of business on June 21, 2024. Reply submissions must be filed no later than the close of business on June 28, 2024. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1353) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on June 7, 2024.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 7, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–12885 Filed 6–12–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–52]

Coconut Grove Pharmacy; Decision and Order

On September 8, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Coconut Grove Pharmacy (Respondent) of Florida. Administrative Law Judge Exhibit (ALJX) 1 (OSC/ISO), at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration (registration), Control No. FC1162382, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1),[1] 824(a)(4)).[2]

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ), who, on March 2, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (RD or Recommended Decision). The RD recommended that Respondent's revocation be revoked. RD, at 86. Following the issuance of the RD, Respondent filed exceptions.[3]

Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[4] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

I. Findings of Fact

Florida Standard of Care

Thomas E. Hamilton, Pharm.D., testified as the Government's expert regarding pharmacy practice and standards in the state of Florida. RD, at 12–13; Tr. 182–83. Dr. Hamilton testified that he has over twenty years of experience as a Florida pharmacist and is currently employed as a pharmacist in Northern Miami. RD, at 12; Tr. 176–78, 181.[5] As for Respondent, Mr. Robert M. Parrado, R.Ph., testified as Respondent's expert. RD, at 36; Tr. 497–98. Mr. Parrado testified that he has been a licensed pharmacist in Florida for over fifty years and has served on the Florida Board of Pharmacy in various roles, including as Chairman and as a member of the rules committee. RD, at 37; Tr. 493–96.[6] Regarding Mr. Parrado's testimony, the Agency agrees with the ALJ that Mr. Parrado's testimony was not consistent nor logical (particularly when compared to his prior testimony in other matters) as Mr. Parrado at times contradicted the language of Florida's regulations and used the term ''red flag'' inconsistently in a way that created confusion; as such, his testimony warrants only minimal weight. RD, at 48–49.[7] Where Mr. Parrado's testimony diverges from that of Dr. Hamilton, the Agency, like the ALJ, will credit Dr. Hamilton. RD, at 49.[8]

Dr. Hamilton testified that the standard of care for pharmacists in Florida is informed by the regulations

[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/ISO, 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] According to Agency records, Respondent's registration expired on August 31, 2023. The fact that a registrant allows its registration to expire during the pendency of an OSC/ISO does not impact the Agency's jurisdiction or prerogative under CSA to adjudicate the OSC/ISO to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68,76–79 (2019).

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

[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 8–49.

[5] For Dr. Hamilton's full qualifications, *see* RD, at 12–13, Government Exhibit (GX) 9.

[6] For Mr. Parrado's full qualifications, *see* RD, at 36–37, Respondent Exhibit (RX) 27.

[7] The Agency incorporates herein the entire summary of Mr. Parrado's testimony as well as the ALJ's credibility assessment of Mr. Parrado as set forth in the Recommended Decision, at 36–49.

[8] The ALJ found, and the Agency agrees, that Dr. Hamilton's testimony was credible, internally consistent, and generally logically persuasive. RD, at 26. As noted by the ALJ, ''[a]lthough at times [Dr. Hamilton's] explanation of the factual support and basis for some of his opinions and conclusions was brief, overall he presented an objective analysis.'' *Id.* As such, the Agency finds Dr. Hamilton's testimony to be credible and reliable and affords it significant weight. *Id.*

promulgated by the Florida Board of Pharmacy (the Board), including Florida Administrative Code sections 64B16–27.800, 64B16–27.810, and 64B16–27.831. RD, at 13; Tr. 183–84. Florida Administrative Code section 64B16–27.800 states that pharmacies ''shall'' maintain a ''patient record system,'' that ''provide[s] for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs,'' and ''shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.'' Fla. Admin. Code section 64B16–27.800(1)–(2).[9] It also states that ''[t]he pharmacist shall record any related information indicated by a licensed health care practitioner.'' *Id.* Dr. Hamilton testified that this regulation requires pharmacists to document in the patient profile known information that is specific to a patient, especially information about a specific drug or reasons that a patient is prescribed a specific drug, to guide future decision making and justify dispensing. RD, at 13; Tr. 185, 194.

Florida Administrative Code section 64B16–27.810 requires that, prior to dispensing, a pharmacist ''review the patient record and each new and refill prescription . . . to promote therapeutic appropriateness by identifying: (a) Over-utilization or under-utilization; (b) Therapeutic duplication; (c) Drug-disease contraindications; (d) Drug-drug interactions; (e) Incorrect drug dosage or duration of drug treatment; (f) Drug-allergy interactions; [and] (g) Clinical abuse/misuse.'' Fla. Admin. Code section 64B16–27.810. The regulation further states that ''[u]pon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'' *Id.* section 64B16–27.810(2). Regarding this regulation, Dr. Hamilton testified that in the practice of pharmacy, the ''things to look for'' when verifying or assessing a prescription are termed ''red flags'' and the term ''red flag'' means ''caution'' or ''something to bring your heightened awareness to.'' RD, at 14; Tr. 185–86, 188.[10] Dr. Hamilton further testified that the practice of pharmacy in Florida requires that when a pharmacist recognizes any of the ''things to look for'' or ''red flags'' in a prescription, ''those things must be resolved, and that resolution must be documented before dispensing medication.'' [11] RD, at 14; Tr. 192, 273, 275–76, 353.

Lastly, Florida Administrative Code section 64B16–27.831 states that ''in filling valid prescriptions for controlled substances,'' pharmacists should ''exercise[e] sound professional judgment,'' and ''dispens[e] controlled substances for a legitimate medical purpose in the usual course of professional practice'' considering ''each patient's unique situation.'' Fla. Admin. Code section 64B16–27.831. Dr. Hamilton testified that this regulation sets forth the standards for validating prescriptions for controlled substances as well as addresses how Florida pharmacists are to assess whether a prescription is written for a ''legitimate medical purpose,'' which Dr. Hamilton defines as the pharmacist's ''corresponding responsibility.'' RD, at 15; Tr. 185.[12] Dr. Hamilton further testified that the ''corresponding responsibility'' of pharmacists is to work with physicians to take care of patients, to make sure that prescriptions written by physicians are not filled blindly, and to make sure that a prescription is correct for and used correctly by the patient. RD, at 15; Tr. 188. Dr. Hamilton noted that if red flags in a prescription have not been resolved, the prescription is not valid under the above regulation and should not be filled. RD, at 15; Tr. 275–76.[13]

Respondent's Improper Dispensing

Failure To Maintain Records

As mentioned above, Dr. Hamilton testified that any red flags present in a controlled substance prescription must be resolved before dispensing the prescription and such resolution must be documented. RD, at 25; Tr. 192. Dr. Hamilton testified that red flag resolution should appear on a prescription or in an electronic patient profile as ''some kind of note'' or documentation that references resolution of the red flag. RD, at 14; Tr. 228. Further, Dr. Hamilton testified that the need to document red flag resolution is for patient safety purposes so that information relating to the red flag resolution is ''readily retrievable.'' RD, at 14, 25; Tr. 192–93, 228. Ultimately, Dr. Hamilton asserted that ''if there [is] no documentation, nothing happened.'' RD, at 14, 25; Tr. 193.

Upon reviewing the documentation for the seven patients at issue in the current matter who filled their prescriptions at Respondent over a span of nearly two years, Dr. Hamilton found that there were no notations resolving the red flags present in the prescriptions. RD, at 25; Tr. 197–276; *see* GX 2–8. Because he did not find any documentation of the identification or resolution of the red flags present in these prescriptions, Dr. Hamilton found, in his expert opinion, that Respondent's dispensing fell below the Florida standard of care and that Respondent failed to meet its corresponding responsibility. RD, at 25–26; Tr. 214–15, 227–29, 242–43, 251–52, 255–57, 261–64, 265–276.

As for Respondent's argument, Mr. Parrado opined—based almost exclusively on the representations of Respondent's Pharmacist-in-Charge (PIC) about Respondent's process for

[9] This regulation requires that pharmacists ''ensure that a reasonable effort is made to obtain'' this information. *Id.* section 64B16–27.800(2).

[10] Although the term ''red flag'' itself is not used in the Florida regulation, Dr. Hamilton testified that pharmacists know the term to mean ''caution'' and the term is regularly used in the education and practice of pharmacists in Florida. RD, at 14 n.21; Tr. 186–188, 283, 344–345. Dr. Hamilton also testified that there are not a finite number of red flags and red flags could be ''almost anything'' that causes concern. RD, at 14; Tr. 208.

[11] Mr. Parrado disagreed with Dr. Hamilton regarding the documentation of red flags and their resolution; he testified that if there is a concern with a prescription, a pharmacist can resolve the concern and fill the prescription, but documentation of the concern and its resolution is strictly discretionary by the language of Florida law. RD, at 38–39; Tr. 509–10, 520–21. However, when testifying previously on behalf of the Government in *Superior Pharmacy I & II,* Mr. Parrado stated that (1) a pharmacist would ''absolutely'' document resolution of a red flag; (2) anytime a pharmacist has a concern with a prescription, the pharmacist '' 'always [does] what [he/she has] to do to resolve it and then [documents] it on the prescription' ''; and (3) '' 'the standard of practice has always been [that] [a pharmacist documents] it on the prescription.' '' RD, at 43 (citing *Superior Pharmacy I & II,* 81 FR 31310, 31321 (2016)); Tr. 532–34. Here, like the ALJ, the Agency credits the testimony of Dr. Hamilton and finds that the Florida standard of care requires that any red flags present in a prescription must be resolved before dispensing and such resolution must be documented. RD, at 81; Tr. 192–93, 228–29. The Agency also agrees with the ALJ that from a plain reading of the laws at issue, documentation of red flags and their resolution is not discretionary, as argued by Mr. Parrado above, but required. RD, at 81.

[12] Dr. Hamilton testified that a valid prescription is a prescription written for a legitimate medical purpose. RD, at 15–16; Tr. 276.

[13] There is some confusion in the record about the term ''red flag.'' Mr. Parrado seems to believe that when a prescription has characteristics of one or more red flags, but those red flags are resolved, then there is no red flag. *See* Tr. 571 (''just because there is [a] characteristic of a red flag [does not] mean that there is one''). This definition is debilitatingly circular, and it would seem that Mr. Parrado believes that there is a red flag only when a pharmacist determines that a prescription cannot be filled. When the Government, Dr. Hamilton, the ALJ, and the Agency use the phrase ''red flag,'' they are referring to the ''things to look for'' identified in Fla. Admin. Code section 64B16–27.810 (what Mr. Parrado would call a ''potential red flag,'' Tr. 571). Under this definition, prescriptions with red flags that were properly resolved can be filled, and prescriptions with unresolvable red flags cannot be filled.

validating prescriptions—that writing ''verified'' on the prescriptions and/or patient profiles at issue was sufficient to indicate that the prescriptions were validated according to Florida laws, regulations, and standards, and that Respondent met its corresponding responsibility. RD, at 41–42; Tr. 547, 608–09.[14]

The Agency credits Dr. Hamilton's testimony and finds that the Florida standard of care requires that any red flags present in a prescription must be resolved before dispensing and such resolution must be documented. *See supra* n.11. The Agency also finds that writing only ''verified'' on a prescription or patient profile is not sufficient to identify and resolve any red flags that may be present.

The ALJ found, and the Agency agrees, that the standard of care in Florida requires that any red flags present for a prescription or patient must be resolved before dispensing and that resolution must be documented. RD, at 81 (citing Tr. 192–93, 228–29). The ALJ found, and the Agency agrees, that Respondent failed to do this, rendering Respondent's dispensing practices outside the usual course of professional practice and in violation of the Florida standard of care. *Id.*[15]

Prescription Drug Cocktails

According to Dr. Hamilton, a combined prescription of drugs in different classes or drugs that have synergistic effects is a drug-drug interaction red flag that must be resolved before dispensing the prescription. RD, at 16; Tr. 203, 238. Regarding combinations of opioids and benzodiazepines, Dr. Hamilton testified that the Food and Drug Administration (FDA) has issued a Black Box Warning—FDA's highest warning—advising prescribers and pharmacists to avoid the combination because both drugs classes affect the central nervous system, cause respiratory depression, increase the risk of overdose, and when taken together, have an ''exponentially higher effect on the body.'' RD, at 16, 59; Tr. 203–05, 238, 294. Dr. Hamilton testified that an additional red flag combination is the combination of drugs that have opposite effects on the brain, such as a stimulant (an ''upper'') combined with a depressant (a ''downer''). RD, at 16; Tr. 238, 240.

Regarding combinations of opioids and benzodiazepines, Dr. Hamilton found that Patient A.R. was simultaneously filling prescriptions for immediate-release opioids (oxycodone-acetaminophen 10–325 and tramadol) and a benzodiazepine (alprazolam). RD, at 3–4 (Stip. 6), 17, 61; Tr. 205; GX 2a, at 1–2; GX 2d. Dr. Hamilton also found that Patient J.C. was filling prescriptions for a benzodiazepine (temazepam) at Respondent while PDMP data showed that Patient J.C. was filling prescriptions for an opioid (oxycodone) at a different pharmacy; similarly, Patient M.W. was filling prescriptions for an opioid (oxycodone) at Respondent while PDMP data show that Patient M.W. was filling prescriptions for a benzodiazepine (alprazolam) at a different pharmacy. RD, at 4–5 (Stip. 8), 7 (Stip. 12), 17, 61–62; Tr. 235–38, 268–69; GX 4a, at 2–3; GX 8a, at 1–2. Dr. Hamilton opined that Respondent should have recognized that the prescriptions for these three patients presented red flags and these red flags needed to be properly resolved before dispensing. RD, at 17, 61–62; Tr. 203, 208, 237–38, 268–69.

Regarding other dangerous combinations, Dr. Hamilton found that Patient J.C. was simultaneously filling prescriptions for a stimulant (methylphenidate) and a depressant benzodiazepine (temazepam). RD, at 4–5 (Stip. 8); Tr. 240; GX 4a; GX 4d. Again, Dr. Hamilton opined that these prescriptions presented red flags and Respondent needed to properly resolve these red flags before dispensing. RD, at 18; Tr. 240.

As for Respondent's argument, Mr. Parrado testified that after he reviewed prescriber and patient affidavits, he was of the opinion that the drug combinations presented in this case did not raise a red flag because the red flag was resolved ''originally and over time in [the PIC's] continuing conversations with the patients and the doctors.'' RD, at 41; Tr. 574–75. As discussed *supra,* even assuming *arguendo* that Respondent recognized the drug combination red flags and attempted to resolve them, writing only ''verified'' on a prescription or patient profile is not sufficient to actually resolve a red flag. Accordingly, the Agency credits the testimony of Dr. Hamilton that the drug combination red flags present in the prescriptions at issue were not properly resolved prior to Respondent's dispensing.

The ALJ found, and the Agency agrees, that the standard of care in Florida requires that prior to dispensing, a pharmacist document resolution of the drug cocktail or drug-drug interaction red flags that were present here due to simultaneous dispensing of opioids with benzodiazepines and benzodiazepines with stimulants. RD, at 64 (citing Tr. 185–86, 192, 203, 238, 273, 275–76). The ALJ found, and the Agency agrees, that Respondent failed to do this, rendering Respondent's dispensing practices outside the usual course of professional practice and in violation of the Florida standard of care. *Id.*

Immediate-Release and High Dosage Opioids

According to Dr. Hamilton, prescriptions of opiates alone can create red flags that have to be resolved before dispensing when: two separate immediate-release opioids are prescribed (''therapeutic duplication''); when opioids are prescribed in their highest strength version; or when immediate-release opioids intended to treat acute pain (as opposed to those intended to treat chronic pain) are prescribed for extended periods of time (''incorrect drug dosage or duration of drug treatment''). RD, at 18, 66; Tr. 198–200, 206, 216, 243; Fla. Admin. Code section 64B16–27.810(b), (e). Regarding high dosages of opioids, Dr. Hamilton testified that a dosage of 90 MMEs[16] per day or greater warrants caution when determining whether to fill the prescription. RD, at 18–19; Tr. 208–210.[17] Regarding immediate-release opioids prescribed for extended durations, Dr. Hamilton opined that filling immediate-release opioid prescriptions month-over-month for an extended time[18] is concerning and

[14] Previously, in *Hills Pharmacy,* Mr. Parrado testified that writing ''verified'' (paired with a name) on a prescription does not tell you anything, that ''it was nothing,'' and ''that it was unclear what the pharmacist verified.'' RD, at 45–46 (citing *Hills Pharmacy, LLC,* 81 FR 49816, 49825 (2016)); Tr. 547; GX 12.

[15] In its Exceptions, Respondent argues that the prescriptions at issue were legitimate prescriptions written for a legitimate medical purpose. Respondent's Exceptions to Recommended Decision (Exceptions), at 1–13. The Agency reiterates that even assuming *arguendo* that the prescriptions at issue were fully legitimate, it was nonetheless Respondent's corresponding responsibility under the Florida standard of care, as discussed above and throughout this Decision, to recognize the red flags present in the prescriptions, resolve the red flags, and document such resolution appropriately, which Respondent undeniably failed to do. Respondent also argues in its Exceptions that the Government failed to prove that Respondent did not take proper steps to validate the prescriptions at issue. Exceptions, at 13–20, 25–28. Again, and as discussed throughout this Decision, even assuming *arguendo* that Respondent validated the prescriptions at issue, Respondent was required to document such steps and writing only ''verified'' was insufficient.

[16] MME is a measurement of opioid strength based on milligram units of morphine per day and MMEs for all opioids prescribed concurrently are added together to determine the total MME per day. RD, at 18 n.26; Tr. 209–212.

[17] Dr. Hamilton testified that the red flag of a high dosage of opioids can be justified if a patient is not opioid naïve, has been using opioids for an extended time, or has a ''certain disease state'' such as cancer. RD, at 19, 66; Tr. 210, 341.

[18] Dr. Hamilton did not testify as to a specific time period that would cause concern, but made

constitutes a red flag that needs to be resolved before dispensing. RD, at 20–21, 69; Tr. 206, 244, 253.

In reviewing Respondent's dispensing, Dr. Hamilton found that Patients A.R. and J.K. were both filling prescriptions for a combination of two immediate-release opioids (oxycodone-acetaminophen 10–325 with tramadol and oxycodone-acetaminophen 10–325 with oxycodone, respectively). RD, at 3–4 (Stip. 6), 6–7 (Stip. 10), 19–20, 68; Tr. 199–200, 243–45; GX 2a, 2d. Dr. Hamilton opined that these instances of therapeutic duplication constituted red flags that had to be resolved before dispensing. RD, at 19–20, 68; Tr. 200, 208, 243, 245. Mr. Parrado testified that for at least one of the patients prescribed two simultaneous immediate-release opioids, Respondent originally had a therapeutic duplication concern and ''spoke with a doctor'' who resolved the concern, so there was ''no longer a concern'' and there was ''no reason [for the Respondent] to continue doing anything else.'' RD, at 41; Tr. 571. However, when testifying on behalf of the Government in *Superior Pharmacy I & II,* Mr. Parrado stated that a pharmacy ''is never to dispense two immediate use opioids at once, at the same time for the same patient.'' RD, at 43 (citing *Superior Pharmacy I & II,* 81 FR 31327); Tr. 531.

As for immediate-release opioids prescribed for extended durations, Dr. Hamilton found the following: Patient A.R was filling prescriptions for immediate-release opioids (oxycodone-acetaminophen and tramadol) over a span of approximately two years; Patient J.K. was filling prescriptions for immediate-release opioids (oxycodone and oxycodone-acetaminophen 10–325) over a span of approximately one-and-a-half-years; Patient C.S. was filling prescriptions for an immediate-release opioid (hydromorphone, at the highest strength,[19] while an extended-release version is available) over a span of approximately one-and-a-half years; and Patients J.L. and M.W. were both filling prescriptions for a high-strength, immediate-release opioid (oxycodone 30 mg) month-over-month for approximately one-and-a-half years and approximately one year, respectively. RD, at 3–4 (Stips. 6–7), 5–7 (Stips. 9–10, 12), 20–21; Tr. 205–06, 218, 243–44, 253, 265; GX 2a; GX 2d; GX 3a; GX 3c; GX 5a; GX 5d; GX 6a; GX 6c; GX 8a; GX 8d. Dr. Hamilton opined that these prescriptions presented red flags and Respondent needed to properly resolve these red flags before dispensing. RD, at 20–21, 69; Tr. 206, 218. 244, 253, 265.

Concerning high dosage opioid prescriptions, Dr. Hamilton found the following: Patient A.R. was filling prescriptions for oxycodone-acetaminophen 10–325 and tramadol that together totaled 120 MMEs per day; Patient C.S. was filling prescriptions for hydromorphone at the highest strength (8 mg) totaling as much as 260 MMEs per day; Patient J.L. was filling prescriptions for oxycodone at the highest strength (30 mg) totaling approximately 135 MMEs per day; Patient M.G. was filling prescriptions for oxycodone at the highest strength (30 mg) totaling between 135 and 270 MMES per day; and Patient M.W. was filling prescriptions for oxycodone at dosages of either 15 mg or 30 mg totaling between 90 and 265 MMEs per day. RD, at 3–4 (Stips. 6–7), 5–6 (Stip. 9), 7 (Stips. 11–12), 21–22; Tr. 210–12, 218, 253–55, 258, 260, 265, 267; GX 2a; GX 2d; GX 3a; GX 3c; GX 6a; GX 6c; GX 7a; GX 7d; GX 8a; GX 8d. Once more, Dr. Hamilton opined that these prescriptions presented red flags that Respondent needed to properly resolve before dispensing. RD, at 21–22, 70–71; Tr. 210–12, 218, 253–55, 258, 267.

As for Respondent's argument, Mr. Parrado testified generally that based on his review of the records and conversations with Respondent's PIC, there were no incorrect drug dose or duration of treatment red flags because the patients had long-term pain and had developed opioid tolerance as established through the PIC's purported conversations with the patients and prescribers. RD, at 41; Tr. 575–76. As discussed *supra,* even assuming *arguendo* that Respondent recognized these red flags and attempted to resolve them, writing only ''verified'' on a prescription or patient profile is not sufficient to actually resolve a red flag. Accordingly, the Agency credits the testimony of Dr. Hamilton that the therapeutic duplication and incorrect drug dosage or duration of drug treatment red flags were not properly resolved prior to Respondent's dispensing.

The ALJ found, and the Agency agrees, that the standard of care in Florida requires that prior to dispensing, a pharmacist document resolution of the therapeutic duplication red flags (prescribing of two immediate-release opioids) and incorrect drug dosage or duration of treatment red flags (immediate-release opioids prescribed for extended durations and opioids prescribed in their highest strength) that were present here. RD, at 73 (citing Tr. 185–86, 192, 273, 275–76). The ALJ found, and the Agency agrees, that Respondent failed to do this, rendering Respondent's dispensing practices outside the usual course of professional practice and in violation of the Florida standard of care. *Id.*

Alternating Between Cash and Insurance [20]

According to Dr. Hamilton, a patient paying for some prescriptions with insurance while paying for others with cash is a red flag, but only for the prescriptions paid for in cash. RD, at 23; Tr. 231. Concerning this issue, Dr. Hamilton found that Patient J.C. was paying for some medications with insurance while paying for other, controlled medications with cash, which was a red flag that needed to be resolved before dispensing. RD, at 24; Tr. 240–41; GX 4d. Further, Dr. Hamilton found that Patient M.W. was using cash to pay for oxycodone at Respondent while using insurance to pay for alprazolam at a different pharmacy. RD, at 24–25; Tr. 270; GX 8a. Again, Dr. Hamilton opined that this was a red flag that needed to be resolved before dispensing. RD, at 25; Tr. 270–71. Regarding Patient J.C. paying for his methylphenidate prescription with cash, the PIC testified that he spoke with Dr. R., Patient J.C.'s physician, about Patient J.C.'s prescription and Dr. R. told the PIC that Patient J.C. had limited insurance. RD, at 29 n.37; Tr. 461–62.

Again, as discussed *supra,* even assuming *arguendo* that Respondent recognized these red flags and attempted to resolve them, writing only ''verified'' on a prescription or patient profile is not sufficient to actually resolve a red flag. Accordingly, the Agency credits the testimony of Dr. Hamilton that the red flag of alternating between cash and insurance was not properly resolved prior to Respondent's dispensing.

The ALJ found, and the Agency agrees, that the standard of care in Florida requires that prior to dispensing, a pharmacist document resolution of the red flag of alternating between cash and insurance that was present here. RD, at 77 (citing Tr. 185–86, 192, 273, 275–76). The ALJ found, and the Agency agrees, that Respondent failed to do this, rendering Respondent's dispensing practices outside the usual course of

clear that taking immediate-release opioids for ''30, 60 days maximum'' would be acceptable and that over two years would be ''very concerning.'' RD, at 20; Tr. 205–206.

[19] Dr. Hamilton opined that ''having the highest possible strength of an immediate-release opiate is definitely a red flag.'' RD, at 20; Tr. 218.

[20] This Decision and Order does not address allegations concerning the high cash payment/high pricing red flag due to the number and egregiousness of the rest of the allegations.

professional practice and in violation of the Florida standard of care. *Id.*[21]

II. Discussion

A. The Five Public Interest Factors

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 [its] 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 52–53; *see also id.* at 52 n.58 (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 51–82.

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/ISO, at 2–7.[22] Specifically, federal law requires that ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice,'' and 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), 1306.06; *see also* 21 U.S.C. 829. Federal law also emphasizes that although ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a).[23]

As for state law, Florida Administrative Code section 64B16–27.810 requires that, prior to dispensing, a pharmacist ''review the patient record and each new and refill prescription . . . to promote therapeutic appropriateness by identifying: (a) Over-utilization or under-utilization; (b) Therapeutic duplication; (c) Drug-disease contraindications; (d) Drug-drug interactions; (e) Incorrect drug dosage or duration of drug treatment; (f) Drug-allergy interactions; [and] (g) Clinical abuse/misuse.'' Fla. Admin. Code section 64B16–27.810. The regulation further states that ''[u]pon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'' *Id.* section 64B16–27.810(2).

In addition, Florida Administrative Code section 64B16–27.800 states that pharmacies ''shall'' maintain a ''patient record system,'' that ''provide[s] for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs,'' and ''shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.'' Fla. Admin. Code section 64B16–27.800(1)–(2).[24] It also states that ''[t]he pharmacist shall record any related information indicated by a licensed health care practitioner.'' *Id.*

Lastly, Florida Administrative Code section 64B16–27.831 states that ''in filling valid prescriptions for controlled substances,'' pharmacists should ''exercise[e] sound professional judgment,'' and ''dispens[e] controlled substances for a legitimate medical purpose in the usual course of professional practice'' considering ''each patient's unique situation.'' Fla. Admin. Code section 64B16–27.831.

In the current matter, the Agency agrees with the ALJ's analysis that Respondent's dispensing fell below the Florida standard of care—and thus was outside the usual course of professional practice—because, as detailed above, Respondent dispensed numerous controlled substance prescriptions to seven patients without properly addressing and resolving clear red flags of abuse and/or diversion including drug cocktails, immediate-release and high dosage opioids, and patients alternating between paying for prescriptions with cash and insurance. *See* RD, at 51–82. 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. RD, at 81–82. 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.*

III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Respondent's registration, the burden

[21] Respondent argues in its Exceptions that none of the prescriptions at issue were actually abused or diverted. Exceptions, at 20–23. Nonetheless, 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).

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

[23] Further, federal law ''prohibit[s] a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose.'' *Id.*

[24] This regulation requires that pharmacists ''ensure that a reasonable effort is made to obtain'' this information. *Id.* section 64B16–27.800(2).

shifts to the registrant to show why it 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, it must both accept responsibility and demonstrate that it 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).

Here, and as noted by the ALJ, the PIC, as Respondent's pharmacy manager, did not admit any fault or accept any responsibility for his conduct in filling the prescriptions at issue. RD, at 83.[25] As such, the ALJ concluded, and the Agency agrees, that Respondent has not demonstrated unequivocal acceptance of responsibility for its actions. *Id.* at 84 (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79188, 79201–202 (2016)).[26]

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 given that the PIC filled many of the prescriptions at issue, yet failed to acknowledge that any red flags existed or required resolution, ''the interests of specific deterrence, even standing alone, motivate powerfully in favor of revocation.'' RD, at 85; Tr. 361, 363–76. 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 the failure to properly address and document resolution of red flags can be excused. RD, at 85–86.

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. *Id.* at 84. As stated by the ALJ, ''Respondent dispensed many controlled substances over a two-year period without any regard for its obligations to identify, resolve, or document any red flags of potential abuse or diversion'' and with awareness of both its obligations and the existence of numerous red flags in the prescriptions that it was filling and dispensing. *Id.* at 84–85.

In sum, Respondent has not offered any credible evidence on the record that rebuts the Government's case for revocation of its registration and Respondent has not demonstrated that it can be entrusted with the responsibility of registration. *Id.* at 86. Accordingly, the Agency will order that Respondent's registration be revoked.[27]

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. FC1162382 issued to Coconut Grove Pharmacy. 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 Coconut Grove Pharmacy to renew or modify this registration, as well as any other pending application of Coconut Grove Pharmacy for additional registration in Florida. This Order is effective July 15, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on June 6, 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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[25] Nor did Respondent's owner, A.V., acknowledge any fault or accept any responsibility for Respondent's improper dispensing practices. *Id.* at 83–84.

[26] 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 79202–303); *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801, 74,810 (2015). Even so, in the current matter, neither the PIC nor A.V. outlined any remedial measures taken by Respondent. RD, at 83–84.

[27] Regarding Respondent's additional assertions in its Exceptions that the pharmacy being served with an OSC/ISO did not allow it an opportunity to submit a corrective action plan (Exceptions, at 30), the Agency notes that Respondent had ample opportunity in presenting its case-in-chief to fully accept responsibility for its improper practices and to offer remedial measures, but Respondent failed to do so, *see supra.* Further, regarding Respondent's noting that the PIC has never previously faced disciplinary measures for his dispensing (Exceptions, at 29), this point was addressed by the ALJ in considering Public Interest Factors A, C, and E (*see supra* II.A.) and has been considered by the Agency.

DEPARTMENT OF JUSTICE

Office of the Attorney General

[A.G. Order No. 5945–2024]

Attorney General Designation of Switzerland as a ''Qualifying State''

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: In accordance with an Executive order, the Attorney General has designated Switzerland as a ''qualifying state.''

DATES: June 13, 2024. The designation is to become effective on the date of entry into force of an amendment to Annex 1 to the Swiss Data Protection Ordinance listing the United States for data transferred in reliance on the Swiss–U.S. Data Privacy Framework.

FOR FURTHER INFORMATION CONTACT: Susan Hennessey, Chief Counsel Performing the Duties of the Deputy Assistant Attorney General, National Security Division, United States Department of Justice, Washington, DC 20530; telephone: (202) 514–1057. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Executive Order 14086 of October 7, 2022 (Enhancing Safeguards for United States Signals Intelligence Activities), establishes a two-level redress mechanism for the review of qualifying complaints by individuals filed through an appropriate public authority in a ''qualifying state'' and alleging certain violations of U.S. law concerning signals intelligence activities. A country or regional economic integration organization may be designated as a qualifying state by the Attorney General if he determines, in consultation with the Secretary of State, the Secretary of Commerce, and the Director of National Intelligence, that it meets the requirements set forth in section 3(f) of Executive Order 14086. The Attorney General has made those determinations on the basis of the information contained in the ''Memorandum in Support of Designation of Switzerland as a Qualifying State Under Executive Order 14086'' prepared by the National Security Division of the Department of