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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Hollywood Medical Rehabilitation Care, Inc.; Decision And Order

I. INTRODUCTION

On November 4, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Hollywood Medical Rehabilitation Care, Inc., of Los Angeles, California (Respondent). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 5. The OSC proposed the revocation of Respondent's DEA registration, No. RH0554053, alleging that Respondent "failed to comply with standards established by 21 U.S.C. 823(h)," applicable to narcotic treatment programs. *Id*. at 1; *see* 21 U.S.C. 823(a). Specifically, the OSC alleged that Respondent failed to maintain adequate records, as required by 21 U.S.C. 823(h)(2), and that Respondent's egregious recordkeeping violations rendered DEA unable to conduct an audit. *Id.* at 2-4 (citing 21 CFR 1304.11(a)-(c), 1304.11(c), 1304.21(a), (d), 1304.04(a), (f)(2), 1304.24(a), 1305.05).

A DEA Diversion Investigator personally served the OSC on Respondent on November 6, 2024; accordingly, the Agency finds that service was proper. RFAA 1, at 1; RFAAX 2. The OSC notified Respondent of its right to file with DEA a written request for hearing within 30 days of receiving the OSC, and of its obligation to file an answer in the form set forth in 21 CFR 1316.47. RFAAX 1, at 4 (citing 21 CFR 1301.43). The OSC also notified Respondent that if it failed to file a request for hearing or answer, it would be deemed to have waived its right to a hearing and be in default. *Id.*

On November 26, 2024, Respondent submitted a timely request for hearing, but did not file an answer. RFAA, at 1-2. The same day, the assigned Administrative Law Judge (ALJ) issued an Order for Prehearing Statements (OPS) and reminded Respondent of the statutory

requirement to file an answer "no later than 30 days following the date of receipt of the [OSC]." *Id.* (21 CFR 1301.37(d)(2)-(3)). The OPS cautioned Respondent that if it failed to file an answer by the statutory deadline, it "w[ould] face an appropriate remedy (e.g., waiver of its right to a hearing, entry of default, allegations being deemed admitted, and/or dismissal of its request for hearing)." OPS, at 1.

Respondent did not file an answer by the statutory deadline of December 6, 2024, and on December 9, 2024, the Government filed a Motion to Terminate Proceedings. RFAA, at 1-2. On December 9, 2024, the ALJ issued an Order to Show Cause for Failure to File an Answer, giving Respondent a deadline of December 11, 2024, to file an answer and "a pleading showing cause for its failure to file a timely Answer and why this tribunal should not deem Respondent in default, dismiss the [request for hearing], and terminate these proceedings." Order to Show Cause for Failure to File an Answer, at 2. Respondent failed to file an answer or any other pleadings by the ALJ's deadline. *Id.* Accordingly, on December 12, 2024, the ALJ granted the Government's motion, found Respondent to be in default, and terminated the proceedings. Order Denying Respondent's Motion for Relief from Final Order (Termination Order), at 2-3; *see also* RFAAX 4 (citing 21 CFR 1301.43(c)(2)).

On December 31, 2024, 19 days after the ALJ terminated the matter, Respondent submitted an untimely answer, a Declaration by Respondent's attorney (Mr. H.W.), and a Motion to Seek Relief from the ALJ's Termination Order (First Motion to Seek Relief), arguing that there was "good cause" to excuse Respondent's untimely answer based on Mr. H.W.'s inadvertent mistakes and illness. RFAA, at 2; RFAAX 5. On January 3, 2025, the ALJ denied Respondent's Motion to Seek Relief, finding that the Tribunal did not have jurisdiction to consider Respondent's motion because the matter had already been dismissed. RFAAX 6, at 2 (citing 1301.43(c)(3) ("Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing "good cause" to excuse its default with the Office

of the Administrator.")). The ALJ also noted that Respondent had not demonstrated "good cause" for its failure to file a timely answer. *Id.* n.1.

On January 6, 2025, the Government submitted an RFAA to the Administrator requesting that the Agency issue a final order revoking Respondent's registration on the basis that Registrant had "failed to comply with standards established by 21 U.S.C. 823(h)," applicable to narcotic treatment programs. RFAAX 1, at 1; *see* 21 U.S.C. 823(a). The Government requested final agency action based on Respondent's failure to file a timely answer, which resulted in the ALJ's finding that Respondent was in default. RFAA, at 1 (citing 21 CFR 1301.43(c), (f), 1301.46); *see also* 21 CFR 1316.67. On January 8, 2025, Respondent submitted a Motion to Seek Relief from Final Order with the Administrator (Second Motion to Seek Relief), which presented substantially similar arguments to the First Motion to Seek Relief.

II. DEFAULT DETERMINATION

A. Respondent is in Default Based on Its Failure to File an Answer

The Agency agrees with the ALJ that Respondent is in default based on its "fail[ure] to plead (including by failing to file an answer) or otherwise defend." *See* 21 CFR 1301.43(c)(3); RFAAX 6, at 2. After Respondent failed to file an answer along with its request for hearing on November 26, 2024, the ALJ issued an order reminding Respondent that it was required to file an answer by December 6, 2024. When Respondent failed to file an answer by this deadline, the ALJ issued an order giving Respondent an additional five days to file an answer and to show cause for the missed deadline. Respondent failed to file an answer or any other pleadings by the ALJ's deadline, and, accordingly, the ALJ dismissed the matter.

The Agency finds that the ALJ's dismissal of the matter due to Respondent's noncompliance was an appropriate exercise of her powers and duties under the Administrative Procedure Act (APA) and the Controlled Substances Act's (CSA) implementing regulations, which, among other things, require her to "regulate the course of the hearing," "dispose of procedural requests or similar matters," and "take other action authorized by agency rule

consistent with this subchapter." 5 U.S.C. 556(c)(5), (9), and (11); *see Andrew Konen, M.D.*, 90 Fed. Reg. 40,650, 40,651 (2025) ("Accordingly, the Agency concludes that the Agency ALJ assigned to this matter clearly has the duty and the power to issue scheduling orders, to rule on matters concerning those scheduling orders, and "to take all necessary action to avoid delay, and to maintain order. 21 CFR 1316.52").

B. The Factual Basis for Respondent's Motion to Set Aside the Default

The Agency may set aside a default if the respondent demonstrates "good cause" for the failures which led to the default. 21 CFR 1301.43(c). Respondent filed two motions (the First and Second Motions for Relief) seeking to demonstrate "good cause" for failing to file a timely answer. *Id.* 1301.43(c)(2). According to these motions and the accompanying filings, Respondent's failure to file an answer along with his request for hearing on November 21, 2024, was an oversight for which Respondent's attorney, Mr. H.W., takes full responsibility. *Id.* at 2. Respondent asserts that in early December, after the deadline for filing an answer had passed, "DEA served additional documents on [Mr. H.W.'s] office, which were dutifully entered into the client's file by clerical staff, some of which [Mr. H.W.] was not aware." *Id.* at 6. Mr. H.W. represents that during the "critical period of time in December, 2024, he grew increasingly ill with what would ultimately be diagnosed as a bout with COVID, gradually clouding his cognition and judgment resulting in large part a failure to calendar critical deadlines." *Id.* Due to Mr. H.W.'s illness, he "inadvertently failed to take note of the Tribunal's [December 9, 2024 Order] and the accompanying deadline date and therefore, failed to file its response to the [Order]" by the December 11 deadline. RFAAX 5, at 2-3. The Agency notes that the requirement to file an answer existed prior to the December 6, 2024 Order.

Respondent argues that Mr. H.W.'s illness constitutes "good cause" for the Agency to excuse Respondent's failure to file a timely answer. *Id.* at 3-4. Respondent believes that it would be greatly prejudiced by a dismissal, which would be the "equivalent of a death knell to Respondent's rehabilitation center." *Id.* at 3-4. On the other hand, Respondent does not believe

that the Government would be prejudiced if Respondent were permitted to file an untimely answer. *Id.* at 2-4. Respondent argues that "deciding a matter on the merits is fairer and advances the cause of justice more so than a dismissal based upon procedural deficiencies, albeit errors caused by its counsel." *Id.* at 3.

C. The Agency's Interpretation of "Good Cause" in The Default Rule

i. Relevant authorities for interpreting "good cause" in the default rule

Neither the text of the default rule—which became effective on December 14, 2022—nor the Notice of Proposed Rulemaking (NPRM) for the rule, defines "good cause." 21 CFR 1301.43; 85 FR 61662. As "good cause" is the same standard used in the prior iteration of 21 CFR 1301.43(d),[1] the Agency has applied this standard for decades. In doing so, the Agency has occasionally referenced federal legal authorities; for example, the Agency has referenced Supreme Court and Circuit Court decisions addressing and applying the "good cause" standard in contexts where, like here, there is noncompliance with a scheduling order or a missed deadline.[2] *See, e.g.*, *Konen*, 90 Fed. Reg. at 40,654; *Keith Ky Ly, D.O.*, 80 Fed. Reg. 29,025, 29,027 n.2, 29,028 (2015) (explaining that the Agency "has frequently looked to [federal procedural] rules for guidance in interpreting its procedural rules").

ii. The Agency's application of the default rule's "good cause" standard

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[1] "If any person entitled to a hearing or to participate in a hearing pursuant to . . . [21 CFR] 1301.32 or . . . [21 CFR] 1301.34-1301.36 fails to file a request for a hearing or a notice of appearance, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure."

[2] These federal cases interpret the "good cause" standard in the context of Federal Rules of Civil or Appellate Procedure governing various stages of litigation where important considerations underlying specific rules—such as a strong preference for allowing litigants to file a responsive pleading before a final judgment has been rendered—may impact whether "good cause" is interpreted leniently or strictly. Although these federal cases may be instructive, the Agency remains responsible for interpreting and applying the "good cause" standard as Congress intended it to be applied in the context of 21 CFR 1301.43 (a rule that was intended to "conserve scarce agency resources and greatly increase the efficiency of the adjudicatory process," NPRM, 85 FR at 61664), the CSA, and the CSA's implementing regulations. *See, e.g.*, *Kamir Garces-Mejias, M.D.*, 72 FR 54,931, 54,932 (2007) ("Agency proceedings brought under section 304 of the [CSA] are not governed by the Federal Rules of Civil Procedure, but rather, [the CSA's implementing] regulations and the rules set forth in the applicable provisions of the [CSA]. . . . Indeed, this Agency has never held that the "good cause" standard of 21 CFR 1301.43(d), which addresses conduct constituting a waiver of the right to a hearing, is to be construed in the same manner as the federal courts interpret the "good cause" standard under F.R.C.P. 55(c) for setting aside the entry of a default.").

Although the Agency has occasionally excused an attorney's inadvertent mistake when the attorney has "promptly corrected its omission,"[3] the Agency has repeatedly rejected respondents' requests to excuse multiple missed litigation deadlines due to inadvertence, illness, or busy schedules. *See, e.g.*, *Konen*, 90 Fed. Reg. at 40,654 (finding that respondent failed to demonstrate "good cause" for missing several deadlines when respondent's attorney's busy schedule and illness did not preclude him from performing other tasks); *Kamir Garces Mejias, M.D.,*72 Fed. Reg. 54,931 (2007) (rejecting respondent's argument that his attorney's busy schedule constituted "good cause" for several missed deadlines), *Rene Casanova, M.D.*, 77 Fed. Reg. 58,150, 58,150 n.2 (2012) (affirming the ALJ's denial of respondent's consent motion for a ten-day extension—filed the same day the exceptions were due—because he had been in trial the week before).

In the context of interpreting various rules of Federal Civil and Appellate Procedure permitting extensions, some federal courts have interpreted the "good cause" or "excusable neglect"[4] standard strictly, and disallowed extensions when litigants have failed to demonstrate that their illnesses were so severe that they prevented them from requesting an extension or notifying the court of their inability to meet a deadline. *See, e.g.*, *Miller v. Chicago Transit Authority*, 20 F.4th 1148, 1153-54 (7th Cir. 2021) (finding that counsel's explanations of his medical problems were "so vague as to be worthless," and noting that it was "[counsel's] burden to provide the district court sufficient information to demonstrate that his illness was of such a magnitude that he could not, at a minimum, request an extension of time to file his response," where counsel also cited a busy schedule and an office relocation as reasons for the missed deadline) (internal quotations omitted); *Acosta v. DT & C Global Mgmt., LLC*, 874 F.3d 557,

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[3] *Edge Pharmacy*, 81 Fed. Reg. at 72,101 (Agency accepted updated version of Government's declaration originally submitted unsigned); *see also Tony T. Bui, M.D.*, 75 Fed. Reg. 49,979, 49,980 (2010) (ALJ found "good cause" to excuse Respondent's untimely hearing request where Respondent's counsel promptly re-submitted request returned due to incomplete mailing address).

[4] The Agency "has interpreted the 'good cause' standard for assessing the timeliness of hearing requests as encompassing cases of excusable neglect, mistake or inadvertence." *John P. Moore, III, M.D.*, 82 Fed. Reg. 10,398, 10,400 (2017).

560–61 (7th Cir. 2017) (upholding the district court's rejection of a "health problems" excuse, given the "lack of corroborating information"); *Proctor v. Northern Lakes Community Mental Health*, 560 Fed.Appx. 453, 454-55 (6th Cir. 2014) (finding that the district court did not abuse its discretion in failing to find excusable neglect when the plaintiff, who was hospitalized for three days and housebound for three weeks due to "meningitis that caused adverse mental and physical effects" and "spinal and other physical pain which compromised her mobility," did not demonstrate that her illness rendered her "*unable* to file a notice of appeal").

D. Respondent Failed to Demonstrate "Good Cause" for Setting Aside the Default

Here, the Agency agrees with the ALJ that Respondent has not provided "good cause" for its failure to file a timely answer. *See* RFAAX 6, at 2. Respondent missed two important deadlines: First, Respondent failed to file an answer by the statutory deadline of December 6, 2024, despite being notified of the deadline in the OSC on November 6, and reminded of the deadline in the OPS on November 26. Second, Respondent failed to respond to the ALJ's Order to Show Cause for Failure to File an Answer, which set a deadline of December 11, 2024. Respondent's Motion for Relief and Answer was filed 25 days after the statutory deadline for filing an answer and 20 days after the ALJ's deadline to show cause.

Mr. H.W. asserts that the missed deadlines were a result of inadvertence and illness. However, Mr. H.W. illness did not begin until December, so his illness should not have significantly impacted Respondent's ability to comply with the first statutory deadline of December 6. *See In re President Casinos, Inc.*, 397 B.R. 468, 473-74 (B.A.P. 8th Cir. 2008) (affirming the district court's dismissal in part because the creditor's attorney did not provide sufficient details about the duration of the attorney's incapacity following an emergency appendectomy, and noting that "[t]he fact that [the creditor's attorney] became ill does not excuse the period of time when [he] was not ill. . . ."). Mr. H.W. did not act quickly to rectify the mistake. Mr. H.W. did not submit any additional filings with the Tribunal until December 31, 2024, despite receiving several notifications of the missed deadline, including in the

Government's motion to terminate on December 9, the ALJ's Order to Show Cause on December 9, and the ALJ's dismissal order on December 12. Mr. H.W. represented that "during th[is] critical period of time" he was suffering from "exhaustion and malaise, which ultimately culminated into an episode of Covid," but he did not provide evidence demonstrating that he was so ill that he was unable to notify the tribunal of his inability to respond. RFAAX 5, at 3, 6. Mr. H.W. represented that he "request[ed] that the firm's other senior counsel [] take over the process," but "[t]hat newly-assigned [] counsel took time to familiarize himself with the file, while dealing with his own pre-holiday deadlines." Motion to Seek Relief from Final Order, Jan. 8, 2025, at 4. However, Mr. H.W. has not explained why the newly-assigned counsel was unable to notify the Tribunal of Mr. H.W.'s incapacity and communicate Respondent's intention to continue with litigation, notwithstanding several critical missed deadlines. Mr. H.W. also has not explained why his clerical staff—who, according to Mr. H.W.'s declaration, "dutifully entered [the additional documents served on his office] into the client's file"—were unable to notify the tribunal of Mr. H.W.'s inability to respond. RFAAX 5, at 6.

Moreover, while the Agency appreciates Respondent's arguments that it would be unfair to hold Respondent accountable for his attorney's mistakes, the Supreme Court has reaffirmed the common principle that "clients must be held accountable for the acts and omissions of their attorneys." *See Pioneer Inv. Services Co.*, 507 U.S. at 396. In *Pioneer*, the Supreme Court found that the district court had erred in "suggest[ing] that it would be inappropriate to penalize respondents for the omissions of their attorney," noting instead that "the proper focus is upon whether the neglect of respondents *and their counsel* was excusable." *Id.* at 397. Accordingly, the Agency finds, in agreement with the ALJ, that Respondent has not provided "good cause" to set aside the default. *See* RFAAX 6, at 2.

"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.* § 1301.43(f)(1).

III. APPLICABLE LAW

A. The Alleged Statutory and Regulatory Violations

As discussed above, the OSC alleges that Respondent violated multiple provisions of the CSA and its implementing regulations. As the Supreme Court stated in *Gonzales v. Raich*, "the main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. . . . To effectuate these goals, Congress devised a closed regulatory system making it unlawful to . . . dispense[ ] or possess any controlled substance except in a manner authorized by the CSA." 545 U.S. 1, at 12-13 (2005). In maintaining this closed regulatory system, "[t]he CSA and its implementing regulations set forth strict requirements regarding registration, . . . drug security, and recordkeeping." *Id.* at 14.

Here, the OSC's allegations concern the CSA's "strict requirements regarding registration[,] . . . drug security, and recordkeeping" and, therefore, go to the heart of the CSA's "closed regulatory system" specifically designed "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Id*.

B. Improper Dispensing, Recordkeeping, and Unaccounted For Controlled Substances

According to DEA's implementing regulations, narcotic treatment programs "shall maintain, on a current basis, a complete and accurate record of each controlled substance . . . received, sold . . . or otherwise disposed of . . . ." 21 CFR 1304.21(a).[5] These records must include "the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed." *Id.* 1304.21(d). Narcotic treatment programs also must maintain an

[5] 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. Narcotic treatment programs are explicitly named in 21 CFR 1304.04(f) as a registrant that must maintain records.

"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." *Id.* 1304.11(a)-(c). These inventories and 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." *Id.* 1304.04(a).

Additionally, narcotic treatment programs 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). Finally, if a narcotic treatment program wishes to authorize a non-registered individual to order schedule I and II controlled substances on its behalf, it must execute a power of attorney for that individual, which "must be available for inspection together with other order records." *Id.* 1305.05(a).

IV. FINDINGS OF FACT

The Agency finds that, in light of Respondent's default, the factual allegations in the OSC are deemed admitted. Respondent is deemed to have admitted that during two scheduled inspections, on April 21, 2023, and May 20, 2024, DEA investigators discovered numerous recordkeeping violations that prevented DEA from conducting an audit. RFAAX 3, at 2-3. Respondent admits that DEA's inspections revealed the following recordkeeping violations: (1) a failure to maintain a complete and accurate record of all controlled substances on hand, (2) a failure to take an accurate initial inventory of all controlled substances on hand, (3) a failure to provide biennial inventory reports of all stocks of controlled substances on hand, (4) a failure to maintain complete and accurate continuing records of all controlled substances on hand, (5) a failure to record dates of the receipt, distribution, transfer, or destruction of controlled substances, (6) a failure to maintain records for two years, (7) a failure to maintain records in a readily retrievable manner, (8) a failure to abide by recordkeeping requirements for maintenance

treatment programs, and (9) a failure to execute a power of attorney for individuals to issue orders for controlled substances on Respondent's behalf. Accordingly, the Agency finds substantial record evidence of each of these nine recordkeeping violations.[6]

V. DISCUSSION

A. The Controlled Substances Act and Implementing Regulations

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)[][7] 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:

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[6] The OSC also alleges, and it is deemed admitted, that Respondent entered into two Memoranda of Agreement (MOA) with DEA—one on July 22, 2019 (2019 MOA), and one on June 26, 2023 (2023 MOA). The OSC further alleges, and it is deemed admitted, that Respondent violated the terms of these MOAs by failing to update DEA regarding changes in its employees' information and failing to comply with all recordkeeping requirements referenced in 21 CFR 1304.11, 1304.24, 1304.25, and all other sections related to narcotic treatment facilities. The OSC does not allege that these MOA violations constitute an additional ground for revoking Respondent's registration. Accordingly, the Agency considers these factual allegations as background information.

[7] 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.").

(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."

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. 47,411, 47,413 (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. The Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, 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. 21 U.S.C. 823(a).

A. Allegation that Registrant Has Failed to Comply with the Requirements of Section 823(h)

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[8] of this title) 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: (1) failed to maintain a complete and accurate record of all controlled substances on hand, (2) failed to take an accurate initial inventory of all controlled substances on hand, (3) failed to provide biennial inventory reports of all stocks of controlled substances on hand, (4) failed to maintain complete and accurate continuing records of all controlled substances on hand, (5) failed to record dates of the receipt, distribution, transfer, or destruction of controlled substances, (6) failed to maintain records for two years, (7) failed to maintain records in a readily retrievable manner, (8) failed to abide by recordkeeping requirements for maintenance treatment programs, and (9) failed to execute a power of attorney for individuals to issue orders for controlled substances on Respondent's behalf. Therefore, the Agency finds substantial record evidence that Respondent violated federal law, namely 21 CFR 1304.11(a)-(c), 1304.11(c), 1304.21(a), (d), 1304.04(a), (f)(2), 1304.24(a), 1305.05.

Accordingly, the Agency finds that Respondent has failed to comply with the requirements for registration under 21 U.S.C. 823(h)(2), and thus finds that the Agency is authorized to revoke Respondent's registration under 21 U.S.C. 824(a). The Agency further finds that Respondent failed to provide any evidence to rebut the Government's *prima facie* case.

VI. SANCTION

Here, the Government has met its *prima facie* burden of showing that the Agency is authorized to revoke Respondent's registration due to Respondent's numerous recordkeeping violations, which disqualify it from registration under 21 U.S.C. 823(h)(2). Accordingly, the burden shifts to Respondent to show why it can be entrusted with registration. *Morall*, 412 F.3d. at 174; *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,904 (2018.

[8] The CSA's regulations implementing 21 U.S.C. 827 are found in 21 CFR 1304, Records and Reports of Registrants.

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, 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 he will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). A registrant's acceptance of responsibility must be unequivocal. *Jones Total Health Care Pharmacy*, 881 F.3d 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 & n.4. The Agency has also considered the need to deter similar acts by the registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 Fed. Reg. at 46,972-73.

Here, although Respondent initially requested a hearing, it was deemed to be in default based on its "fail[ure] to plead (including by failing to file an answer) or otherwise defend." *See* 21 CFR 1301.43(c)(3); RFAA, at 1-2. Respondent has thus not availed itself of the opportunity to refute the Government's case.[9] As such, Respondent has not convinced the Agency as to its future compliance with the CSA[10] nor made any demonstration that it can be entrusted with a

[9] Respondent filed an untimely Answer which admits to many of the allegations in the OSC, including that it "(c) failed to provide biennial inventory of all stacks of controlled substances; (f) failed to keep records for two years; (g) failed to keep records in a readily retrievable manner; (h) *generally*, failed to abide by recordkeeping requirements for maintenance treatment programs, and (i) failed to execute a power of attorney for individuals to issue orders for controlled substances." Respondent's Proposed Answer, December 31, 2024, at 4. The Answer also "acknowledg[es] that it failed to maintain complete and accurate record of many controlled substances on hand and take an accurate initial inventory of many controlled substances on hand." *Id.* at 3.

[10] Respondent's hearing request states that Respondent will take actions to come into compliance with the CSA, such as tasking two different individuals with maintaining and reconciling records, and requests that DEA allow it to operate for a probationary period during which time DEA may conduct unannounced visits. RFAAX 3, at 1. Respondent's Motion to Seek Relief from Final Order asserts that it "intended for these statements to provide the corrective action plan afforded to respondents by 21 [] 824(c)(3), which requires the Attorney General to review any corrective action plan submitted and determine whether the relevant proceedings 'should be discontinued or deferred for the purposes of modification, amendment, or clarification of such plan.'" RFAAX 5, at 3. Respondent's motion

registration. Moreover, the evidence presented by the Government shows that Respondent violated the CSA, further indicating that Respondent cannot be entrusted.

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. RH0554053 issued to Hollywood Medical Rehabilitation Care. 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 Hollywood Medical Rehabilitation Care to renew or modify the named registrations, as well as any other pending application of Hollywood Medical Rehabilitation Care for additional registration in California. 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 30, 2025, by Administrator Terrance 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 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.

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further asserts that it "ha[s] not received any response by the Attorney General regarding the proposed corrective action." *Id.*

The Agency does not consider Respondent's remediation statements in its hearing request to be a corrective action plan. The OSC instructed that any corrective action plan "should be clearly labeled 'Corrective Action Plan'" and submitted by email to Thomas W. Prevoznik, Assistant Administrator, Diversion Control Division." RFAAX 1, at 4. The OSC further instructed that the corrective action plan should be submitted separately from the answer and request for hearing. *Id.* at 5. Respondent's request for hearing does not constitute a corrective action plan because it was not properly submitted or properly labeled as a corrective action plan. Nevertheless, in light of Respondent's default and the extensive nature of Respondent's recordkeeping violations, Respondent has not ensured the Agency that it can be entrusted with a registration.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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