with the responsibility of registration. 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. FV3660037 issued to Mary A. Vreeke, 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 Mary A. Vreeke, M.D. to renew or modify this registration, as well as any other pending application of Mary A. Vreeke, M.D., for additional registration in California. This Order is effective October 16, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 10, 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. 2024–20939 Filed 9–13–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–48]

Awesome Care Pharmacy, Inc.; Decision and Order

On June 1, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Awesome Care Pharmacy, Inc., (Respondent) of Houston, Texas. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration Number FA2332346 (registration), 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.* at 1 (quoting 21 U.S.C. 824(d)).[1] 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. 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ), who, on February 6, 2024, 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 59. Following the issuance of the RD, Respondent filed exceptions.[2] Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[3] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD and summarizes and clarifies portions thereof herein.[4]

[1] Respondent argues in its Exceptions to the Recommended Decision (Exceptions) that the ISO ''led to the 'wrongful takings' of its DEA license'' because the hearing established that no diversion occurred and there was ''no imminent harm, no harm, and no damage, threat or harm to the 'public interest.' '' Exceptions, at 1 (citing Tr. 8, 14, 52–53, 55, 69, 179–81, 192). However in this case, the evidence showed that Respondent repeatedly dispensed dangerous combinations of controlled substances that posed serious risks to patients without first resolving blatant red flags of drug abuse and diversion. Respondent's repeated dispensing of controlled substances outside the usual course of the professional practice and in violation of federal and state law established ''a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Respondent's registration. 21 U.S.C. 824(d). Thus, the Agency finds that at the time the Government issued the OSC/ISO, there was clear evidence of imminent danger. Moreover, the immediate suspension aspect of the Government's case was final as of the date the OSC/ISO was issued by the Administrator, and is not the subject of these proceedings. 21 U.S.C. 824(d)(1) (''A[n immediate] suspension . . . shall continue in effect until the conclusion of [administrative enforcement] proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.''); 21 CFR 1301.36(h) (''Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction.'').

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

[3] The Agency adopts the ALJ's summary of each witness' testimony, as well as the ALJ's assessment of each witness' credibility, except as clarified herein. *See* RD, at 4–53.

[4] Respondent argues in its Exceptions that the ALJ was biased towards the Government. Respondent's only record support for this assertion is a citation to the transcript where the ALJ thanks the Government for printing certain documents in large enough font for him to read. Exceptions, at 3 (citing Tr. 46–47). Respondent cites no authority suggesting that the ALJ's expression of appreciation for a chosen font size reflects bias especially where, as here, the ALJ thanked both parties at the end of the hearing for their zealous advocacy. Tr. 522.

I. Findings of Fact

Texas Standard of Care

Katherine Salinas testified as the Government's expert regarding the standard of care for pharmacy practice in the State of Texas. RD, at 6; Tr. 96–97. Ms. Salinas has been licensed as a pharmacist in Texas for over thirty years and has dispensed medications in retail pharmacies since 1992. RD, at 6; Tr. 89–91, 167. Ms. Salinas served as a Compliance Officer with the Texas Board for approximately nine years, where she inspected approximately 2,700 pharmacies, and she currently works as the Medication Safety and Drug Diversion Supervisor for the University of Texas Medical Branch. RD, at 6–7; Tr. 93–95.[5]

Dr. Okpala, Respondent's owner and Pharmacist-in-Charge (PIC), testified on Respondent's behalf. Dr. Okpala testified that he has been licensed as a pharmacist in Texas since 1993. RD, at 20; Tr. 373, 376–77; RX 2, at 2.[6] The Agency agrees with the ALJ that Dr. Okpala has a significant personal interest in the outcome of these proceedings. RD, at 24. Additionally, the Agency finds that Dr. Okpala's testimony at times contradicted the language of Texas's regulations. Therefore, to the extent that Dr. Okpala's testimony diverges from the Texas regulations and the testimony of Ms. Salinas, the Agency will credit Ms. Salinas's testimony.[7]

Ms. Salinas testified that the standard of care in Texas is informed by DEA regulations and Texas laws and regulations, including Texas Administrative Code § 291.29(b), which requires pharmacists to ''make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.'' 22 Tex. Admin. Code § 291.29(b); RD, at 7–8; Tr. 98–100. Ms.

[5] For Ms. Salinas's full qualifications, see RD, at 6–7, Government Exhibit (GX) 10.

[6] The Agency incorporates herein the entire summary of Dr. Okpala's testimony. RD, at 19–24.

[7] The ALJ found Dr. Okpala's testimony to be ''generally credible,'' while noting that Dr. Okpala failed to lay an adequate foundation for his testimony that the patients in this case suffered from chronic pain. RD, at 24. The ALJ determined that ''[t]o the extent that [Dr. Okpala's] testimony differs from the testimony of other testifying witnesses, I will consider his personal interest in this case, and I will give his testimony the weight it deserves in light of other evidence and testimony presenting during the hearing.'' *Id.* The Agency agrees with the amount of weight that the ALJ afforded Dr. Okpala's testimony, except as clarified herein.

Salinas testified that this obligation is known as the pharmacist's ''corresponding responsibility,'' and it is the ''foundation . . . of good pharmacy practice.'' RD, at 7; Tr. 98, 327.

Ms. Salinas testified that the Texas Administrative Code ''lists out several patterns that the pharmacist needs to be aware of to assess [a] prescription and determine if [it] was indeed issued for a legitimate medical purpose.'' RD, at 7; Tr. 98. Consistent with Ms. Salinas's testimony, Texas Administrative Code § 291.29(f) states that ''[a] pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility,'' and provides a list of nineteen ''patterns (*i.e.,* red flag factors) [that] are relevant to preventing the non-therapeutic dispensing of controlled substances.'' 22 Tex. Admin. Code § 291.29(f). The statute further states that these red flags ''shall be considered by evaluating the totality of the circumstances rather than any single factor.'' *Id.* Ms. Salinas testified that the statute's list of red flags is not exhaustive. RD, at 8; Tr. 98, 104–06. A red flag is ''anything that should make the pharmacist question [a] prescription and whether or not [it] is safe and appropriate.'' Tr. 106. Ms. Salinas identified some examples of red flags, including that multiple patients are receiving essentially the same pattern of prescriptions from a small number of prescribers, or that prescriptions are for commonly abused drugs, such as opioids, benzodiazepines, and cough syrups. Tr. 105.

Ms. Salinas testified that a pharmacist should evaluate a prescription for red flags by looking at all of the details on the face of the prescription (*e.g.,* name, address, date of birth, quantity of drug prescribed), checking the Prescription Monitoring Program (PMP), running a public search for the provider to see if there are any disciplinary orders, talking to the patient, and calling the prescribing doctor to discuss any potential red flags. RD, at 8; Tr. 106–08. If the pharmacist identifies any red flags that indicate that the prescription might not be legitimate, then the pharmacist must attempt to resolve those red flags by ''taking into account [the] bigger picture,'' including conversations with the patient and prescriber, relevant statutes and laws, discussions with colleagues, and PMP data. RD, at 8, 10; Tr. 106–08, 209–10, 304–05, 307–08, 313, 317–18, 327. Ms. Salinas testified that if the pharmacist determines that the red flag cannot be resolved, then the pharmacist should not fill the prescription. RD, at 8; Tr. 107. If, on the other hand, the pharmacist determines that the red flag can be resolved, Ms. Salinas testified that the pharmacist must document the resolution of the red flag, the rationale behind the decision to dispense the medication, and the pharmacist's discussions with the prescriber. RD, at 8–10; Tr. 107–12, 142, 327.

Consistent with Ms. Salinas's testimony, the Texas Administrative Code states that ''[p]rior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.'' 22 Tex. Admin. Code § 291.33(c)(2)(A)(iv). Subparagraph C specifies that the following information about the pharmacist's consultation with the prescriber shall be documented ''on the prescription or in the pharmacy's data processing system associated with the prescription'': ''(i) date the prescriber was consulted; (ii) name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.'' *Id.* at § 291.33(c)(2)(C); RD, at 9; Tr. 112. Ms. Salinas testified that the purpose of documentation is to show that the pharmacist saw the red flags and resolved them. RD, at 9; Tr. 112.

Finally, the Texas Administrative Code requires pharmacists to ''exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense, which requires ''verify[ing] the order with the practitioner prior to dispensing'' ''[i]f the pharmacist questions the accuracy or authenticity of a prescription drug order.'' 22 Tex. Admin. Code § 291.34(b)(1)(A).

Respondent's Improper Dispensing

Ms. Salinas testified that she reviewed Respondent's PMP history, dispensing history, and a subset of patient profiles, Tr. 115, and she testified about the red flags that she observed with the prescriptions for these patients, including drug cocktails, pattern prescribing, prescriptions lacking diagnosis codes, patients receiving controlled substances from multiple prescribers, and gaps in prescriptions exceeding one month. RD, at 11–19.

Drug Cocktails

One of the potential red flags identified by the Texas Administrative Code is when ''prescriptions by a prescriber . . . are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, . . . or any combination of these drugs.'' 22 Tex. Admin. Code § 291.29(f)(3). Ms. Salinas testified that a combination of drugs is referred to as a ''drug cocktail.'' RD, at 11; Tr. 122, 328–29. For example, when combined, hydrocodone (an opioid) and carisoprodol (a muscle relaxant)—which are both highly abusable on their own—can create a potentially dangerous drug cocktail that increases the risk of respiratory depression, overdose, or death. RD, at 11; Tr. 118–22, 136, 143, 147, 153, 290, 328–29.[8] Ms. Salinas testified that the risks to patients from taking these drugs together continue for as long as they are taking them, not just the first time they are prescribed. RD, at 11; Tr. 329. In this case, Ms. Salinas testified that A.T., T.B., K.B., and S.D. were all receiving a dangerous cocktail of hydrocodone and carisoprodol. RD, at 11; Tr. 118–22, 136, 143, 147, 153, 328–29.

As for Respondent, Dr. Okpala testified that the combination of hydrocodone-acetaminophen and carisoprodol did not present a red flag because these medications are combined to produce a ''synergistic effect'' that is more effective for treating chronic pain. RD, at 34–35; Tr. 419–20, 457. However, Dr. Okpala did not produce adequate evidence that these patients actually suffered from chronic pain or that these drugs were prescribed together to produce a synergistic effect. Nor did Dr. Okpala acknowledge that these drugs can be very dangerous when combined. Thus, the ALJ found, and the Agency agrees, that the frequent prescribing of the drug cocktail of hydrocodone and carisoprodol was a red flag that Respondent should have identified, resolved, and documented prior to dispensing. RD, at 36.

Pattern Prescribing

The Texas Administrative Code identifies several red flags that Ms. Salinas referred to as ''pattern prescribing,'' including that: (1) the pharmacy ''dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially

[8] DI Fernandez similarly testified that hydrocodone-acetaminophen and carisoprodol are ''very popular in Houston and are highly diverted,'' and they are considered ''a dangerous combination.'' RD, at 34; Tr. 24–25.

paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner,'' 22 Tex. Admin. Code § 291.29(f)(1); (2) ''the pharmacy operates with a reasonably discernible pattern of overall low prescription dispensing volume, maintaining relatively consistent [one-to-one] ratio of controlled substances to dangerous drugs and/or over-the-counter products dispensed as prescriptions,'' *id.* at § 291.29(f)(2); and/or (3) ''prescriptions for controlled substances are commonly for the highest strength of the drug and/or for large quantities (*e.g.,* monthly supply), indicating a lack of individual drug therapy in prescriptions issued by the practitioner,'' *id.* at § 291.29(f)(5). RD, at 11–12; Tr. 129, 339.

In this case, Ms. Salinas testified that Respondent's dispensing to A.T., T.B., K.B., and S.D. reflected a repeated pattern of large quantities of carisoprodol and hydrocodone in the highest strength available. RD, at 12, 37; Tr. 118–19, 132–33, 136, 143, 147, 339. The highest strength of carisoprodol is 350 mg, and Respondent frequently dispensed 60 to 80 tablets per month to patients. RD, at 12; Tr. 121. The highest strength of hydrocodone-acetaminophen is 10/325 mg, and Respondent frequently dispensed quantities exceeding 100 tablets per month to patients, which Ms. Salinas testified is a red flag. RD, at 12, 37; Tr. 120–21, 143. Ms. Salinas testified that hydrocodone-acetaminophen is highly addictive and is ''one of the pattern drugs that [she sees] most often . . . with patterns of . . . abuse.'' RD, at 12–13; Tr. 120–21, 149. Ms. Salinas testified that hydrocodone is best when limited to short-term use, so it is a red flag to see hydrocodone prescribed month after month. RD, at 12–13, 37; Tr. 122, 143, 148–51, 339–40. Ms. Salinas testified that hydrocodone may be prescribed for over three months to patients suffering from chronic pain,[9] but the pharmacist must still exercise the ''corresponding responsibility to determine if that [is] appropriate.'' Tr. 150. Ms. Salinas also testified that Respondent often dispensed hydrocodone and carisoprodol along with non-controlled drugs, such as ibuprofen, naproxen, or multivitamins, reflecting the one-to-one ratio identified in the Texas Administrative Code. RD, at 11; Tr. 121–22, 129, 153.

As for Respondent, Dr. Okpala testified that the repeated prescriptions for maximum-strength controlled substances in large quantities over multiple months did not present a red flag because these patients all had chronic pain. RD, at 39; Tr. 406–08, 490, 497, 510. However, the ALJ found, and the Agency agrees, that Dr. Okpala did not present sufficient evidence to establish that these patients had chronic pain. RD, at 39. Dr. Okpala testified that he concluded that they had chronic pain based on the frequency they saw their prescribing doctors,[10] the conversations and interactions he had with the patients and prescribers, and the types of medications prescribed. RD, at 39; Tr. 406–08, 490, 497, 510. Dr. Okpala testified that it was ''common sense'' for a pharmacist to conclude that a patient suffers from chronic pain when the patient is receiving monthly prescriptions for hydrocodone-acetaminophen. RD, at 39; Tr. 342, 497. He further testified that knowing the cause of the patients' pain would not impact his decision to dispense the prescriptions presented in this case. RD, at 52; Tr. 501

However, Ms. Salinas testified that the nature of the drug prescribed does not communicate a diagnosis to the pharmacist, and the pharmacist should not assume why the drug was prescribed. RD, at 16; Tr. 306, 329–30. Moreover, Ms. Salinas testified that there was no documentation on the prescriptions suggesting that the repeated hydrocodone prescriptions were for chronic pain. RD, at 15, 41–42; Tr. 150–51, 251–55. Finally, even assuming that Respondent did discuss the diagnoses with the patients or prescribers, the lack of any documentation of those conversations renders Respondent's dispensing outside of the standard of care. RD, at 14, 38; Tr. 150–51; 22 Tex. Admin. Code § 291.33(c)(2)(A)(iv).

Thus, the ALJ found, and the Agency agrees, that repeated prescriptions for high quantities and high strengths of commonly-abused drugs, sometimes in combination with non-controlled substances in a one-to-one ratio, was a red flag that Respondent should have identified, resolved, and documented prior to dispensing. RD, at 39–40.

Prescriptions Lacking Specific Diagnoses

Another potential red flag identified by the Texas Administrative Code is when prescriptions for controlled substances ''contain nonspecific or no diagnoses, or lack the intended use of the drug.'' 22 Tex. Admin. Code § 291.29(f)(4); RD, at 14; Tr. 128. Ms. Salinas testified that the diagnosis code is especially important when hydrocodone or carisoprodol is prescribed, because those medications are a red flag. RD, at 14; Tr. 127. Ms. Salinas testified that in this case, there was generally no documentation on the face of a prescription related to a patient's diagnosis, so she could not determine whether a patient was being prescribed hydrocodone for chronic or acute pain, which may impact the length of time a patient is prescribed hydrocodone. RD, at 15; Tr. 150–51. Ms. Salinas testified that diagnoses of ''pain'' or ''chronic pain syndrome'' are not specific enough under the Texas Administrative Code, and should trigger a red flag analysis. RD, at 15; Tr. 331–32. Ms. Salinas testified that she was unable to determine the purpose of the prescriptions or the type of pain that the medications were intended to treat. RD, at 15–16; Tr. 252–53, 329.

As for Respondent, Dr. Okpala presented conflicting testimony regarding whether ''pain'' was a diagnosis, but ultimately testified that pain may be used as a diagnosis. RD, at 42; Tr. 484–85. Dr. Okpala also testified that neither DEA nor Texas regulations requires the inclusion of diagnosis codes on the face of a prescription. RD, at 42; Tr. 448, 507. Finally, Dr. Okpala testified that he knew that the patients in this case had chronic pain, although the Agency found above that this conclusion was not adequately supported.

The ALJ found, and the Agency agrees, that Ms. Salinas's testimony was more credible on this issue because it was supported by the relevant provisions of the Texas Administrative Code, which identify nonspecific diagnosis codes as a relevant red flag factor. RD, at 42; 22 Tex. Admin. Code § 291.29(f)(4). Thus, the ALJ found, and the Agency agrees, that the lack of specific diagnoses to justify the controlled substance prescriptions was a red flag that Respondent should have identified, resolved, and documented prior to dispensing. RD, at 42–43.

Gaps in Prescriptions

Ms. Salinas testified that another potential red flag is when gaps between usually-consistent monthly

[9] Ms. Salinas testified that chronic pain is pain that ''lasts greater than three months.'' RD, at 14 n.51; Tr. 150.

[10] The ALJ found, and the Agency agrees, that Dr. Okpala's testimony that he knew the patients had chronic pain based on the frequency of their visits was concerning. RD, at 39. As the ALJ noted, the fact ''[t]hat these patients frequently visited prescribers and received repeated prescriptions for high quantities and similar dosage units of controlled substances on a monthly basis is the very red flag indicative of a lack of personalized care identified by Ms. Salinas and the Texas Administrative Code.'' *Id.*

prescriptions exceed a month, because this indicates that the patient is not taking the controlled substance as prescribed. RD, at 18, 48–49; Tr. 140. Ms. Salinas testified that if a pharmacist observes a gap, the pharmacist should have a discussion with the patient to ensure that the patient is taking the medication correctly and document that discussion. RD, at 18–19; Tr. 140, 142. The pharmacist should also contact the prescribing physician to determine the purpose of the gap, and document that conversation if the red flag is resolved. RD, at 19; Tr. 341–42. The ALJ found, and the Agency agrees, that gaps between prescriptions exceeding one month was a red flag that Respondent should have identified, resolved, and documented prior to dispensing. RD, at 49–50.[11]

Respondent's Dispensing to A.T., T.B., K.B., and S.D.

Ms. Salinas testified in more detail about the prescriptions that she reviewed for A.T., T.B., K.B., and S.D. Ms. Salinas testified that she identified the following red flags with the prescriptions that Respondent dispensed to A.T.: (1) A.T. was receiving pattern prescriptions for a dangerous cocktail of hydrocodone and carisoprodol, RD, at 12; Tr. 118–19, 120–21; (2) A.T. was receiving the same controlled substances from at least six prescribers,[12] RD, at 17; Tr. 118–19, 136–38; (3) A.T. was also receiving non-controlled substances, such as ibuprofen and biofreeze, which implicates the one-to-one controlled to non-controlled substances pattern identified in the Texas Administrative Code, RD, at 17; Tr. 132, 137–38; (4) A.T. repeatedly received a high quantity of carisoprodol along with a high quantity of hydrocodone, which is a strong opioid that is best when limited to short-term use, RD, at 12; Tr. 119, 122–23; (5) many of A.T.'s prescriptions lacked a diagnosis code or any language indicating the purpose of the prescription, and others contained a non-specific diagnosis code of ''chronic pain syndrome,'' RD, at 15; Tr. 136–37, 331–32; GX 2, at 10–11, 84; and (6) there was a gap in A.T.'s prescriptions of over a month that indicated that she was not taking the medications as prescribed, RD, at 18–19; Tr. 139–41. Ms. Salinas testified that there was no documentation indicating that Respondent identified or resolved any of these red flags, and that Respondent therefore failed to exercise its corresponding responsibility and abide by the standard of care in its dispensing to A.T. RD, at 9; Tr. 139.[13]

Ms. Salinas testified that she identified the following red flags with the prescriptions that Respondent dispensed to T.B.: (1) T.B. was receiving pattern prescriptions for a dangerous cocktail of hydrocodone and carisoprodol, RD, at 11, Tr. 132–22; GX 5; (2) T.B. was also receiving non-controlled substances, such as ibuprofen and lisinopril, which implicates the one-to-one controlled to non-controlled substances pattern identified in the Texas Administrative Code, RD, at 12–13; Tr. 129–30, 131–32; GX 5; (3) T.B. was receiving these medications from multiple prescribers, RD, at 13, 17; Tr. 130–33; (4) T.B. repeatedly received a high quantity of carisoprodol along with a high quantity of hydrocodone (always over 100 tablets), which is a strong opioid that is best when limited to short-term use, RD, at 12–13; Tr. 122–23, 129–33; and (5) none of T.B.'s prescriptions for a fifteen-month period contained diagnosis codes. RD, at 15; Tr. 125–126, 333–34. Ms. Salinas testified that there was no documentation indicating that Respondent identified or resolved any of these red flags, and that Respondent therefore failed to exercise its corresponding responsibility and abide by the standard of care in its dispensing to A.T. RD, at 9; Tr. 134–35.[14]

Ms. Salinas testified that she identified the following red flags with the prescriptions that Respondent dispensed to K.B.: (1) K.B. was receiving pattern prescriptions for a dangerous cocktail of hydrocodone and carisoprodol in the same quantity each month, RD, at 11, 13; Tr. 143; GX 7; (2) K.B. was also receiving non-controlled substances, such as ibuprofen and biofreeze, which implicates the one-to-one controlled to non-controlled substances pattern identified in the Texas Administrative Code, RD, at 17; Tr. 129–32, 144–45; GX 6, at 1–2; (3) K.B. was receiving these medications from multiple prescribers, RD, at 17; Tr. 143–45; GX 6 at 1–2; (4) K.B. repeatedly received a high quantity of hydrocodone (over 100 tablets), which is a strong opioid that is best when limited to short-term use, RD, at 13; Tr. 122–23, 143; and (5) the vast majority of K.B.'s prescriptions lacked a diagnosis code. RD, at 15; Tr. 143–44; GX 6, at 24–25. Ms. Salinas testified that there was no documentation indicating that Respondent identified or resolved any of these red flags, and that Respondent

[11] Respondent, through counsel, argued in its closing argument that the Government is improperly tasking Respondent with communicating with prescribers during time periods where prescriptions are not presented to the pharmacy. RD, at 49; Tr. 520. Respondent argued that ''[t]he societal interest, including that of pharmacies, is to minimize the use and abuse of opioids,'' and thus Respondent should not be responsible for communicating with physicians when a patient is not prescribed controlled substances after previous, repeated monthly prescriptions. RD, at 49; Tr. 521. The ALJ found, and the Agency agrees, that this argument misconstrues Ms. Salinas's testimony. RD, at 49. According to Ms. Salinas, lengthy gaps in habitual prescriptions provides evidence of potential abuse and diversion. RD, at 49; Tr. 140. Ms. Salinas is not testifying that Respondent must attempt to dispense more medication to a patient when that patient is not issued the typical monthly prescription. RD, at 49. Rather, Respondent must contact the prescribing physician and document that communication when a patient returns to the pharmacy to receive the previously regular medication after a significant gap in treatment. *Id.;* Tr. 140–42, 154, 341–42. Aside from the argument presented in its closing statement, the Respondent presented no evidence to rebut Ms. Salinas's expert testimony that gaps between prescriptions presented a red flag that required documented resolution prior to dispensing. RD, at 49. Therefore, the Agency agrees with the ALJ and credits Ms. Salinas's unrebutted expert testimony about this red flag. *Id.* at 49–50.

[12] The Texas Administrative Code identifies patients ''obtaining similar drugs from multiple practitioners'' as a potential red flag factor, and Ms. Salinas testified that this is a common red flag that must be identified, resolved, and documented prior to dispensing. 22 Tex. Admin. Code § 291.29(f)(10); RD, at 16; Tr. 123–34; 340. The ALJ found that the Government had not proven that multiple prescribers was a red flag in this case because Dr. Okpala testified that several of the prescribers worked together in a group practice, that he visited the group practice frequently to ensure that the patients were being treated appropriately, and that he maintained professional relationships with all of the prescribers. RD, at 23, 43–47; Tr. 386–89, 391, 394, 398–99, 406, 467, 490, 502. However, Dr. Okpala's testimony on this issue is more relevant to whether the red flag of multiple prescribers can be resolved in this case, not whether multiple prescribers is a red flag that warrants follow up. Dr. Okpala's testimony actually supports the conclusion that multiple prescribers was a red flag. He testified that he visited the group practice on at least twenty occasions to ''make sure [the prescribers] [did] what [they were] supposed to do for patients,'' RD, at 23, 44; Tr. 387–89, 391, 394, which suggests that he felt the need to surveil the clinic, and he even testified that the doctors told him, ''okay, if you're doubting me, stay there and watch.'' Tr. 393. Thus, the Agency credits Ms. Salinas's credible expert testimony, as supported by Texas law, that multiple prescribers was a red flag that should have been identified, resolved, and documented. Dr. Okpala did not document any of his discussions with the prescribers or any other steps that he took to resolve this red flag, which is required by Texas law and the standard of care. 22 Tex. Admin. Code § 291.33(c)(2)(A)(iv); RD, at 8–10; Tr. 107–12, 142, 327. Even without this finding, the combination of other red flags is ''so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy.'' *Lewisville Medical Pharmacy,* 87 FR at 59,459 (citing *The Pharmacy Place,* 86 FR 21,008, 21,013 (collecting Agency decisions)).

[13] For more details about the prescriptions that Respondent filled for A.T. without identifying and resolving these red flags, *see* RD, at 30–50; GX 2–3.

[14] For more details about the prescriptions that Respondent filled for T.B. without identifying and resolving these red flags, *see* RD, at 30–50; GX 4–5.

therefore failed to exercise its corresponding responsibility and abide by the standard of care in its dispensing to K.B. RD, at 9; Tr. 146, 155; GX 6, 7.[15]

Ms. Salinas testified that she identified the following red flags with the prescriptions that Respondent dispensed to S.D: (1) S.D was receiving pattern prescriptions for a dangerous cocktail of hydrocodone and carisoprodol in the same quantity each month, RD, at 11, 13; Tr. 147; GX 9; (2) S.D. was also receiving non-controlled substances, such as gabapentin and naproxen, which implicates the one-to-one controlled to non-controlled substances pattern identified in the Texas Administrative Code, RD, at 13; Tr. 153; (3) S.D. was receiving these medications from multiple prescribers, RD, at 17; Tr. 132, 147, 151–52; GX 8 at 1–2; (4) S.D. repeatedly received a high quantity of hydrocodone, which is a strong opioid that is best limited to short-term use, RD, at 13; Tr. 122–23, 147; (5) none of S.D.'s prescriptions contain diagnosis codes, RD, at 15; Tr. 151; GX 8, at 9–10; and (6) there were gaps in S.D's prescriptions that indicated that S.D. was not taking the medications as prescribed. RD, at 19; Tr. 154. Ms. Salinas testified that there was no documentation indicating that Respondent identified or resolved any of these red flags, and that Respondent therefore failed to exercise its corresponding responsibility and abide by the standard of care in its dispensing to S.D. RD, at 9; Tr. 153–54; GX 8, 9.[16]

As for Respondent, Dr. Okpala testified that he did not observe any red flags with any of the prescriptions in this case, so there was ''[n]othing to resolve'' and nothing to document. Tr. 402. Respondent's counsel asked Dr. Okpala what he did if he encountered ''[prescriptions] that looked like red flags,'' and Dr. Okpala testified that he would follow up, call physicians, and speak to patients. RD, at 21; Tr. 402, 467, 479–80. Dr. Okpala testified that he ''did that on all these prescriptions.'' Tr. 467. When Government counsel asked Dr. Okpala why there were no notes on the prescriptions or in the patient file, Dr. Okpala replied, ''I mean, I know the patients; I know the doctors. I did my job professionally as a pharmacist, and I used my professional judgment, and that's what I did.'' Tr. 480.

Dr. Okpala's testimony that the prescriptions in this case did not present any red flags is simply not credible. The patterns presented by these prescriptions are specifically identified in the Texas Administrative Code as potential red flag factors, and Ms. Salinas offered credible expert testimony with respect to each red flag. Dr. Okpala testified that he took steps to verify the legitimacy of these prescriptions, despite his belief that there were no red flags. However, even assuming *arguendo* that Dr. Okpala did take these steps for the relevant prescriptions, he did not document his actions as required by the Texas standard of care. Moreover, it is unclear what Dr. Okpala would have discussed with the patients and physicians if he did not believe that any red flags existed. RD, at 51. Therefore, the Agency does not credit Dr. Okpala's testimony that these prescriptions did not present red flags, or that Dr. Okpala satisfied his obligation to ensure that there were no red flags. RD, at 51.

Thus, the ALJ found, and the Agency agrees, that the standard of care in Texas requires that any red flags present for a prescription must be resolved before dispensing and that the resolution must be documented. RD, at 27–53. The ALJ also found, and the Agency agrees, that Respondent failed to do this, rendering Respondent's dispensing to A.T., T.B., K.B., and S.D. outside the usual course of professional practice and in violation of the Texas standard of care. *Id.* The Agency further finds that Respondent failed to exercise sound professional judgment in filling the prescriptions in this case. RD, at 9; Tr. 328.

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 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (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 27–33; *see also id.* at 27 n.78 (finding that Factors A, C, and E do not weigh for or against revocation [17]).

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 27–54.

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 21,156, 21,162 (2022). In the current matter, the Government has alleged that Respondent violated numerous federal and state laws regulating controlled substances. OSC/ISO, at 2–9. 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

[15] For more details about the prescriptions that Respondent filled for K.B. without identifying and resolving these red flags, *see* RD, at 30–50; GX 6–7.

[16] For more details about the prescriptions that Respondent filled for S.D. without identifying and resolving these red flags, *see* RD, at 30–50; GX 8–9.

[17] Regarding Respondent's argument that the lack of disciplinary action against Respondent or Dr. Okpala was not given appropriate weight in the public interest analysis (Exceptions, at 2–3), this point was addressed by the ALJ in considering Public Interest Factors A, C, and E and the Agency agrees with the ALJ's analysis.

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). DEA has consistently interpreted this provision as prohibiting 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.'' *Medicine Shoppe-Jonesborough,* 73 FR 364, 381 (2008) (citing *Medic-Aid Pharmacy,* 55 FR 30,043, 30,044 (1990)). DEA has further held that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990).

As for state law, Texas Administrative Code § 291.29(b) requires pharmacists to ''make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.'' 22 Tex. Admin. Code § 291.29(b). The statute further requires pharmacists to ''make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility,'' by considering a list of nineteen ''patterns (*i.e.,* red flag factors) [that] are relevant to preventing the non-therapeutic dispensing of controlled substances.'' *Id.* § 291.29(f). These red flag factors ''shall be considered by evaluating the totality of the circumstances rather than any single factor.'' *Id.*

In addition, Texas law requires pharmacists to ''exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order they dispense,'' which requires ''verify[ing] the order with the practitioner prior to dispensing'' ''[i]f the pharmacist questions the accuracy or authenticity of a prescription drug order.'' *Id.* 291.34(b)(1)(A). Finally, Texas law requires that ''[p]rior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained . . . .'' *Id.* § 291.33(c)(2)(A)(iv).

In the current matter, the Agency agrees with the ALJ's analysis that Respondent's dispensing fell below the Texas standard of care, and thus was outside the usual course of professional practice, because, as detailed above, Respondent dispensed numerous controlled substance prescriptions to four patients without properly addressing and resolving clear red flags of abuse and diversion including dangerous drug cocktails, pattern prescriptions for high doses and quantities of commonly abused controlled substances, and patients receiving controlled substances from multiple prescribers. *See* RD, at 27–53.

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 27–53. Accordingly, the Agency 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.*

Respondent's Exceptions

Respondent argues in its Exceptions that the determination of whether a red flag exists is subjective and it is made by the pharmacist based on the totality of circumstances at the time of dispensing. Exceptions, at 3, 8–11. Respondent argues that the ALJ erred by giving more weight to Ms. Salinas's testimony about the existence of red flags than to Dr. Okpala's, because ''an expert witness's testimony cannot replace the subjective thoughts of a pharmacist when they are filling a prescription.'' *Id.* Respondent further argues that the duty to resolve and document the resolution of a red flag only arises if the pharmacist subjectively determines that a red flag exists. *Id.*

The Agency has repeatedly rejected these arguments. In a recent case in Texas, the respondent's owner and PIC testified, like Dr. Okpala, that red flags explicitly listed in Texas law were not actually red flags, and that there is no duty to document if the pharmacist does not identify any red flags. *Lewisville Medical Pharmacy,* 87 FR 59,456, 59,459 (2022). The Agency found that this testimony was ''evidence that Respondent was willfully blind to red flags on the prescriptions it filled,'' and that it ''evidences, at best, a deep and endemic understanding of Texas and federal law.'' *Id.* at 59,459–60. Here, the Agency likewise finds that Dr. Okpala's testimony reflects a troubling indifference towards Texas law and supports a finding that he was willfully blind to the numerous red flags presented by the prescriptions in this case.

Respondent also argues in its Exceptions that Dr. Okpala knew that the prescriptions were issued for a legitimate medical purpose because he had spoken to the doctors and he knew that they had valid doctor-patient relationships with the patients at issue. Exceptions, at 7–10. This argument again reflects a deep misunderstanding of a pharmacist's professional obligations under federal and Texas law. A pharmacist must always exercise his corresponding responsibility to identify, resolve, and document red flags, even where the prescriptions are ultimately determined to be legitimate, and even where there ultimately is a valid doctor-patient relationship. Respondent undeniably failed to fulfill this obligation. Respondent's Exception also implies that every prescription that is issued in a valid doctor-patient relationship is legitimate, but Respondent offers no support for this assertion. And regardless of whether Respondent believed that the prescribers in this case had valid doctor-patient relationships with their patients, the evidence overwhelmingly suggests that the prescriptions that they issued were not legitimate. Prior Agency decisions have consistently found that prescriptions with a similar list of red flags were ''so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy,'' [18] and Ms. Salinas credibly testified that there were numerous red flags that created doubt as to whether the prescriptions in this case were legitimate. RD, at 9; Tr. 336. Ms. Salinas's testimony that the prescriptions raised numerous suspicions—such as repeated pattern prescriptions for high-dose opioids and dangerous combinations of controlled substances—stands in stark contrast to Dr. Okpala's testimony that it was ''common sense'' to assume that hydrocodone was permissibly being prescribed for chronic pain. RD, at 39; Tr. 342, 497. This testimony reflects a troubling indifference towards the dangers posed by repeated prescriptions for a Schedule II controlled substance, and it further reinforces that Dr. Okpala does not understand his corresponding responsibility.

Finally, Respondent argues in its Exceptions that the Government failed to prove that the prescriptions were

[18] *Lewisville Medical Pharmacy,* 87 FR at 59,459 (citing *The Pharmacy Place,* 86 FR 21,008, 21,013 (collecting Agency decisions)).

invalid, that they were issued for non-therapeutic purposes, or that Respondent dispensed them inaccurately. Exceptions, at 2, 7–8. Again, Respondent's Exception misconstrues the applicable legal standard. The Government need not demonstrate that a prescription was invalid, non-therapeutic, or illegitimate in order to prove that a pharmacist violated his corresponding responsibility. The Government need only prove that the pharmacist failed to identify, resolve, and document red flags presented by a prescription, which, here, Respondent repeatedly failed to do.

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 it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18,882, 18,910 (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 62,316, 62,339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33,738, 33,746 (2021).

Here, and as noted by the ALJ, Respondent's PIC explicitly denied any responsibility for repeatedly filling prescriptions in violation of state and federal law. RD, at 55. Dr. Okpala repeatedly testified that he did not observe any red flags with any of the prescriptions in this case and that he strictly follows the relevant law and regulations. RD, at 55; Tr. 402, 414–15, 452, 460, 467, 474–75, 503. As such, the ALJ concluded, and the Agency agrees, that Respondent has not demonstrated unequivocal acceptance of responsibility for its actions. RD, at 56–57 (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,201–202 (2016)).[19]

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 74,800, 74,810 (2015). In this case, the Agency agrees with the ALJ that the interests of specific deterrence motivate in favor of revocation given that Respondent's PIC filled many of the prescriptions at issue, yet failed to acknowledge that any red flags existed or required resolution. RD, at 58–59. As the ALJ noted, Respondent continues to reject the notion that pharmacists have a duty to identify and resolve red flags prior to dispensing, which indicates that Respondent has not been rehabilitated. *Id.* at 55–56. Respondent argues in its Post-Hearing Brief (PHB) that ''there is no cause of action in Texas for 'red flags' or failing to meet 'corresponding duty,' '' despite having been confronted in this proceeding with numerous federal and state laws that explicitly articulate this obligation. *Id.* (citing Respondent's PHB, at 5). Portions of Dr. Okpala's testimony indicate that Dr. Okpala is more focused on avoiding further government scrutiny than complying with federal and state law. RD, at 56. Dr. Okpala testified that he has never had a problem in his thirty years of practicing pharmacy, but that he will maintain better documentation in the future because ''having this court order [ ] told [him] that.'' RD, at 56; Tr. 402–03, 468. Further, Dr. Okpala's failure to acknowledge the dangers of concurrent prescriptions for opioids and benzodiazepines is troubling and indicates that Respondent cannot be trusted to safely dispense controlled substances. The Agency also agrees with the ALJ that the interests of general deterrence 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. *Id.* at 59.

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. *Id.* at 57–58. As the ALJ noted, Respondent dispensed dangerous combinations of controlled substances to four patients over a two-year period without resolving multiple red flags indicative of abuse and diversion. *Id.* at 57–58. Ms. Salinas testified that the nature of the controlled substances issued by the Respondent ''put people in danger.'' [20] *Id.* at 58; Tr. 288. 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. RD, at 58–59. 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. FA2332346 issued to Awesome Care 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 Awesome Care Pharmacy, to renew or modify this registration, as well as any other pending application of Awesome Care Pharmacy, for additional registration in Texas. This Order is effective October 16, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 10, 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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[19] 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 5,479, 5,498 n.33 (2019) (citing *Jones Total Health Care Pharmacy,* 81 FR at 79,202–303); *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,801, 74,810 (2015). Even so, in the current matter, Respondent did not identify any relevant remedial measures.

[20] Respondent noted in its Exceptions that none of the medications it dispensed caused adverse reactions, which Respondent argues supports a conclusion that ''Respondent did not fill any 'unlawful' prescription [sic].'' Exceptions, at 7. However, it is not necessary for the Agency to find patient harm to revoke a registration. *Melanie Baker, N.P.,* 86 FR 23,998, 24,009 (2021); *Larry C. Daniels, M.D.,* 86 FR 61,630, 61,660–61 (2021); *Jeanne E. Germeil, M.D.,* 85 FR 73,786, 73,799 n.32 (2020). Moreover, Ms. Salinas testified that a pharmacist's corresponding responsibility to address red flags remains in place even if a patient does not physically suffer any adverse effects from a medication or drug cocktail. RD, at 9; Tr. 329.