



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### By Grace Inc. Counseling Services; Decision And Order

#### I. INTRODUCTION

On October 29, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to By Grace Inc. Counseling Services of Baltimore, Maryland (Respondent). OSC, at 1. The OSC proposed the revocation of Respondent’s DEA registration, No. RB0369733, alleging that Respondent, a narcotic treatment program (NTP), “demonstrated a lack of effective controls and procedures to guard against the diversion of controlled substances” and committed numerous recordkeeping violations that rendered DEA unable to determine an accurate and complete inventory of the controlled substances on hand. *Id.* at 2-4 (citing 21 U.S.C. 823(g); 21 U.S.C. 824(a)<sup>1</sup>; 21 CFR 1304.11(a)-(c), 1304.11(c), 1304.21(a), (d), 1304.04(a), (f)(2), 1304.24(a), 1305.05). The Government additionally alleged in its Prehearing Statement that Respondent materially falsified its application for a DEA registration by falsely responding “no” to Liability Question 4—which asks whether any officer of the corporation has ever been convicted of a crime in connection with controlled substances—and by failing to disclose that its owner was convicted of unlawful possession of controlled substances in Maryland. Administrative Law Judge Exhibit (ALJX) 6, at 2-3.<sup>2</sup>

After conducting a hearing, Administrative Law Judge Paul E. Soeffing (ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the

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<sup>1</sup> In addition to alleging that Respondent violated 21 U.S.C. 823(h) by failing to maintain adequate records of its dispensing of controlled substances, the OSC alleged that Respondent’s recordkeeping violations rendered its registration inconsistent with the public interest under 21 U.S.C. 824(a). OSC, at 2. Because the Government’s Post-Hearing Brief discussed Respondent’s recordkeeping violations in the context of 21 U.S.C. 823(h) rather than analyzing the public interest factors, the Agency treats the public interest allegation as abandoned and does not consider it.

<sup>2</sup> The Government also alleged that Respondent ordered controlled substances when it lacked state authority. The Agency agrees with the ALJ that the Government did not provide notice in the OSC of the laws violated by this conduct, nor did the Government demonstrate through substantial evidence that Respondent lacked state authority when it ordered the controlled substances. RD, at 18-19.

Administrative Law Judge (Recommended Decision or RD) on May 14, 2025. The RD recommended that the Agency revoke Respondent's registration. RD, at 28. On June 3, 2025, the Government timely filed exceptions. The Agency adopts and hereby incorporates by reference the ALJ's credibility findings,<sup>3</sup> findings of fact, conclusions of law related to the Government's recordkeeping allegations, sanctions analysis, and recommended sanction, and summarizes and clarifies portions thereof herein. The Agency does not adopt the ALJ's conclusions of law related to the Government's material falsification allegation. Specifically, the Agency disagrees with the ALJ's conclusion that the Agency does not have authority to revoke an NTP's registration based on the material falsification of a DEA application and the Agency finds that the Government's material falsification allegation is supported by substantial evidence.

## **II. RESPONDENT'S RECORDKEEPING VIOLATIONS**

### **A. Applicable Law**

Congress enacted the Controlled Substances Act (CSA) "to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). A particular concern of Congress was "the need to prevent the diversion of drugs from legitimate to illicit channels," and it "devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Id.* at 12-13.

The CSA's requirements under this closed regulatory system include that "every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the [DEA] a registration." 21 U.S.C. 822(a)(2); *see also Gonzales v. Raich*, 545 U.S. at 27-28. To protect the American people and ensure compliance with the CSA, Congress empowered the Agency to deny, suspend, or revoke a DEA registration if the registrant failed to comply with the

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<sup>3</sup> The Agency adopts the ALJ's summary of each witness's testimony, as well as the ALJ's assessment of each witness's credibility. *See* RD, at 2-13.

CSA's recordkeeping requirements. 21 U.S.C. 824(a); 21 U.S.C. 823(h); *Gonzales v. Oregon*, 546 U.S. 243, 251 (2006).

The Respondent in this case is registered as an NTP under 21 U.S.C. 823(h). Under Section 304 of the CSA, “a registration pursuant to section 823(h)[] of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(h)[]<sup>4</sup> of this title.” 21 U.S.C. 824(a). Section 823(h) outlines three prerequisites for a practitioner applying for a registration to dispense narcotic drugs for maintenance treatment or detoxification treatment:

- (1) “the applicant . . . is determined by the Secretary to be qualified . . . to engage in the treatment with respect to which registration is sought;”
- (2) “the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs”; and
- (3) “the Secretary determines that the applicant will comply with standards established by the Secretary . . . respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.”

21 U.S.C. 823(h).

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<sup>4</sup> The subsection of 21 U.S.C. 823 applicable to narcotic treatment programs was modified on December 2, 2022, and again on December 28, 2022. Prior to the modifications, the relevant subsection applicable to narcotic treatment programs was designated as 21 U.S.C. 823(g)(1), and it had three subparts, A-B, which outlined the prerequisites for registration as a narcotic treatment program. On December 2, 2022, the subsection was redesignated as 21 U.S.C. 823(h)(1), and it retained the same three subparts as the previous version, A-B. On December 28, 2022, the subsection was again redesignated as 21 U.S.C. 823(h), and the three subparts outlining the registration prerequisites were redesignated as 1-3. The December 28, 2022, citation is used throughout this decision.

21 U.S.C. 824(a), which authorizes the Attorney General to suspend or revoke the registration of a narcotic treatment if the registration prerequisites are not met, references back to the relevant subsections of 21 U.S.C. 823. Prior to December 2, 2022, the revocation provisions of § 824(a) referred to the registration prerequisites in § 823(g)(1)(A-B). On December 2, 2022, 21 U.S.C. 824(a) was modified to reference the registration prerequisites in § 823(h)(1)(A-B). However, 21 U.S.C. 824(a) was not modified again to reflect the December 28, 2022 redesignation from 823(h)(1) to 823(h). As explained below, this was clearly an unintentional technical error.

As currently written, 21 U.S.C. 824(a) would only authorize the Attorney General to revoke a registration if the applicant is not “qualified . . . to engage in the treatment with respect to which registration is sought,” because it only references 823(h)(1), and not (h)(2) or (h)(3). However, there have not been any substantive changes to § 823 or § 824 that reflect an intent to limit the Attorney General's authority to revoke or suspend. Section 823(h) continues to clearly state that a registrant is not qualified to possess a registration unless all three subparts are met. Therefore, the Agency concludes that the failure to modify § 824(a) on December 22, 2022, was an oversight, and that Congress intended for the Attorney General to retain authority to suspend or revoke a registration if a registrant fails to adhere to any of the three registration prerequisites or standards referred to in section 823(h). *See Dept. of Def., Army Air Force Exchange Serv. v. Fed. Labor Relations Auth.*, 659 F.2d 1140, 1160 (D.C. Cir. 1981), cert. denied, 455 U.S. 945 (1982) (A statute should be read in a “manner which effectuates rather than frustrates the major purpose of the legislative draftsmen.”).

As the Agency has previously observed, “in contrast to every other category of registration set forth in section 823, Congress did not characterize these three provisions as ‘factors’ to be considered and given discretionary weight ‘[i]n determining the public interest.’ . . . Rather, the three subparagraphs of section 823[h] are conditions for registration.” *Turning Tide, Inc.*, 81 Fed. Reg. 47411, 47413 (2016).

In this matter, the Government’s evidence in support of its *prima facie* case relates to Respondent’s failure to comply with the requirements of 21 U.S.C. 823(h)(2) regarding “maintenance of records” for narcotic drugs. RFAAX 3, at 1-4.

#### **i. Continuing Records**

According to the CSA and its implementing regulations, every registrant dispensing controlled substances, including NTPs, “shall maintain, on a current basis, a complete and accurate record of each controlled substance . . . received, sold, delivered, or otherwise disposed of . . .” 21 U.S.C. 827(a)(3); 21 CFR 1304.21(a).<sup>5</sup> These records must include “the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed.” 21 CFR 1304.21(d). NTPs also must maintain a dispensing log with the following details about each narcotic controlled substance dispensed: “(1) Name of substance; (2) Strength of substance; (3) Dosage form; (4) Date dispensed; (5) Adequate identification of patient (consumer); (6) Amount consumed; (7) Amount and dosage form taken home by patient; and (8) Dispenser’s initials.” *Id.* § 1304.24(a). The Agency has repeatedly emphasized the importance of maintaining an accurate count of controlled substances on hand, observing that “the inability to account for a significant number of dosage units creates a grave risk of diversion.” *Houston Maintenance Clinic*, 83 Fed. Reg. 42144, 42157 (2018) (citing *Med. Shoppe-Jonesborough*, 73 Fed. Reg. 364, 367 (2008); *Paul H. Volkman, M.D.*, 73 Fed. Reg. 30630, 30644 (2008)).

#### **ii. Inventories**

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<sup>5</sup> Pursuant to 21 CFR 1304.03, 1304.21, every registrant, unless exempted, must comply with the recordkeeping and inventory requirements outlined in DEA’s implementing regulations. NTPs are explicitly named in 21 CFR 1304.04(f) as a registrant that must maintain records.

NTPs also must maintain an “initial inventory . . . of all stocks of controlled substances on hand on the date [the pharmacy] first engages in the . . . dispensing of controlled substances,” as well as a “biennial inventory . . . of all stocks of controlled substances on hand.” 21 CFR 1304.11(a)-(c); *see also* 21 U.S.C. 827 (“every registrant . . . shall . . . as soon [] as such registrant first engages in the . . . dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand”). A biennial inventory “may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.” 21 CFR 1304.11(a). A biennial inventory shall include, for each controlled substance in finished form: (1) the name of the substance; (2) the finished form of the substance (e.g., 10 mg tablet); (3) the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle); and (4) the number of commercial containers of each such finished form (e.g. four 100-tablet bottles). 21 CFR 1304.11(e)(1)(iii); *see* 21 CFR 1304.11(e)(6) (“Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.”). The registrant must make an exact count or measure of controlled substances listed in Schedule I or II. 21 CFR 1304.11(e)(6)(i). For substances in Schedules III, IV, or V, the registrant must “make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.” 21 CFR 1304.11(e)(6)(ii). Inventories and other records must be retained in a readily retrievable manner “for at least 2 years from the date of such inventory or records, for inspection and copying.” 21 CFR 1304.04(a).

### **iii. DEA Form 222**

The CSA’s implementing regulations specify the manner in which a DEA registrant authorized to order Schedule I and II controlled substances must fill out and execute a DEA Form 222. When a purchaser initiates an order of controlled substances, the purchaser fills out

the form according to 21 CFR 1305.12. Then, the purchaser makes a copy of the original Form 222 and submits the original to the supplier from which it is ordering. 21 CFR 1305.13(a). Once the order is filled, the purchaser must record on its copy of the Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser. 21 CFR 1305.13(e). If a DEA Form 222 cannot be filled for any reason, “the supplier must return the original DEA Form 222 to the purchaser with a statement as to the reason,” and the purchaser must maintain these records. 21 CFR 1305.15(b), (d). “The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.” 21 CFR 1305.17(a). “DEA Forms 222 must be maintained separately from all other records of the registrant. . . [and] are required to be kept available for inspection for a period of two years.” 21 CFR 1305.17(c).

#### **iv. Powers of Attorney**

Generally, only persons who are registered to handle Schedule I or II controlled substances may obtain and use a DEA Form 222 or issue electronic orders for Schedule I or II controlled substances. 21 CFR 1305.04(a). However, a registrant may execute a power of attorney to authorize one or more individuals to issue orders for Schedule I and II controlled substances on the registrant’s behalf. 21 CFR 1505.05. If the registrant is not an individual, the power of attorney must be executed by an officer of the registrant in addition to the person to whom the power of attorney is being granted and two witnesses. 21 CFR 1305.05(d). A power of attorney may be revoked at any time by the person who signed the most recent application for DEA registration or reregistration, and the revocation form must be signed by two witnesses. 21 CFR 1305.05(e), (f). Powers of attorney must be “retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney,” and they “must be available for inspection together with other records.” 21 CFR 1305.05(a).

#### **B. Findings of Fact**

Respondent has a history of recordkeeping violations that have resulted in the issuance of Letters of Admission (LOA) by DEA. Tr. 23; RD, at 3-4. The first LOA in 2015 cited several recordkeeping violations, including failing to maintain a biennial inventory, failing to properly fill out DEA Forms 222, and storing 70 bottles of methadone (a Schedule II controlled substance) on the floor of the nurses' station. Tr. 27; GX 2, at 1; RD, at 3. Respondent entered a Memorandum of Agreement ("MOA") with DEA in 2018 in which Respondent agreed that it had committed numerous recordkeeping violations, including failing to maintain a biennial inventory, failing to accurately record the number of packages received on DEA Forms 222, and failing to maintain a functioning alarm system. Tr. 27-29; GX 3, at 1; RD, at 3, 16. The MOA referenced recordkeeping violations that DEA investigators had discovered during audits in 2009, 2014, and 2017. GX 3, at 1; RD, at 17.

DEA issued another LOA in 2022 outlining further recordkeeping violations found during a September 7, 2022 inspection, including failing to indicate on the biennial inventory whether it was taken at the beginning of business or the close of business, failing to have two witnesses execute a power of attorney, and failing to maintain a written record of individuals authorized to receive controlled substances. Tr. 30-32; GX 4, at 1; RD, at 3. Respondent denied these violations in its Answer to the OSC, ALJX 3, at 1, but the Government submitted a letter written by Respondent on January 23, 2023, indicating that Respondent was taking corrective action to remedy the violations outlined in the 2022 LOA. GX 4, at 3; RD, at 17. This letter indicates that Respondent was aware of the recordkeeping violations in 2022 and did not contest them.

DEA received a complaint from the Maryland Behavioral Health Administration about Respondent in February of 2024 and DEA conducted an onsite inspection of Respondent on March 28, 2024. Tr. 20-21, 158; RD, at 4. DEA investigators<sup>6</sup> were unable to complete the

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<sup>6</sup> Two Diversion Investigators, DI1 and DI2, testified at the hearing about the investigation. They are referred to collectively throughout this Decision as "DEA investigators," or individually as DI1 and DI2.

inspection on that date because Respondent's owner, Pamela Dukes (Ms. Dukes), was unable to provide access to the dispensing room or to retrieve requested records, including dispensing records and DEA Forms 222. Tr. 37-38, 160; RD, at 4.

DEA investigators returned to Respondent on April 17, 2024, to complete the audit. Tr. 39-40, 160. Ms. Dukes, S.R. (a nurse), and Respondent's attorney were present. Tr. 40, 45; RD, at 4. DEA investigators retrieved some DEA Forms 222 and dispensing records and conducted a closing count and an alarm test. Tr. 40-41, 43-44, 46; GX 8, 10, 13. At the conclusion of the April 17, 2024 onsite visit, DEA investigators requested, but did not receive, powers of attorney, an alarm testing report, medical licenses, and additional DEA Forms 222. Tr. 47-48. Subsequently, Respondent provided investigators with the powers of attorney via email on April 19 and April 20, 2024. Tr. 48-49, 161; GX 9. Respondent also provided two additional dispensing reports via email. Tr. 51-53; GX 18.

DEA uncovered numerous recordkeeping violations during the 2024 audit.

#### Continuing Records

DEA's audit of Respondent's controlled substances revealed overages and shortages. Tr. 94-134; GX 12; RD, at 5, 23-24. These included an overage of 102,043 milligrams of methadone liquid,<sup>7</sup> an overage of four 5-mg tablets of methadone,<sup>8</sup> a shortage of eleven 10-mg tablets of methadone, and a shortage of 378 40-mg tablets of methadone. Tr. 106-07, 112-23, 135, 143; GX 12; RD, at 24. The audit also showed that Respondent had commingled 40-mg methadone tablets from various manufacturers into one column of dispensing thereby failing to keep a complete and accurate count of the controlled substances. Tr. 74, 120-21, 174; RD, at 24.

Respondent did not provide any reconciliation for the overages and had no comment on the overages during the closing discussion on July 22, 2024. Tr. 108, 175; RD, at 6. The closing

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<sup>7</sup> The overage indicates that Respondent dispensed more methadone than Respondent had on hand. Tr. 106-07, 143; RD, at 6.

<sup>8</sup> A shortage indicates that tablets that should be on site are missing. Tr. 112-14; RD, at 6. Respondent's only explanation for the shortage was that the methadone had been used. Tr. 114-15; RD, at 6.

discussion was conducted with S.R. and Ms. Dukes' child because Ms. Dukes excused herself before the closing discussion began. Tr. 124; RD, at 6. DEA investigators were therefore unable to do a reconciliation that reduced the shortage. Tr. 166. At the hearing, Ms. Dukes disputed the Government's calculations of the overages and shortages, but even under Ms. Dukes' calculations, there were still minor overages and shortages.<sup>9</sup> ALJX 18, at 7-8.

Accordingly, the Agency finds substantial evidence that Respondent's controlled substances inventory contained unexplained overages and shortages, which demonstrates that Respondent failed to maintain a complete and accurate record of controlled substances.

Further, DEA investigators reviewed the dispensing records supplied by Respondent on July 22, 2024, and they did not include all the information required by 21 CFR 1304.24(a). Tr. 127, 131-34; GX 11; RD, at 24. The records were missing the patient's full name, the name of the controlled substance and/or the dosage form, the amount administered on site, and/or the take-home dosage. Tr. 132-34; GX 11, at 1-17; RD, at 7, 24. Accordingly, the Agency finds substantial record evidence that Respondent's dispensing records did not contain the information required by 21 CFR 1304.24(a)(3).

### Inventories

DEA investigators received five biennial inventories, dated April 4, 2022, October 24, 2022, April 4, 2023, October 1, 2023, and April 4, 2024. Tr. 55; GX 8; RD, at 4, 20. The testimony and evidence demonstrated and the Agency finds substantial evidence that all five inventories failed to include the number of units in each commercial container, Tr. 57-62; GX 8; that the inventories on April 4, 2022, October 24, 2022, and April 4, 2023, failed to indicate

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<sup>9</sup> Ms. Dukes testified that there were "glitches" in the software Respondent used to conduct inventories and testified that the electronic reports would never be accurate. Tr. 241, 244, 249; RD, at 10. Ms. Dukes testified that Respondent maintained hand count inventories that reconciled the shortages. Tr. 244; RD, at 10. For example, Ms. Dukes testified that Respondent's hand count inventories for the 12-month period from April 2023 to April 2024 showed that only 1.25 tablets of Methadone and 0.08 milligrams of liquid Methadone were missing. Tr. 244-45.

DII testified that she did not accept Ms. Dukes' reconciliation because the hand records did not contain adequate information. Tr. 129, 135; GX 11. For example, they did not contain the name of the controlled substance, they did not adequately identify the patients, they did not indicate how much of a particular controlled substance was consumed at the window during the dispensing or how much was taken home by the patient, and, other than the first page, they did not include the dosage form. Tr. 132-134; GX 11, at 1-17.

whether the inventory was taken at the beginning or the close of business, Tr. 57-59; GX at 3-5; and that the inventory on April 4, 2024, failed to properly name the substance. Tr. 61-62; GX 8, at 1; RD, at 20.

#### Powers of Attorney

The Government introduced four powers of attorney into evidence. Tr. 65-71; GX 9. The testimony and evidence demonstrated and the Agency finds substantial evidence that all four powers of attorney lacked the requisite witness signatures and therefore were improperly executed and/or improperly revoked. Tr. 65-71; GX 9; RD, at. Specifically, the powers of attorney for J.M. and Y.B. and two powers of attorney for S.R. were missing the second witness signature needed for proper execution, and the revocation of the power of attorney for Y.B. was missing the witness signatures needed for proper revocation. Tr. 66-71; GX 9; RD, at 21.

#### DEA Forms 222

The testimony and evidence demonstrated and the Agency finds substantial evidence that fifteen DEA Forms 222 were not properly executed because they did not include the proper name or strength of the controlled substance, they did not include the date the controlled substances were received or included incorrect dates, and/or they indicated the wrong number of packages or package size. Tr. 74-85, 88-91; GX 13, RD, at 5, 22. The testimony and evidence also demonstrated, and the Agency finds substantial evidence that, S.R. executed fourteen DEA Forms 222 without a properly executed power of attorney authorizing her to order controlled substances on Respondent's behalf. Tr. 92-93; GX 13, 15; RD, at 22. Finally, the testimony and evidence demonstrated and the Agency finds substantial evidence that Respondent failed to attach a cancellation form to a DEA Form 222 for an order that was cancelled by the distributor. Tr. 89-90; GX 13; RD, at 23.

#### **C. Conclusions of Law**

Evidence is considered under section 823(h)(2) when it reflects a failure to comply with "standards established by the Attorney General respecting . . . the maintenance of records (in

accordance with [21 U.S.C.] 827 . . . ) on such drugs.” 21 U.S.C. 823(h)(2). Here, based on Respondent’s admissions and the findings above, the Agency finds substantial evidence that Respondent: failed to maintain a complete and accurate record of each controlled substance received and disposed of, in violation of 21 U.S.C. 827(a)(3) and 21 CFR 1304.21(a); failed to maintain a dispensing log containing the details required by 21 CFR 1304.24(a); failed to conduct and maintain a biennial inventory with the details required by 1304.11(e)(1)(iii); failed to properly execute fifteen DEA Forms 222, in violation of 21 CFR §§ 1305.13, 1305.15, 1307.74; failed to properly execute and/or revoke four powers of attorney, in violation of 21 CFR 1305.05(d), (e); allowed an individual without a properly executed power of attorney to order controlled substances, in violation of 21 CFR § 1305.04; and failed to attach a cancellation form to one DEA Form 222, in violation of 21 CFR §§ 1305.17(a) and 1305.15(d).

The Agency finds that the Government’s evidence satisfies its *prima facie* burden of demonstrating that Respondent has failed to comply with the requirements of 823(h)(2) regarding “maintenance of records” for narcotic drugs.<sup>10</sup> 21 U.S.C. 823(a); 21 CFR 1301.44. The Agency also finds that there is insufficient mitigating evidence to rebut the Government’s *prima facie* case.

### **III. Allegation that Respondent Materially Falsified DEA Applications**

#### **A. Applicable Law**

##### **i. Material Falsification of an Application by an NTP**

In this case, there is disagreement about whether DEA has authority under 21 U.S.C. 824(a)(1) to deny, suspend, or revoke an NTP’s registration if the NTP has materially falsified an application for a DEA registration. The ALJ concluded that DEA does not have such authority and declined to consider the Government’s material falsification allegation. The Government

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<sup>10</sup> Respondent’s recordkeeping violations provide an independent and sufficient basis to revoke Respondent’s registration. As discussed below, Respondent repeatedly committed recordkeeping violations over the course of nearly a decade despite DEA’s multiple attempts to bring Respondent into compliance. Respondent’s failure to unequivocally accept responsibility for these violations demonstrates that DEA cannot trust Respondent with a registration and that revocation is necessary to achieve goals of specific and general deterrence.

filed Exceptions disagreeing with the ALJ. The Agency agrees with the Government and finds that the CSA authorizes DEA to suspend or revoke an NTP's registration if DEA makes a finding under any of the subsections of 21 U.S.C. 824(a), including that the registrant has materially falsified an application ((a)(1)), has been convicted of a felony related to controlled substances ((a)(2)), has lost state authority to handle controlled substances ((a)(3)), or has been excluded from participation in a federal healthcare program ((a)(5)).<sup>11</sup> This interpretation is supported by a plain language reading of Section 824(a) and is the most logical implementation of Congress' intent.

### Background

The CSA's provisions governing registration requirements to manufacture, distribute, or dispense controlled substances are outlined in 21 U.S.C. 823. Section 823 contains separate subsections identifying the registration requirements for different categories of registrants, including manufacturers (section 823(a), (c), (e)), distributors (sections 823(b), (f)), practitioners (section 823(g)), and NTPs (section 823(h)).

The CSA's provisions governing DEA's authority to revoke or suspend DEA registrations are outlined in 21 U.S.C. 824(a). Section 824(a) has two unlettered paragraphs that outline the circumstances under which DEA is authorized to suspend or revoke a registration. The first unlettered paragraph outlines DEA's authority to suspend or revoke any registration granted under 21 U.S.C. 823 if DEA makes a finding related to any of 824(a)'s five subsections (material falsification, felony conviction, loss of state authority, public interest, or federal healthcare exclusion). The second paragraph of Section 823(a) outlines an additional ground for

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<sup>11</sup> The Agency believes that the most logical, plain language interpretation of 21 U.S.C. 824(a) authorizes DEA to revoke an NTP's registration if DEA determines that the NTP's registration is inconsistent with the public interest under 21 U.S.C. 824(a)(4). However, 21 U.S.C. 824(a)(4) instructs the Agency to consider the public interest factors applicable to the registrant under 21 U.S.C. 823, and 21 U.S.C. 823(h) does not identify public interest factors applicable to NTPs. The registration provisions for other registrants—such as practitioners and manufacturers—do identify applicable public interest factors. If the Agency were confronted with a public interest case involving an NTP, the Agency would apply the set of public interest factors under section 823 that are most relevant to the entity's operation considering the facts of the case.

DEA to revoke an NTP's registration if the NTP "has failed to comply with any standard referred to in section 823(h)," which outlines the registration requirements for NTPs.

#### DEA's Authority to Revoke an NTP's Registration

The ALJ, referencing prior Agency decisions, concluded that the second paragraph of section 824(a)—which was added in 1974 with the passage of the Narcotic Addict Treatment Act of 1974 (NATA)—identifies the *only* grounds available for DEA to revoke the registration of an NTP, and that DEA is not authorized to revoke an NTP's registration based on the grounds in section 824(a)(1)-(5). RD, at 14-16 (citing *Turning Tide, Inc.*, 81 Fed. Reg. 47411, 47413 (2016)<sup>12</sup>; *Houston Maintenance Clinic*, 83 Fed. Reg. 42144, 42156 (2018)). The Agency does not find support for this interpretation in 21 U.S.C. 823 or 824(a). A plain language reading of the first paragraph of section 824(a)—which gives DEA authority to revoke "[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or list I chemical" for five enumerated reasons—supports the Agency's interpretation that it may revoke the registration of an NTP (which is "a registration pursuant to section 823") for any of the five enumerated reasons. There is no language in section 824(a) or 823 that contradicts the straightforward language in the first paragraph or implies that DEA may not revoke the registration of an NTP based on the grounds enumerated in the first paragraph.

The ALJ did not identify any authority suggesting that Congress intended for NTPs—which dispense the most addictive and dangerous of the controlled substances—to have fewer guardrails than other registrants. Of course, an NTP who materially falsifies an application or whose owner has committed a felony related to controlled substances is just as likely to pose a

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<sup>12</sup> In *Turning Tide*, a prior administration determined that DEA did not have authority to revoke an NTP's registration on public interest grounds in part because the NTP registration provision, 21 U.S.C. 823(h), does not seem to authorize DEA to deny an NTP's application on public interest grounds, in contrast to the registration provisions for manufacturers, distributors, and practitioners. 21 U.S.C. 823. The prior administration also inferred that because the revocation provision in 21 U.S.C. 824(a) contains a second paragraph that states that it specifically applies to NTPs, Congress did not intend for the first paragraph to apply to NTPs. As discussed herein, the Agency interprets these provisions differently. Nevertheless, in this case, the Agency is tasked with determining whether it has authority to revoke an NTP's registration based on a material falsification allegation, not a public interest allegation, as in *Turning Tide*. The potential complexities associated with applying the public interest factors to an NTP are not present in a material falsification case.

threat to the public as any other registrant who does the same. Thus, the Agency believes that its plain language interpretation implements Congress' intent.

In its Exceptions, the Government identifies a portion of NATA's legislative history that supports the Agency's conclusion that Congress did not intend to limit the Agency's authority to revoke registrations of NTPs. NATA was passed on May 14, 1974, and amended the CSA to require, among other things, that "[p]ractitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment" must "obtain annually a separate registration for that purpose." 88 Stat. 124, sec. 3, codified at 21 U.S.C. 823(g) (1974). NATA also added the subparagraph referenced above to section 21 U.S.C. 824(a) adding additional grounds for revocation of NTPs' registrations.

The Senate Bill that introduced these amendments (S. 1115, Mar. 6, 1973) proposed to add "or" between the already-included revocation grounds (which, at the time, were limited to material falsification, felony conviction, and loss of state authority) and the new paragraph containing the additional revocation ground for NTPs. S. 1115, 93rd Cong., 1st Sess., at 3 (Mar. 6, 1973). The inclusion of "or" would have removed any ambiguity as to whether an NTP's registration could be revoked on the original revocation grounds. The bill that was ultimately passed included alternate language from the text of the House Bill, introduced as H.R. 12503 by Representative Hastings on February 4, 1974, which laid out the new revocation grounds for NTPs as a separate sentence and did not include the word "or." H.R. 12503, 93rd Cong., 2d Sess., at \*3 (Feb. 4, 1974). However, as the Government observes in its Exceptions, "nothing in the legislative history suggests that there is any meaningful difference between the bills' differing approaches to amending 21 U.S.C. 824(a), or that Congress intended the House bill's approach to limit the Attorney General's authority for revoking/suspending NTP registrations." Government's Exceptions, at 5.

Accordingly, the Agency concludes that it has authority to revoke an NTP's registration based on the material falsification of an application.

## ii. Material Falsification of an Application

A DEA registration may be denied, suspended, or revoked upon a finding that the applicant or registrant materially falsified any application filed pursuant to or required by the CSA. 21 U.S.C. 824(a)(1).<sup>13</sup> To present a *prima facie* case for material falsification, the Government’s record evidence must show (1) the submission of an application, (2) containing a false statement and/or omitting information that the application requires, (3) when the submitter knew or should have known that the statement is false and/or that the omitted information existed and the application required its disclosure, and (4) the false statement and/or required but omitted information is material, that is, it “connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] ‘shall’ consider” when analyzing “whether issuing a registration ‘would be inconsistent with the public interest.’” *Frank Joseph Stirlacci, M.D.*, 85 Fed. Reg. 45229, 45238 (2020) (citing 21 U.S.C. 823 and *Kungys*, 485 U.S. at 771); *see also Sasha Melissa Ikramelahai*, 90 Fed. Reg. 32017, 32019 (2025); *Michael Bouknight*, 90 Fed. Reg. 31247, 31249 (2025).

Regarding materiality, *Kungys* holds that a statement is material if it is “predictably capable of affecting, *i.e.*, had a natural tendency to affect, the [Agency’s] official decision,” or stated differently, “had a natural tendency to influence the decision.” *Kungys*, 485 U.S. at 771-72. As already discussed, materiality, for the purposes of the CSA, is tied to the factors that the Administrator “shall” consider when determining whether issuance of a registration “would be inconsistent with the public interest.” 21 U.S.C. 823; *Kungys*, 485 U.S. at 771-72; *Stirlacci*, 85 Fed. Reg. at 45234, 45238. The Government must establish material falsification with record evidence that is clear, unequivocal, and convincing. *Kungys*, 485 U.S. at 772; *Stirlacci*, 85 Fed. Reg. at 45230-39.

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<sup>13</sup> A statutory basis to deny an application pursuant to section 823 is also a basis to revoke or suspend a registration pursuant to section 824, and vice versa, because doing “otherwise would mean that all applications would have to be granted only to be revoked the next day . . . .” *Robert Wayne Locklear, M.D.*, 86 Fed. Reg. 33738, 33744-45 (2021) (collecting cases).

The Supreme Court’s decision in *Kungys v. United States*, 485 U.S. 759 (1988), and its progeny, guide the Agency’s implementation of these CSA provisions.

## **B. Findings of Fact**

Respondent submitted its initial application for a DEA registration in 2008 and has submitted at least 16 renewal applications since then. Tr. 193:24-194:7, GX 14a, 14b. On each application, Respondent answered “no” to Liability Question 4, which states, “If the applicant is a corporation, association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substances under state or federal law[...]?” GX 14b. The testimony and evidence demonstrated, and the Agency finds clear and convincing record evidence, that these responses were false. Ms. Dukes, the owner of Respondent and signatory on Respondent’s DEA registration applications, was convicted of Controlled Dangerous Substance unlawful possession—a crime related to controlled substances—on June 5, 1991, in Anne Arundel District Court. GX 15.

## **C. Conclusions of Law**

As the Agency found above, Respondent submitted at least 17 applications for a DEA registration that contained false statements.<sup>14</sup> These false statements were material because they “deprived [DEA] of information potentially relevant to” the Agency’s analysis. *Stirlacci*, 85 Fed. Reg. at 45234-35; 21 U.S.C. 823(h). Respondent’s falsities are connected to two of the determinations that must be made before registering an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment. 21 U.S.C. 823(h). First, the falsity is potentially relevant to DEA’s determination of whether the applicant will “comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records . . . on such drugs.” 21 U.S.C. 823(h)(2). Second, the falsity is potentially relevant to the Health and Human Services analysis regarding whether the applicant will “respect[] the quantities of narcotic drugs which may be provided for

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<sup>14</sup> Ms. Dukes testified at the hearing that she did not know that she had been convicted of a crime because “it [] showed up as nolle processed.” Tr. 215-16. Respondent seems to concede in its Post-Hearing Brief that Ms. Dukes knew about the conviction, but that her “failure to disclose was the result of a good-faith belief that the aged conviction, having long since been resolved, was not material to the registration process.” ALJX 18, at 13. Accordingly, the Agency finds that Ms. Dukes knew about the conviction that she failed to disclose.

unsupervised use by individuals in such treatment.” 21 U.S.C. 823(h)(3). Because Respondent’s false statements deprived the Agency of information potentially relevant to its analysis, they were “predictably capable of affecting . . . [DEA’s] official decision” regarding whether Applicant met “the requirements for” registration. *Kungys*, 485 U.S. at 771. DI2 testified that if Respondent had disclosed Ms. Dukes’ conviction, DEA would have conducted “further research into the charges and how it could potentially affect [Respondent’s] handling controlled substances in their proposed business activity.” Tr. 195.

In sum, the Agency finds clear, unequivocal, and convincing record evidence that Respondent submitted materially false applications for registration.<sup>15</sup> 21 U.S.C. 824(a)(1).<sup>16</sup>

As a result of this established violation, the Agency finds that the Government has established a *prima facie* case for sanction, that Registrant did not rebut that *prima facie* case, and that there is clear, unequivocal, and convincing record evidence supporting the revocation of Registrant’s registration. 21 U.S.C. 824(a)(1).

#### IV. SANCTION

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<sup>15</sup> Respondent argues in its Post-Hearing Brief that Ms. Dukes’ failure to disclose her criminal conviction was not a material misrepresentation because the conviction occurred in 1991, nearly three decades ago and approximately seventeen years before Respondent’s first DEA application. ALJX 18, at 13. According to Respondent, the conviction occurred during “a period of Ms. Duke[s]’ life that has no bearing on her current professional conduct or eligibility,” and “[s]ince that time, Ms. Dukes has fully been rehabilitated, maintained an unblemished professional record, and had no further interactions with law enforcement or disciplinary authorities.” *Id.* In support of Respondent’s argument regarding materiality, Respondent asserts that “[c]ourts have repeatedly rejected attempts to use ‘distant, isolated convictions as dispositive grounds for denial without evidence of current risk or misconduct’” and provides a citation to a case that the Agency was unable to locate. Respondent’s Post-Hearing Brief, at 14 (citing *Garcia v. Drug Enforcement Admin.*, 2013 U.S. App. LEXIS 24307 (D.C. Cir. 2013)). Because it was unable to locate this case, the Agency cannot verify Respondent’s assertion.

Respondent further argues that the Government has not met its burden of proof regarding materiality because it “has not shown that this seventeen-year-old conviction—if it had been disclosed—would have led to a denial of the application.” ALJX 18, at 13. However, the Government need not prove that the application would have been denied, but rather that the information that was omitted was “predictably capable of affecting . . . [DEA’s] official decision” regarding whether Applicant met “the requirements for” registration. *Kungys*, 485 U.S. at 771. DEA has held that information is material if it “connect[s] to at least one of [the section 823] factors that, according to the CSA, [the Administrator] ‘shall’ consider” when analyzing whether or not to register an applicant. *Frank Joseph Stirlacci, M.D.*, 85 Fed. Reg. 45229, 45238 (2020) (citing 21 U.S.C. 823 and *Kungys*, 485 U.S. at 771); *see also Sasha Melissa Ikramelahai*, 90 Fed. Reg. 32017, 32019 (2025); *Michael Bouknight*, 90 Fed. Reg. 31247, 31249 (2025). As discussed above, Respondent’s conviction relates to two such factors and DI2 testified that DEA would have conducted further research if Respondent had disclosed this conviction. Therefore, the Agency concludes that Respondent’s failure to disclose Ms. Dukes’ conviction was material.

<sup>16</sup> Although Respondent’s material falsification of its DEA applications provides an additional ground to revoke Respondent’s registration, the Agency would have revoked Respondent’s registration solely based on the substantial evidence that Respondent has repeatedly violated recordkeeping regulations over the course of nearly a decade. Based on Respondent’s recidivism, revocation is necessary to achieve goals of specific and general deterrence.

Where, as here, the Government has met its prima facie burden of showing that Respondent's continued registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to Respondent to show why it can be entrusted with 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 Fed. Reg. 18882 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.*, 84 Fed. Reg. 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 respondent and by the community of registrants. *Jeffrey Stein, M.D.*, 84 Fed. Reg. at 46972-73.

#### **A. Acceptance of Responsibility**

Here, the ALJ found, and the Agency agrees, that Respondent did not unequivocally accept responsibility for its misconduct. RD, at 27. Although Respondent stated multiple times in its post-hearing brief that it accepts responsibility for the recordkeeping violations, *e.g.*, ALJX 18, at 7, 14, Respondent repeatedly minimized these violations. For example, Respondent referred to them as "technical missteps" and argued that it was "grossly misguided" for the Government to assert that these errors warranted revocation. *Id.* Respondent's attempts to minimize this egregious misconduct undermine any purported acceptance of responsibility.

*Michael A. White v. Drug Enf't Admin.*, 626 F. App'x 493, 496-97 (5th Cir. 2015); *see also* *Phong H. Tran, M.D.*, 90 Fed. Reg. at 14385.

Respondent also attempted to shift blame for the overages and shortages to “glitches” in the Methasoft software it used and suggested that it was “not fair” that DEA investigators conducted a physical hand count of controlled substances at the nurse’s station and did not provide her with documentation. RD, at 26 (citing tr. 241, 249). Ms. Dukes opted out of the closing discussion on July 22, 2024, which would have been her opportunity to reconcile any overages or shortages. Tr. 108, 175; RD, at 6. Respondent’s implication that DEA’s investigation was unfair is not supported by the record and undermines any acceptance of responsibility. *Cf. Ester Mark, M.D.*, 86 Fed. Reg. 16760, 16762 (2021) (finding that the respondent did not accept responsibility because she “pass[ed] blame on DEA for not telling her how to comply with recordkeeping requirements”).

Respondent also provided incredulous testimony about the material falsification charge that amounted to a denial of responsibility and raised significant concerns about the Agency’s ability to trust Respondent moving forward. Ms. Dukes initially testified that she did not disclose her criminal conviction in response to Liability Question #4 because she did not know that she was convicted of any crime until she was served with the OSC. Tr. 215. She further testified that she answered “no” because:

I didn’t understand it. I don’t know. It was . . . so long ago, and it looked like – it was [sic] showed up as nolle processed. [] I don’t know what I thought. I don’t know. I was told that. I don’t know. I just – I’m not going to sit here. I don’t know. I just don’t know. I was confused. I don’t know.

Tr. 215-16. She continued to explain that she did not know about the conviction until she received the OSC and discussed it with her lawyer. Tr. 216. It is not credible for Ms. Dukes to testify that she did not know that she was convicted of a crime when court records show that she pled guilty and served one year of probation. GX 15, at 1. Moreover, if Ms. Dukes was uncertain how to truthfully respond to Liability Question #4, she should have investigated and inquired rather than submitting a falsified form to a federal Agency.

## **B. Remedial Measures**

When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ajay S. Ahuja, M.D.*, 84 Fed. Reg. 5479, 5498 n.33 (2019) (citing *Jones Total Health Care Pharmacy*, 81 Fed. Reg. at 79202-03); *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74800, 74801, 74810 (2015). Even so, the Agency finds that Respondent's evidence of remedial measures would not change the result of this case even if Respondent had unequivocally accepted responsibility. Respondent's limited remedial evidence consisted of Ms. Dukes' testimony that she has employed engineers to rectify issues with Respondent's electronic inventory system and that Respondent now utilizes two large, graduated cylinders to accurately measure its Methadone. ALJX 18, at 8. The Agency finds that these remedial efforts are trivial considering Respondent's decade of recordkeeping errors, and they are not sufficient to restore the Agency's trust.

## **C. Deterrence and Egregiousness**

In addition to unequivocally accepting responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick*, 80 Fed. Reg. at 74810. In this case, the Agency agrees with the ALJ that the interests of specific deterrence militate in favor of revocation given Respondent's repeated recordkeeping violations over nearly a decade and Respondent's failure to remediate despite "repeated actions by DEA to educate the Respondent and bring it into compliance with DEA requirements." RD, at 28. The interests of general deterrence also support revocation, as a lack of sanction in the current matter would send a message to the registrant community that the failure to maintain accurate records can be excused. *Id.* As the ALJ stated, where Respondent has "failed to comply with the requirements concerning controlled substances, despite numerous attempts by the agency to bring the respondent into long-term compliance, the unmistakable message to the regulated community of imposing no sanction or a limited sanction that permits the continued handling of controlled substances by the respondent would be that such conduct can be overlooked." *Id.*

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. As the ALJ stated, "Respondent's violations were not limited to a single instance or a single type of violation, but consisted of widespread violations involving numerous biennial inventories over several years, overages and shortage of controlled substances, improper combination of controlled substances in its records, incorrectly filling out DEA 222 forms, and incorrectly executing powers of attorney."<sup>17</sup> RD, at 27.

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

### **ORDER**

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. RB0369733 issued to By Grace Inc. Counseling Services. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending applications of By Grace Inc. Counseling Services to renew or modify the named registrations, as well as any other pending application of By Grace Inc. Counseling Services for additional registration in Maryland. This Order is effective **[insert Date Thirty Days From the Date of Publication in the Federal Register]**.

### **SIGNING AUTHORITY**

This document of the Drug Enforcement Administration was signed on September 25, 2026, by DEA Administrator Terrance C. Cole. 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

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<sup>17</sup> Respondent's Post-Hearing Brief cites to a 2010 DEA decision and asserts that, in that case, "DEA declined to revoke a pharmacy's registration despite 'significant' recordkeeping issues, noting the absence of diversion and the registrant's good-faith corrective measures." *East Main Street Pharmacy*, 75 Fed. Reg. 66149 (2010). Respondent misrepresents the case's holding – the Agency determined that the case was moot. Moreover, the Agency affirmed the issuance of an Immediate Suspension Order and noted that, "[w]hile there is only the suspension order to review . . . , had Respondent filed a renewal application, I would have denied it." *Id.* at 66165.

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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