the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2018, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: August 27, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–19640 Filed 8–30–24; 8:45 am]

BILLING CODE 7020–02–P

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 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.

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

[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 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.

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 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. section 422.13(f); *see also* 49 Pa. Code section 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 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.

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

[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.

[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.

[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 section 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.

[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.

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 CFR 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 section 18.152(a)(2); 63 Pa. Cons. Stat. section 422.13(a), (e), (f).

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, 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 FR 15227, 15230 (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 FR 37507, 37508 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 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 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (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 CFR 1306.04(a).[13] As for

[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.

[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 section 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 section 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.''), section 18.158(d)(4) (''The supervising physician shall countersign the patient record within 10 days.''), section 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.

[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).

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 described in the written agreement.'' 49 Pa. Code section 18.152(a)(2); 63 Pa. Cons. Stat. section 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 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 FR 18882, 18910 (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 FR 62316, 62339 (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 FR 33738, 33746 (2021).[16]

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 section 18.142; 63 Pa. Cons. Stat. section 422.13). Respondent also claimed that ''[i]f the supervising physician fails to fulfill 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

[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.

[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 FR 23998, 24009 (2021); *Larry C. Daniels, M.D.,* 86 FR 61630, 61660–61 (2021); *Jeanne E. Germeil, M.D.,* 85 FR. 73786, 73799 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 FR 24228, 24258 n.KK (2022) (citing *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45239 (2020) (declining to accept community impact arguments); *Richard J. Settles, D.O.,* 81 FR 64940, 64945 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 FR 30564, 30608 n.39 (2022) (citing *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801, 74810 (2015)); *see also Lon F. Alexander, M.D.,* 82 FR 49704, 49728 (2017) (collecting cases).

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 FR 79188, 79201–02 (2016)).[17]

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 FR 74810. 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 FR 21139, 21144–45 (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 FR 10083, 10095 (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]

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MM3329578 issued to Stephen McCarthy, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of 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 October 3, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 19, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–19730 Filed 8–30–24; 8:45 am]

BILLING CODE 4410–09–P

[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 FR 5479, 5498 n.33 (2019) (citing *Jones Total Health Care Pharmacy,* 81 FR 79202–03); *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801, 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.

[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 FR 21008, 21016 (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 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.

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's Committee on Strategy hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Tuesday, September 3, 2024, from 2–3 p.m. eastern.

PLACE: This meeting will be via videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Chair's Opening Remarks; Presentation and discussion of NSF's FY 2026 Budget Submission to the Office of Management and Budget; Committee recommendation to NSB related to NSF's FY 2026 Budget Submission to the Office of Management and Budget.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Ann E. Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2024–19780 Filed 8–29–24; 11:15 am]

BILLING CODE 7555–01–P