written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3729'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: March 5, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–05041 Filed 3–8–24; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–51]

Mark Fenzl, D.O.; Decision and Order

On August 11, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) and Immediate Suspension Order (ISO) to Mark Fenzl, M.D. (Respondent), of Florida immediately suspending and seeking to revoke his DEA Certificate of Registration, Control No. FF7471840, and alleging that his ''continued registration is inconsistent with the public interest.'' OSC, at 1 (citing 21 U.S.C. 823(g)(1) [1]).

A hearing was held before DEA Administrative Law Judge Teresa A. Wallbaum (the ALJ). On April 10, 2023, the ALJ issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (RD), which recommended that the Agency revoke Respondent's registration. RD, at 40. Respondent did not timely file exceptions to the RD.[2] Having reviewed the entire record, the Agency, except as noted below,[3] adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[4] findings of fact, conclusions of law, and recommended sanction in the RD and summarizes, expands upon, and clarifies portions thereof herein.

I. Findings of Fact

The Agency finds from clear, unequivocal, and convincing evidence that Respondent committed numerous failures in his prescribing conduct that fell below the standard of care in Florida. Specifically, the Agency finds that from June 2020 through April 2022, Respondent issued controlled substances to Patients J.H., C.K., G.K., and J.K. without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 17–30.

Florida Standard of Care

Dr. Lynch provided expert testimony on the applicable standard of care for prescribing controlled substances in Florida.[5] RD, at 6–7, 11–17; Tr. 141–

[1] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

[2] On May 8, 2023, after the deadline to file exceptions passed and the ALJ certified the record to the Administrator, Respondent submitted a document entitled ''Appeal to the Drug Enforcement Agency Administrator.'' Respondent's document appears to be an untimely attempt to file exceptions to the RD. *See* 21 CFR 1316.66(a), 1316.67. On that basis, they were not considered in this Decision. Further, even if these exceptions had been timely submitted, they contain arguments raised by Respondent in earlier filings that were addressed by the ALJ, lack the required specific and complete citations to the record, are contradicted or unsupported by the record, and/or otherwise lack merit. Accordingly, the Agency finds these untimely exceptions to be unpersuasive. *See Yogeshwar Gill, M.D.,* 88 FR 55,076, 55,076 n.3 (2023).

[3] See footnote 14, *infra.*

[4] 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 3–11. The Agency agrees with the ALJ that the testimony by the Diversion Investigator (DI), which focused on the investigative steps completed in the case and establishing the foundations for many of the exhibits received into the record, was sufficiently detailed, plausible, and internally consistent to be afforded full credibility. *See id.* at 5–6. The Agency also agrees with the ALJ's assessment that Dr. Paul Lynch, M.D., the Government's expert witness, was reliable and persuasive. *See id.* at 6. His testimony was based on extensive relevant experience and consistent with applicable Florida law, and Respondent was unpersuasive in his efforts to challenge Dr. Lynch's objectivity and reliability. *See id.* at 7. Regarding Respondent's testimony, the Agency adopts the ALJ's assessment that although Respondent testified candidly, his recollection was unreliable and at times contradicted by documentary evidence. *See id.* at 11. Therefore, the ALJ appropriately gave his testimony limited weight. *See id.* at 11. As the ALJ noted, Respondent's testimony on Florida's standard of care was vague, and he characterized pain management as an ''area of weakness'' for him. *See id.* at 11 (quoting Tr. 516–17). Accordingly, consistent with the ALJ's findings, to the extent that Respondent disagreed with Dr. Lynch's testimony regarding the Florida standard of care governing pain management, the Agency gives controlling weight to Dr. Lynch's testimony. *See id.* at 11.

[5] The Agency adopts and incorporates by reference the entirety of the ALJ's findings regarding the standard of care in Florida and the related summary of Dr. Lynch's expert testimony.

473. According to Dr. Lynch, the standard of care stems from state statutes and additional, established practices that supplement, or expand upon, those statutes. RD, at 11; Tr. 149, 263–64. The standard of care requires the pain management practitioner to take a ''complete medical history.'' RD, at 13; Fla. Stat. § 456.44(3)(a). A thorough medical history should include a review of prior treatments and tests and a social history regarding possible substance abuse or mental health issues. RD, at 13; Tr. 157–59. The Florida standard of care also requires a physical examination before prescribing controlled substances and at each subsequent visit where controlled substances are prescribed. RD, at 13; Tr. 165–66, 349; *see also* Fla. Stat. § 456.44(3)(a). For any visit, the standard of care requires taking and recording vital signs. RD, at 13; Tr. 308. The physician must document and discuss abnormal vital signs, and failing to follow up on a patient with higher-than-normal vital signs is ''significantly outside the standard of care.'' RD, at 13–14; Tr. 310, 345–48, 394–95.

For pain management, the physical examination must involve a targeted examination of the area of pain and a ''neurologic or behavioral interaction with the patient'' to look for signs of intoxication. RD, at 13; Tr. 166, 437–38. When patients have a spinal issue, the standard of care includes an examination of all four extremities for strength, sensation, reflexes, and range of motion. RD, at 13; Tr. 166. The failure to even touch a patient in a physical exam for more than two years ''is considerably outside the standard of care.'' RD, at 13; Tr. 312. While the standard of care ''is pretty broad on how frequent imaging should be,'' it typically requires new images every two to three years. RD, at 13; Tr. 321. It is not, however, sufficient to simply order imaging; the patient must obtain the image. RD, at 13; Tr. 339–40. In this case, the physical examinations often stated simply that a patient was ''Alert, Responsive, Interactive, which means they're just there, that they showed up, that they're alive.'' RD, at 13; Tr. 261–62. Such a physical examination is ''not an appropriate exam,'' and does not satisfy the requirement in Florida Statutes Section 456.44 that a physician must conduct a physical examination sufficient to establish an appropriate diagnosis that justifies prescribing controlled substances. RD, at 14; Tr. 262.

The Florida standard of care requires a pain management physician to engage in regular patient visits and ongoing monitoring ''to look for risk factors of abuse or misuse or diversion of the medications.'' RD, at 14; Tr. 164–65; *see also* Fla. Stat. § 456.44(3)(d). One method of monitoring is the legal requirement to check the Prescription Drug Monitoring Program (PDMP) each time a practitioner writes a controlled substance prescription, which allows a practitioner to determine if the patient is obtaining the same drugs from another doctor or frequenting different pharmacies. RD, at 14; Tr. 169–70. Another method of monitoring is urine drug screening and testing with documentation of the results in the patient's record. RD, at 14; Tr. 216–18, 223–24. If there are signs of an abnormal or aberrant drug test result, Florida law establishes the steps a practitioner must take to address that aberrant result. RD, at 15; Tr. 169, 224, 247–48; *see also* Fla. Stat. § 456.44(3)(g). Evidence of diversion exists if a patient fails to test positive for a controlled substance that is currently being prescribed. RD, at 15; Tr. 224. If there are signs of diversion, Florida Statutes Section 456.44 requires that the practitioner stop prescribing the controlled substance and discharge the patient. RD, at 15; Tr. 169, 247–48; *see also* Fla. Stat. § 456.44(3)(g). Evidence of abuse exists if a patient tests positive for a substance that is not prescribed or for an illicit substance. RD, at 15; Tr. 224–25, 370–71. If there is evidence of abuse, Section 456.44 requires the practitioner to refer the patient to an addiction medicine specialist.[6] RD, at 15; Tr. 169, 224–25; *see also* Fla. Stat. § 456.44(3)(g). While there is a gray area on whether it could be acceptable to continue to prescribe opioids when there are signs of abuse, in ''most cases of abuse of cocaine [and] methamphetamine'' the continued prescribing would not be within the standard of care because of the risk of death. RD, at 15; Tr. 248–50.

Prescribing doses of opioids with a high Morphine Milligram Equivalent (MME)[7] caries significant risks, including risk of death. RD, at 16; Tr. 257–58. Moreover, prescribing a combination of an opioid, a benzodiazepine, and a muscle relaxant (here, carisoprodol) is dangerous because together they produce a risk of synergistic respiratory depression; this ''leads to a patient that's heavily sedated and is [at] high risk for overdose and death.''[8] RD, at 16 (quoting Tr. 256–57). The combination, known as ''the cocktail, the Houston cocktail, the trinity, [or] the holy trinity,'' is ''sought after'' due to the ''particularly powerful high to the patient.'' RD, at 16 (quoting Tr. 256).

Documentation is a requirement under the Florida standard of care. RD, at 17; Tr. 160–61. ''The medical record shall . . . document the presence of one or more recognized medical indications for the use of a controlled substance.'' Fl. Stat. § 456.44(3)(a); RD, at 17; *see also* Fl. Stat. § 456.44(3)(f); Tr. 160–61. In addition to documenting the physical examination, ''the medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or co-existing diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse.'' RD, at 17 (quoting Tr. 160); Fla. Stat. § 456.44(3)(a). Documentation is also important for the purposes of periodic review of the plan and continuation of treatment by another physician. RD, at 17; Tr. 159–60. Generally, having a ''clear and complete and accurate'' medical record ''is really important for the practice of medicine.'' RD, at 17 (quoting Tr. 171).

The Florida standard of care does not create a separate standard for practitioners who ''inherit'' patients on controlled substance prescriptions. RD, at 12; Tr. 298–99. In other words, regardless of whether a patient is currently on controlled substance medications prescribed by another doctor, the Florida statute and standard of care require *any* practitioner to take a medical history and conduct an appropriate physical examination before prescribing and require practitioners to revisit prior plans on a regular basis to see if the controlled substance prescriptions are effective. RD, at 12; Tr. 213, 298–99.

The Patients

Patient J.H.

Regarding Patient J.H., the Agency finds that Respondent issued controlled substance prescriptions for morphine,

[6] An addiction medicine specialist is defined as a board-certified psychiatrist with a subspecialty certification or eligible for certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in addiction medicine through the American Osteopathic Association. RD, at 15 n.16; Fla. Stat. § 456.44(1)(b).

[7] MME is a standard that determines how powerful a particular medication is by comparing the prescribed medication and dosage to the original standard of morphine, historically used to manage pain. RD, at 16; Tr. 257–58.

[8] The Food and Drug Administration (FDA) has issued a warning—the so-called ''Black Box Warning''—regarding the risks of prescribing opioids and benzodiazepines in combination. RD, at 16; Tr. 173–80, 182; GX 15–17.

oxycodone, carisoprodol,[9] and diazepam [10] from July 2020 through February 2022 without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 17–21; GX 6, 20; Tr. 200, 262–63. Based on Dr. Lynch's testimony and the record as a whole, these prescriptions were issued without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care because Respondent failed to (1) establish an appropriate diagnosis to justify the controlled substance prescriptions (RD, at 17–18; GX 6, 20; Tr. 199, 201–03, 207, 211–14, 252, 255–56, 262); (2) establish an appropriate medical justification for high-risk combination prescriptions with high-risk MMEs (RD, at 20–21; GX 6, 20; Tr. 250, 253–54, 256–57, 259–61); (3) appropriately address potential signs of abuse and diversion, despite at least seven aberrant drug test results (RD, at 18–20; GX 6; Tr. 204, 217, 219, 221–25, 227–31, 233–35, 238, 246–48); and (4) maintain adequate medical records with sufficient documentation [11] (RD, at 21; GX 6; Tr. 261–62).

Patient C.K.

Regarding Patient C.K., the Agency finds that Respondent issued controlled substance prescriptions for hydrocodone,[12] carisoprodol, and alprazolam [13] from July 2020 through April 2022 without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 22–24; GX 8, 21; Tr. 312–15. Based on Dr. Lynch's testimony and the record as a whole, these prescriptions were issued without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care because Respondent failed to (1) establish an appropriate diagnosis to justify the controlled substance prescriptions (RD, at 22; GX 8, 21; Tr. 269–74); (2) adequately address signs of potential abuse and diversion, despite at least two aberrant drug test results (RD, at 22–23; GX 8; Tr. 277–86, 502–03); (3) appropriately address C.K.'s dangerous vital signs (RD, at 23; GX 8; Tr. 300–01, 303–07, 309); (4) establish an appropriate medical justification for high-risk combinations (RD at 23–24; GX 8, 21; Tr. 311–12); and (5) maintain adequate medical records with sufficient documentation (RD, at 24; GX 8; Tr. 308–09, 311–12).

Patient G.K.

Regarding Patient G.K., the Agency finds that Respondent issued controlled substance prescriptions for morphine, oxycodone, carisoprodol, and alprazolam from June 2020 through April 2022, without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida.[14] *See* RD, at 25–27; GX 10, 22; Tr. 353–54.

Based on Dr. Lynch's testimony and the record as a whole, these prescriptions were issued without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care because Respondent failed to (1) establish an appropriate diagnosis to justify the controlled substance prescriptions (RD, at 25; GX 10, 22; Tr. 322–23, 325–26, 328–29, 331–37); (2) appropriately address G.K.'s dangerous vital signs (RD, at 25–26; GX 10; Tr. 344–47, 350–52); (3) establish an appropriate medical justification for high-risk combination prescriptions with high-risk MMEs (RD, at 26; GX 10, 22; Tr. 340–43, 352–54); and (4) maintain adequate medical records with sufficient documentation (RD, at 26; GX 10; Tr. 352–54).

Patient J.K.

Regarding Patient J.K., the Agency finds that Respondent issued controlled substance prescriptions for morphine, oxycodone, and lorazepam [15] from August 2020 through April 2022 and carisoprodol from July 2020 through January 2022 without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 27–30; GX 12, 23; Tr. 397–98. Based on Dr. Lynch's testimony and the record as a whole, these prescriptions were issued without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care because Respondent failed to (1) establish an appropriate diagnosis to justify the controlled substance prescriptions (RD, at 27–28; GX 12, 23; Tr. 359–67, 387–89); (2) adequately address signs of potential abuse and diversion, despite at least two aberrant drug test results (RD, at 28; GX 12; Tr. 370–78, 385, 496–97); (3) appropriately address J.K.'s dangerous vital signs (RD, at 29; GX 12; Tr. 391–96); (4) establish an appropriate medical justification for high-risk combination prescriptions with high-risk MMEs (RD, at 29; GX 12, 23; Tr. 389–90); and (5) maintain adequate medical records with sufficient documentation (RD, at 29–30; GX 12; Tr. 396–97).

II. Discussion

Under the 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). The CSA requires that the Agency consider the following factors for the public interest determination:

(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).

[9] Carisoprodol is a Schedule IV controlled substance sold under the brand name Soma. Prehearing Ruling, at 2. The generic name (carisoprodol) is used in this decision.

[10] Diazepam is a Schedule IV controlled substance sold under the brand name Valium. Prehearing Ruling, at 2. The generic name (diazepam) is used in this decision.

[11] Respondent asserted that some documentation related to the four patients was missing from the medical files produced through the Government's administrative subpoenas and admitted into evidence as Government Exhibits 6, 8, 10, and 12. RD, at 36; Tr. 496–97, 500–07. The Agency has considered Respondent's claims regarding missing documentation. In agreement with the ALJ, any missing documentation does not change the outcome of this Decision. *See* RD, at 36–37. As Dr. Lynch reliably testified, any missing documents relate to only portions of the patients' treatment, and there are numerous other examples of prescribing that fell well below the standard of care. RD, at 37.

[12] Hydrocodone is a Schedule II controlled substance. Prehearing Ruling, at 2. Norco is a brand name medication that contains hydrocodone. *Id.* The generic name (hydrocodone) is used in this decision.

[13] Alprazolam is a Schedule IV controlled substance sold under the brand name Xanax. Prehearing Ruling, at 2; Tr. 182. The generic name (alprazolam) is used in this decision.

[14] The ALJ noted that Respondent also issued prescriptions to G.K. for the Schedule V controlled substance pregabalin (sold under the brand name of Lyrica). RD, at 25–26. As Respondent's prescribing of pregabalin was not included in the OSC/ISO, the Agency does not make any findings on the prescribing of this controlled substance.

[15] Lorazepam is a Schedule IV controlled substance sold under the brand name Ativan. Prehearing Ruling, at 3; Tr. 355. The generic name (lorazepam) is used in this decision.

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 inquiry is ''focuse[d] on protecting the public interest.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

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 revoking Respondent's registration is confined to Factors B and D. *See* RD, at 31 n.50 (finding that Factors A, C, and E do not weigh for or against the sanction sought by the Government).

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). DEA regulations require that for a controlled substance prescription 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 CFR 1306.04(a).

Based on Dr. Lynch's reliable and persuasive expert opinion, the Agency finds that Respondent issued controlled substance prescriptions outside of the usual course of professional practice and beneath the Florida standard of care in violation of federal law. *See supra* Section I. Further, the Agency finds that Respondent violated Florida Statutes Section 456.44(3) with regard to Patients J.H., C.K., G.K., and J.K., by failing to take proper medical histories and conduct adequate medical examinations that supported prescribing controlled substances and/or failing to monitor the patients' medication compliance and address signs of abuse and/or diversion.[16] RD, at 34. The Agency also finds that for each of the four patients at issue, Respondent failed to maintain sufficiently detailed medical records that properly documented a diagnosis for each patient that supported prescribing controlled substances, thereby violating Florida Statutes Section 456.44(3) and Florida Administrative Code Rule 64B8–9.003.

Respondent's arguments fail to refute the evidence of unlawful and inappropriate prescribing. Although Respondent testified to his positive behavior of discharging approximately forty percent of one clinic's patients, such positive behavior cannot outweigh the evidence of prescribing contrary to the public interest. RD, at 33; Tr. 486, 489–90; *see, e.g., Ester Mark, M.D.,* 86 FR 16760, 16771 (2021); *Randall L. Wolff, M.D.,* 77 FR 5106, 5153 (2012). Nor do his broad arguments on the effects of the Government's enforcement decisions on pain clinics and the populations they serve undermine the Government's *prima facie* case. RD, at 34–35; *see Stephen E. Owusu, D.P.M.,* 87 FR 3343, 3351 n.21 (2022) (''the Agency has consistently held that community impact is not a relevant consideration under the public interest factors''); *George Pursley, M.D.,* 85 FR 80162, 80188 n.82 (2020); *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45239 (2020).

Regarding the Florida standard of care, Dr. Lynch credibly and reliably refuted Respondent's various suggestions that he met that standard, including the arguments that (1) titrating patients off opioids creates a risk of suicide, especially if the patient has been on opioids or benzodiazepines for a considerable period of time and/or has comorbid conditions such as anxiety disorder[17] (Tr. 29–30, 36–40, 628–29); (2) the standard of care is different for patients who cannot afford testing or alternative treatments (Tr. 30–32, 45, 429–30, 564); and (3) the standard of care is different when a practitioner ''inherits'' patients who are already on opioids (Tr. 41–44). RD, at 35. Moreover, Respondent's version of the standard of care is not supported by the applicable Florida statutes. RD, at 35; *see* Fla. Stat. § 456.44(3).

In sum, and in agreement with the RD, the Agency finds that the record contains substantial evidence that Respondent prescribed and dispensed controlled substances in violation of both federal and state law. *See* RD, at 34; 21 CFR 1306.04(a); Fla. Stat. § 456.44(3); Fla. Admin. Code r. 64B8–9.003. In weighing Factors B and D, the Agency finds that the Government has established a *prima facie* case that Respondent committed acts that render his registration inconsistent with the public interest and support revocation of his registration. *See* 21 U.S.C. 823(g)(1).

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent's registration, the burden shifts to the respondent 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 respondent 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). 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).

Here, Respondent has failed to fully accept responsibility or offer any basis for the Agency to trust him, despite his past misconduct, with the responsibility of a registration. RD, at 37–39. Respondent did not accept responsibility for most of the areas where his prescribing history fell short of both the standard of care and his obligations under federal and Florida law. RD, at 38. Although Respondent acknowledged that he could have kept better notes and been more diligent at detailing patients' care, this limited acceptance of responsibility was inadequate in light of his repeated insistence that the prescriptions were justified and issued within the standard of care. RD, at 38, 40; Tr. 511, 518–20, 524, 529–30, 567, 600. Additionally, Respondent's attempt to shift blame for his misconduct to other employees of the clinic was unpersuasive and further highlighted the insufficiency of his

[16] While Respondent argued that the patients were being treated by a drug and alcohol counselor, that counselor was not a psychiatrist or an addiction medicine specialist under Florida law. RD, at 34; Tr. 586; *see* Fla. Stat. § 456.44; *see also* Tr. 168–69.

[17] Dr. Lynch referenced Respondent's own exhibits and other sources to discuss that there is also an association with a higher likelihood of suicide for patients who start taking opioids, patients who continue taking opioids, patients taking opioids at a high MME level, patients with signs of abuse or misuse of substances, and patients with mental health issues. RD, at 35; Tr. 458–61. Similarly, Dr. Lynch explained that while stopping a benzodiazepine prescription is associated with a higher likelihood of suicide, so too is prescribing benzodiazepines in the first instance and maintaining benzodiazepines. RD, at 35; Tr. 459, 461, 463. Moreover, Respondent's numerous other failures, including his lack of appropriate documentation of the justifications for continued prescribing, violated federal and Florida law.

limited acceptance of responsibility. RD, at 38; Tr. 503–04, 515, 590, 606–08.

While a respondent may present evidence of remedial measures taken to prevent reoccurrence of behavior inconsistent with registration, it is not necessary for the Agency to consider remedial measures when a respondent lacks unequivocal acceptance of responsibility. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019); *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801, 74810 (2015). The Agency need not consider remedial measures given the lack of acceptance of responsibility, nevertheless Respondent did not present any evidence of remedial measures for consideration. *See* RD, at 39; *Ahuja,* 84 FR at 5498 n.33; *Glick,* 80 FR at 74801, 74810.

In addition to acceptance of responsibility, the Agency looks to the egregiousness and extent of the misconduct, *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases), and considers both specific and general deterrence when determining an appropriate sanction. *Glick,* 80 FR at 74810. Here, Respondent's inappropriate and unlawful prescribing of controlled substances was egregious and warrants a sanction. *See* RD, at 39. The record contains substantial evidence that Respondent improperly issued an extensive number of prescriptions to four patients at two clinics over the course of nearly two years. RD, at 9, 17–30; Tr. 490–91; *see supra* Section I. Respondent prescribed controlled substances to patients without taking appropriate action to address clear and repeated signs of diversion and abuse. RD, at 39; *see supra* Section I. Even when patients arrived at their appointments with vital signs indicating a medical crisis or emergency, Respondent failed to address their dangerous medical situations and continued the same prescribing in violation of the applicable standard of care. RD, at 39; *see, e.g.,* Tr. 303, 345–46, 392. In this case, the Agency believes that revocation of Respondent's registration would deter Respondent and encourage the general registrant community to properly manage patients' treatment under the requirements of the CSA, including when faced with evidence of abuse and diversion. *See* RD, at 39.

In light of the above considerations, there is insufficient evidence that Respondent's behavior is unlikely to recur in the future such that the Agency can entrust him with a registration. In sum, Respondent has not offered sufficient mitigating evidence on the record to rebut the Government's case for revocation of his registration. RD, at 37–40. The public interest factors weigh in favor of revocation. RD, at 40. Accordingly, the Agency will order that Respondent's registration be revoked.

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. FF7471840 issued to Mark Fenzl, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Mark Fenzl, M.D., to renew or modify this registration, as well as any other pending application of Mark Fenzl, M.D., for additional registration in Florida. This Order is effective April 10, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on February 20, 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.

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DEPARTMENT OF JUSTICE

[OMB Number 1121–0147]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Reinstatement, With Change, of a Previously Approved Collection for Which Approval Has Expired: Census of State and Federal Adult Correctional Facilities

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Justice Statistics (BJS), Department of Justice (DOJ) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until May 10, 2024.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Laura Maruschak, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531, (email: *laura.maruschak@usdoj.gov;* telephone: 202–598–0802).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: The Census of State and Federal Adult Correctional Facilities (CCF) is part of the larger Bureau of Justice Statistics' (BJS) portfolio of establishment surveys that inform the nation on the characteristics of adult correctional facilities and persons sentenced to State and Federal prisons. The CCF collects data at the facility level. Data obtained are intended to describe the characteristics of confinement and community-based adult correctional facilities that are operated by (1) State correctional and BOP authorities or (2) private entities that primarily house inmates for State correctional or BOP authorities. The data collected inform issues related to