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Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Moustafa M. Aboshady, M.D.; Decision and Order

On January 18, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Moustafa M. Aboshady, M.D. (Applicant). Request for Final Agency Action (RFAA), Attachment (Attach.) A, at 1, 3. The OSC proposed the denial of Applicant's application for a DEA registration, No. W23147064C, in Salt Lake City, Utah. *Id.* at 1. The OSC alleged that Applicant's application should be denied because he has "been mandatorily excluded from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a-7(a)." *Id.* (citing 21 U.S.C. 824(a)(5)).

The OSC notified Applicant of his right to "file with DEA a written request for a hearing," and that if he failed to file such a request, he would "be deemed to have waived [his] right to a hearing and to be in default." *Id.* at 2 (citing 21 CFR 1301.43). The OSC further notified Applicant that if he requested a hearing but failed to "timely file an answer, plead, or otherwise defend," he would "be deemed to have waived the right to a hearing and to be in default, and DEA may enter an order terminating the proceeding." *Id.* (citing 21 CFR 1301.43(c)(2), (c)(3), (d)). The OSC also notified Applicant that "[d]efault constitutes a waiver of [his] right to a hearing and an admission of the factual allegations of the [OSC]." *Id.* (citing 21 CFR 1301.43(e)).

On February 6, 2024, the OSC was served on Applicant by email. RFAA, at 1. On February 13, 2024, Applicant filed a timely hearing request with the DEA Office of Administrative Law Judges (OALJ) and the matter was assigned to the Chief Administrative Law Judge (Chief ALJ). *Id.* at 2. On the same day, the Chief ALJ issued an Order for

Prehearing Statements and Directing Compliance (Order), noting that Applicant had failed to file an answer to the OSC as required by DEA regulations, and establishing a deadline of February 21, 2024, for filing an answer. RFAA, Attach. B, at 1-2 (citing 21 CFR 1301.37(d), 1316.47(b)).

On February 20, 2024, the day before the Chief ALJ's deadline for filing an answer, Applicant informed OALJ by email that he desired additional time to respond to the Order because he was in the process of hiring a lawyer. RFAA, Attach. C, at 1. That same day, the Chief ALJ denied the request for additional time, explaining that filing an answer could be completed within the allotted time and that "more time could be allowed for preparation if/when he was successful in procuring representation." *Id.* at 1-2. On February 21, 2024, Applicant submitted a Corrective Action Plan, but he did not file an answer. *Id.* at 2.

On February 22, 2024, the day after the answer was due, the Government filed a Motion to Terminate Proceedings (Motion to Terminate), arguing that Applicant had waived his right to a hearing by failing to file an answer and by failing to show good cause for such failure. *Id.* at 2. On the same day, the Chief ALJ issued a Briefing Order directing Applicant to file a response to the Motion to Terminate by February 28, 2024. *Id.* On February 27, 2024, Applicant sent an email to OALJ indicating that he "request[ed] to withdraw[] [his] application." ¹ *Id.* Applicant did not otherwise respond to the Motion to Terminate. On February 28, 2024, the Chief ALJ issued an Order Terminating Proceedings (Termination Order), finding that the Motion to Terminate stood unopposed and that Applicant's withdrawal request demonstrated that he was "no longer seeking a hearing on the matter." *Id.* Applicant has not filed a motion to set aside the Termination Order. 21 CFR 1301.43(c)(3).

"In the event that [an applicant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67." 21 CFR 1301.43(f)(1). Here, the Government has requested final agency action based on

¹ To the extent that Applicant's email can be construed as a desire to withdraw his application for registration, the Agency has considered the relevant factors and denies Applicant's withdrawal request because it is not in the public interest. See *Edge Pharmacy*, 81 FR 72092, 72102 (2016) (discussing 21 CFR 1301.16(a)).

Applicant's default pursuant to 21 CFR 1301.43(c), (f), because Applicant did not timely file an answer to the OSC, did not "otherwise defend" himself against the Government's Motion to Terminate, has not filed a motion with the Administrator to set aside the Termination Order, has indicated a desire to withdraw his hearing request or application, and has not filed a motion with the Administrator to set aside the default. See also *id.* § 1316.67.

The Agency finds that Applicant is in default based on his failure to "plead . . . or otherwise defend himself," as evidenced by his failure to substantively respond to the Government's Motion to Terminate, his failure to file a motion to set aside the Chief ALJ's termination order, and his request to withdraw his application.² *Id.* § 1301.37(c)(3).

I. Applicable Law

Pursuant to 21 U.S.C. 824(a)(5), the Attorney General is authorized to suspend or revoke a registration upon finding that the registrant "has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42." *Id.* § 824(a)(5).³ The Agency has consistently held that it may also deny an application upon finding that an applicant has been excluded from a federal health care program. *Arvinder Singh, M.D.*, 81 FR 8247, 8248 n.3 (2016) (quoting *Kwan Bo Jin, M.D.*, 77 FR 35021, 35021 n.2 (2012)) ("[W]here a registration can be revoked under [21 U.S.C.] 824, it can, *a fortiori*, be denied under [21 U.S.C.] 823 since the law would not require an agency to indulge in the useless act of granting a license on one day only to withdraw it on the next."); *Robert Wayne Locklear, M.D.*, 86 FR 33745 (citing *South Corp. v. United States*, 690 F.2d 1369, 1374 (Fed. Cir. 1982)) ("A statutory construction which would impute a useless act to Congress will be viewed as unsound and rejected.").

² Here, the OSC was served on February 6, 2024. The matter was terminated from the hearing stage on February 28, 2024, which was well after the Chief ALJ's established deadline for filing an answer, but before the regulatory deadline set forth in 21 CFR 1301.37(d). Because the Agency already finds Applicant to be in default based on 1301.37(c)(3), it need not consider whether Applicant is in default under 21 CFR 1301.37(c)(2).

³ In its OSC, the Government relies upon grounds Congress provided to support revocation/suspension, not denial of an application. Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.*, 86 FR 33738, 33744-45 (2021) (collecting cases).

II. Findings of Fact

The Agency finds that, in light of Applicant's default, the factual allegations in the OSC are admitted. 21 CFR 1301.43(e). Accordingly, Applicant is deemed to have admitted that in 2018 he was convicted of one count of conspiracy to make false statements in connection with health care benefits programs in violation of 18 U.S.C. 371 and two counts of making false statements in connection with health care benefits programs or aiding and abetting in violation of 18 U.S.C. 1035.⁴ RFAA, Attach. A, at 2. Applicant further admits that, as a result of his conviction,⁵ the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG), mandatorily excluded Applicant from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a-7(a), for a minimum of 15 years. *Id.* The exclusion became effective on August 30, 2019. *Id.*

Accordingly, the Agency finds substantial record evidence that Applicant has been excluded from participation in Medicare, Medicaid, and all Federal health care programs.

III. Discussion

The OSC's sole allegation is that Applicant's application should be denied as a result of his mandatory exclusion "from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a-7(a)." RFAA, Attach. A, at 1 (citing 21 U.S.C. 824(a)(5)). Here, the Agency found above that HHS/OIG mandatorily excluded Applicant from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a-7(a), for a minimum of 15 years. *Id.* at 2. Accordingly, the Agency finds that the Government established a *prima facie* case for denying Applicant's registration, that Applicant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the denial of Applicant's application. 21 U.S.C. 824(a)(5).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing

⁴ Applicant further admits that his conviction was upheld on appeal in 2020. RFAA, Attach. A, at 2.

⁵ The underlying conviction forming the basis for mandatory exclusion from participation in federal health care programs need not involve controlled substances to provide the grounds for revocation or denial pursuant to section 824(a)(5). *Jeffrey Stein, M.D.*, 84 FR 46,968, 46,971-46,972 (2019); *see also Narciso Reyes, M.D.*, 83 FR 61678, 61681 (2018); *KK Pharmacy*, 64 FR 49507, 49510 (1999) (collecting cases).

that Applicant's application for a registration should be denied, the burden shifts to the Applicant to show why he can be entrusted with the responsibility carried by a registration. *Morall*, 412 F.3d. at 174; *Jones Total Health Care Pharmacy*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 FR 18882 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 833. A registrant's acceptance of responsibility must be unequivocal. *Id.* at 830-31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. DEA Administrators have also considered the need to deter similar acts by the specific registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46972-73.

Here, although Applicant initially requested a hearing, he failed to "plead . . . or otherwise defend" and was deemed to be in default. 21 CFR 1301.43(c)(3). To date, Applicant has not filed any motion to set aside the default with the Office of the Administrator. 21 CFR 1301.43(c). Applicant has thus failed to answer the allegations contained in the OSC and has not otherwise availed himself of the opportunity to refute the Government's case. As such, Applicant has made no representations as to his future compliance with the CSA nor made any demonstration that he can be entrusted with registration. Moreover, the evidence presented by the Government shows that Applicant was convicted of charges related to making false statements in connection with health care benefits programs, further indicating that Applicant cannot be entrusted.

Accordingly, the Agency will order the denial of Applicant's application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the pending application for a DEA Certificate of Registration, Control No. W23147064C, submitted by Moustafa M. Aboshady, M.D., as well as any other pending application of Moustafa M. Aboshady, M.D., for additional registration in Utah. This Order is effective May 16, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on April 10, 2025, by Acting Administrator Derek Maltz. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Empire Pharmacy Inc.; Skyline Pharmacy Inc.; Decision and Order

I. Introduction

On October 31, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registrations (OSC/ISO) to Empire Pharmacy, Inc., and Skyline Pharmacy, Inc., of Philadelphia, Pennsylvania (collectively, Registrants). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 18. The OSC/ISO informed Registrants of the immediate suspension of their DEA Certificates of Registration, Nos. FE8167733 and FS0903840, pursuant to 21 U.S.C. 824(d), alleging that Registrants' continued registration constitutes "'an imminent danger to the public health or safety.'" *Id.* at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrants' registrations, alleging that Registrants' continued registration is inconsistent with the