



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mark Agresti, M.D.; Decision and Order

On November 29, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Mark Agresti, M.D., of Palm Beach, Florida (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant’s DEA Certificate of Registration No. BA2032441, alleging that Registrant has “been mandatorily excluded from Federal health care programs pursuant to 42 U.S.C. § 1320a-7(a).” *Id.* at 1 (citing 21 U.S.C. 824(a)(5)).

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.¹ “A default, unless excused, shall be deemed to constitute a waiver of the registrant’s/applicant’s right to a hearing and an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

Further, “[i]n the event that a registrant . . . 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.” *Id.* at 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant’s default pursuant to 21 CFR 1301.43(c), (e), (f), 1301.46. RFAA, at 4; *see also* 21 CFR 1316.67.

FINDINGS OF FACT

¹ Based on the Government’s submissions in its RFAA dated November 26, 2024, the Agency finds that service of the OSC on Registrant was adequate. The included Declaration from a DEA Diversion Investigator (DI) indicates that on December 1, 2023, the DI traveled to Registrant’s attorney’s office and personally served Registrant’s attorney with a copy of the OSC. RFAAX 3, Attachment D. Registrant’s attorney signed a Form DEA-12, confirming receipt of the OSC. *Id.*

The Agency finds that, in light of Registrant’s default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant admits that in 2022, he was convicted of one count of conspiracy to commit health care fraud and wire fraud, and 11 counts of health care fraud, in violation of 18 U.S.C. 1349, 1347. RFAAX 2, at 2. As a result of Registrant’s conviction,² the United States Department of Health and Human Services, Office of Inspector General (HHS/OIG), mandatorily excluded Registrant from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a-7(a) for a minimum period of 47 years. *Id.* The exclusion became effective on January 19, 2023. *Id.* Accordingly, the Agency finds substantial record evidence that Registrant has been excluded from participation in Medicare, Medicaid, and all Federal health care programs.

DISCUSSION

Pursuant to 21 U.S.C. 824(a)(5), the Attorney General may 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.”

The OSC solely alleges that Registrant’s registration should be revoked 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).” RFAAX 2, at 1 (citing 21 U.S.C. 824(a)(5)). Above, the Agency found that HHS/OIG mandatorily excluded Registrant from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a-7(a), for a minimum of 47 years. *Id.* at 2. Accordingly, the Agency finds that the Government established a *prima facie* case for revoking Registrant’s registration, that Registrant did not rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Registrant’s registration. 21 U.S.C. 824(a)(5).

SANCTION

² 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). See *Moustafa M. Aboshady, M.D.*, 90 Fed. Reg. 15,992, 15,993 n.5 (2025) (collecting cases).

Where, as here, the Government has presented a *prima facie* case showing that Registrant's registration should be revoked, the burden shifts to Registrant to show why he can be entrusted with the responsibility carried by a registration. *Morall v. Drug Enforcement Admin.*, 412 F.3d 165, 174 (D.C. Cir. 2005); *Jones Total Health Care Pharmacy*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882 (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 Fed. Reg. 46,968, 46,972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency has required that registrants who have committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that they 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, the Agency has found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. The Agency has also considered the need to deter similar acts by the specific registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 Fed. Reg. at 46,972-73.

Here, Registrant failed to answer the allegations contained in the OSC, submit a corrective action plan, or otherwise avail himself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to his future compliance with the CSA nor demonstrated that he can be entrusted with registration. Moreover, the evidence presented by the Government shows that Registrant was convicted of charges related to health care fraud, further indicating that Registrant cannot be entrusted with registration.

Accordingly, the Agency will order the revocation of Registrant's registration.

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BA2032441, issued to Mark Agresti, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Mark Agresti, M.D., to renew or modify this registration, as well as any other pending application of Mark Agresti, M.D., for additional registration in Florida. This Order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on July 1, 2025, by Acting Administrator Robert J. Murphy. 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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