA application for a registration asks: "Has the applicant ever been convicted of a crime in connection with

controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or [is] any such action pending?" Government's Motion, GE-1, at 2; Government's Motion, GE-10, at 1. Respondent answered "no" to this question. Government's Motion, GE-1, at 2; Government's Motion, GE-10, at 1. The HHS/OIG Exclusion letter makes it clear that Respondent knew or should have known that his "no" response to this question was false. Government's Motion, GE-4, at 1-2.

The second liability question that Respondent answered on his online DEA application for a registration asks: "Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?" Government's Motion, GE-1, at 2; Government's Motion, GE-10, at 1. Respondent answered "no" to this question. Government's Motion, GE-1, at 2; Government's Motion, GE-10, at 1. The DEA-104 Voluntary Surrender of Controlled Substances Privileges form that Respondent signed, however, makes it clear that Respondent knew or should have known that his "no" response to this question was false. Government's Motion, GE-8, at 1.

DEA approved Respondent's application and, on October 17, 2014, assigned DEA Certificate of Registration No. FR4900305 to him. Government's Motion, GE-1, at 1.

On April 17, 2017, Respondent submitted an online DEA renewal application for his DEA registration No. FR4900305. Government's Motion, GE-1, at 1; Government's Motion, GE-11 (Respondent's DEA Form 224A submitted on April 17, 2017), at 1. The online DEA renewal application Respondent submitted includes "yes" or "no" liability questions that an applicant must answer to advance to the next page of the online DEA renewal application. Government's Motion, GE-1, at 1; Government's Motion, GE-11, at 1.

The first liability question that Respondent answered on his online DEA renewal application asks: "Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or [is] any such action pending?" Government's Motion, GE-1, at 1; Government's Motion, GE-11, at 1. Respondent answered "no" to this question. Government's Motion, GE-1, at 1; Government's Motion, GE-11, at 1. Again, the HHS/OIG Exclusion letter makes it clear that Respondent knew or should have known that his "no" response to this question was false. Government's Motion, GE-4, at 1-2.

The second liability question that Respondent answered on his online DEA renewal application asks: "Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?" Government's Motion, GE-1, at 1; Government's Motion, GE-11, at 1. Respondent answered "no" to this question. Government's Motion, GE-1, at 1; Government's Motion, GE-11, at 1. Again, the DEA-104 Voluntary Surrender of Controlled Substances Privileges form that Respondent signed makes it clear that Respondent knew or should have known that his "no" response to this question was false. Government's Motion, GE-8, at 1.

DEA approved Respondent's renewal application on April 19, 2017. Government's Motion, GE-1, at 1.

In sum, Respondent is currently registered as a practitioner in schedules II through V under DEA Certificate of Registration FR4900305 at Calle Fernandez Garcia 306, Luquillo, Puerto Rico 00773. Government's Motion, GE-1, at 1. Respondent's registration expires on April 30, 2020. *Id*.

DISCUSSION

The Material Falsification Allegation

Pursuant to 21 U.S.C. § 824(a)(1), the Attorney General may suspend or revoke a registration issued under section 823 of Title 21, "upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter." According to Agency precedent, the Government must show that a respondent "knew or should have known" that his response to a liability question was false. *Samuel S. Jackson, D.D.S.*, 72 FR 23,848, 23,852 (2007). Also according to Agency precedent, a respondent's claim that he misunderstood a liability question is not a defense. *Alvin Darby, M.D.*, 75 FR 26,993, 26,999 (2010).

According to the Supreme Court, Federal courts' "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, 701-02 (D.C. Cir. 1956) (other citation omitted)). The Court explicitly addressed what 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, supra*, 485 U.S. at 771 (emphasis in original). Instead, the Court articulated the specific test as "whether the misrepresentation or concealment was predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision." *Id.*

As already discussed, when Respondent submitted an online DEA application for a registration and an online DEA renewal application, he answered "no" to whether he had ever been excluded from participation in Medicare and to whether he had ever surrendered a

registration for cause. As I already found above, Respondent's four answers were false and he "knew or should have known" that they were false.

I next determine the "materiality" of Respondent's four answers. 21 U.S.C. § 824(a)(1). Concerning Respondent's false statements about his voluntary surrender of DEA registration No. BR3465944, the DEA-104 that Respondent executed does not indicate the underlying reason(s) for Respondent's "alleged failure to comply with the Federal requirements pertaining to controlled substances." Government's Motion, GE-8, at 1. Further, as the ALJ noted, the DEA-104 reveals nothing about whether Respondent's "alleged failure" "had a natural tendency to affect" an Agency decision. R.D., at 13-14 (quoting *Michel P. Toret, M.D.*, 82 FR 60,041, 60,043 (2017) quoting *Kungys, supra,* 485 U.S. at 771). I found no evidence in the record concerning the materiality of Respondent's two false answers about his voluntary surrender. Thus, I agree with the ALJ that the record does not support a finding that Respondent's two false answers about his voluntary surrender of registration No. BR3465944 were "materially" false. 21 U.S.C. § 824(a)(1).

Concerning Respondent's false statements regarding his mandatory exclusion, the Agency has never before considered the materiality of a respondent's false answers about his mandatory exclusion as that question is posed in this case. I find the ALJ's analysis persuasive: "Considering that exclusion from a federal health care program under 42 U.S.C. § 1320a-7(a) is an independent basis for revoking [a] registration . . ., it is reasonable to conclude that information regarding an applicant's mandatory exclusion by HHS would be 'capable of influencing the [DEA's] decision."" R.D., at 13 (citations omitted). I agree with the ALJ. I find that Respondent's failure to disclose his mandatory exclusion from a Federal health care program is material. *Id.* Thus, I find that there is substantial evidence in the record that Respondent

materially falsified a DEA registration application and a DEA registration renewal application concerning his mandatory exclusion. 21 U.S.C. § 824(a)(1).

The Allegation of Mandatory Exclusion from a Federal Health Care Program

Pursuant to 21 U.S.C. § 824(a)(5), the Attorney General may suspend or revoke a registration issued under section 823 of Title 21, "upon a finding that the registrant ... has been excluded ... from participation in a program pursuant to section 1320a-7(a) of Title 42." Agency precedent makes clear that revocation under 21 U.S.C. § 824(a)(5) may be appropriate regardless of whether or not the misconduct that led to the mandatory exclusion involved controlled substances. KK Pharmacy, 64 FR 49,507, 49,510 (1999) (collecting cases) (The Agency "has previously held that misconduct which does not involve controlled substances may constitute grounds, under 21 U.S.C. 824(a)(5), for the revocation of a DEA Certificate of Registration."); Melvin N. Seglin, M.D., 63 FR 70,431, 70,433 (1998) ("[M]isconduct which does not involve controlled substances may constitute grounds for the revocation of a DEA registration pursuant to 21 U.S.C. 824(a)(5)."); Stanley Dubin, D.D.S., 61 FR 60,727, 60,728 (1996) (Registration revoked and pending applications for renewal denied when registrant's "actions cast substantial doubt on ... [his] integrity."); George D. Osafo, M.D., 58 FR 37,508, 37,509 (1993) (Submission of fraudulent medical claims and larceny convictions indicated that registrant "placed monetary gain above the welfare of his patients, and in so doing, endangered the public health and safety.").

Under 42 U.S.C. § 1320a-7(a)(1), the HHS OIG is required to exclude from participation in any Federal health care program any individual who has been convicted of a criminal offense "related to the delivery of an item or service under ... [42 U.S.C. 1395 *et seq.*] or under any State health care program." Based on the uncontroverted evidence in the record, as already discussed,

I found that Respondent has been excluded from participation in any capacity in Medicare, Medicaid, and all Federal health care programs and that Respondent is still excluded from participation in these programs. Accordingly, I find that the evidence in the record satisfies the Government's *prima facie* burden to support the revocation of Respondent's registration under 21 U.S.C. § 824(a)(5).

SANCTION

Where, as here, the Government has met its *prima facie* burden, the burden shifts to Respondent to show why he can be entrusted with a registration. Respondent, however, did not submit evidence for the record. Instead, he stated that the documents are self-explanatory, that he "will not make any statement regarding this administrative action," and that "[t]he issue is hereby submitted for final ruling." R.D., at 7. Thus, the question now is whether revocation is the appropriate sanction under the facts I have found: two separate violations whose statutory sanctions include revocation. 21 U.S.C. § 824(a)(1) and (5).

I agree with the ALJ's analysis and conclude that revocation is independently the appropriate sanction for each of the separate violations the facts support. In particular, I agree with the ALJ's analysis that, even though the underlying misconduct which led to Respondent's conviction and mandatory exclusion did not involve controlled substances, it did involve the unlawful use of Respondent's prescribing authority. R.D., at 17. As the ALJ stated, "This type of fraudulent behavior does not inspire confidence that ... [Respondent] can be trusted with a prescription pad bearing a DEA registration number." *Id.* After all, if Respondent signed blank certificates of medical necessity for durable medical equipment that was not medically necessary, "it is doubtful that DEA can expect ... [Respondent] to honestly prescribe controlled substances for only legitimate medical purposes." *Id.*

Further, Respondent materially falsified two DEA applications. One such falsification,

alone, is sufficient, without proof of any other misconduct, to revoke a registration. *Toret, supra*,

82 FR at 60,043. As the ALJ stated, "[N]ot only has the Government proven two independent

bases for revoking ... [Respondent's] registration ..., but ... [Respondent] has not advanced

any evidence that he 'can be trusted to responsibly discharge his obligations as a registrant."

R.D., at 17-18 (citation omitted).

Accordingly, based on the evidence in the record supporting two independent bases for

revocation, I shall order that Respondent's DEA registration be revoked and that any pending

application of Respondent to renew or to modify that registration be denied.

Order

Pursuant to 28 C.F.R. § 0.100(b) and the authority thus vested in me by 21 U.S.C. 824(a),

I order that DEA Certificate of Registration No. FR4900305 issued to Narciso A. Reyes, M.D.,

be, and it hereby is, revoked. Pursuant to 28 C.F.R. § 0.100(b) and the authority thus vested in

me by 21 U.S.C. 823(f), I further order that any pending application of Narciso A. Reyes, M.D.,

to renew or to modify this registration, be, and it hereby is, denied. This Order is effective

[insert Date Thirty Days From the Date of Publication in the Federal Register].

Dated: November 19, 2018.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2018-26047 Filed: 11/29/2018 8:45 am; Publication Date: 11/30/2018]

12