APPENDIX A

Opinion of the United States Court of Appeals
for the Third Circuit (July 21, 2025)

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-2704

STEPHEN MCCARTHY, P.A.,
Petitioner

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION

On Petition for Review of an
Order of the Drug Enforcement Administration
(Agency No. 23-40)

Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
May 20, 2025

Before: PHIPPS, CHUNG, and ROTH, Circuit Judges

(Filed: July 21, 2025)

OPINION*

CHUNG, Circuit Judge.

Stephen McCarthy, P.A., petitions for review of the order issued by the

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* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

Administrator of the Drug Enforcement Administration (DEA) revoking his Certificate of Registration (COR) and denying any pending applications to modify or renew that COR. He argues that the Administrative Law Judge (ALJ) who recommended revocation was unconstitutionally protected from removal and that the ALJ's decision adopted by the Administrator was arbitrary and capricious and an abuse of discretion. Because McCarthy has failed to show the requisite link between any allegedly unconstitutional removal protections and his injury and because the revocation decision was neither arbitrary and capricious nor an abuse of discretion, we will deny the petition.

I. BACKGROUND[1]

McCarthy is a physician assistant who held a DEA COR allowing him to prescribe Schedule II through V controlled substances. McCarthy prescribed controlled substances despite the fact that he was not being supervised by a physician with whom he had a written agreement as required by Pennsylvania law. See 63 Pa. Stat. § 422.13(a), (e); 49 Pa. Code § 18.152(a). In response to his conduct, on April 21, 2023, the DEA issued McCarthy an Order to Show Cause why his continued registration was not inconsistent with the public interest. See 21 U.S.C. § 824. Due to his apparent misconduct, the order proposed revoking McCarthy's COR and denying any pending applications for modification or renewal of his registration.

On August 31, 2023, a hearing was held before ALJ Paul E. Soeffing. The DEA presented evidence that between August 24, 2022, and September 20, 2022, and again

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[1] Because we write for the parties, we recite only the facts pertinent to our decision.

between October 6, 2022, and November 8, 2022, McCarthy issued approximately seventeen prescriptions for controlled substances while not covered by a written agreement. McCarthy did not dispute this. Instead, he argued that, during the time, he believed he was covered by a previous agreement with "Dr. F." Although that agreement was inactivated in October of 2019, McCarthy claimed that he believed this agreement was still in place because he never received notice of its termination, because his lack of communication with Dr. F was not unusual so there was no reason to believe otherwise, and because the Pennsylvania Licensing System (PALS) did not show that the agreement was inactive. The ALJ rejected these arguments because McCarthy acknowledged that PALS was not always reliable and because the evidence indicated that the termination letter ending McCarthy's written agreement with Dr. F was provided to McCarthy, that McCarthy and Dr. F were no longer employed by the same employer, that Dr. F and McCarthy spoke on only one occasion in 2019, and that McCarthy did not list Dr. F as the supervising physician on the prescriptions he issued during the relevant time period.

The ALJ concluded that the DEA had therefore proven its prima facie case that McCarthy's continued registration was inconsistent with the public interest. Accordingly, the burden shifted to McCarthy to show that he could be entrusted with a COR. After considering McCarthy's failure to unequivocally admit fault, his limited remedial action, the egregiousness of his conduct, and the need for deterrence, the ALJ determined that McCarthy had not met his burden and recommended that his COR be revoked and any pending applications for renewal or modification of his COR be denied. The Administrator of the DEA adopted the ALJ's recommendation in its entirety and

ordered that McCarthy's COR be revoked and any pending applications for renewal or modification of his COR be denied.

McCarthy timely petitioned for review.

II. DISCUSSION[2]

McCarthy asks us to vacate the Administrator's order asserting that the ALJ was unconstitutionally protected from removal and that the ALJ's decision adopted by the Administrator was arbitrary and capricious and an abuse of discretion. We reject both arguments and will affirm.[3]

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[2] The DEA had jurisdiction pursuant to 21 U.S.C. §§ 823(g)(1) and 824(a) and 28 C.F.R. § 0.100(b). We have jurisdiction pursuant to 21 U.S.C. § 877. We review questions of constitutional law de novo. Dinnall v. Gonzales, 421 F.3d 247, 251 (3d Cir. 2005). "Agency decisions, such as the ... Administrator's Order, may be set aside only if arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law." Humphreys v. Drug Enf't Admin., 96 F.3d 658, 660 (3d Cir. 1996) (citing 5 U.S.C. § 706(2)(A)). Such agency decisions are entitled to "substantial deference" and "we must not simply substitute our judgment for that of the agency." Id. at 664. Additionally, the agency's findings of fact are "conclusive" "if supported by substantial evidence." 21 U.S.C. § 877.

[3] McCarthy also raises an Appointments Clause challenge, asserting that the ALJ was not appointed by the Attorney General as he argues is required. He did not raise this challenge before the agency, and the parties dispute whether he can properly raise it now. See generally Carr v. Saul, 593 U.S. 83 (2021) (discussing issue exhaustion in administrative adjudications and concluding that issue exhaustion did not apply to Appointments Clause challenges to the appointment of Social Security Administration ALJs). We assume without deciding that he can raise his Appointments Clause challenge now and reject it as factually incorrect. Because this challenge was not raised before the agency, the initial record contained no information regarding who appointed the ALJ. On appeal, the Government moved to supplement the record and provided a document showing that the ALJ had been appointed by the Attorney General on December 1, 2020. We now grant that motion, see Acumed LLC v. Advanced Surgical Servs., Inc., 561 F.3d 199, 226 (3d Cir. 2009), and reject McCarthy's Appointments Clause challenge, see U.S. Const. art. II, § 2, cl. 2.

A. Removal Protections Challenge

DEA ALJs are removable by the Attorney General "only for good cause established and determined by the Merit Systems Protection Board." 5 U.S.C. § 7521(a).[4] Members of the Merit Systems Protection Board, in turn, are removable by the President, but "only for inefficiency, neglect of duty, or malfeasance in office." 5 U.S.C. § 1202(d). McCarthy argues, and the Government now concedes, that this structure amounts to unconstitutional "multilevel protection from removal" under Free Enter. Fund v. Pub. Co. Acct. Oversight Bd., 561 U.S. 477, 484 (2010). Of course, the Government's concession does not govern our analysis. Cf. Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803). Nonetheless, we need not resolve this thorny issue here because McCarthy cannot bring his removal-protection challenge.

In order to bring a removal-protection challenge, a litigant "must show that the constitutional infirmity actually caused harm." NLRB v. Starbucks Corp., 125 F.4th 78, 88 (3d Cir. 2024) (petitioner failed to link removal-protection infirmity to an actual harm and therefore could not bring challenge); see also CFPB v. Nat'l Collegiate Master Student Loan Tr., 96 F.4th 599, 607 (3d Cir. 2024) ("[A]ctions taken by an improperly insulated director are not 'void' and do not need to be 'ratified' unless a plaintiff can show that the removal provision harmed him." (quoting Collins v. Yellen, 594 U.S. 220, 259 (2021))). Stated differently, a litigant must show a causal "link" between the

[4] "Section 7521 applies to any ALJs appointed under 5 U.S.C. § 3105. DEA ALJs are appointed under 5 U.S.C. § 3105 pursuant to 5 U.S.C. § 556(b)(3) and 21 C.F.R. § 1316.42(f)." Rabadi v. Drug Enf't Admin, 122 F.4th 371, 375 n.5 (9th Cir. 2024).

asserted removal-protection-infirmity and an actual harm. Nat'l Collegiate, 96 F.4th at 615; see Starbucks Corp., 125 F.4th at 88–89. McCarthy argues that the revocation of his COR is a greater injury than the injury at issue in Starbucks, but he fails to address the requisite causal link. McCarthy does not show, or even argue, that his injury would have been lessened or eliminated if the ALJ did not have unconstitutional removal protections. Accordingly, his removal-protection challenge fails. See Starbucks, 125 F.4th at 88; Nat'l Collegiate, 96 F.4th at 615.

B. Arbitrary and Capricious Challenge

McCarthy next argues that the Administrator's decision to revoke his COR was arbitrary and capricious or an abuse of discretion. See 5 U.S.C. § 706(2)(A). He concedes that the "Administrator's choice of sanction 'is entitled to substantial deference'" and that "[o]rdinarily, the mere unevenness in the application of a sanction will not render its application in a particular case 'unwarranted in law.'" Opening Br. 25 (quoting Chein v. Drug Enf't Admin., 533 F.3d 828, 835 (D.C. Cir. 2008)); see also Butz v. Glover Livestock Comm'n Co., 411 U.S. 182, 187 (1973). Nonetheless, relying on D.C. Circuit case law, he contends that an agency abuses its discretion if the penalty it imposes is an unrecognized or unexplained "flagrant departure" from past practice and that the DEA's actions here were such a departure. Chein, 533 F.3d at 835 (quoting Morall v. Drug Enf't Admin., 412 F.3d 165, 183 (D.C. Cir. 2005)). This standard seems to just be an application of the principle that agencies must "generally 'display awareness' of a change in [agency] position." N.J. Bd. of Pub. Utils. v. FERC, 744 F.3d

74, 104 (3d Cir. 2014) (quoting FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009)).

To make this point, McCarthy primarily relies on "summaries" of eight DEA adjudications. McCarthy's counsel now acknowledges that seven of these summaries were inaccurate, that the eighth decision does not exist, and that the summaries and non-existent decision were all generated by Artificial Intelligence (AI). McCarthy's counsel further acknowledges that he never took care to confirm the accuracy of the summaries or even that the decisions existed.[5] Accordingly, we will not consider this portion of his brief.[6] Cf. Grant v. City of Long Beach, 96 F.4th 1255 (9th Cir. 2024) (striking brief and dismissing appeal for a similar issue).

McCarthy cites two additional cases but neither supports his position. In one case, the DEA imposed a sanction short of revocation because the respondent accepted responsibility for her actions. See Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 463 (DEA Jan. 6, 2009). Krishna-Iyer thus sits neatly in DEA's framework where a sanction

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[5] We ordered McCarthy's counsel to provide the cases to the Court and explain if and how he verified the accuracy of his summaries. In his response, McCarthy's counsel acknowledged that he knew that he had submitted erroneous summaries and a non-existent case to this Court long before the filing of his response. We are separately ordering McCarthy's counsel to show cause why he should not be sanctioned for his conduct, particularly for his lack of candor to the Court.

[6] McCarthy's counsel also concedes that the Government has successfully rebutted the eight summaries. This provides us with another reason not to consider this portion of the brief. See United States v. Batista, 483 F.3d 193, 199 n.4 (3d Cir. 2007) (noting that an argument was waived because it was conceded).

short of revocation can be imposed if a respondent accepts responsibility.[7] But here the Administrator found that McCarthy only partially accepted responsibility and that finding was supported by substantial evidence due to, among other things, his attempts to justify his conduct and shift the blame to other parties. Therefore, Krishna-Iyer does not reflect that revocation of McCarthy's COR was a flagrant departure from DEA practice.

In the other case, the DEA revoked the registrant's COR, in part because she failed to fully take responsibility for her actions, and the D.C. Circuit denied the petition for review. See St. Croix v. Drug Enf't Admin., No. 21-1116, 2022 WL 2092177, at **1–2 (D.C. Cir. June 10, 2022) (per curiam). This is consistent with the DEA's treatment of McCarthy's case, wherein he was found to only partially accept responsibility for his conduct. McCarthy argues nonetheless that his behavior was less egregious than the conduct in St. Croix. Assuming that is true, it only shows the range of conduct that DEA determines to be inconsistent with the public interest and justifying a revocation, not that revocation here is a flagrant departure from DEA practice.

McCarthy briefly makes a few additional arguments that all lack merit. McCarthy argues that the Administrator failed to acknowledge the ways in which McCarthy did take responsibility. The Administrator did consider McCarthy's limited acceptance of responsibility, she just found it lacking.

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[7] McCarthy concedes that the DEA may look to the registrant's acceptance of responsibility in determining if continued registration is consistent with the public interest. Some DEA cases regarding the acceptance of responsibility focus on the fact that the violation was intentional or knowing.

McCarthy also argues that his punishment should not have been as severe because the violations were "based on [his] misunderstanding" that he was still being supervised by Dr. F. Opening Br. 29. The Administrator considered this argument and determined that McCarthy's asserted belief was not "reasonable," App. 168. This conclusion was supported by substantial evidence as the Administrator explained that any misunderstanding could have been avoided with "basic due diligence" and "proper and ongoing communication" between McCarthy and his former supervising physician, App. 173. In any case, under DEA precedent, unintentional misconduct can justify revoking a COR. See Fares Jeries Rabadi, M.D., 87 Fed. Reg. 30,564, 30,603 n.35 (DEA May 19, 2022), petition for rev. denied, 122 F.4th 371 (9th Cir. 2024).

McCarthy next argues that his COR should not have been revoked because the DEA failed to show that his misconduct resulted in the diversion of any prescribed drugs or in harm to any patients. The Administrator considered this argument, and its rejection of this argument was not an abuse of discretion. Agency precedent is clear that the DEA can find that continued registration is inconsistent with the public interest, even when a harm has not yet been realized. See Melanie Baker N.P., 86 Fed. Reg. 23,998, 24,009 (DEA May 5, 2021).

McCarthy next claims that revoking his "COR is not in the public interest insofar as he provides critical, specialized psychiatric care which is not easily replaceable." Opening Br. 31. Again, the Administrator considered and rejected this argument consistent with DEA policy and practice. See Brenton D. Wynn, M.D., 87 Fed. Reg. 24,228, 24,258 n.KK (DEA Apr. 22, 2022). In short, the Administrator considered and

rejected all of McCarthy's mitigation arguments, and McCarthy fails to show how rejecting these arguments was arbitrary and capricious. See Humphreys, 96 F.3d at 662–64 (holding Deputy Administrator's decision arbitrary and capricious where he "fail[ed] to discuss the one and only defense raised by Humphreys" and explaining that "this is not simply a case where we disagree with the Deputy Administrator's application of relevant mitigating aspects of the statutory factors to settled facts").

Finally, McCarthy argues that the Administrator failed to consider sanctions less drastic than revocation, such as a suspension of his COR or reprimand. That is simply not true. The Administrator considered lesser punishments but ultimately concluded that revocation was appropriate because McCarthy failed to show he could be trusted with a COR.[8]

III. CONCLUSION

For the forgoing reasons, we will deny the petition for review.

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[8] McCarthy raises three additional arguments that are all forfeited. One is forfeited because it was raised in a footnote. John Wyeth & Bro. Ltd. v. CIGNA Int'l Corp., 119 F.3d 1070, 1076 (3d Cir. 1997). The others are forfeited because they were raised for the first time in a reply brief. Hoxworth v. Blinder, Robinson & Co., 903 F.2d 186, 204 n.29 (3d Cir. 1990).

APPENDIX B

Judgment of the United States Court of Appeals
for the Third Circuit (July 21, 2025)

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-2704

STEPHEN MCCARTHY, P.A.,
Petitioner

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION

On Petition for Review of an
Order of the Drug Enforcement Administration
(Agency No. 23-40)

Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
May 20, 2025

Before: PHIPPS, CHUNG, and ROTH, Circuit Judges

JUDGMENT

This cause came to be considered on the record from the Drug Enforcement Administration and was submitted on May 20, 2025, pursuant to Third Circuit L.A.R. 34.1(a).

On consideration whereof, it is now hereby ADJUDGED and ORDERED that the petition for review is DENIED. Costs will be taxed against Petitioner.

All of the above in accordance with the opinion of this Court.

ATTEST:

s/ Patricia S. Dodszuweit
Clerk

DATE: July 21, 2025

OFFICE OF THE CLERK

PATRICIA S. DODSZUWEIT

CLERK

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT
21400 UNITED STATES COURTHOUSE
601 MARKET STREET
PHILADELPHIA, PA 19106-1790
Website: www.ca3.uscourts.gov

TELEPHONE
215-597-2995

July 21, 2025

Anita Gay
United States Department of Justice
Asset Forfeiture Program
145 N Street NE
Room 2E-404
Washington, DC 20530

Daniel A. Pallen
114 W Front Street
Media, PA 19063

RE: Stephen McCarthy v. DEA
Case Number: 24-2704
Agency Case Number: DEA 23-40

ENTRY OF JUDGMENT

Today, **July 21, 2025,** the Court entered its judgment in the above-captioned matter pursuant to Fed. R. App. P. 36.

If you wish to seek review of the Court's decision, you may file a petition for rehearing. The procedures for filing a petition for rehearing are set forth in Fed. R. App. P. 40, 3rd Cir. LAR 35 and 40, and summarized below.

Time for Filing:
14 days after entry of judgment.
45 days after entry of judgment in a civil case if the United States is a party.

Form Limits:
3900 words if produced by a computer, with a certificate of compliance pursuant to Fed. R. App. P. 32(g).
15 pages if hand or type written.

Attachments:

A copy of the panel's opinion and judgment only.
Certificate of service, unless the petition is filed and served through the Court's electronic-filing system.
Certificate of compliance if petition is produced by a computer.
No other attachments are permitted without first obtaining leave from the Court.

Unless the petition specifies that the petition seeks only panel rehearing, the petition will be construed as requesting both panel and en banc rehearing. A party seeking both forms of rehearing must file the petitions as a single document. Fed. R. App. P. 40(a).

A party who is entitled to costs pursuant to Fed.R.App.P. 39 must file an itemized and verified bill of costs within 14 days from the entry of judgment. The bill of costs must be submitted on the proper form which is available on the court's website.

A mandate will be issued at the appropriate time in accordance with the Fed. R. App. P. 41.

Please consult the Rules of the Supreme Court of the United States regarding the timing and requirements for filing a petition for writ of certiorari.

For the Court,

s/ Patricia S. Dodszuweit
Clerk

s/ Pamela Batts – Case Manager

APPENDIX C

Decision and Order of the DEA Administrator
(August 19, 2024)

BILLING CODE: 4410-09-P

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Docket No. 23-40
STEPHEN MCCARTHY, P.A.
DECISION AND ORDER

On April 21, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Stephen McCarthy, P.A., (Respondent) of Allentown, Pennsylvania. OSC, at 1, 4. The OSC proposed the revocation of Respondent's DEA Certificate of Registration, Control No. MM3329578, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* at 1 (citing 21 U.S.C. §§ 823(g)(1), 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ), who, on October 27, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 30. Following the issuance of the RD, Respondent filed his Exceptions to the Recommended Decision (Exceptions).[1] Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[2] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as

[1] The Agency has reviewed and considered Respondent's exceptions and addresses them herein, but ultimately agrees with the ALJ's recommendation.

[2] The Agency adopts the ALJ's summary of each of the witnesses' testimonies as well as the ALJ's assessment of each of the witnesses' credibility. *See* RD, at 2-13. The Agency agrees with the ALJ that the testimony from the DEA Diversion Investigator (DI), which was primarily focused on the introduction of the Government's documentary evidence and the DI's involvement with the case, was generally consistent without indication of any animosity towards Respondent and thus was fully credible and warranted substantial weight. *Id.* at 5. The Agency also agrees with the ALJ that the testimony from Dr. F., which was focused on Dr. F.'s role as a supervisory physician, her written supervisory agreement with Respondent, and her experience with the Pennsylvania Licensing System, was genuine and internally consistent and thus was fully credible and warranted substantial weight. *Id.* at 8. Finally, the Agency agrees with the ALJ that the testimony from Respondent, which was focused on his experience as a physician assistant operating under supervising agreements, his understanding regarding his written agreement with Dr. F., and his descriptions of the prescriptions he issued during the relevant time period, appeared genuine but for one major inconsistency regarding his use of auto-populated settings identifying Dr. M. as the supervising physician during the relevant time. *Id.* at 12; *see also infra* III. Based on this inconsistency and Respondent's

found in the RD.

I. FINDINGS OF FACT

1. Respondent's Written Agreement with Dr. F.

Respondent is a certified physician assistant licensed to practice in Pennsylvania and has been practicing since October 2014. RD, at 8; Tr. 56. Respondent was employed at Nulton Diagnostic & Treatment Center (Nulton) between May 2019 and August 14, 2022. RD, at 8; Tr. 57. Beginning in October 2020 and lasting through August 2022, Respondent was also employed at PA Treatment Center. RD, at 8; Tr. 57-58. Dr. F. is a psychiatrist licensed to practice in Pennsylvania who began working for Nulton in 2019. RD, at 5; Tr. 40. Dr. F. did not work at PA Treatment Center. Tr. 37-38.

Dr. F. met Respondent in approximately the spring of 2019 while she was considering a job at Nulton. RD, at 6; Tr. 40-41. Respondent testified that this initial meeting was the only time he ever spoke to Dr. F. RD, at 10, Tr. 9. Dr. F. testified that after the initial meeting, she entered into a written agreement with Respondent wherein Dr. F. served as Respondent's supervising physician. RD, at 6; Tr. 41. However, shortly after Dr. F. began work at Nulton, her supervisory capacities were allocated elsewhere, so she and Respondent never actually engaged in a supervisory relationship even during the pendency of the agreement. RD, at 7; Tr. 46. Dr. F. testified that the written agreement lasted from August 22, 2019, to October 7, 2019. RD, at 6; Tr. 41, 46. Respondent testified that while working at Nulton, he had supervising agreements with various physicians, including Dr. F. RD, at 8; Tr. 58.

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personal interest in the outcome of the proceedings, the ALJ found, and the Agency agrees, that Respondent's testimony warranted reduced weight, especially where in conflict with the testimony of other witnesses and evidence presented during the hearing. *Id.* at 12-13.

Dr. F. testified that generally, a written agreement is made between a board-certified physician and a physician assistant and that these agreements have two major components: the first, "to delegate the medical services that the [physician assistant] should perform," and the second, "that the physician should be supervising the [physician assistant] to carry out those medical services or those medical duties." RD, at 6; Tr. 41.[3] Dr. F. testified that when she is supervising a physician's assistant, she "make[s] it a point to sign off on every note individually, to at least scan the notes for consistency."[4] RD, at 6; Tr. 41-42. Dr. F. also testified that once a year, she does "a deep dive in each individual case to make sure that it's moving correctly." RD, at 6; Tr. 42. Dr. F. explained that any time one of her supervisees wants to make any major medical changes, the supervisee will contact her and they will either text or have a phone conversation about it. RD, at 6; Tr. 42. Dr. F. further explained that her "fingers are closely laced into every case that's supervised under [her] name" and she meets in "weekly face-to-face telecommunication supervision, where [she] bring[s] up individual challenging cases" with her supervisees. RD, at 6; Tr. 42. Despite her agreement with Respondent, Dr. F. never actually functioned as a supervisor for Respondent. RD, at 6-7; Tr. 43.

Respondent testified that "under Pennsylvania law, [his] duties as a physician assistant are to evaluate, treat, and provide care to patients under the supervision of a doctor." RD, at 8; Tr. 56-57.[5] Respondent testified that his "role in [a] written agreement is defined by the written

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[3] Respondent similarly testified that a written agreement requires that both the physician and physician assistant sign a document agreeing to the terms of supervision; the physician must also "specify in very basic terms what the duties of the physician assistant will be under the agreement." RD, at 9; Tr. 59.

[4] Dr. F. testified that "notes" are legally required records based on patient encounters with the supervising physician or the physician assistant and are expected to contain basic information regarding the patient's visit. RD, at 6 n.18; Tr. 42-43.

[5] Respondent asserted, however, that a supervising physician "is not required by law" to review Respondent's charts and treatment because Respondent has been "practicing for more than a year." RD, at 9 n.24; Tr. 84. Respondent provided no citation to Pennsylvania law to support this assertion, nor does the Agency find any support for this assertion in Pennsylvania regulations. Such lack of support detracts from Respondent's overall credibility as well as the weight afforded Respondent's statement.

agreement itself." RD, at 9; Tr. 82. According to Respondent, in his experience, he has an "independent caseload of patients" wherein he has "made decisions regarding their treatment without input from the physician, and . . . consulted the physician only in times of question, in times [] when [he is] uncertain about how to proceed with treatment or if [he has] questions about managing a patient." RD, at 9; Tr. 83. In this case, however, it is important to note that Pennsylvania regulations provide that a physician assistant "shall not independently prescribe or dispense drugs." 63 Pa. Cons. Stat. § 422.13(f); *see also* 49 Pa. Code § 18.152(a)(2).

Respondent asserted that "the supervising physician's role is to provide oversight of [his] treatment . . . [but] what that degree of oversight is[,] is dictated by the written agreement itself." RD, at 9; Tr. 83. Respondent testified that "in almost all the written agreements [he has] participated in, the physicians were very hands off and only communicated with [him] if there was a particular issue." RD, at 9; Tr. 83-84.[6]

Respondent testified that even when his written agreement with Dr. F. was active (according to the Government's documentary evidence), he "never consulted with her." RD, at 10; Tr. 94. Dr. F. also testified that she did not talk or consult with Respondent regarding patient care or any other matters in 2022. RD, at 7; Tr. 45. Not only did Respondent not consult with Dr. F., he testified that he had no conversations with Dr. F. at all during the course of their agreement. RD, at 10 n.27; Tr. 95. Even so, Respondent claimed that his non-existent relationship with Dr. F. was "not that unusual," and that he has had "supervising physicians [he has] never met or spoken to." Tr. 96. Respondent did not testify regarding whether or not he

[6] Respondent noted that in one instance, he never even met the supervising physician, never reviewed a case with the supervising physician, never did a case review, and never spoke with the supervising physician. RD, at 9 n.24; Tr. 84. Respondent reiterated that it was not unusual for him to have little communication with his supervising physician and that he has supervising physicians whom he has never met or spoken to. RD, at 9 n.24; Tr. 96-97.

had written controlled substance prescriptions under the authority of those supervising physicians he had never spoken to.

2. Notification of Termination of Respondent's Agreement with Dr. F.

It is undisputed that the agreement between Respondent and Dr. F. ended in October 2019. RD, at 10; Tr. 85-86. However, Respondent testified that he was never notified that the agreement was terminated, so he believed that from August 2022 through November 2022, he was still covered under the agreement with Dr. F. RD, at 8, 10; Tr. 58, 86. Respondent testified that he believed the agreement remained in place even after he left Nulton in August 2022, because he believed that "[a]ccording to the law, the agreement does not end when your employment ends." Tr. 98.[7]

Dr. F. testified that she did not contact Respondent regarding inactivation of their agreement and did not discuss her receipt of the termination letter from the Board with Respondent. RD, at 7; Tr. 46-48.

The Agency notes that the October 8, 2019 termination letter indicates that Respondent was provided a copy of the letter. *See* GX 14. However, in support of his belief that the agreement between himself and Dr. F. remained in effect, Respondent produced a 2023 printout from the Pennsylvania Licensing System (PALS) website that includes the "association start date" for the supervisory agreement between Respondent and Dr. F., but no "association end date." Respondent Exhibit 2, at 5. Testimony from both parties support a finding that the PALS system could contain inaccuracies. RD, at 7, 11, 23; Tr. 51, 98-99.

[7] Respondent again provided no citation to Pennsylvania law to support this assertion, nor does the Agency find any support for this assertion in the Pennsylvania regulations. *See* 49 Pa. Code § 18.172 ("The physician assistant is required to notify the Board, in writing, of a change in . . . employment . . . [and] provide the Board with the new . . . address of employment and name of registered supervising physician."). Once more, as well as in other instances in this Decision, such lack of support detracts from Respondent's overall credibility as well as the weight afforded Respondent's statement.

3. Respondent's Improper Prescribing

It is undisputed that between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022, Respondent issued approximately seventeen (17) prescriptions for controlled substances to patients[8] without being party to a written agreement with a supervising physician. RD, at 21; Tr. 71-81; GX 8, 12. However, Respondent testified that when he prescribed the relevant controlled substances, he did so while believing that he was operating under a valid written agreement with Dr. F. RD, at 11; Tr. 81. None of the patients who received the 17 prescriptions were treated at Nulton; they were treated at the PA Treatment Center where Dr. F. had never been employed. RD, at 23; Tr. 72, 75, 77-79, 104. Further, on cross-examination, Respondent acknowledged that Dr. F.'s name did not appear on the relevant prescriptions and that the "supervising prescriber" section of the prescriptions was blank.[9] RD, at 11-12, 25; Tr. 88-91; GX 8.[10]

Federal law requires that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Moreover, Pennsylvania regulations provide that a physician assistant may only perform medical services as approved within a written agreement with a supervising physician; "shall not independently prescribe or dispense drugs"; and may not "[p]rescribe or dispense drugs except as described in the written agreement." 49 Pa. Code § 18.152(a)(2); 63 Pa. Cons. Stat. § 422.13(a), (e), (f).

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[8] Respondent testified about the multiple patients whom he treated during his time at the PA Treatment Center as well as the risks of harm associated with abrupt cessation of medication, particularly for patients diagnosed with opioid disorders. RD, at 11; Tr. 71-81.

[9] According to Respondent, a pharmacy would typically fill out the information on the prescription identifying the supervising prescriber, and it was thus his practice to leave the supervising prescriber section blank. RD, at 12; Tr. 91, 93-94.

[10] The ALJ noted that the note portion of some of the prescriptions indicates that the supervising physician was Dr. M., whose agreement with Respondent terminated in December 2021. RD, at 25; Tr. 88-90, 92; RX 1, at 5.

Here, the Agency finds that Respondent and Dr. F. had a valid supervisory agreement in place from August 22, 2019, to October 7, 2019, while both were employed at Nulton. The Agency further finds that Dr. F. never supervised Respondent during that time period. Further, as noted by the ALJ, there was no regular review of patient records, no reports of Respondent's activities, and no channels of communication at all between Respondent and Dr. F. RD, at 25.[11] Dr. F. and Respondent only ever spoke once, and that was prior to the time the Agreement was entered.

The Agency further finds that Respondent left Nulton in August of 2022. Thereafter, he issued 17 prescriptions to patients at a different practice, PA Treatment Center, where Dr. F. did not work and would not have access to the patient's records. It is undisputed that Respondent was not covered by any supervisory agreement at the time those prescriptions were issued. Even assuming Respondent truly believed that his agreement with Dr. F. remained valid,[12] the Agency,

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[11] In his Exceptions, Respondent reiterates similar claims to his hearing testimony such as: "[t]here are cases where physician assistants have operated under an implied supervising agreement and where the specifics of such agreements were informally understood rather than formally documented"; Respondent's lack of communication with Dr. F. was "actually reflective of broader practices within the profession, where such supervisory relationships are often more formal than substantive"; and "[i]t is a common practice for physician assistants to operate with significant autonomy, despite what is often written in the formal agreements." Exceptions, at 2. However, Respondent provided no evidence to support these claims other than his testimony which has already been considered, and which is inconsistent with Dr. F.'s credible testimony as well as with Pennsylvania law. *Id.*; *see also* RD, at 22 (citing 49 Pa. Code § 18.122 ("An appropriate degree of supervision includes: (A) active and continuing overview of the physician assistant's activities . . . (B) Immediate availability of the supervising physician to the physician assistant for consultations. (C) Personal and regular review within 10 days by the supervising physician of the patient records upon which entries are made by the physician assistant.")); 49 Pa. Code § 18.158(a)(4) ("A physician assistant may only prescribe a drug for a patient who is under the care of the physician responsible for the supervision of the physician assistant."), § 18.158(d)(4) ("The supervising physician shall countersign the patient record within 10 days."), § 18.158(d)(3) ("The physician assistant shall report, orally or in writing, to the supervising physician within 36 hours, a drug prescribed or medication dispensed by the physician assistant while the supervising physician was not physically present . . . ."). As discussed throughout this Decision, Respondent's continued failure to provided supporting evidence for his claims repeatedly detracts from his overall credibility as well as the weight afforded to his unsupported statements.

[12] In his Exceptions, Respondent took issue with the ALJ's "assumption that [Respondent] should have known about the termination of his supervisory agreement" and claimed that "[t]he ALJ's expectations were not in accordance with the legal requirements of the state of Pennsylvania" which, Respondent alleges, "require[] clear and direct communication regarding the status of such agreements." Exceptions, at 3. Respondent provided no evidence or citations to the law to support this claim. *See supra* n.11. Regardless, as stated herein, the Agency finds that Respondent, even if he believed the agreement remained valid, had no reasonable belief that he could issue the relevant prescriptions pursuant to that agreement under the circumstances.

in agreement with the ALJ, does not believe that Respondent held a reasonable belief that he could rely on that agreement to issue prescriptions to patients at a practice at which Dr. F. had never worked and after not speaking with Dr. F. for over three years. RD, at 25. The Agency finds that Respondent issued the relevant prescriptions independently.

II. DISCUSSION

A. The Five Public Interest Factors

Under the Controlled Substances Act (CSA), "[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.
(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.
(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.
(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 Fed. Reg. 37,507, 37,508 (1993).

The Government has the burden of proof in this proceeding. 21 C.F.R. § 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. § 823(g)(1), the Government's evidence in support of its *prima facie* case for revocation of Respondent's registration is confined to Factors B and D. RD, at 15; *see also id.* at 15 n.33 (finding that Factors A, C, and E do not weigh for or against revocation).

Having reviewed the record and the RD, the Agency agrees with the ALJ, adopts the ALJ's analysis, and finds that the Government's evidence satisfies its *prima facie* burden of showing that Respondent's continued registration would be "inconsistent with the public interest." 21 U.S.C. § 824(a)(4); RD, at 13-26.

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualeh Ashraf, M.D.*, 88 Fed. Reg. 1,095, 1,097 (2023); *Kareem Hubbard, M.D.*, 87 Fed. Reg. 21,156, 21,162 (2022). In the current matter, the Government has alleged that Respondent violated numerous federal and state laws regulating controlled substances. OSC, at 1-2. Specifically, federal law requires that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a).[13] As for state law, Pennsylvania regulations provide that a physician assistant may only perform medical services as approved within a written agreement with a supervising physician; "shall not independently prescribe or dispense drugs"; and may not "[p]rescribe or dispense drugs except as

[13] The Agency need not adjudicate the criminal violations alleged in the instant OSC. *Ruan v. United States*, 142 S. Ct. 2370 (2022) (decided in the context of criminal proceedings).

described in the written agreement." 49 Pa. Code § 18.152(a)(2); 63 Pa. Cons. Stat. § 422.13(a), (e), (f).

In the current matter, the Agency agrees with the ALJ's analysis that Respondent repeatedly issued controlled substance prescriptions outside the usual course of professional practice by issuing such prescriptions while lacking an active agreement with a supervisory physician as required by state law. RD, at 17-18. Indeed, as noted by the ALJ, Respondent failed to maintain any supervisee/supervisor relationship, and with Dr. F. in particular, "Respondent's failure to communicate at all with [Dr. F.] – even when Respondent changed employers – makes it hard to accept that Respondent truly believed he still had an active supervisory agreement with [Dr. F.]." *Id.* at 18.[14]

As Respondent's conduct displays clear violations of the federal and state regulations described above, the Agency agrees with the ALJ and hereby finds that Respondent repeatedly violated federal and state law relating to controlled substances. *Id.* at 26. Accordingly, the Agency agrees with the ALJ and finds that Factors B and D weigh in favor of revocation of

[14] In his Exceptions, Respondent argues that the ALJ's "federal interpretation of Pennsylvania law is overly strict and inconsistent with actual state practices," but fails to provide any evidence supporting this claim other than noting the lack of action against Respondent by the Pennsylvania state board of medicine. Exceptions, at 2; *see also id.* at 4 ("[Respondent] maintains a Pennsylvania state license, suggesting that the state regulatory body did not find [his] actions sufficiently harmful to merit any kind of sanction"). As mentioned above, the lack of state action against Respondent was addressed by the ALJ in his analysis of public interest Factor A. *See* RD, at 15 n.33. Respondent also claims that "the ALJ lacks the necessary expertise to interpret state-specific legal standards correctly . . . [and] does not understand the nuances of how supervising agreements are communicated and understood in the context of Pennsylvania law, thereby leading to an incorrect conclusion about [Respondent's] compliance." According to Respondent, "Pennsylvania law does not explicitly define the frequency or nature of interaction required between a supervising physician and a physician assistant. The law allows for varying degrees of supervision, therefore the [ALJ] applied an unduly stringent standard." *Id.* To these arguments, the Agency notes that Respondent had ample opportunity in presenting his case-in-chief to offer testimony from an expert witness regarding Pennsylvania standards, but did not do so. The Agency also reiterates that Respondent has repeatedly failed to provide citation to specific Pennsylvania law. *See supra* n.5, 7, 11, 12. As such, the Agency, in agreement with the ALJ, has considered the plain language of the relevant Pennsylvania law and the record as a whole in making its analysis.

Respondent's registration and thus finds Respondent's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. § 823(g)(1). *Id.*[15]

III. SANCTION

Where, as here, the Government has established sufficient grounds to revoke Respondent's registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 Fed. Reg. 62,316, 62,339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 Fed. Reg. 33,738, 33,746 (2021).[16]

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[15] In his Exceptions, Respondent argues that there is no evidence of any harm or abuse resulting from his prescribing at issue. Exceptions, at 4. Agency precedent is clear that proof of actual, subsequent harm is not required when a registrant has acted inconsistently with the public interest. *Melanie Baker, N.P.*, 86 Fed. Reg. 23,998, 24,009 (2021); *Larry C. Daniels, M.D.*, 86 Fed. Reg. 61,630, 61,660-61 (2021); *Jeanne E. Germeil, M.D.*, 85 Fed. Reg. 73,786, 73,799 n.32 (2020). Respondent also argues that revoking his registration "is not in the public interest, especially since he provides critical specialized psychiatric care that is not easily replaceable." Exceptions, at 5. Nonetheless, "[t]he CSA requires [the Agency] to consider Respondent's controlled substance dispensing experience, among other things, not whether Respondent's practice of medicine as a whole [is] beneficial to the community." *Brenton D. Wynn, M.D.*, 87 Fed. Reg. 24,228, 24,258 n.KK (2022) (citing *Frank Joseph Stirlacci, M.D.*, 85 Fed. Reg. 45,229, 45,239 (2020) (declining to accept community impact arguments); *Richard J. Settles, D.O.*, 81 Fed. Reg. 64,940, 64,945 n.16 (2016)).

[16] In his Exceptions, Respondent argues that "[t]he expectation of unequivocal acceptance of responsibility does not consider the complexity of this individual case" and asserts that "it is reasonable and entirely appropriate for [Respondent] to partially acknowledge fault while also presenting legitimate explanations or mitigating factors for his actions. It is also objectively true that [Respondent] has taken the steps necessary already to ensure complete rectification and future compliance." Exceptions, at 4. The Agency has held repeatedly that "[a] registrant's acceptance of responsibility must be unequivocal, or relief for sanction is not available, and where there is equivocation any evidence of remedial measures is irrelevant." *Fares Jeries Rabadi, M.D.*, 87 Fed. Reg. 30,564,

Here, and as noted by the ALJ, Respondent did admit some fault regarding his use of auto-populated settings identifying Dr. M. as the supervising physician during the relevant time despite the fact that his written agreement with Dr. M. had been inactivated in December 2021. RD, at 27-28; Tr. 92-93. Respondent also acknowledged that his agreement with Dr. F. was indeed inactivated in October 2019 based on the termination letter introduced into evidence by the Government. RD, at 28; Tr. 85-86; *see* GX 14. However, as noted by the ALJ, Respondent repeatedly asserted that he believed that he was covered by his agreement with Dr. F. when he issued the prescriptions at issue and that he had not received notice of the inactivation of their agreement. RD, at 28; Tr. 67-69, 81, 86, 98. Further, "Respondent did not find his lack of communication with [Dr. F.] as grounds for concern, and indicated that he regularly treats patients without communicating with a supervising physician." RD, at 28; Tr. 83-84, 96-97, 101-102. Respondent "further justified his conduct, testifying that patients under his care were at risk of withdrawal effects had he ceased issuing prescriptions." RD, at 28; Tr. 71-81. As the ALJ concluded, "[t]his explanation completely discounts the Respondent's responsibility to transfer care to another practitioner when learning that he can no longer provide the needed care, and further emphasizes the fact that the Respondent was essentially operating as a solo practitioner with no established relationship with a supervising physician who could assume care." RD, at 28.

Notably, in his Exceptions, Respondent asserted that "Pennsylvania law regarding the supervision of physician assistants places the responsibility of supervision on the supervising physician, not the physician assistant." Exceptions, at 3 (citing 49 Pa. Code § 18.142; 63 Pa. Cons. Stat. § 422.13). Respondent also claimed that "[i]f the supervising physician fails to fulfill

30,608 n.39 (2022) (citing *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74,800, 74,801, 74,810 (2015)); *see also Lon F. Alexander, M.D.*, 82 Fed. Reg. 49,704, 49,728 (2017) (collecting cases).

these responsibilities, the fault does not lie with the PA, especially if the PA was acting under the assumption of being properly supervised." *Id.* Nowhere in the Pennsylvania law cited by Respondent does it appear to place the sole responsibility on the supervising physician for a physician assistant's actions. Moreover, this argument demonstrates a blatant attempt by Respondent to shift the blame to his supervising physician for his own failure to exercise basic due diligence in staying apprised of whether an agreement critical to the propriety of his work as a physician's assistant remained active. Respondent also attempted to shift the blame to the PALS system, stating in his Exceptions that "[i]t is unreasonable to expect [Respondent] not to consider the information in an official state licensing portal accurate or to expect it to be error-prone. The responsibility lies with the state to make sure the system is functioning properly." Exceptions, at 3. As previously noted, Respondent himself acknowledged that the PALS system can be inaccurate regarding the dates for current agreements, *see supra* I.2; Tr. 64, and once again, basic due diligence on the part of Respondent as well as proper and ongoing communication with his supervising physician would have ensured that Respondent would not have needed to rely solely on PALS to know whether their supervising agreement remained active.

Ultimately, the ALJ concluded, and the Agency agrees, that Respondent has not demonstrated unequivocal acceptance of responsibility for his actions. *Id.* (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.*, 81 Fed. Reg. 79,188, 79,201-02 (2016)).[17]

[17] 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. 5,479, 5,498 n.33 (2019) (citing *Jones Total Health Care Pharmacy*, 81 Fed. Reg. at 79,202-03); *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74,800, 74,801, 74,810 (2015). Even so, in the current matter, the ALJ noted, and the Agency has considered, that Respondent is presently covered by a written agreement with Dr. P. RD, at 28 n.44; Tr. 63-64; RX 1, at 3.

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. at 74,810. In this case, the Agency agrees with the ALJ that, regarding specific deterrence, "there is no reason to believe that the Respondent's behavior will not recur in the future, as he failed to accept responsibility and repeatedly attempted to justify his conduct." RD, at 29 (citing *Gilbert Y. Kim, D.D.S.*, 87 Fed. Reg. 21,139, 21,144-45 (2022)). Further, the Agency agrees with the ALJ that 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 "one can ignore the law and yet incur no consequences from having done so." *Id.* at 29-30 (citing *Joseph Gaudio, M.D.*, 74 Fed. Reg. 10,083, 10,095 (2009)). Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious, as Respondent issued seventeen controlled substance prescriptions to multiple patients without an active written agreement in place with a supervising physician. *Id.* at 29.[18]

In sum, Respondent has not offered any credible evidence on the record to rebut the Government's case for revocation of his registration and Respondent has not demonstrated that he can be entrusted with the responsibility of registration. *Id.* at 30. Accordingly, the Agency will order that Respondent's registration be revoked.[19]

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[18] In his Exceptions, Respondent argues that "even if it is believed that [Respondent] is guilty of misconduct, that misconduct . . . was not of a severity that warrants the extreme measure of revocation." Exceptions, at 4. Respondent also claims, without citing to any specific Agency precedent, that "[s]imilar or more severe violations have resulted in lesser punishments, such as fines, reprimands, or temporary suspension" and "revocation would represent an inconsistency in the application of penalties." *Id.* The Agency possesses discretion to order a sanction lesser than revocation, however, the Agency finds that "exercising that discretion here would ill-serve the public interest" because "Respondent has not shown that [he] can be entrusted with the responsibility carried by [his] registration – having failed to accept responsibility for [his] conduct, [the Agency has] no assurance that Respondent would not repeat the conduct if [he was] to retain a registration." *The Pharmacy Place*, 86 Fed. Reg. 21,008, 21,016 (2021).

[19] For his final Exception, Respondent argues that the ALJ's removal restrictions are unconstitutional under *Jarkesy v. SEC*, which held that the removal protections for ALJs of the Securities and Exchange Commission (SEC) are unconstitutional (while declining to decide whether that conclusion would entitle the plaintiff to vacatur of the challenged agency decision). *Jarkesy v. SEC*, 34 F.4th 446, 463-465, 463 n.17 (5th Cir. 2022), *aff'd on other*

ORDER

Pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a), I hereby revoke DEA Certificate of Registration No. MM3329578 issued to Stephen McCarthy, P.A. Further, pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 823(g)(1), I hereby deny any pending applications of Stephen McCarthy, P.A., to renew or modify this registration, as well as any other pending application of Stephen McCarthy, P.A., for additional registration in Pennsylvania. This Order is effective **[insert Date Thirty Days From the Date of Publication in the Federal Register].**

Date: AUG 19 2024

Anne Milgram
Administrator

grounds, *SEC v. Jarkesy*, 603 U.S. ___ (2024), No. 22-859 (June 27, 2024). *Jarksey* was decided on the understanding that "the SEC Commissioners may only be removed by the President for good cause," and thus there were "two layers of insulation" that "impede[d] the President's power to remove" the SEC's ALJs. *Id.* at 464-465. By contrast, there is no doubt that the President may remove the Attorney General at will. Accordingly, *Jarkesy* can and should be distinguished from the instant situation with respect to DEA's ALJs, and the Agency finds Respondent's Exception to be unpersuasive.

APPENDIX D

Recommended Rulings, Findings of Fact, Conclusions of Law,
and Decision of the Administrative Law Judge (October 27, 2023)

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Stephen McCarthy, P.A.**	**Docket No. 23-40**

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Paul E. Soeffing
U.S. Administrative Law Judge

October 27, 2023

Jennifer L. Holsclaw, Esq.
for the Government

Kristy Castagna, Esq.
Kyle Thompson, Esq.
for the Respondent

The Drug Enforcement Administration ("DEA") Acting Assistant Administrator, Diversion Control Division, issued an Order to Show Cause ("OSC") on April 21, 2023, seeking to revoke the DEA Certificate of Registration ("COR"), No. MM3329578, of Stephen McCarthy, P.A. ("the Respondent").[1] The OSC seeks revocation pursuant to 21 U.S.C. § 824(a)(4) and denial of any applications for any DEA registrations, based on the Government's view that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(g)(1).

On March 24, 2023,[2] the Respondent, through counsel, timely filed a Request for Hearing ("RFH") and a Request for Extension of Time to File an Answer ("Respondent's Request for Extension of Time").[3] On May 24, 2023, the tribunal issued an Order for Prehearing Statements and Granting in Part Respondent's Request for Extension of Time to File an Answer ("OPHS").[4] On June 20, 2023, the Respondent timely filed an Answer.[5] A hearing was conducted in a hybrid hearing format on August 31, 2023, at the DEA Hearing Facility in Arlington, Virginia, with the Government and its representative appearing in person at the DEA Hearing Facility, and the Government's witness and the Respondent participating through the utilization of video-teleconference ("VTC") technology. The specific issue to be adjudicated by the Administrator, with the assistance of this Recommended Decision, is whether the record as a whole establishes by substantial evidence that the Respondent's registration should be revoked on the grounds alleged by the Government.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

THE ALLEGATIONS

The Government alleges that the Respondent's DEA COR, No. MM3329578, should be

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[1] ALJ Ex. 1.
[2] The RFH and Request for Extension of Time are dated May 23, 2023, but were filed after 5:00 p.m. on that day and are thus deemed filed by the Respondent on May 24, 2023. *See* 21 C.F.R. § 1316.45.
[3] ALJ Exs. 3, 4.
[4] ALJ Ex. 5.
[5] *See* ALJ Exs. 5 at 2, 8.

revoked, and that any applications for any DEA registrations should be denied, pursuant to 21 U.S.C. § 824(a)(4), because the Respondent, a physician assistant, issued controlled substance prescriptions without being covered by a written agreement with a supervising physician as required by the Commonwealth of Pennsylvania. ALJ Ex. 1 at 1-3.

THE EVIDENCE

STIPULATIONS OF FACT

The Government and the Respondent agreed to the following stipulations, which I recommend be accepted as fact in these proceedings:[6]

1. Respondent is registered with DEA as a mid-level practitioner-physician assistant in Schedules II through V under DEA COR No. MM3329578.
2. Respondent's DEA registered address is 21 N. 7th Street, Apt. B2, Allentown, PA 18101.
3. Respondent's DEA COR expires by its own terms on January 31, 2024.
4. Respondent currently possesses a Commonwealth of Pennsylvania physician assistant license, under state license number MA057132.
5. Respondent's state physician assistant license expires by its own terms on December 31, 2024.
6. Dextroamphetamine is a Schedule II stimulant.
7. Adderall is the brand name for dextroamphetamine.
8. Lisdexamfetamine is a Schedule II amphetamine.
9. Vyvanse is the brand name for lisdexamfetamine.
10. Buprenorphine is a Schedule III narcotic analgesic.
11. Suboxone is a brand name for buprenorphine.
12. Phentermine is a Schedule IV stimulant.

GOVERNMENT'S CASE

The Government presented its case-in-chief through the testimony of two witnesses: (1)

[6] ALJ Exs. 9 at 1-3, 10 at 1-2, 11 at 2-3.

DEA Diversion Investigator ("DI") Louis Callavini; and (2) Elizabeth Fourcade, M.D.

DI Louis Callavini[7]

DI Callavini has been a DEA Diversion Investigator with the Philadelphia Field Division, Allentown Resident Office, for approximately eleven (11) years. Tr. 22; Gov't Ex. 13 at 1 ¶ 1. DI Callavini completed approximately four months of specialized training at the DEA Academy in Quantico, Virginia. Gov't Ex. 13 at 1 ¶ 1. As a Diversion Investigator, DI Callavini investigates alleged violations of the Controlled Substances Act ("CSA") by engaging in preregistration investigations and onsite investigations, inspecting applicants seeking a DEA COR, and collecting and reviewing documents and other records from official government sources. Tr. 22; Gov't Ex. 13 at 1-2 ¶ 2.

DI Callavini is the lead DEA case agent on DEA's investigation regarding the Respondent. Gov't Ex. 13 at 2 ¶ 4. DI Callavini testified that he learned of the Respondent through another Diversion Investigator from the Philadelphia Division office. Tr. 23. DI Callavini was assigned to investigate the Respondent and "determine if [the Respondent] was issuing controlled substance prescriptions while not covered under a written agreement with a physician" as required by the law of the Commonwealth of Pennsylvania. Tr. 23; Gov't Ex. 13 at 3 ¶ 7. In conducting this investigation, DI Callavini drafted an administrative subpoena[8] issued to the Office of the General Counsel/PA Department of State seeking "[c]opies of **all** written agreements for [the Respondent], medical physician assistant . . . Pennsylvania Medical License MA057132 for the dates between the issuance of [the Respondent's] Pennsylvania medical license as a medical physician assistant and present." Gov't Exs. 2, 13 at 3 ¶ 8 (emphasis in original).

In March of 2023, DI Callavini received copies of written agreements held between the Respondent and supervising physicians between 2014 and March 1, 2023.[9] Gov't Ex. 13 at 3 ¶

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[7] Government Exhibits 1-8 and 12-14 were offered and admitted through DI Callavini.
[8] Gov't Ex. 2.
[9] DI Callavini also received a "Certificate and Attestation" from the Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs, attesting that the attached documents were "full, true and correct copies of the license applications and renewals . . . as well as Written Agreements held between [the Respondent] and supervising physicians . . . ." Gov't Exs. 3 at 1, 13 at 3-4 ¶ 10.

9. In addition to copies of the agreements, DI Callavini received email notifications that had previously been sent to the Respondent, notifying the Respondent when certain written agreements were inactivated. Gov't Ex. 13 at 3 ¶ 9. Among the documents received by DI Callavini were written agreements between the Respondent and two physicians: Dr. Gene Levinstein[10] and Dr. Dale Sommons.[11] Gov't Ex. 13 at 4-5 ¶ 11-14. The agreement between Dr. Levinstein and the Respondent was filed on March 21, 2022 and was inactivated on August 23, 2022. Gov't Exs. 4, 5 at 1, 13 at 4 ¶ 11-12. The agreement between Dr. Sommons and the Respondent was filed on September 26, 2022 and was inactivated on October 5, 2022. Gov't Exs. 6, 7 at 1, 13 at 5 ¶ 13-14. According to copies of emails received by DI Callavini, the Respondent was notified of inactivation of the agreements with Dr. Levinstein and Dr. Sommons upon the date of inactivation. Gov't Exs. 5 at 1, 7 at 1, 13 at 4-5 ¶ 11-14. Based on these agreements, DI Callavini determined that the Respondent "was not covered under any written agreement for the periods between on or about August 24, 2022, and September 20, 2022, and between on or about October 6, 2022, and November 8, 2022." Gov't Ex. 13 at 5-6 ¶ 15.

After receiving the copies of written agreements between the Respondent and supervising physicians, DI Callavini observed DI Stephen Dougherty[12] run a query in the Commonwealth of Pennsylvania Prescription Drug Monitoring Program ("PDMP"),[13] showing prescriptions issued by the Respondent from November of 2021 through February of 2023. Gov't Ex. 13 at 6 ¶ 16-17. Reviewing the data produced by the query,[14] DI Callavini determined that the Respondent "prescribed controlled substances during time periods in which he was not the subject of a written agreement, in violation of Commonwealth of Pennsylvania law." Gov't Ex. 13 at 6 ¶ 17.

DI Callavini issued "various administrative subpoenas to various pharmacies" to obtain copies of controlled substance prescriptions issued by the Respondent for the time periods between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022. Gov't Ex. 13 at 7 ¶ 19. DI Callavini received seventeen (17) copies of

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[10] Gov't Ex. 4.
[11] Gov't Ex. 6.
[12] DI Callavini shares an office with DI Dougherty, and provided DI Dougherty with the Respondent's COR prior to the PDMP query. Gov't Ex. 13 at 6 ¶ 17.
[13] "PDMP is a state run database which tracks all the Schedule II through V controlled substances dispensed throughout the Commonwealth of Pennsylvania." Gov't Ex. 13 at 6 ¶ 16.
[14] DI Dougherty forwarded the results of the PDMP query via email to DI Callavini in the form of an Excel spreadsheet. Gov't Ex. 13 at 6 ¶ 17; *see* Gov't Ex. 12.

controlled substance prescriptions[15] "unlawfully issued" by the Respondent to individuals and filled at various pharmacies during periods where Respondent was not subject to a written agreement. Gov't Ex. 13 at 7-8 ¶ 19-21.

On cross-examination, DI Callavini acknowledged that the Respondent was covered by more than one written agreement during the course of 2022. Tr. 27. DI Callavini testified that he received a copy of the written agreement entered into between the Respondent and Dr. Fourcade, along with a copy of a termination letter[16] indicating inactivation of said agreement. Tr. 27-29.

On redirect, DI Callavini testified that the copy of the termination letter from the Pennsylvania State Board of Medicine ("the Board") regarding the agreement between the Respondent and Dr. Fourcade is dated October 8, 2019. Tr. 32-33. The termination letter indicated that the Board had processed a request to inactivate the prior written agreement. Tr. 33. On re-cross, DI Callavini testified that although the termination letter indicated that it was sent to the Respondent, there was no indication regarding how it was sent or whether it was delivered to Respondent. Tr. 34.

DI Callavini's testimony was primarily focused on the introduction of the Government's documentary evidence and his involvement with this case. His testimony was generally consistent and there was no indication he harbors any animosity towards the Respondent. As a public servant, DI Callavini has no personal stake in the DEA's action on the Respondent's registration. I therefore will fully credit his testimony and give it substantial weight.

Elizabeth Fourcade, M.D.

Dr. Fourcade is a psychiatrist licensed to practice in the Commonwealth of Pennsylvania. Tr. 40. Dr. Fourcade received a BA in psychology from Yale in 2003, and graduated from medical school at Case Western Reserve University School of Medicine in 2013. Tr. 38. She passed her psychiatric board exam in 2018, and began working for Nulton Diagnostic & Treatment Center ("Nulton") in 2019. Tr. 37, 40.

[15] Gov't Ex. 8.
[16] *See* Gov't Ex. 14.

Background

Dr. Fourcade met the Respondent on one occasion during a pre-employment interview in approximately the spring of 2019 while she was considering a job at Nulton.[17] Tr. 40-41. Dr. Fourcade testified that after the initial meeting, she entered into a written agreement with the Respondent wherein she served as Respondent's supervising physician. Tr. 41. Dr. Fourcade testified that this agreement lasted from August 22, 2019 to October 7, 2019. Tr. 41.

Respondent's Written Agreement with Dr. Fourcade

Dr. Fourcade testified that a written agreement is between a "Board-certified physician and a physician assistant." Tr. 41. Dr. Fourcade testified that these agreements have "two major components." Tr. 41. The first component is "to delegate the medical services that the [physician assistant] should perform." Tr. 41. The second component is "that the physician should be supervising the [physician assistant] to carry out those medical services or those medical duties." Tr. 41.

Dr. Fourcade testified that what it means to supervise a physician assistant is "legally . . . a bit fuzzy to [her]," but that in her experience, she "make[s] it a point to sign off on every note individually, to at least scan the notes for consistency."[18] Tr. 41-42. Further, Dr. Fourcade testified that "[o]nce a year, [she does] a deep dive in each individual case to make sure that it is moving correctly. Anytime one of [her] supervisees wants to make any major medical changes, they're to contact [her] and [they] either text of it or have a phone conversation . . . ." Tr. 42. Dr. Fourcade testified that her "fingers are closely laced into every case that's supervised under [her] name," and she meets in "weekly face-to-face telecommunication supervision, where [she] bring[s] up individual challenging cases" with her supervisees. Tr. 42. Dr. Fourcade testified

[17] Dr. Fourcade testified that the pre-employment interview took place via teleconference. Tr. 40.

[18] Dr. Fourcade testified that "notes" are legally required records based on patient encounters with the supervising physician or the physician assistant. Tr. 42. Dr. Fourcade testified that at Nulton, the process is "very formalized" and there is an "electronic medical record" used for entering information from patient encounters. Tr. 42. The notes are expected to contain basic information, including "the patient's name, the reason that they're there, any interventions that [the physician or physician assistant] did to treat them, [and the physician or physician assistant's] impression of their case . . . ." Tr. 43. Dr. Fourcade testified that notes are "required for every patient every time." Tr. 43.

that she did not engage in any type of these supervising behaviors with the Respondent. Tr. 43.

Dr. Fourcade testified that the written agreement between her and the Respondent is no longer in place.[19] Tr. 43. Dr. Fourcade testified that she has not been a part of any other written agreements with the Respondent. Tr. 45. Furthermore, Dr. Fourcade testified that she did not talk to or consult with the Respondent regarding patient care or any other matters in 2022. Tr. 45.

On cross-examination, Dr. Fourcade testified that "[t]he original intent [of her supervising agreement with the Respondent] was that [she] would be [the Respondent's] supervisor, but shortly after [she] began work at Nulton, it was decided that [her] supervisory capacities were better allocated elsewhere, and so [she and the Respondent] never actually engaged in a supervisory relationship, although [they] did have an agreement in place." Tr. 46. Dr. Fourcade testified that she did not contact the Respondent regarding inactivation of the agreement, and further testified that she "had no personal relationship with [the Respondent], and it was [her] understanding that [Nulton] was terminating that agreement to utilize [her] supervisory capacities elsewhere." Tr. 46. Dr. Fourcade did not discuss her receipt of the termination letter from the Board with the Respondent, and is unaware whether the Respondent received notice of the termination letter from the Board. Tr. 47-48.

The Pennsylvania Licensing System ("PALS")

On cross-examination, Dr. Fourcade testified that PALS is "a system within the [Commonwealth] of Pennsylvania that is used to communicate electronically regarding licensing status."[20] Tr. 49. When asked whether she would be surprised to find that PALS does not indicate that her written agreement with the Respondent was terminated, Dr. Fourcade testified that "[r]egretfully, that would not surprise [her]." Tr. 51. Dr. Fourcade testified that "[t]here are many physician complaints within . . . Pennsylvania noting that [PALS] is often outdated." Tr. 51. Dr. Fourcade testified that she is unable to manually inactivate or update agreements in PALS, and agreements are instead inactivated by "an employee of the [Commonwealth] of

[19] Dr. Fourcade testified that the agreement was terminated by the Board on October 7, 2019. Tr. 43.

[20] Dr. Fourcade testified that she uses PALS once every two years to renew her medical license. Tr. 49.

Pennsylvania." Tr. 51. Dr. Fourcade testified that "theoretically," PALS should include information related to supervising agreement start and end dates. Tr. 51-52.

Dr. Fourcade's testimony was focused on her role as a supervising physician, her written agreement with the Respondent, and her experience with PALS. Her testimony was genuine and internally consistent. Dr. Fourcade has no personal stake in DEA's action regarding the Respondent's registration. I therefore find her testimony to be credible and I will give it substantial weight.

RESPONDENT'S CASE

The Respondent presented his case-in-chief through the testimony of one witness, the Respondent himself.

Stephen McCarthy, P.A.[21]

Mr. McCarthy is a certified physician assistant licensed to practice in the Commonwealth of Pennsylvania. Tr. 56. The Respondent graduated from an accredited physician assistant program at Salus University in 2014, with an M.S. in physician assistant studies.[22] Tr. 56. The Respondent has been practicing as a physician assistant since October of 2014.[23] Tr. 56.

Background

The Respondent testified that "under Pennsylvania law, [his] duties as a physician assistant are to evaluate, treat, and provide care to patients under the supervision of a doctor." Tr. 56-57. The Respondent testified that he was employed at Nulton between May of 2019 and August 14, 2022. Tr. 57. In August of 2022, the Respondent was also employed at PA Treatment Center, where he had been working since October of 2020. Tr. 57-58.

While working at Nulton, the Respondent testified that he had supervising agreements with various physicians, including Dr. Fourcade. Tr. 58. The Respondent testified that he did not receive notification of the inactivation of his written agreement with Dr. Fourcade. Tr. 58.

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[21] Respondent Exhibits 1-2 were offered and admitted through the Respondent.
[22] Respondent also obtained a bachelor's degree in medical studies from Salus University in 2013. Tr. 56.
[23] Respondent has concentrated in psychiatry and addiction medicine during his practice as a physician assistant. Tr. 57.

The Respondent testified that the process to get approval for a written agreement requires "both the physician and the physician assistant [to] sign a document agreeing to the terms of supervision and the physician must specify in very basic terms what the duties of the physician assistant will be under the agreement." Tr. 59.

On cross-examination, the Respondent testified that his "role in the written agreement is defined by the written agreement itself." Tr. 82. The Respondent testified that in his experience, he has an "independent caseload of patients" wherein he has "made decisions regarding their treatment without input from the physician, and . . . consulted the physician only in times of question, in times of when [he is] uncertain about how to proceed with treatment or if [he has] questions about managing a patient." Tr. 83. The Respondent testified that "the supervising physician's role is to provide oversight of [his] treatment . . . [but] what that degree of oversight is is dictated by the written agreement itself." Tr. 83. The Respondent further testified that "in almost all the written agreements [he has] participated in, the physicians were very hands off and only communicated with [him] if there was a particular issue."[24] Tr. 83-84.

Respondent's Supervising Agreements as Reflected in PALS

The Respondent testified that PALS is "used for managing licenses . . . [i]t's also used for managing supervising agreements, associations with supervising physicians, and it's also used for communication with the state Board of Medicine . . . ." Tr. 58-59. The Respondent testified that the PALS online portal "is more recent," and has been in use since "at least 2019." Tr. 59.

The Respondent testified that PALS contains a section called "managed associations," which contains records of current and prior supervising agreements between physicians and physician assistants. Tr. 61. The Respondent testified that "[f]or all associations, it lists a start

[24] Respondent testified that "in one case, [he] never even met . . . the supervising physician." Tr. 84. In this agreement, Respondent testified that he "never reviewed a case with [the supervising physician] . . . never did a case review . . . never spoke with [the supervising physician]." Tr. 84. Respondent stated that the supervising physician "is not required by law" to review Respondent's charts and treatment because Respondent has been "practicing for more than a year." Tr. 84. Respondent also testified that in his experience, it was not unusual for him to have little communication with his supervising physician, and that he has "supervising physicians [he has] never met or spoken to." Tr. 96-97. Respondent testified that he never spoke with the following providers listed in PALS: Jane Marie Jesse, Padma Palvai, and Cesar Fabiani. Tr. 101-02; *see* Resp't Ex. 1 at 4.

date, but if the association is no longer active, it lists an end date that indicates when that supervision was terminated." Tr. 61. The Respondent testified that his PALS managed associations page[25] currently reflects that he has a supervising agreement with Dr. Richard Paul Paczynski, which was activated on February 1, 2023. Tr. 63-64; Resp't Ex. 1 at 3. The Respondent testified that the start date for supervising agreements contained in PALS does not reflect the date an agreement was activated, because "Pennsylvania law states that the agreement begins as soon as it is signed by both parties" and the PALS start date merely reflects "when the board approved the agreement." Tr. 64.

The Respondent testified that PALS reflects supervising agreements between himself and multiple Nulton physicians, as well as physicians employed by the PA Treatment Center. Tr. 65-66. The Respondent testified that he received notification of the inactivation of his written agreements with other physicians listed in PALS, including Dr. Levinstein and Dr. Sommons. Tr. 66-67. However, the Respondent testified that he never received a notification that his written agreement with Dr. Fourcade was inactivated.[26] Tr. 67-69.

On cross-examination, the Respondent acknowledged that his agreement with Dr. Fourcade ended in October of 2019, based on the termination letter presented at the hearing. Tr. 85-86. However, the Respondent testified that because he was never notified, he still believed that he was covered under the agreement with Dr. Fourcade in August through November of 2022. Tr. 86. The Respondent testified that he did not consult or otherwise communicate with Dr. Fourcade between August and September of 2022, or between October 6, 2022, and November 8, 2022. Tr. 94-95. The Respondent testified that "even during the time when the written agreement was active according to [the Government's] documents, [he] never consulted with [Dr. Fourcade]."[27] Tr. 94. The Respondent testified that he only spoke to Dr. Fourcade on one occasion: during her initial hiring process at Nulton in approximately the summer of 2019.

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[25] Resp't Ex. 1.

[26] Respondent testified that prior to the hearing, he had never received and was unfamiliar with the letter of inactivation introduced as Government Exhibit 14. Tr. 69-70.

[27] Respondent acknowledged that his lack of communication with Dr. Fourcade while the agreement was in place was contrary to what Dr. Fourcade testified she normally does in a supervisory position, but reiterated that he had no conversation with Dr. Fourcade during the course of their agreement. Tr. 95.

Tr. 96. The Respondent further testified that although he left Nulton in August of 2022, he believed that the agreement with Dr. Fourcade remained in place.[28] Tr. 98.

The Respondent testified that although PALS shows no "association end date" pertaining to his agreement with provider Jane Marie Jesse,[29] this agreement is distinguished from his agreement with Dr. Fourcade because the Jane Marie Jesse agreement was labeled as a "temporary written agreement" in PALS. Tr. 98-99. The Respondent also testified that he did not agree with Dr. Fourcade's assessment of PALS.[30] Tr. 100.

Prescriptions Issued by Respondent Between August 24, 2022 and November 8, 2022

The Respondent testified about multiple patients he treated during his time at the PA Treatment Center and the risks associated with abrupt cessation of medication. *See* Tr. 71-81. The Respondent testified that for many of his patients, "[t]here is certainly the risk of very unpleasant withdrawal syndrome" when abruptly stopping medication. Tr. 72. Specifically for patients diagnosed with opioid disorders, the Respondent testified that abruptly stopping medication would "absolutely" cause harm to the patient.[31] Tr. 76, 78-79, 81. The Respondent testified that when he prescribed controlled substances for patients in August and October of 2022, he believed that he was operating under a valid written agreement with Dr. Fourcade. Tr. 81.

On cross-examination, the Respondent acknowledged that Dr. Fourcade's name did not appear on prescriptions issued by him between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022. Tr. 88-90. The Respondent acknowledged that prescriptions he issued on October 31, 2022, and November 3, 2022, referenced a Dr. John Mitchell under the "notes" section of each prescription. Tr. 88-90; *see also* Gov't Ex. 8 at 23-26.

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[28] Respondent testified that "[a]ccording to the law, the agreement does not end when your employment ends." Tr. 98. Respondent also testified that none of the patients for whom he issued the prescriptions that are at issue in these proceedings were treated at Nulton. Tr. 104.
[29] *See* Resp't Ex. 1 at 4.
[30] Respondent stated that he was "not sure [Dr. Fourcade] provided any evidence to substantiate [PALS] inaccuracy" and that "[p]erhaps it was mistaken or misinformed, but she's lacking objective evidence to substantiate her claims that the PALS system is inaccurate." Tr. 100.
[31] Respondent testified that "[t]here is quite a bit of controlled scientific . . . data from controlled substance studies that abrupt cessation of suboxone most often leads to return to active addiction . . . [a]nd also increased overdose risk." Tr. 76.

The Respondent acknowledged that his written agreement with Dr. John Mitchell was inactivated in December of 2021. Tr. 92; *see also* Resp't Ex. 1 at 5. However, the Respondent testified that "back when Dr. Mitchell was supervising [him], [the Respondent] had set the computer to auto-populate that field with his information, and it was an error on [Respondent's] part not to make that change to the auto-populate settings . . . it's a computer error that's not reflective of [Respondent's] actual supervising agreement at the time."[32] Tr. 92-93. The Respondent acknowledged that the "supervising prescriber" section on said prescriptions was blank. Tr. 88, 91. The Respondent testified that a pharmacy would typically fill out the information on the prescription identifying the supervising prescriber, and it was thus his practice to leave the supervising prescriber section blank. Tr. 91, 93-94.

Respondent's testimony focused on his experience as a physician assistant operating under supervising agreements, his understanding regarding the scope and timeframe of his written agreement with Dr. Fourcade, and his description of the prescriptions he issued during the relevant time-period in this case. His testimony appeared genuine, however I note one glaring inconsistency. The Respondent's testimony in this hearing indicated that his prescriptions issued on October 31, 2022, and November 3, 2022, contained the name of "Dr. Mitchell" in the notes section based on an auto-populate error that remained in place since Respondent was supervised by Dr. Mitchell. The record indicates (and it was not disputed) that Respondent's supervision agreement with Dr. Mitchell ended on December 1, 2021. There are multiple prescriptions contained in the record, issued after December 1, 2021, that do not contain Dr. Mitchell's name in the section where Respondent claimed the auto-population error occurred. *Compare* Gov't Ex. 8 at 23 *with* Gov't Ex. 8 at 12 (failing to include Dr. Mitchell's name in the "Message" section); *compare* Gov't Ex. 8 at 24 *with* Gov't Ex. 8 at 11, 18, 22 (failing to include Dr. Mitchell's name in the "MD Notes" section), 17, 21 (leaving the "MD Notes" section blank); *compare* Gov't Ex. 8 at 25-26 *with* Gov't Ex. 8 at 13 (failing to include a "Notes" section), 14 (failing to include Dr. Mitchell's name in the "Notes" section). If this error in the prescriptions was truly a result of failure to notice an auto-populate setting, it is unclear why this error did not occur in other prescriptions issued after December 1, 2021, but prior to those issued on October 31, 2022, and November 3, 2022. As the Respondent in this case, Mr. McCarthy also has a

[32] On redirect, the Respondent testified that he "auto-populated it a long time ago, and [he] . . . forgot to remove that when Dr. Mitchell ceased to be [his] supervising physician." Tr. 103.

significant personal interest in the outcome of these proceedings. Based on this identified inconsistency and the Respondent's personal interest, I will give his testimony somewhat reduced weight, especially where it is in conflict with the testimony of other witnesses and evidence presented during the hearing.

ANALYSIS

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman v. SEC*, 450 U.S. 91, 100-01 (1981). The Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). The Supreme Court has defined "substantial evidence" as such "relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz v. U.S. Dep't of Justice*, 873 F.2d 1089, 1092 (8th Cir. 1989) (citing *Trawick v. DEA*, 861 F.2d 72, 77 (4th Cir. 1988) (quoting *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966)), all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007) (citing *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005)). The ultimate disposition of the case must "be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury." *Steadman*, 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall*, 412 F.3d at 183, but "mere unevenness" in application does not, standing alone, render a particular discretionary action unwarranted. *Chein v. DEA*, 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Morall*, 412 F.3d at 183 (quoting *Butz v. Glover Livestock Comm'n Co.*, 411 U.S. 182, 188 (1973))). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496

(1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall*, 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. § 557(b); *River Forest Pharmacy, Inc. v. DEA*, 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8 (1947).

In the adjudication of a revocation of a DEA registration, the DEA has the burden of proving that the requirements for such revocation or suspension are satisfied. 21 C.F.R. § 1301.44(e). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.*, 74 Fed. Reg. 20,727, 20,734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the "egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others." *David A. Ruben, M.D.*, 78 Fed. Reg. 38,363, 38,364 (2013).

FINDINGS AS TO ALLEGATIONS

PUBLIC INTEREST DETERMINATION: THE STANDARD

Pursuant to 21 U.S.C. § 824(a)(4), the Administrator may suspend or revoke a registration if the Respondent "has committed such acts as would render his registration under section 823 [(21 U.S.C. § 823)] of this title inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a)(4). Pursuant to 21 U.S.C. § 823(g)(1), the Administrator may revoke a registration if persuaded that maintaining such registration would be inconsistent with the public interest. The following factors shall be considered in determining the public interest:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority. [Factor 1]

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances. [Factor 2]

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances. [Factor 3]

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances. [Factor 4]

(E) Such other conduct which may threaten the public health and safety. [Factor 5]

21 U.S.C. § 823(g)(1)(A)-(E). "These factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's registration should be revoked. *Id.*; *David H. Gillis, M.D.*, 58 Fed. Reg. 37,507, 37,508 (1993); *see also Morall*, 412 F.3d at 173-74; *Henry J. Schwarz, Jr., M.D.*, 54 Fed. Reg. 16,422, 16,424 (1989).

Moreover, the Agency is "not required to make findings as to all of the factors," *Hoxie*, 419 F.3d at 482; *see also Morall*, 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any detail. *Trawick*, 861 F.2d at 76 (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . ." *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459, 462 (2009).

Factors Two and Four: The Respondent's Experience in Dispensing Controlled Substances, and His Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government alleges public interest Factors Two and Four.[33] ALJ Exs. 11 at 2 n.1, 12 at 2. The DEA often analyzes Factor Two and Factor Four together. *See, e.g., Fred Samimi,*

[33] As to Factor One, 21 U.S.C. § 823(g)(1)(A), the record contains no recommendation from any state licensing board or professional disciplinary authority, but, aside from cases establishing a complete lack of state authority, the presence or absence of such a recommendation has not historically been a case-dispositive issue under the Agency's precedent. *Stodola*, 74 Fed. Reg. at 20,730 n.16; *Krishna-Iyer*, 74 Fed. Reg. at 461. Two different forms of recommendations have appeared in Agency decisions: (1) an explicit recommendation regarding the DEA's decision to issue or sanction a COR; and (2) the action of the relevant state authority regarding state licensure under its jurisdiction on the same matter that is the basis for the OSC. *Mark A. Wimbley*, 86 Fed. Reg. 20,713, 20,725 (2021); *see also, Jennifer L. St. Croix, M.D.*, 86 Fed. Reg.

M.D., 79 Fed. Reg. 18,698, 18,709 (2014); *John V. Scalera, M.D.*, 78 Fed. Reg. 12,092, 12,098 (2013). Under Factor Two, the DEA analyzes a registrant's "experience in dispensing . . . controlled substances." 21 U.S.C. § 823(g)(1)(B). This analysis focuses on the registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. *Kansky J. Delisma, M.D.*, 85 Fed. Reg. 23,845, 23,852 (2020) (citing *Randall L. Wolff, M.D.*, 77 Fed. Reg. 5106, 5121 n.25 (2012)). The DEA gives no more than nominal weight to evidence that a practitioner has engaged in lawful dispensing to thousands of other patients. *Syed Jawed Akhtar-Zaidi, M.D.*, 80 Fed. Reg. 42,962, 42,968 (2015) (citing *Krishna-Iyer*, 74 Fed. Reg. at 463); *see also Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 386 n.56 (2008) (ruling that no amount of lawful conduct could outweigh "flagrant violations" and make the misconduct somehow consistent with the public interest), *aff'd Medicine Shoppe-Jonesborough v. DEA*, 300 F. App'x 409 (6th Cir. 2008). Under Factor Four, the DEA analyzes an applicant's compliance with Federal and State controlled substance laws with the analysis focusing on violations of State and Federal laws and regulations concerning controlled substances. 21 U.S.C. § 823(g)(1)(D); *Delisma*, 85 Fed. Reg. at 23,852 (citing *Volkman v. DEA*, 567 F.3d 215, 223-24 (6th Cir. 2009)).

Regarding Factor Two, the Respondent has approximately nine (9) years of experience practicing as a physician assistant and dispensing controlled substances. Tr. 56. The Respondent concentrated his practice in psychiatry and addiction medicine. Tr. 57. The Respondent was employed as a physician assistant at PA Treatment Center during the time period relevant to the OSC allegations, where he issued prescriptions for controlled substances, including Adderall and Suboxone, related to ADHD and opioid addiction. Tr. 57-58, 71-81, 104; *see* Gov't Ex. 8.

19,010, 19,022 (2021) (affording minimal weight to a state board reprimand due to differences in evidence considered by the state in issuing its order); *Jeanne E. Germeil, M.D.*, 85 Fed. Reg. 73,786, 73,799 (2020) (recognizing that its prior final orders have considered this dichotomy of sources for Factor One consideration).

As to Factor Three, the record does not contain any conviction records for the Respondent under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances. 21 U.S.C. § 823(g)(1)(C).

As to Factor Five, the Government's allegations and evidence fit squarely within the parameters of Factors Two and Four and do not raise "other conduct which may threaten the public health and safety," 21 U.S.C. § 823(g)(1)(E), thus Factor Five militates neither for nor against the sanction sought by the Government in this case.

Regarding Factor Four, the record establishes multiple instances in which the Respondent failed to comply with applicable Federal and State Laws. DEA regulations require that for a prescription for a controlled substance to be effective it must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. 21 C.F.R. § 1306.04(a). A prescription for a controlled substance is legitimate only if "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); *see, e.g., MacKay v. DEA*, 664 F.3d 808, 815 (10th Cir. 2011) (applying state law to determine if a prescription complied with 21 C.F.R. § 1306.04(a)); *Marcia L. Sills, M.D.*, 82 Fed. Reg. 36,423, 36,443-44 (2017) (discussing 21 C.F.R. § 1306.04(a)). "A [practitioner] who engages in the unauthorized practice of [his profession] is not a 'practitioner acting in the usual course of professional practice.'" *United Prescription Servs., Inc.*, 72 Fed. Reg. 50,397, 50,407 (2007). "A controlled-substance prescription issued by a [practitioner] who lacks the license necessary to practice [his profession] within a State is therefore unlawful under the CSA." *Id.*

The corresponding Pennsylvania law[34] provides that "[a] physician assistant may perform a medical service delegated by an approved physician . . . according to a written agreement . . . ." 63 PA. CONS. STAT. § 422.13(a), (e). Pennsylvania law further provides that "[a] physician assistant shall not independently prescribe or dispense drugs." 63 PA. CONS. STAT. § 422.13(f). Pennsylvania law ultimately prohibits a physician assistant from "[p]rovid[ing] medical services except as described in the written agreement . . . [and] [p]rescrib[ing] or dispens[ing] drugs except as described in the written agreement." 49 PA. CODE § 18.152(a)(1)-(2).

The Government has introduced a preponderance of evidence to prove that the Respondent issued controlled substance prescriptions while practicing without an active written agreement that provided him authority to do so. The Government introduced hard copies and PDMP data of controlled substance prescriptions issued by the Respondent. The Government also introduced letters noticing inactivation of active agreements between the Respondent and his supervising physicians. The record shows that the Respondent issued multiple prescriptions for controlled substances during periods where he lacked an active written agreement with a

[34] The relevant Pennsylvania statutes were introduced as Government Exhibits 9-11, and were offered and admitted during the hearing based on prior official notice taken during the Prehearing Conference. Tr. 21.

supervising physician. Perhaps most troublesome is Respondent's apparent failure to maintain any supervisee/supervisor relationship. Respondent's failure to communicate at all with Dr. Fourcade – even when Respondent changed employers – makes it hard to accept that Respondent truly believed he still had an active supervisory agreement with Dr. Fourcade. Therefore, the evidence reveals a concerning pattern of a practitioner who repeatedly issued controlled substance prescriptions outside the usual course of professional practice by continuing to treat patients and prescribe controlled substances to them without an active written agreement, or in fact any supervisory physician oversight, as required by state law.

Background

Within his Answer and during the Prehearing Conference, the Respondent, through counsel, admitted to OSC Allegations 1 and 2. Accordingly, OSC Allegations 1 and 2 were and are **SUSTAINED** as factual matters, consistent with the Prehearing Ruling issued by the tribunal. ALJ Exs. 8 at 1, 11 at 2.

Periods of Lack of State Authority and Unlawful Prescribing of Controlled Substances

Federal law provides that a prescription for a controlled substance is legitimate only if "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); *see MacKay*, 664 F.3d at 815 (applying state law to determine if a prescription complied with 21 C.F.R. § 1306.04(a)). "A [practitioner] who engages in the unauthorized practice of [his profession] is not a 'practitioner acting in the usual course of professional practice.'" *United Prescription Servs., Inc.*, 72 Fed. Reg. at 50,407. Pennsylvania law prohibits a physician assistant from "[p]rescrib[ing] or dispens[ing] drugs except as described in the written agreement." 49 PA. CODE § 18.152(a)(2). Pennsylvania law authorizes a physician assistant to perform medical services "delegated by an approved physician . . . [and] according to a written agreement . . . ." 63 PA. CONS. STAT. § 422.13(a), (e). "A physician assistant shall not independently prescribe or dispense drugs" under Pennsylvania law. 63 PA. CONS. STAT. § 422.13(f).

The Government alleges that the Respondent issued seventeen (17) prescriptions for controlled substances without an active written agreement between on or about August 24, 2022 to September 20, 2022, and between on or about October 6, 2022 to November 8, 2022. ALJ Ex.

1 at 2-3 ¶ 4, 6. The Government alleges that because the Respondent was not party to any written agreement during the above time-periods, Respondent was without authority to handle controlled substances in Pennsylvania. *Id.* The Government therefore alleges that the Respondent issued these controlled substance prescriptions in violation of Federal and Pennsylvania law. *Id.* at 3 ¶ 7.

Respondent's Written Agreements with Dr. Levinstein and Dr. Sommons

DI Callavini testified that in response to an administrative subpoena, he received copies of written agreements made between the Respondent and supervising physicians between the issuance of Respondent's Pennsylvania physician assistant medical license and March 1, 2023. Gov't Exs. 2, 13 at 3 ¶ 8-9. In addition to the copies of written agreements, DI Callavini received copies of inactivation notices emailed to the Respondent on the date of agreement termination. Gov't Exs. 5, 7, 13 at 3 ¶ 9. Among the written agreements received by DI Callavini were agreements between the Respondent and two supervising physicians: Dr. Gene Levinstein and Dr. Dale Sommons. Gov't Exs. 4, 6. The written agreement with Dr. Levinstein was activated on March 21, 2022, and was terminated on August 23, 2022. Gov't Exs. 4, 5; Resp't Ex. 1 at 4. The written agreement with Dr. Sommons was activated on approximately September 26, 2022, and was terminated on October 5, 2022. Gov't Exs. 6, 7; Resp. Ex. 1 at 4. Both written agreements granted the Respondent the ability to prescribe and dispense controlled substances. Gov't Exs. 4 at 3, 6 at 2. Both inactivation notices also indicate that the Respondent was notified via email. Gov't Ex. 5, 7.

The Respondent testified that he received a notification of the inactivation of his written agreements with Dr. Levinstein and Dr. Sommons. Tr. 66-67. Furthermore, the Respondent's PALS account indicates that his agreement with Dr. Levinstein was terminated on August 23, 2022, and his agreement with Dr. Sommons was terminated on October 5, 2022. Resp't Ex. 1 at 4.

Therefore, based on the unrebutted testimony of the Government's representative, the documentary evidence, and the testimony and admissions of the Respondent, OSC Allegation 3

is **SUSTAINED**, except for the allegation that the start date of the written agreement was March 31, 2022,[35] and OSC Allegation 5[36] is **SUSTAINED**.

Lack of Authority to Prescribe or Dispense Controlled Substances

Pennsylvania law limits a physician assistant's ability to practice to only those medical services "delegated by an approved physician . . . [and] according to a written agreement . . . ." 63 PA. CONS. STAT. § 422.13(a), (e). "A physician assistant shall not independently prescribe or dispense drugs," and is prohibited from "[p]rescrib[ing] or dispens[ing] drugs except as described in the written agreement." 63 PA. CONS. STAT. § 422.13(f); 49 PA. CODE § 18.152(a)(2).

The Government alleges that between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022, the Respondent unlawfully issued approximately seventeen (17) prescriptions to patients without being party to a written agreement with a supervising physician. ALJ Ex. 1 at 2-3 ¶ 4, 6. In opposition, the Respondent alleges that he believed that he had an active written agreement with supervising physician Elizabeth Fourcade, M.D., which gave Respondent the authority to prescribe or dispense controlled substances during the time-periods at issue. ALJ Exs. 10 at 2, 13 at 1. The Respondent alleges that he was never notified of the termination of his agreement with Dr. Fourcade, and that PALS supported this belief because it does not contain an inactivation date for his agreement with Dr. Fourcade. ALJ Exs. 10 at 2, 13 at 1; Resp't Ex. 1 at 5; Tr. 58, 86.

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[35] OSC Allegation 3 alleges Respondent was covered by a written agreement "on or about March 31, 2022." ALJ Ex. 1 at 2 ¶ 3. The Government noted in its Prehearing Statement that the correct start date was March 21, 2022. ALJ Ex. 9 at 2 n.1. The documentary evidence also shows that the agreement start date was March 21, 2022. Gov't Ex. 4 at 3; Resp't Ex. 1 at 4. Despite the date error in the OSC, none of the prescriptions at issue fall within the March 21-31, 2022 time range and so the error is immaterial.

[36] OSC Allegation 5 alleges that "[o]n or about September 21, 2022, [the Respondent] had been covered by a written agreement with a supervising physician that gave [him] the authority to prescribe or dispense controlled substances." ALJ Ex. 1 at 3 ¶ 5. The documentary evidence indicates that the application for the written agreement was submitted on September 21, 2022. Gov't Ex. 6 at 1. However, PALS indicates that the agreement was not activated until September 26, 2022. Resp't Ex. 1 at 4. This slight difference in timeframe is ultimately immaterial to the allegation, as OSC Allegation 4 focuses on prescriptions issued "[b]etween on or about August 24, 2022, and **September 20, 2022** . . . ." ALJ Ex. 1 at 2 ¶ 4 (emphasis added).

Dr. Fourcade and the Respondent met on one occasion around the spring or summer of 2019, while Dr. Fourcade was considering a job at Nulton.[37] Tr. 40-41, 96. After this initial meeting, Dr. Fourcade and the Respondent entered into a written agreement wherein Dr. Fourcade would serve as his supervising physician. Tr. 41. The agreement was activated on August 22, 2019. Resp't Exs. 1 at 5, 2. According to Dr. Fourcade, the agreement with the Respondent terminated on October 7, 2019. Tr. 41, 43. Dr. Fourcade testified that upon inactivation of her agreement with the Respondent in 2019, she did not contact Respondent or discuss her receipt of the termination letter with him. Tr. 46-48. DI Callavini testified that he received a copy of the termination letter from the Pennsylvania State Board of Medicine indicating inactivation of the agreement between the Respondent and Dr. Fourcade. Tr. 27-29. The termination letter indicates that it was sent on October 8, 2019, and further indicates that Respondent was "cc'd." Gov't Ex. 14. DI Callavini testified that although the termination letter indicates that the Respondent received a copy, there is no evidence within the letter or otherwise indicating how the letter was sent to the Respondent or whether the Respondent actually received the letter. Tr. 34. Upon seeing the termination letter presented at the hearing, the Respondent acknowledged that his agreement with Dr. Fourcade ended in October of 2019. Tr. 85-86.

Thus, it is undisputed that the Respondent was not covered by a written agreement at the time he issued prescriptions between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022. The Respondent admitted that his agreement with Dr. Fourcade ended in October of 2019, based on the termination letter presented at the hearing. Tr. 85-86. It is further undisputed that between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022, the Respondent issued approximately seventeen (17) prescriptions for controlled substances to patients at the PA Treatment Center. Gov't Ex. 8; Gov't Ex. 12 at 4-7; *see* ALJ Ex. 13 at 1-4. As discussed above, the Respondent acknowledged that his agreement with Dr. Levinstein was active from March 21, 2022 to August 23, 2022, and his agreement with Dr. Sommons was active from September 26, 2022 to October 5, 2022. Furthermore, the Respondent acknowledged prescribing controlled substances to multiple patients during the time periods in which he was not party to a written agreement. *See* Tr. 71-81.

[37] Respondent was employed at Nulton between May of 2019 and August 14, 2022. Tr. 57.

Therefore, based on the unrebutted testimony of the Government's representative, the documentary evidence, the testimony and admissions of the Respondent, and my findings as to OSC Allegations 3 and 5, OSC Allegations 4 and 6 are **SUSTAINED**.

Respondent's Written Agreement with Dr. Fourcade

Under Pennsylvania law, "[s]upervision" of a physician assistant is defined as:

(i) Oversight and personal direction of, and responsibility for, the medical services rendered by a physician assistant. The constant physical presence of the supervising physician is not required so long as the supervising physician and the physician assistant are, or can be, easily in contact with each other by radio, telephone or other telecommunication device.
(ii) An appropriate degree of supervision includes:
    (A) Active and continuing overview of the physician assistant's activities to determine that the physician's directions are being implemented.
    (B) Immediate availability of the supervising physician to the physician assistant for necessary consultations.
    (C) Personal and regular review within 10 days by the supervising physician of the patient records upon which entries are made by the physician assistant.

49 PA. CODE § 18.122.

As discussed above, the Respondent acknowledged that based on the termination letter, his agreement with Dr. Fourcade was inactivated in October of 2019. Tr. 85-86. The Respondent's primary contention, therefore, is that although he was not covered by an active agreement, he believed that the agreement with Dr. Fourcade remained active, justifying his issuance of prescriptions during periods where he was not actually covered by any written agreement with a supervising physician. Tr. 86.

The Respondent supports this contention through two primary arguments: (1) PALS indicates that Respondent's 2019 agreement with Dr. Fourcade remains active and Respondent did not otherwise receive notice of inactivation, and (2) Respondent's lack of communication with Dr. Fourcade was not unusual in his experience, and thus he had no reason to believe that the agreement was inactive.

Regarding the Respondent's first argument, it is undisputed that PALS does not include an associated end date for Respondent's agreement with Dr. Fourcade. Resp't Ex. 1 at 5. However, there is conflicting testimony regarding whether PALS is a reliable method of

verifying active agreements between physicians and physician assistants.[38] *See* Tr. 51, 59, 100. Furthermore, there is substantial evidence indicating that the Respondent received, at the very least, constructive notice of the termination of his agreement with Dr. Fourcade. First, the evidence demonstrates that a termination letter was issued on October 8, 2019, and indicates that the Respondent was provided a copy. Gov't Ex. 14. Second, the Respondent testified that none of the patients he issued prescriptions to during the relevant time period were treated at Nulton, where he initially met Dr. Fourcade and where Dr. Fourcade was employed. *See* Tr. 72, 75, 77-79, 104. Furthermore, Respondent ceased working for Nulton in August of 2022, yet asserts that he still believed that his agreement with Dr. Fourcade was in place in the subsequent months because "[a]ccording to the law, the agreement does not end when your employment ends." Tr. 98. Taking this assertion by the Respondent as true despite the lack of affirmative evidence, his agreement with Dr. Fourcade had unquestionably ended, and the fact that none of the patients he treated were at Nulton – and he was no longer working for Nulton – further harms his claim that he earnestly believed the agreement with Dr. Fourcade remained in place. Third, the Respondent himself acknowledged certain complications with PALS that impact the reliability of the system. The Respondent testified that the association start date listed in PALS for his current agreement with Dr. Paczynski is inaccurate, because the agreement was allegedly entered into in late September of 2022, but PALS indicates that the agreement was active on February 1, 2023 – nearly four months later. Tr. 64; Resp't Ex. 1 at 3.

The weight of testimony and documentary evidence supports an inference that even if the Respondent was not actually aware that his agreement with Dr. Fourcade was inactivated, he should have been aware that he was not covered by this agreement in August through November of 2022. That PALS did not include an association end date for the Respondent's agreement with Dr. Fourcade, standing alone, does not support Respondent's argument that he had no reason to believe the agreement with Dr. Fourcade was no longer active.

Regarding the Respondent's second argument, it is undisputed that the Respondent and Dr. Fourcade did not communicate after their initial meeting in the spring or summer of 2019.

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[38] Dr. Fourcade testified that, in her experience, PALS "is often outdated." Tr. 51. Dr. Fourcade was thus "not surpise[d]" to learn that PALS did not reflect that her agreement with Respondent was inactivated. Tr. 51. Respondent testified that the PALS online portal "is more recent," and generally disagreed with Dr. Fourcade's opinion that PALS is subject to inaccuracies. Tr. 59, 100.

Furthermore, it is undisputed that the Respondent and Dr. Fourcade had a valid written agreement, active from August 22, 2019 to October 8, 2019. Gov't Ex. 14; Resp't Ex. 1 at 5.

Dr. Fourcade testified that the "original purpose" of her agreement with the Respondent was for her to be Respondent's supervising physician once she began work at Nulton. Tr. 46. However, shortly after Dr. Fourcade joined Nulton, "it was decided that [her] supervisory capacities were better allocated elsewhere." Tr. 46. Although there was an agreement in place, Dr. Fourcade testified that she and the Respondent "never actually engaged in a supervisory relationship." Tr. 46. The Respondent likewise testified that he did not consult with Dr. Fourcade at any time after their initial meeting. Tr. 94, 96.

While the Respondent indicates that this lack of communication supports his belief that the agreement was still in place,[39] the complete absence of a supervisory relationship with Dr. Fourcade instead further supports a finding that Respondent's belief that the agreement remained in place is unfounded. Dr. Fourcade testified that one of the "major components" of supervisory agreements between physicians and physician assistants is "that the physician should be supervising the [physician assistant] to carry out those medical services or those medical duties" delegated to the physician assistant by the supervising physician. Tr. 41. Dr. Fourcade acknowledged that the extent of supervision necessary is subject to interpretation, but that it is her personal practice to remain very involved in the practice of physician assistants that she is supervising.[40] Tr. 41-42.

The Respondent testified that in his experience, he would often make decisions regarding patient care "without input from the physician, and . . . consulted the physician only in times of question." Tr. 83. The Respondent indicated that in "almost all" of the written agreements he has been a party to, "the physicians were very hands off and only communicated with [him] if there was a particular issue." Tr. 83-84. However, both of the written agreements that the Government entered into evidence provided for monitoring on at least a weekly basis.[41] Respondent's written agreement with Dr. Levinstein provided that "[c]harts will be reviewed and cosigned several times per week." Gov't Ex. 4 at 5. Respondent's written agreement with Dr.

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[39] *See* Tr. 94-96.
[40] Dr. Fourcade testified that she did not engage in any of her standard supervising behaviors with the Respondent. Tr. 43.
[41] *See* Gov't Exs. 4, 6.

Sommons provided that "[a] supervising Physician will meet with the Physician Assistant no less than once a week for formal supervision." Gov't Ex. 6 at 3.

Although the Respondent testified that he has been part of multiple supervisory agreements where he never spoke with his supervising physician,[42] it is concerning that the Respondent believed he was part of a supervisory agreement with Dr. Fourcade lasting over three (3) years, during which time he spoke with her on one occasion in 2019, before the agreement was even active. Lack of communication aside, there is additionally no evidence that it was even possible for Dr. Fourcade to supervise the Respondent in treating patients at the PA Treatment Center. There was no regular review of patient records, no reports of the Respondent's activities, and no open channels of communication between Respondent and Dr. Fourcade. *See* 49 PA. CODE § 18.122 (indicating that while "constant physical presence . . . is not required," the physician and physician assistant must be able to easily contact each other).

Furthermore, the actions of the Respondent in issuing prescriptions to patients during the relevant time periods suggest that the Respondent did not actually believe he was issuing those prescriptions under the authority of Dr. Fourcade. Dr. Fourcade's name did not appear on any of the prescriptions written by the Respondent during the relevant time period. Tr. 88-90; Gov't Ex. 8. Instead, the note portion of some of the prescriptions indicates that the supervising physician was "Dr. John Mitchell," whose agreement with the Respondent terminated in December of 2021. Tr. 88-90, 92; Resp. Ex. 1 at 5. The absence of any indication that the Respondent was acting under the supervision of Dr. Fourcade makes it highly questionable that Respondent truly believed that his agreement with Dr. Fourcade, which lasted for just over one month in 2019 at a different place of employment, was still controlling and granted him the authority to issue controlled substance prescriptions to patients during the time period of August to November of 2022. Rather, the evidence strongly suggests not only that the Respondent was not a party to any written agreement between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022, but that it was not reasonable for Respondent to believe that he was party to any active supervision agreements.

[42] Tr. 96-97, 101-02.

On consideration of the whole of the record, it is clear that Public Interest Factors Two and Four militate strongly in favor of the imposition of a registration sanction in this case.

Therefore, based on my findings as to Allegations 3, 4, 5, and 6, my findings that the Respondent issued controlled substance prescriptions without an active written agreement in violation of Federal and state law, and my finding that the Respondent was not justified in his asserted belief that his agreement with Dr. Fourcade remained active, OSC Allegation 7 is also **SUSTAINED**.

Government's Burden of Proof and Establishment of a *Prima Facie* Case

Based upon my review of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. § 824(a). As the Government has met its burden[43] in demonstrating that the revocation it seeks is authorized, to avoid sanction, it becomes incumbent upon the Respondent to demonstrate that given the totality of the facts and circumstances revocation is not warranted. *See Medicine Shoppe-Jonesborough*, 73 Fed. Reg. at 387. That is, upon the preponderant establishment of the Government's *prima facie* case, the burden shifts to the Respondent to show why he should continue to be entrusted with a DEA registration. *See Kaniz F. Khan-Jaffery, M.D.*, 85 Fed. Reg. 45,667, 45,689 (2020); *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,910 (2018).

Acceptance of Responsibility and Rehabilitative Measures

With the Government's *prima facie* burden having been met, an unequivocal acceptance of responsibility stands as a condition precedent for the Respondent to prevail. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.*, 81 Fed. Reg. 79,188, 79,201 (2016). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay*, 664 F.3d at 819-20. Accordingly, the Respondent must "present[] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration." *Med. Shoppe-Jonesborough*, 73 Fed. Reg. at 387 (quoting *Samuel S. Jackson*, 72 Fed. Reg.

[43] *See* 21 C.F.R. § 1301.44(e).

23,848, 23,853 (2007)). As past performance is the best predictor of future performance, the DEA has repeatedly held that where an applicant or registrant has committed acts inconsistent with the public interest, the applicant or registrant must accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995).

In order to rebut the Government's *prima facie* case, the Respondent must demonstrate both an unequivocal acceptance of responsibility and also a demonstrable plan of action to avoid similar conduct in the future. *See Jeri Hassman, M.D.*, 75 Fed. Reg. 8193, 8236 (2010). While analytical frameworks applied to prior Agency actions provide useful guidance and helpful structure, such tools cannot distract the Agency from its critical mission to keep the public safe by only issuing and maintaining CORs in cases where the public is adequately protected. The central issue is whether, based on the evidence of record, including the Respondent's established misdeeds, the Agency can trust the Respondent with the authority to handle controlled substances. The Agency has provided the following framework for its analysis in this regard:

> The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations. A registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction; as is whether the registrant's acceptance of responsibility is unequivocal.

Heavenly Care Pharmacy, 85 Fed. Reg. 53,402, 53,420 (2020) (internal citations omitted).

Agency precedent is clear that a respondent must "unequivocally admit fault" as opposed to a "generalized acceptance of responsibility." *The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,510 (2014); *see also Lon F. Alexander, M.D.*, 82 Fed. Reg. 49,704, 49,728 (2017). To satisfy this burden, the respondent must show "true remorse" or an "acknowledgment of wrongdoing." *Michael S. Moore, M.D.*, 76 Fed. Reg. 45,867, 45,877 (2011). The Agency has made it clear that unequivocal acceptance of responsibility is paramount for avoiding a sanction. *Robert L. Dougherty, M.D.*, 76 Fed. Reg. 16,823, 16,834 (2011) (citing *Krishna-Iyer*, 74 Fed. Reg. at 464).

The Respondent admitted to some fault, but did not accept responsibility, let alone unequivocal responsibility, for his actions. When discussing the inclusion of "Dr. Mitchell" on prescriptions issued by the Respondent during the relevant time-period (and nearly one year after the termination of the Respondent's active agreement with Dr. Mitchell), Respondent stated that

"it was an error on [his] part" not to make a change to auto-correct settings. Tr. 92-93. The Respondent additionally acknowledged that his agreement with Dr. Fourcade was inactivated in October of 2019, based on the termination letter received by DI Callavini and introduced by the Government. Tr. 85-86.

Although the Respondent admitted that his agreement with Dr. Fourcade was inactivated in 2019, he testified that he still believed that he was covered when he issued prescriptions for controlled substances between August 24, 2022, and September 20, 2022, and between October 6, 2022, and November 8, 2022. Tr. 81, 86, 98. Multiple times, the Respondent reiterated that he never received notice of the inactivation of his agreement with Dr. Fourcade. Tr. 67-69, 86. The Respondent did not find his lack of communication with Dr. Fourcade as grounds for concern, and indicated that he regularly treats patients without communicating with a supervising physician. Tr. 83-84, 96-97, 101-02. The Respondent further justified his conduct, testifying that patients under his care were at risk of withdrawal effects had he ceased issuing prescriptions. *See* Tr. 71-81. This explanation completely discounts the Respondent's responsibility to transfer care to another practitioner when learning that he can no longer provide the needed care, and further emphasizes the fact that the Respondent was essentially operating as a solo practitioner with no established relationship with a supervising physician who could assume care. The Respondent's testimony thus fails to show "true remorse" or an "acknowledgment of wrongdoing." *See Moore*, 76 Fed. Reg. at 45,877. "[T]o be granted a registration when grounds for denial exist, an [a]pplicant must convince the Administrator that . . . his misconduct will not reoccur and that he can be entrusted with registration." *Kareem Hubbard, M.D.*, 87 Fed. Reg. 21,156, 21,164-65 (2022). I find that the Respondent has not met that burden in this case.

Therefore, I do not find that the Respondent has demonstrated an "unequivocal acceptance of responsibility" for his actions. *Jones Total Health Care Pharmacy*, 81 Fed. Reg. at 79,201-02.[44]

[44] Where a registrant has not accepted responsibility, it is not necessary to consider evidence of 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 79,202-03). In the instant case, the Respondent's only testimony regarding remedial action was that he is presently covered by a written agreement with Dr. Paczynski. Tr. 63-64; Resp't Ex. 1 at 3.

Egregiousness and Deterrence

While a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g.*, *Joseph Gaudio, M.D.*, 74 Fed. Reg. 10,083, 10,094 (2009); *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,502-04 (2007). The egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer, M.D.*, 76 Fed. Reg. 19,386, 19,387-88 (2011) (explaining that a respondent can "argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation"); *Paul H. Volkman*, 73 Fed. Reg. 30,630, 30,644 (2008). *See also Gregory D. Owens, D.D.S.*, 74 Fed. Reg. 36,751, 36,757 n.22 (2009). Further, in determining whether and to what extent imposing a sanction is appropriate, besides the egregiousness of the offenses established by the Government's evidence, consideration must also be given to the Agency's interest in both specific and general deterrence. *Ruben*, 78 Fed. Reg. at 38,385.

Here, the egregiousness of the offense favors revocation. The Respondent issued seventeen (17) controlled substance prescriptions to multiple patients without an active written agreement in place with a supervising physician, and thus acted beneath the applicable standard of care and outside the usual course of professional practice in violation of Federal and state law.

Furthermore, considerations of specific and general deterrence in this case militate in favor of revocation. As to specific deterrence, there is no reason to believe that the Respondent's behavior will not recur in the future, as he failed to accept responsibility and repeatedly attempted to justify his conduct. *See Gilbert Y. Kim, D.D.S.*, 87 Fed. Reg. 21,139, 21,144-45 (2022) (stating that "[g]iven [the Respondent's failure to accept responsibility], the tribunal can only conclude that granting Respondent a COR would put the public at risk of Respondent's previous . . . behavior."). I am not convinced that the Respondent understands that his controlled substance prescribing did not meet the applicable legal standards. *See Lewisville Medical Pharmacy*, 87 Fed. Reg. 58,456, 59,460 (2022). Therefore, a sanction of revocation of the Respondent's COR is appropriate.

The interests of general deterrence compel a like result. I must consider whether imposing no sanction would signal to others that one can ignore the law and yet incur no

consequences from having done so. *See Gaudio*, 74 Fed. Reg. at 10,095. As the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben*, 78 Fed. Reg. at 38,385. Where the record demonstrates that the Government has borne its burden and established that the registrant improperly prescribed controlled substances and ignored obligations to comply with Federal and state laws, the unmistakable message to the regulated community of imposing no sanction would be that such conduct can be overlooked. Therefore, I find that the egregiousness of the Respondent's behavior and the interests of specific and general deterrence support the revocation sought by the Government.

RECOMMENDATION

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. Furthermore, I find that the Respondent has failed to meet his burden to overcome the Government's case. I cannot overlook the egregiousness of the Respondent's offenses, his failure to unequivocally accept responsibility, and the need for specific and general deterrence in this case, each of which, even standing alone, provides a compelling reason for revocation.

Accordingly, it is respectfully recommended that the Respondent's DEA COR, No. MM3329578, be **REVOKED**, and that any pending applications for renewal or modification of Respondent's registration, or for additional DEA registrations, be **DENIED**.

Dated: October 27, 2023

PAUL SOEFFING Digitally signed by PAUL SOEFFING Date: 2023.10.27 15:32:45 -04'00'

PAUL E. SOEFFING
U.S. Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on October 27, 2023, caused a copy of the foregoing to be delivered to the following recipients: (1) Jennifer L. Holsclaw, Esq., Counsel for the Government, via email at Jennifer.L.Holsclaw@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov; (2) Kristy Castagna, Esq., Counsel for the Respondent, via email at kcastagna@kilcoynelaw.com; and (3) Kyle Thompson, Esq., Counsel for the Respondent, via email at kthompson@kilcoynelaw.com.

TAYONNA EUBANKS (Affiliate)

Digitally signed by TAYONNA EUBANKS (Affiliate)
Date: 2023.10.27 15:38:03 -04'00'

Tayonna A. Eubanks
Secretary (CTR)
Office of Administrative Law Judges

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-2704

STEPHEN MCCARTHY, P.A.,
Petitioner

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION

(Agency No. 23-40)

SUR PETITION FOR REHEARING

Present: CHAGARES, *Chief Judge*, HARDIMAN, SHWARTZ, KRAUSE, RESTREPO, BIBAS, PORTER, MATEY, PHIPPS, FREEMAN, MONTGOMERY-REEVES, CHUNG, ROTH* *Circuit Judges*

The petition for rehearing filed by the Petitioner in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

s/ Cindy K. Chung
Circuit Judge

Date: September 22, 2025
Gch/cc: All Counsel of Record

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* Judge Roth's vote is limited to panel rehearing only.