DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 24–1]

Neumann's Pharmacy, LLC; Decision and Order

On September 12, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Neumann's Pharmacy, LLC, of Tallulah, Louisana (Respondent). OSC, at 1. The OSC proposed the revocation of Respondent's DEA Certificate of Registration Number FN4373293, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 824(a)(4), 823(g)(1)).

A hearing was held before DEA Administrative Law Judge Teresa A. Wallbaum (the ALJ), who, on June 18, 2024, issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), recommending that Respondent's registration be revoked. RD, at 41. Respondent filed exceptions to the RD.[1] Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,[2] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD and summarizes and clarifies portions thereof herein.

I. Louisiana Standard of Care

Dr. DiGi Graham testified as the Government's expert regarding the standard of care for pharmacy practice in the State of Louisiana. *Id.* at 5; Tr. 96–97. Dr. Graham has been licensed as a pharmacist in Oklahoma [3] for approximately thirty years and has extensive experience dispensing medications in retail pharmacies. RD, at 6; Tr. 90–91. Dr. Graham has worked for several independent pharmacies, including opening her own compounding and retail pharmacy in 2002, and she currently works as a consultant. *Id.* The Agency agrees with the ALJ that Dr. Graham was a reliable and persuasive witness who drew on her own experience in retail pharmacy, clearly articulated the standard of care in Louisiana,[4] and ''clearly identified each source [that] she consulted to form her opinion on the standard of care for pharmacies in Louisiana.'' *Id.* at 7; Tr. 7. Thus, the Agency agrees with the ALJ that Dr. Graham's testimony was fully credible and reliable. RD, at 7.

Dr. Julie Akers, a Washington-licensed pharmacist,[5] and Laura Neumann, Respondent's owner and Pharmacist-in-Charge (PIC), testified on Respondent's behalf. Dr. Akers has been working as a pharmacist for approximately twenty-five years. *Id.* at 8; Tr. 275. Dr. Akers started her career as a retail pharmacist, eventually progressing to a management position where she oversaw compliance of thirty pharmacies, before transitioning to academia in 2013.[6] RD, at 8; Tr. 274–75. The Agency agrees with the ALJ that Dr. Akers ''has limited reliability as an expert'' because her testimony regarding the standard of care ''was, at times, unclear and contradictory.'' RD, at 9. For example, as discussed in more detail below, Dr. Akers offered contradictory testimony about whether the standard of care requires pharmacists to document the resolution of red flags.[7] *Id.* Thus, the Agency agrees with the ALJ that Dr. Akers's testimony is ''diminished relative to Dr. Graham's,'' and credits Dr. Graham's testimony where the two experts disagree.[8] *Id.*

Ms. Neumann, Respondent's owner and PIC, has been licensed as a pharmacist in Louisiana since 1995. Ms. Neumann worked for several independent pharmacies until she bought Respondent in 2014. *Id.* at 9–10; Tr. 398–400. The Agency agrees with the ALJ that Ms. Neumann had diminished credibility because she was generally guarded and not forthcoming, and her testimony regarding the standard of care was internally inconsistent and confusing. RD, at 13. For example, Ms. Neumann offered contradictory testimony about whether the standard of care requires pharmacists to document the resolution of red flags. RD, at 14; *compare* Tr. 457 (agreeing that the standard of care requires documenting conversations with prescribers and resolution of red flags), *with* Tr. 458 (testifying that there was no obligation to document red flags until 2023). Additionally, Ms. Neumann's testimony primarily consisted of providing *post hoc* justifications for Respondent's dispensing decisions, which are not documented in any of Respondent's records. The Agency does not credit these justifications. *See infra* Section I, Resolving and Documenting Red Flags. Accordingly, the Agency agrees with the ALJ that Ms. Neumann's testimony is entitled to little weight. RD, at 14.

The Corresponding Responsibility

Dr. Graham testified that the Louisiana standard of care requires knowledge of, and compliance with, all applicable Federal and State laws. *Id.;* Tr. 105 (Graham). As relevant here, the Louisiana standard of care is informed by several provisions of the Louisiana Administrative Code. Dr. Graham and Dr. Akers testified that while a prescribing practitioner has the primary responsibility for the proper prescribing of controlled substances, the pharmacist who dispenses the prescription has a

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

[2] The Agency adopts the ALJ's summary of each witness's testimony, as well as the ALJ's assessment of each witness's credibility. *See* RD, at 3–19.

[3] Although Dr. Graham is not licensed as a pharmacist in Louisiana, she familiarized herself with the standard of care for dispensing controlled substances in Louisiana by reviewing provisions of the Louisiana Administrative Code. RD, at 6; Tr. 96–98. She testified that the law governing the practice of pharmacy in Louisiana is substantially similar to the law governing the practice of pharmacy in Oklahoma, the State in which she is licensed, and that she has consulted on other cases in Louisiana. RD, at 6; Tr. 97, 99, 101–02.

[4] For Dr. Graham's full qualifications, *see* RD, at 5–6; GX 10.

[5] Dr. Akers is not licensed as a pharmacist in Louisiana. RD, at 8; Tr. 278–79. However, Dr. Akers reviewed the statutes and regulations pertaining to pharmacy practice in Louisiana, including the portions of the Louisiana Administrative Code cited by the Government in this case, and performed her own individual research on Louisiana pharmacy practice to determine where Louisiana law overlapped with Federal law. RD, at 8; Tr. 278.

[6] For Dr. Akers's full qualifications, *see* RD, at 8–9; RX 1.

[7] Respondent argues in its Exceptions that Dr. Akers's testimony regarding the standard of care for documenting red flags was not contradictory, and that the ALJ erred in finding that Dr. Akers had only ''limited reliability'' as an expert. Exceptions, at 7. As discussed in more detail herein, the Agency agrees with the ALJ's assessment of Dr. Akers's testimony regarding documentation, and with the ALJ's credibility assessment. RD, at 9.

[8] The ALJ also found that Dr. Akers's testimony was diminished relative to Dr. Graham's because ''Dr. Akers did not actually articulate many portions of the standard of care until she was testifying about a specific patient.'' RD, at 9 (citing, *e.g.,* Tr. 325–26). Respondent takes exception to this finding, arguing that it is not necessarily helpful or relevant for an expert to opine on the standard of care in the abstract, because ''[w]hat is required in a given situation depends on what is known to the pharmacist and the unique circumstances peculiar to a patient.'' Exceptions, at 19–20. While the Agency agrees that it is important for an expert witness to testify about the specific circumstances surrounding each patient, it is also important for an expert witness to summarize certain fundamental principles of the standard of care to help the Agency assess whether the expert's opinions are consistent with State and Federal law and to help the Agency adjudicate any disagreements among experts regarding the standard of care. As discussed in the RD and throughout this Decision, Dr. Akers's testimony on the standard of care was often vague and amorphous, which allowed her to draw opportunistic conclusions about each patient based on curated information from patient files. Thus, the Agency agrees with the ALJ's assessment of Dr. Akers's credibility and reliability and with the amount of weight that she afforded Dr. Akers's testimony. RD, at 8–9.

''corresponding responsibility'' to ensure that each prescription was issued for a legitimate medical purpose in the usual course of professional practice. RD, at 14–15; Tr. 107–09 (Graham), 284 (Akers); La. Admin. Code tit. 46, part LIII, sections 2745(B)(1), 2747(E)(2) (2023).[9]

Identifying Red Flags of Abuse or Diversion

To determine whether a prescription was issued for a legitimate medical purpose in the usual course of professional practice, a pharmacist must examine each prescription for ''red flags'' of abuse or diversion of controlled substances. RD, at 15; Tr. 110 (Graham), 285 (Akers). A red flag is ''any little alert that requires [a pharmacist] to dig a little deeper and clarify information prior to dispensing.'' RD, at 15; Tr. 110 (Graham); *see also* Tr. 285 (Akers) (red flags are ''things that are deemed cautionary to where a pharmacist should take pause and use their clinical judgment to review that patient's file and make a determination if it's appropriate, if it meets that legitimate purpose or if it does not''). The Louisiana Administrative Code requires pharmacists to review ''the patient record and each prescription'' for seven ''potential situations,'' including ''drug over-utilization or under-utilization; therapeutic duplication; drug-disease contradictions; drug-drug interactions; inappropriate drug dosage or treatment duration, drug-allergy interactions; or clinical abuse/misuse.'' [10] La. Admin. Code tit. 46, part LIII, section 515(a) (2024); RD, at 15; Tr. 109 (Graham). Dr. Graham and Dr. Akers testified about additional red flags that pharmacists must address and resolve before dispensing a controlled substance.

Dr. Graham testified that drug cocktails are combinations of controlled substances that are known to be diverted and may cause significant patient harm. RD, at 15; Tr. 118–20 (Graham), 288 (Akers). For example, opioids and benzodiazepines are both respiratory depressants that can result in a drug-drug interaction causing significant sedation, respiratory depression, coma, or death when taken together. RD, at 15; Tr. 119–20 (Graham). Thus, Dr. Graham testified that concurrent prescriptions for opioids and benzodiazepines are a red flag in Louisiana. *Id.* Therapeutic duplication is when two or more drugs are prescribed together that ''essentially do the same thing in the body.'' RD, at 15; Tr. 120 (Graham). Dr. Graham testified that this is a red flag because it can cause patient harm. RD, at 15; Tr. 119–20 (Graham).

Dr. Graham further testified that making a ''cash payment'' for a controlled substance, rather than billing insurance, is a red flag, because a patient may pay in cash to evade the insurance company's attempts to monitor for abuse and diversion. RD, at 15; Tr. 81, 121–22, 137–38, 145–46 (Graham). A ''cash payment''—also known as ''private pay''—refers to any type of payment that is made without billing insurance, and can include actual cash, or payments with a debit or credit card. *Id.*

Resolving and Documenting Red Flags of Abuse or Diversion

Two points on which Dr. Graham and Dr. Akers disagreed were the methods of resolving a red flag and the methods of documenting that resolution. RD, at 16. According to Dr. Graham, a pharmacist can resolve a red flag by speaking to the prescriber or the patient, depending on the type of red flag, to obtain more information about whether the prescription was issued for a legitimate medical purpose. *Id.;* Tr. 113. The pharmacist must then document the resolution of the red flag on the hard copy prescription, in the pharmacy's computer system, or in a logbook. RD, at 16; Tr. 112; *see also* La. Admin. Code tit. 46, part LIII, section 1123(L) (2021) (setting forth the recordkeeping requirements for patient profiles, including documenting ''any other comments that are relevant to that patient or a specific drug'').[11] Dr. Graham testified that in the practice of pharmacy, ''we document, or it doesn't happen.'' RD, at 16; Tr. 112, 118. Consistent with Dr. Graham's testimony, Louisiana law requires pharmacists to maintain a patient record system that documents the resolution of red flags, including a pharmacist's comments ''relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug.'' La. Admin Code tit. 46, pt. LIII, section 1123(L).

According to Dr. Akers, a pharmacist may resolve a red flag by examining ''the totality of the patient's file'' with the pharmacy, including the fill history, the diagnosis code on the prescription, and the type of provider who issued the prescription. RD, at 16; *see* Tr. 290–99. Essentially, the pharmacist can look to see whether the patient's file ''tells a clinically appropriate story'' to determine if a prescription was issued for a legitimate medical purpose, without contacting the doctor or speaking to the patient. *See, e.g.,* Tr. 290–92, 295–97, 306–13, 315, 325–26, 335, 359. Although Dr. Akers testified that the standard of care in Louisiana requires pharmacists to identify and document the resolution of red flags, Tr. 361, she implied that the patient profile itself could serve as the requisite documentation of the resolution of a red flag as long as the patient profile contained facts that justify the prescription. *Id.* at 361–62. Under Dr. Akers's view, a pharmacist's documentation can be adequate even if the patient profile does not contain any documentation indicating that the pharmacist actually identified and resolved the red flags, as long as the patient's file ''tells a clinically appropriate story.'' *Id.*

On both points, the ALJ found, and the Agency agrees, that Dr. Graham's testimony is more credible than Dr. Akers's. RD, at 16. Dr. Akers's testimony on resolving and documenting red flags is inconsistent with the pharmacist's independent corresponding responsibility, because it allows the pharmacist to make assumptions about the patient's treatment based on the prescriptions issued rather than investigating the actual purpose of the prescription by speaking to the prescriber or patient. *Id.* at 17. It also allows pharmacists to fabricate any undocumented, *post hoc* explanation that may seem plausible, which would make it impossible for DEA or any other

[9] There were no substantive changes to the relevant portions of the Louisiana Administrative Code cited herein during the time period of the allegations in this case.

[10] Respondent argues that Dr. Graham's articulation of a red flag as ''any little alert that requires [a pharmacist] to dig a little deeper and clarify information prior to dispensing'' is inherently vague and ''contradicts with the clear and express requirements of La. Admin. Code tit. 46, part LIII, section 515(a).'' Exceptions, at 22. While Dr. Graham's articulation of a red flag is certainly broader than the Louisiana statute in that it requires pharmacists to investigate suspicious circumstances beyond those enumerated, Respondent has not offered any explanation for why it believes that Dr. Graham's articulation ''contradicts'' the statute. Both Dr. Graham and Dr. Akers (who articulated a similarly broad definition of red flags) testified that the concept of a red flag derives from the pharmacist's corresponding responsibility under State and Federal law to review each prescription to ensure that it was issued for a legitimate medical purpose prior to dispensing. Tr. 109–11 (Graham), 284 (Akers). The experts' testimony suggests that the corresponding responsibility imposes more expansive prescription review requirements on pharmacists than Louisiana Administrative Code title 46, part LIII, section 515(a).

[11] Dr. Graham testified that if a pharmacist identifies, resolves, and documents the resolution of a red flag on an initial fill of a medication, that resolution may carry forward to future refills. RD, at 16; Tr. 113. The resolution of red flags on refills may be documented by pulling the hard copy of the prescription and signing and dating a note that the pharmacist referenced the resolution. Tr. 114–15.

regulatory body to determine whether the pharmacist actually exercised its corresponding responsibility before filling the prescription.[12] *Id.* As the Eleventh Circuit stated, a respondent pharmacy ''fail[s] to comply with its corresponding responsibility not to fill prescriptions written for illegitimate purposes'' when it fails to ''tak[e] and document[ ] steps to resolve . . . red flags or refusing to fill prescriptions with unresolvable red flags.'' *Pharmacy Doctors Enterprises Inc., d.b.a. Zion Clinic Pharmacy,* 789 F. App'x 724, 731 (11th Cir. 2020). The Eleventh Circuit also categorically labeled ''false'' respondent's suggestion that ''DEA itself has held that the lack of documentation of resolution of a red flag is 'not evidence that a pharmacist failed to resolve a red flag.' '' *Id.*

Dr. Graham's testimony was consistent with the longstanding principle that documentation is a critical step in resolving red flags and dispensing a lawful prescription. When asked whether a failure to document the resolution of a red flag invalidates any efforts to resolve the red flag, Dr. Graham replied, ''Correct. Because if it's not documented, it wasn't done.'' Tr. 191. Thus, the Agency credits Dr. Graham's formulation of the standard of care regarding the resolution of red flags, and finds that if a pharmacist identifies a red flag when presented with a prescription, the Louisiana standard of care requires the pharmacist to: (1) speak to the prescriber or patient to obtain more information about whether the prescription was issued for a legitimate medical purpose; and (2) document the resolution of the red flag on the hard copy prescription, in the pharmacy's computer system, or in a logbook prior to dispensing. RD, at 16, 19; Tr. 112–13.

II. Findings of Fact

Respondent's Improper Dispensing to C.E.

Respondent filled prescriptions for C.E. in July 2021, October 2021, and December 2021 for hydrocodone-acetaminophen (a Schedule II opioid) and clonazepam (a Schedule IV benzodiazepine).[13] RD, at 19; ALJX 11, at 2–3, stips. 11–12, 18; GX 5, at 2; Tr. 127. Dr. Graham testified that this drug cocktail raised a red flag due to the drug-drug interaction. RD, at 19; Tr. 127. Dr. Graham testified that the standard of care required Respondent to resolve this red flag, usually by speaking to the prescriber, and to document the resolution on the hard copy of the prescription, in the pharmacy's computer system, or in a logbook. RD, at 19; Tr. 131.

As for Respondent, Ms. Neumann testified that she resolved the red flag based on the diagnosis codes on the prescriptions and having ongoing conversations with C.E. regarding his medical conditions.[14] RD, at 19; Tr. 443–45. According to Ms. Neumann, C.E. was receiving prescriptions for hydrocodone for ''injuries or shoulder pain'' from Dr. T.N., Ms. Neumann's father, while C.E. was between specialists. RD, at 12; Tr. 443. Regarding the clonazepam, Ms. Neumann testified, ''I think that on the prescription for the clonazepam, it indicates that he was having some anxiety, which is natural when you're in pain.'' *Id.* Ms. Neumann testified that she ''did not see that there was a risk of overdose'' because C.E. only received a few prescriptions. *Id.* Ms. Neumann also testified that C.E. informed her that he had some type of cervical issue. RD, at 12–13; Tr. 444.

However, Ms. Neumann did not document any of these discussions, and there was no documentation resolving the red flag in C.E.'s patient profile or on the hard copy prescriptions. RD, at 19; GX 4, at 1–2, 9–10, 23–26, 48–51; Tr. 130–31, 445. Thus, Dr. Graham opined, and the Agency finds substantial evidence that, Respondent's failure to resolve this red flag and document the resolution rendered Respondent's dispensing to C.E. outside the usual course of professional practice and beneath the Louisiana standard of care.[15] RD, at 20; Tr. 132.

Respondent's Improper Dispensing to J.H.R.

Respondent filled monthly prescriptions for J.H.R. between September 2020 and January 2022 for hydrocodone-acetaminophen and alprazolam (a Schedule IV benzodiazepine). RD, at 20; ALJX 11, at 2–3, stips. 11, 13, 19; GX 7, at 1; Tr. 133–36. Dr. Graham, Dr. Akers, and Ms. Neumann testified that this drug cocktail raised a red flag due to drug-drug interaction. RD, at 20; Tr. 133–34 (Graham), 383 (Akers), 420, 434, 454 (Neumann). Additionally, from March 2021 through September 2021, J.H.R. made cash payments for her controlled substance prescriptions, while billing insurance for her non-controlled substance prescriptions. RD, at 22–23; GX 6, at 2–3; GX 7, at 1–2; Tr. 137–38 (Dr. Graham testifying that the method of payment for non-controlled substances was ''Copay Generic,'' which indicates that insurance was billed, while the method of payment for controlled substances was ''RX Generic,'' which indicates that insurance was not billed). Dr. Graham testified that J.H.R.'s cash payments raised an additional red flag. RD, at 23–

[12] DEA has made clear that ''it is unwilling to credit post hoc written or oral justifications for actions taken as a registrant that were not documented,'' *AARRIC, Inc. d/b/a at Cost RX,* 87 FR 2905, 2916 (2022).

[13] The prescriptions for hydrocodone-acetaminophen and clonazepam were filled on different days, but always within the same week. RD, at 19 n.20; GX 4, at 2. Dr. Graham testified that the fact that the prescriptions were filled on different days does not eliminate the requirement to resolve the red flag because the patient would still be taking the medications at the same time. RD, at 19 n.20; Tr. 128–29.

[14] The Agency does not credit Dr. Akers's testimony about C.E. In order to resolve the red flags associated with the drug cocktail prescribed to C.E., Dr. Akers reviewed C.E.'s patient profile and made several assumptions about his treatment, including that the prescriptions came from a surgical hospital and a neurosurgery clinic, and that there was a ''very realistic probability'' that the prescribing doctor (Dr. C.) was a neurosurgeon. RD, at 17–18 n.17; Tr. 295–99, 306–13. Significantly, however, Dr. Akers's testimony ignored that the majority of the controlled substances at issue, and specifically those alleged in the OSC, were not issued by Dr. C., a neurosurgeon, but by Dr. T.N., Ms. Neumann's father. RD, at 17–18 n.17; GX 4 at 2, 9–10, 23–26, 48–51; GX 5, at 2; *see also* Tr. 443. Moreover, Ms. Neumann did not testify that she conducted the analysis outlined by Dr. Akers to resolve the red flag. Thus, Dr. Akers's testimony highlights that her holistic approach of reviewing the record and making assumptions about the patient's treatment allows a registrant to fabricate *post hoc* justifications that do not necessarily align with the facts.

Furthermore, even assuming, *arguendo,* that Dr. Akers had been able to ''tell[ ] a clinically appropriate story'' about C.E.'s prescriptions that was not contradicted by the record or by Ms. Neumann's testimony, that would not negate Respondent's corresponding responsibility to address, resolve, and document red flags prior to dispensing. Dr. Akers acknowledged that she does not know whether Respondent conducted a red flag review, and she testified that a red flag review was necessary in order for Respondent's dispensing to fall within the standard of care in Louisiana. Tr. 315, 364. The ALJ asked Dr. Akers whether ''dispensing the prescriptions for C.E. [would] fall within the Louisiana standard of care,'' and Dr. Akers replied, ''Yes, it would. *If* the pharmacist did their clinical review and made sure that the medications were for a legitimate purpose and that red flags were resolved.'' *Id.* at 315. She later testified that ''[t]here's nothing on the prescriptions that were provided . . . that documents the review . . . . [T]here's nothing that would tell me a pharmacist did or did not do a [drug utilization review] . . . .'' *Id.* at 364. Thus, the Agency does not credit Dr. Akers's testimony regarding C.E., and rejects Respondent's arguments in its Exceptions that Respondent adequately addressed and resolved the red flags for C.E. Exceptions 11–13.

[15] At the hearing, Respondent's counsel argued that C.E.'s billing of insurance for these prescriptions, the fact that the insurance company did not reject the claims, and that there was no evidence of early refills, ''lends further support to the legitimacy of the prescriptions.'' RD, at 20 n.22; Tr. 300–03. The Agency agrees with the ALJ that these inferences are attenuated and that they do not absolve Respondent from exercising its corresponding responsibility to ensure the legitimacy of the prescriptions prior to dispensing. RD, at 20 n.22.

24; Tr. 112, 121–22, 138–39. Dr. Graham testified that the standard of care required Respondent to resolve these red flags and document their resolution on the hard copy of the prescription, in the pharmacy's computer system, or in a logbook. RD, at 20, 24; Tr. 112, 136.

J.H.R.'s Cash Payments

Regarding the cash payments red flag, Ms. Neumann testified that J.H.R. has been a patient at Respondent since 2015. RD, at 11; Tr. 422–23, 426. Until March 2021, J.H.R. used insurance to pay for all medications, including controlled substances and non-controlled substances. *See* GX 6, at 2–3 (listing the method of payment for all drugs as ''Copay Generic''). Ms. Neumann testified that, at some point around March 2021, J.H.R.'s insurance company rejected coverage for one of her prescriptions. RD, at 11; Tr. 408–09. Ms. Neumann recalled asking J.H.R. whether she had a new insurance card, but J.H.R. reported that she had lost her job and no longer had insurance. *Id.* Ms. Neumann testified that from that point onward, J.H.R. paid for all of her prescriptions out of pocket. RD, at 11; Tr. 410. However, J.H.R.'s patient profile shows that from March 2021 through September 2021, the method of payment for controlled substances was ''RX Generic,'' while the method of paying for non-controlled substances was ''Copay Generic,'' which suggests that J.H.R. still had insurance but chose not to bill insurance for her controlled substances.[16] GX 6, at 2–3.

Ms. Neumann testified that she did not document her conversations with J.H.R., and there was no documentation resolving the cash payments red flag in J.H.R.'s patient profile or on the hard copy prescriptions. RD, at 11; Tr. 412. Thus, Dr. Graham opined, and the Agency finds substantial evidence that, Respondent's failure to resolve this red flag and document the resolution rendered Respondent's dispensing to J.H.R outside the usual course of professional practice and in violation of the Louisiana standard of care. RD, at 22–24; Tr. 139–40.

J.H.R.'s Drug Cocktails

Regarding the drug cocktails, Ms. Neumann acknowledged that the combination of hydrocodone-acetaminophen and alprazolam raised a red flag. RD, at 11; Tr. 420, 434. Ms. Neumann testified that when J.H.R. first became a patient in 2015, she contacted the prescriber, Dr. T.N. (Ms. Neumann's father), and resolved this red flag. RD, at 11; Tr. 420. She testified that she documented the resolution of the red flag on the back of prescriptions issued on August 17, 2015, November 16, 2015, and December 19, 2015, using the notations ''DD,'' ''M0,'' and ''1G.'' RD, at 11; Tr. 420, 422; RX 6 at 2, 4, 6. Dr. Akers testified that ''DD'' indicates a drug duplication, ''M0'' indicates a consultation with the prescriber, and ''1G'' indicates the prescription was filled after consultation with the prescriber. RD, at 11; Tr. 316–318.

The Agency rejects Respondent's arguments that her documentation in 2015 regarding the drug cocktails resolved the red flag for prescriptions issued between 2020 and 2022.[17] There was no documentation resolving the red flag for the prescriptions issued from 2020 through 2022 in J.H.R.'s patient profile or on the hard copy prescriptions. RD, at 21; GX 6, at 1–3, 24–27, 42–45; Tr. 136. Thus, Dr. Graham opined, and the Agency finds substantial evidence that, Respondent's failure to resolve this red flag and document the resolution rendered Respondent's dispensing to J.H.R outside the usual course of professional practice and in violation of the Louisiana standard of care. RD, at 20–22; Tr. 139.

Respondent's Improper Dispensing to S.W.

On six occasions between May 2020 and December 2021, Respondent dispensed diazepam (a Schedule IV benzodiazepine) along with three forms of butalbital (a Schedule III sedative)[18] to S.W. on the same day. RD, at 24; ALJX 11 at 3–4, stips. 9, 10, 14, 20; GX 9; Tr. 140–42. One of the butalbital products contained codeine (a Schedule III controlled opioid). ALJX 11 at 3–4, stips. 9–10. Combining diazepam with codeine and butalbital can increase the risk of respiratory depression, coma, and death, and both Dr. Graham and Dr. Akers testified that this drug cocktail raised a red flag due to the drug-drug interaction. RD, at 24; Tr. 141 (Graham), 335 (Akers). Dr. Graham testified that these prescriptions also raised the red flag of therapeutic duplication. RD, at 25; ALJX 11, at 4, stip. 20; GX 9; Tr. 143–44. Dr. Graham testified that ''there[is] no rationale to use three different [butalbital] products like this together.'' Tr. 143.[19] Dr. Graham

[16] Respondent argues, based on Dr. Akers's testimony, that from March 2021 through September 2021, the non-controlled substance prescriptions were actually paid for using a discount prescription card, rather than insurance. Exceptions, at 14–16; ALJX 27, at 4; RD, at 23. Thus, according to Respondent, J.H.R.'s cash payments were not a red flag, because J.H.R. did not have insurance. *Id.* However, Respondent did not produce any evidence to corroborate Dr. Akers's testimony that a discount prescription card was used, nor is there any documentation in J.H.R.'s patient file indicating that J.H.R. lost her insurance in March 2021. Notably, Ms. Neumann did not testify that J.H.R. used a discount prescription card, nor did she offer any explanation for why J.H.R.'s non-controlled prescriptions continued to show up as ''Copay Generic'' after she allegedly lost her insurance in March of 2021. *See* Tr. 407–10 (testifying that J.H.R.'s insurance card was rejected in March of 2021, and from that point onward, J.H.R. ''paid the total out-of-pocket cost [of the prescriptions] herself.'') Thus, the Agency credits Dr. Graham's testimony that the record indicates that the non-controlled substance prescriptions were paid for using insurance from March 2021 through September 2021, and that this is a red flag that was not resolved. *Id.;* Tr. 137.

[17] Dr. Akers testified that the prescriptions issued from 2020 through 2022 were a ''continuation of therapy'' from the prescriptions in 2015, and that Respondent's notations on the 2015 prescriptions were sufficient to resolve the red flags for the later prescriptions. RD 20–21; Tr. 325–26; Exceptions, at 14–16. On the other hand, Dr. Graham testified that a pharmacist may only carry over a red flag resolution for a refill of a prescription, and refills are not permitted for hydrocodone, a Schedule II controlled substance. RD, at 21; Tr. 113–15; La. Admin. Code tit. 46, part LIII, section 2745(F)(3)(a) (''The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.'').

The ALJ found, and the Agency agrees, that Dr. Graham's testimony on this issue was more credible than Dr. Akers's. RD, at 21–22, 21 n.23. Neither Dr. Akers nor Respondent produced convincing evidence, supported by concurrent documentation, to establish that the 2020 prescriptions were a ''continuation of therapy'' from 2015. RD, at 21–22 n.23. As the ALJ noted, there is a significant gap between the 2015 prescriptions and the first prescription charged in the OSC dated September 2020. *Id.* It is entirely possible that the prescriptions did change between 2015 and 2020. *Id.* Respondent's failure to produce relevant documents for that time period showing that the prescriptions did not change gives rise to an inference that those documents do not exist. *Huthnance* v. *DC,* 722 F.3d 371, 378 (D.C. Cir. 2013) (''Respondent's decision not to provide records gives rise to an inference that any such evidence is unfavorable to Respondent.'')), *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.2d 1329, 1336 (D.C. Cir. 1972); *see also* RD, at 21–22 n.23. *Id.* Thus, without documentation confirming that the prescriptions were a ''continuation of therapy,'' Respondent cannot substantiate its argument. RD, at 21–22 n.23 (citing *Coconut Grove Pharmacy,* 89 FR 50372, 50374 (2024)). Moreover, Dr. Akers acknowledged that she asked Respondent's counsel for J.H.R.'s records for the intervening years, but did not receive them. RD, at 21–22 n.23; Tr. 381–82. Dr. Akers conceded that the missing documents undermined the weight of her opinion. RD, at 21–22 n.23; Tr. 382, 385.

[18] The three butalbital prescriptions included the following combinations: butalbital-aspirin-caffeine, butalbital-acetaminophen-caffeine, and butalbital-aspirin-caffeine with codeine. GX 9.

[19] S.W. paid for all of her controlled substance and non-controlled substance prescriptions using cash, which Dr. Graham testified raised another red flag of abuse or diversion. RD, at 24; Tr. 145; GX 8 at 1–2; GX 9. Respondent argues, based on Dr. Akers's testimony, that cash payments are only a red flag if a patient has insurance, but chooses to pay for controlled substances with cash. RD, at 22 n.25; ALJX 27 at 14; Exceptions, at 5–7. The ALJ found, based on Dr. Graham's testimony, that cash payments are a red flag even if the patient does not have insurance, and concluded that Respondent failed to address and resolve the cash payments red flag for S.W. RD, at 22 n.25, 33; Tr. 121–22, 145.

testified that the standard of care required Respondent to resolve these red flags and document their resolution on the hard copy of the prescription, in the pharmacy's computer system, or in a logbook prior to dispensing. RD, at 24–25; Tr. 142, 145.

S.W.'s Drug Cocktails

As for Respondent, Ms. Neumann testified that she resolved the drug cocktail red flag through conversations with the prescriber, Dr. T.N. (Ms. Neumann's father), who told her that diazepam was indicated for muscle relaxation. RD, at 12; Tr. 436–37. However, there was no documentation of Ms. Neumann's discussions with Dr. T.N., nor was there any documentation resolving the drug-drug interaction red flag in S.W.'s patient profile or on the hard copy prescriptions. RD, at 24–25; Tr. 142, 414, 419; GX 8. Thus, Dr. Graham opined, and the Agency finds substantial evidence that, Respondent's failure to resolve this red flag and document the resolution rendered Respondent's dispensing to S.W. outside the usual course of professional practice and in violation of the Louisiana standard of care. RD, at 24–26; Tr. 147.

S.W.'s Therapeutic Duplication

Ms. Neumann testified that Dr. T.N. informed her that S.W. was taking each medication for a specific type of headache, and S.W. knew when to take each medication. RD, at 12; Tr. 419. Ms. Neumann testified that she spoke to S.W., and S.W. reported that she was alternating the butalbital products.[20] RD, at 12; Tr. 465. Ms. Neumann testified that S.W. is ''highly intelligent and very focused,'' and she counseled S.W. to avoid exceeding acetaminophen dosage limits. *Id.* Ms. Neumann testified that she would not have filled these prescriptions if she had not spoken to Dr. T.N. and S.W., and that these conversations allowed her to resolve this red flag. Tr. 419.

However, there was no documentation of Ms. Neumann's discussions with Dr. T.N. or S.W., nor was there any documentation resolving the therapeutic duplication red flag in S.W.'s patient profile or on the hard copy prescriptions. RD, at 24–25; Tr. 142, 414, 419; GX 8. Thus, Dr. Graham opined, and the Agency finds substantial evidence that, Respondent's failure to resolve this red flag and document the resolution rendered Respondent's dispensing to S.W. outside the usual course of professional practice and in violation of the Louisiana standard of care. RD, at 24–26; Tr. 147.

Respondent's Improper Dispensing to L.N.

On February 7, 2020 and March 6, 2021, Respondent filled controlled substance prescriptions for Ms. Neumann that were issued by Dr. T.N., Ms. Neumann's father.[21] RD, at 26; ALJX 11, at 3, stip. 16; GX 3; Tr. 347–48, 403. Louisiana law prohibits physicians from prescribing controlled substances to certain relatives, including children, except in cases of emergency. RD, at 26; La. Admin. Code, tit. 46, part XLV, section 7603(A)(11) (2024). Ms. Neumann acknowledged that these prescriptions were not lawful and that the Louisiana Administrative Code prohibits providers from issuing prescriptions to family members. RD, at 26; Tr. 405, 347–48. Thus, the Agency finds substantial evidence that Respondent did not dispense these prescriptions in accordance with the standard of care in Louisiana, and that these prescriptions were not dispensed in the usual course of professional practice. RD, at 26.

II. Discussion

A. The Controlled Substances Act (CSA)

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under . . . [21 U.S.C. 823] inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''pharmacy,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[22] The five factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. 243, 292–93 (2006) (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' citing *In re Arora,* 60 FR 4447, 4448 (1995)); 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. *Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007); *Morall,* 412 F.3d. at n.2; *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

According to DEA regulations, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied.'' 21 CFR 1301.44(e); *see also Morall,* 412 F.3d. at 174.

In this matter, while all of the 21 U.S.C. 823(g)(1) factors have been considered, the Agency finds that the Government's evidence in support of its *prima facie* case is confined to factors B and D. RD, at 26–28; *see also id.* at 28 n.30 (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 substantial record evidence that the Government satisfies its *prima facie* burden of showing that Respondent's continued registration is ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4); RD, at 26–34.

B. Allegation That Respondent's Registration Is Inconsistent With the Public Interest

Factors B and/or D—Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

According to the CSA's implementing regulations, a lawful prescription for

Based on the overwhelming nature of the evidence establishing Respondent's other misconduct in its dispensing of controlled substances, the Agency need not reach a factual finding with regard to the cash payment red flag for S.W.

[20] Dr. Akers testified that she deduced from looking at S.W.'s records that S.W. was alternating between the medications rather than taking them at the same time because there was a three-to-four-month gap between the prescriptions. RD, at 17 n.17, 25 n.28; Tr. 335. This alleviated Dr. Akers's concerns about the therapeutic duplication red flag. Tr. 335. However, Dr. Akers acknowledged that there were no instructions on the prescriptions telling the patient to alternate the medications, and there was no documentation in the record indicating that the patient was doing so. *Id.* at 369–71.

[21] These prescriptions were for guaifenesin-codeine, a Schedule V controlled substance (February 7, 2020), butalbital-aspirin-caffeine with codeine (March 6, 2021), and butalbital-aspirin-caffeine (March 6, 2021). ALJX 11 at 3, stips. 8, 16, 17; GX 3; Tr. 347–48, 403.

[22] The five factors of 21 U.S.C. 823(g)(1)(A–E) are:

(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.

controlled substances is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a); *see Gonzales* v. *Oregon, supra,* 546 U.S. at 274, *United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *rehearing den.,* 598 F.2d 620 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979); *see also* La. Admin. Code tit. 46, part LIII, sections 2745(B)(1), 2747(E)(2); GX 11, at 2; *supra* section I. Additionally, Louisiana law prohibits physicians from prescribing controlled substances to certain relatives, including children, except in cases of emergency. RD, at 26; La. Admin. Code, tit. 46, part XLV, section 7603(A)(11).

The Agency agrees with the Government expert's opinion and the ALJ's analysis, and finds that there is substantial record evidence that Respondent's dispensing fell below the Louisiana standard of care, and thus was outside the usual course of professional practice. This is because, as detailed above, the Agency finds that there is substantial record evidence that Respondent: (1) repeatedly dispensed controlled substances to three patients without properly addressing and resolving clear red flags of abuse and diversion, including dangerous drug cocktails with drug-drug interactions, therapeutic duplication, and cash payments for controlled substances; (2) failed to maintain appropriate records that documented the resolution of these red flags; and (3) filled several prescriptions for Ms. Neumann that were issued by Ms. Neumann's father, in violation of State law. *See* RD, at 19–34.

In sum, the Agency finds substantial record evidence that the Government established a *prima facie* case that Respondent violated Federal and State law. Accordingly, the Agency finds that the Government established a *prima facie* case, that Respondent did not successfully rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Respondent's registration. 21 U.S.C. 824(a)(4).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to Respondent to show why it can be entrusted with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy,* 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.,* 83 FR 18882 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy,* 881 F.3d at 833. A registrant's acceptance of responsibility must be unequivocal. *Id.* at 830–31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR 46972 and 46973.

A. Acceptance of Responsibility

Here, the ALJ found, and the Agency agrees, that there is substantial record evidence that Respondent failed to unequivocally accept responsibility for its repeated violations of Federal and State law. RD, at 35–37. Ms. Neumann explicitly denied responsibility for failing to address and resolve red flags. *See, e.g.,* Tr. 410, 420 (testifying that she resolved the red flags for J.H.R), 412–13, 418–19, 435–37 (testifying that she resolved the red flags for SW), 443–45 (testifying that she resolved the red flags for C.E.).[23] Although Ms. Neumann acknowledged that she failed to document the resolution of red flags, she denied that this failure rendered Respondent's dispensing beneath the standard of care. *Id.* at 395–96. She testified that until 2023, it was ''best practice'' to document the resolution of red flags, but it was not required by the standard of care. RD, at 12, 36; Tr. 458. However, she offered no support for how she chose this arbitrary date, which was conveniently outside the date of the allegations in the OSC. As explained above, Ms. Neumann's testimony conflicted with the testimony of Respondent's and the Government's expert, who both testified that documentation was required as part of the standard of care during the time period at issue here. RD, at 36. As the ALJ observed, if Ms. Neumann cannot even acknowledge that Respondent's failure to document fell below the standard of care, she cannot accept responsibility for it. *Id.*[24]

Ms. Neumann also made statements that minimized Respondent's misconduct. *Id.* The most glaring example was Ms. Neumann's characterization of the prescriptions that Respondent filled for Ms. Neumann that were written by Ms. Neumann's father, in violation of Louisiana law. *Id.* Ms. Neumann argues that Respondent's mistakes were ''inadvertent,'' and that she believed ''in good faith'' that the prescriptions were valid. *Id.;* ALJX 27, at 17. However, the law prohibiting physicians from prescribing controlled substances to their family members had been in effect for at least five years when Respondent filled the prescriptions at issue in this case, which indicates that Respondent's misconduct

[23] Respondent argues in its Exceptions that the ALJ erred in finding that Ms. Neumann failed to accept responsibility. Exceptions, at 22–23. Respondent argues that the Government only proved that Respondent failed to document the resolution of red flags, but it did not prove that Respondent failed to address and resolve red flags, so Ms. Neumann is only required to accept responsibility for her failure to document. *Id.* The Agency rejects this argument. As discussed throughout this Decision, documentation is a critical component of addressing and resolving red flags. Dr. Graham testified that in the practice of pharmacy, ''we document, or it doesn't happen.'' RD, at 16; Tr. 112, 118 (Graham). *See also* La. Admin. Code tit. 46, part LIII, section 1123(L) (2021) (setting forth the recordkeeping requirements for patient profiles, including documenting ''any other comments that are relevant to that patient or a specific drug''). The Agency may infer from a registrant's failure to document that the registrant failed to address and resolve red flags. *See supra* Section I, Resolving and Documenting Red Flags. The Agency makes that inference here, because Respondent's documentation in this case does not reflect any attempt to identify, address, or resolve red flags. Thus, in order to unequivocally accept responsibility, Respondent must accept responsibility for failing to address and resolve red flags, as well as for failing to document the resolution. Respondent did not unequivocally accept responsibility for either failure.

[24] *See Pharmacy Doctors Enterprises Inc., d.b.a. Zion Clinic Pharmacy,* 789 F. App'x at 732–33 (''Because the record supports the Acting Administrator's findings that [the respondent's PIC] . . . did not understand the scope of her responsibilities under the CSA, we conclude that the [Acting Administrator's] determination that [the respondent's PIC] did not fully accept responsibility for [the respondent's] misconduct was rational and supported by substantial evidence.'''); *Jones Total Health Care Pharmacy,* 881 F.3d at 833 (''Because the record supports the Acting Administrator's findings that [the respondent] did not acknowledge the prior misconduct and still did not understand the scope of her responsibilities under the CSA, we conclude that the determination that [the respondent] did not fully accept responsibility for [respondent's] misconduct was rational and supported by substantial evidence.'').

was much more serious than inadvertent, good faith violations.[25] *See* 41 La. Reg. 2146 (Oct. 20, 2015). Respondent's attempts to minimize this egregious misconduct undermine any purported acceptance of responsibility. *Michael A. White* v. *Drug Enf't Admin.,* 626 F. App'x 493, 496–97 (5th Cir. 2015); RD, at 36 (citing *Medical Pharmacy,* 86 FFR 72030, 72054 (2021) (''[T]he agency has long considered statements that are aimed at minimizing the egregiousness of its conduct to weigh against a finding of acceptance of full responsibility.''); *Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010).

Respondent's counsel also attempted to shift blame for Respondent's violations to DEA, which further detracts from Respondent's acceptance of responsibility. RD, at 37 (citing *Ester Mark, M.D.,* 86 FR 16760, 16762 (2021) (finding that the respondent did not accept responsibility because she ''pass[ed] blame on DEA for not telling her how to comply with recordkeeping requirements'')). For example, Respondent's counsel blamed DEA for not providing records from outside the timeframe of the OSC—which were likely in Respondent's control—and argued that these records would support Respondent's assertion that it fulfilled its corresponding responsibility. RD, at 37; *see* Tr. 385. Further, in its Post Hearing Brief, Respondent argues that there is a ''profound dearth of regulation or guidance clarifying the nature, scope and extent of a pharmacy's 'corresponding responsibility' and what it specifically requires.'' ALJX 27, at 6. On the contrary, DEA regularly publishes detailed decisions sanctioning pharmacies for violating their corresponding responsibility, which summarize DEA's interpretation of the relevant statutes, cite to relevant Federal court decisions and prior Agency decisions, and apply the legal principles to the facts of the case. These decisions provide ample notice to the registrant community of DEA's expectations. Moreover, Respondent's violations do not involve the application of complex or obscure statutes or regulations. Rather, Respondent's deficiencies outlined in this Decision—such as failure to resolve and document blatant red flags of drug abuse—are core failures that violate bedrock principles of the CSA and the Louisiana standard of care. Accordingly, the ALJ found, and the Agency agrees, that Respondent has not fully and unequivocally accepted responsibility for its misconduct. RD, at 35–37.

B. Remedial Measures

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 and 79203); *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801, 74810 (2015). Even so, the Agency agrees with the ALJ that Respondent's evidence of remedial measures would not change the result of this case, even if Respondent had unequivocally accepted responsibility. RD, at 38. The only ''remedial measures'' that Respondent offered at the hearing were Ms. Neumann's testimony that she now takes continuing education courses regarding Federal and Louisiana law and that she keeps current with bulletins from Louisiana and the DEA. *Id.;* Tr. 407. As Ms. Neumann herself acknowledged, she should have already known the Federal and Louisiana law regarding controlled substance prescribing. Tr. 405. Testifying that she is now doing what she should have done before these proceedings is inadequate to demonstrate that Respondent can now be entrusted with a DEA registration. *See Mireille Lalanne, M.D.,* 78 FR 47750, 47777 (2013) (''The Agency has recognized that a cessation of illegal behavior only when DEA comes knocking at one's door can be afforded a diminished weight borne of its own opportunistic timing.'') (internal quotation marks and citation omitted); *see also Noah David, P.A.,* 87 FR 21165, 21173 n.*G (2022) (''I do not find significant value to the important question of whether [the respondent] can be entrusted with a CSA registration in remedial measures that meet continuing education requirements.'').[26]

C. Deterrence and Egregiousness

In addition to unequivocally accepting responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick,* 80 FR 74810. In this case, the Agency agrees with the ALJ that the interests of specific deterrence militate in favor of revocation given that Respondent's owner filled many of the prescriptions at issue, yet failed to unequivocally accept responsibility and minimized the egregiousness of Respondent's violations. RD, at 40–41. Respondent also failed to demonstrate that it has undertaken sufficient remedial measures to assure the Agency that a sanction short of revocation would be sufficient to prevent future misconduct. *Id.* at 40. 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. *Id.*

[25] Ms. Neumann testified that she regularly filled her prescriptions from her father at another local pharmacy, and that the pharmacy was ''absolutely'' aware of her relationship with her father. Tr. 405. The ALJ interpreted this testimony as an attempt to shift blame for Respondent's misconduct on others, and stated that ''Ms. Neumann testified that she believed the prescriptions issued to her by her father were valid because another pharmacy had been filling the prescription.'' RD, at 37. Respondent argues in its Exceptions that this testimony was not meant to shift blame, but was ''merely to show that [Ms. Neumann] was not acting in bad faith.'' Exceptions, at 23. The Agency appreciates the distinction that Respondent is drawing between shifting blame and justifying her conduct, but the Agency agrees with the ALJ that this testimony was troubling because it implies that Ms. Neumann believes it is reasonable to be unaware of the law if other pharmacists are also unaware. In other words, it reflects an attempt to minimize the egregious conduct of filling prescriptions that were clearly unlawful in Louisiana, and suggests that the Agency cannot trust Respondent to exercise her independent responsibility to ensure compliance with all State, Federal, and local laws.

[26] Respondent discusses additional remedial measures in its Post Hearing Brief and Exceptions that were not addressed at the hearing, and argues that the ALJ erred in finding that its remedial measures were insufficient. ALJX 27, at 20; Exceptions, at 24–26. Respondent further asserts in its Exceptions that ''Respondent wished to discuss remedial measures further at the hearing, but the Government objected to such testimony.'' Exceptions, at 24 (citing Tr. 395). The Agency rejects the implication that Respondent was not given the opportunity to present its evidence of remedial measures at the hearing. Although the Government did object to Ms. Neumann offering testimony about remedial measures that was not disclosed in its Prehearing Statement or Supplemental Prehearing Statement, RD, at 38 n.26; ALJX 10, 16, the ALJ clearly stated that she would give Respondent the opportunity to present that evidence: ''As you know, I tend to let the respondent make her case and I'll weigh it afterwards with that in mind.'' Tr. 295. The ALJ later reiterated that she had ''given [Respondent's counsel] some latitude to have any summary about acceptance of responsibility or remedial measures'' that was not disclosed in the Prehearing Statements. *Id.* at 416–17.

Even though the ALJ offered repeated assurances that she would allow Respondent to present undisclosed testimony about remedial measures, Respondent's counsel chose not to do so. Thus, the ALJ correctly declined to consider evidence of remedial measures that Respondent did not raise at the hearing, and the Agency declines to consider that evidence in this Decision. *See* RD, at 38 n.26. As the ALJ noted, the evidence of remedial measures that Respondent summarizes in its Post Hearing Brief and Exceptions is unsworn and filtered through Respondent's counsel, and the Government has not had an opportunity to challenge this evidence. *Id.;* ALJX 27 at 20; Exceptions, at 24–26. Thus, the Agency agrees with the ALJ that Respondent's remedial measures are not sufficient to restore the Agency's trust, especially in light of Respondent's failure to accept responsibility.

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. *Pharmacy Doctors Enterprises Inc., d.b.a. Zion Clinic Pharmacy,* 789 F. App'x at 732 (''In sum, given the plentiful instances of [respondent] breaking federal and state law in filling prescriptions with indicia that the drugs would be used for non-medical uses, substantial evidence supports the Acting Administrator's findings that [respondent's] conduct was ''egregious'' and that its ''experience in dispensing'' and ''compliance with applicable State[ ] [and] Federal . . . laws relating to controlled substances'' counseled against registration.''); RD, at 39–40. As the ALJ noted, Respondent repeatedly dispensed dangerous combinations of controlled substances to three patients for several years without resolving multiple red flags indicative of abuse and diversion. RD, at 39. Dr. Graham testified that the opioid and benzodiazepine drug cocktail that Respondent repeatedly dispensed is frequently abused and diverted and can result in significant sedation, respiratory depression, coma, or death.[27] *Id.* at 15; Tr. 118–20 (Graham), 288. Adding to the egregiousness, many of the prescriptions that Respondent filled were issued by Dr. T.N., Ms. Neumann's father, and several were issued in clear violation of the Louisiana law prohibiting prescribing controlled substances to family members. The egregiousness of Respondent's conduct is also enhanced by Ms. Neumann's failure to accept responsibility and her lack of knowledge of the Louisiana standard of care and applicable State and Federal laws.

Respondent's Exceptions [28]

Exceptions 1–2, 6

Dr. Graham testified that she was suspended by the Oklahoma Board of Pharmacy for two years related to misconduct when she was an employee at the Apothecary Shoppe from 2000 to 2002. Tr. 93–94. The ALJ found that this testimony enhanced Dr. Graham's credibly and reliability because she exhibited candor and took responsibility for her misconduct. RD, at 7 n.9. Respondent takes Exception to this finding, as well as to the ALJ's finding that Dr. Graham was a ''reliable and persuasive witness.'' Exceptions, at 1–3. Respondent asserts that Dr. Graham's explanations of her misconduct were ''vague,'' that she ''mischaracterized her transgressions,'' and that she ''minimized the severity of her wrongdoing.'' *Id.* Respondent further argues that the ALJ's findings regarding this testimony reflect a lack of impartiality, because the ALJ did not similarly find that Ms. Neumann's credibility was enhanced by her testimony about her disciplinary history. *Id.* at 7.

The Agency rejects Respondent's characterizations of the record and adopts the ALJ's credibility findings with respect to Dr. Graham and Ms. Neumann. Although the Agency agrees that Dr. Graham's initial statements about her misconduct were vague, this is not surprising because the misconduct occurred over 20 years ago, and the hearing was about Respondent's misconduct, not Dr. Graham's. Dr. Graham's decision to disclose her distant disciplinary history when testifying about her professional history reflects candor. Respondent's counsel cross examined Dr. Graham about the specifics of the disciplinary charges, and she readily answered his questions, while acknowledging that she did not recall all of the specifics. Tr. 151–52. The Agency does not find that Dr. Graham mischaracterized her disciplinary history, because Dr. Graham's statements about her misconduct were not meant to be an exhaustive summary of the charges, and there is insufficient evidence on the record about the charges to assess the accuracy of Dr. Graham's characterizations.

Moreover, the record does not support Respondent's contention that Dr. Graham attempted to minimize the severity of her misconduct. On the contrary, Dr. Graham acknowledged that her behavior was wrong, Tr. 153, that her conduct was intentional and knowing, Tr. 158, and that she failed to exercise her corresponding responsibility. *Id.* She testified that the owner asked her to do things that ''were in the dark shades of [a] gray [area]'' that she knew were wrong, but she felt that she could not stand up against the owner for fear of being fired. RD, at 7 n.9; Tr. 93–94, 153. She testified that this was ''easily . . . the worst time in [her] life,'' but ''she learned so much [from] it,'' and it helped her gain confidence as a pharmacist and human being. Tr. 95. Dr. Graham left her job at the Apothecary Shoppe in 2002 and started her own pharmacy so she could ''do what [she] felt was the right thing to do.'' RD, at 7 n.9; Tr. 94. Thus, the Agency rejects Respondent's arguments, finds that this testimony did not detract from Dr. Graham's credibility, and adopts the ALJ's finding that Dr. Graham's testimony was fully credible and reliable. RD, at 7.

Finally, the Agency rejects Respondent's argument that the ALJ exhibited a lack of impartiality when assessing Dr. Graham's and Ms. Neumann's testimony. As the ALJ observed, Ms. Neumann's credibility was diminished by her inconsistent statements about whether documentation is required by the standard of care. RD, at 13–14. Additionally, much of Ms. Neumann's testimony consisted of providing undocumented, *post hoc* explanations for her conduct, which are entitled to little weight. Moreover, the record reflects that Ms. Neumann's testimony about her disciplinary history was not as forthcoming as Dr. Graham's, and therefore detracted from her credibility. Ms. Neumann testified on direct examination that she had not had any disciplinary issues with the licensing board since 1997, but when prompted by Government counsel on cross examination, she acknowledged that Respondent was sanctioned in 2023 for missing narcotics. RD, at 10 n.12; Tr. 403, 461–63. In contrast, Dr. Graham has had a clean record for 20 years, and she affirmatively disclosed her past transgressions on direct examination. Tr. 93–94

Exceptions 3, 15

Respondent argues that Dr. Graham's opinions were conclusory and ''without any factual support whatsoever to assert that certain prescriptions were not issued for a legitimate medical purpose.'' ALJX 27, at 7; RD, at 7 n.10; Exceptions, at 3–5 (''Dr. Graham gave no factual support for her entirely conclusory answers to these questions.''). Respondent further asserts that ''the Government failed to offer any evidence that [Ms. Neumann] knew or should have known that any of the

[27] Respondent argues that there was no evidence of actual diversion, harm to patients, or gross negligence, and its misconduct was not intentional. RD, at 39; ALJX 27, at 8, 21. However, it is not necessary for the Agency to find harm to revoke a registration. *Melanie Baker, N.P.,* 86 FR 23998, 24009 (2021); *Larry C. Daniels, M.D.,* 86 FR 61630, 61660 and 61661 (2021); *Jeanne E. Germeil, M.D.,* 85 FR 73786, 73799 n.32 (2020). Nor is it necessary for the Agency to prove that a registrant committed intentional violations of the CSA to revoke a registration. The Agency has repeatedly held that ''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Paul J. Caragine, Jr.,* 63 FR 51592, 51601 (1998).

[28] Many of the arguments in Respondent's Exceptions were previously raised in Post Hearing Briefs or at the hearing, and were adequately addressed in the RD. To the extent that Respondent's Exceptions have already been adequately addressed in the RD, or throughout this Decision, they are not discussed again in this section.

prescriptions at issue were not written for a legitimate medical purpose.'' Exceptions, at 24.

Importantly, the Government need not prove that the prescriptions were not *issued* for a legitimate medical purpose, but rather that Respondent failed to exercise its corresponding responsibility to ensure that the prescriptions were issued for a legitimate medical purpose. *Suntree Pharmacy and Suntree Medical Equipment, LLC* v. *Drug Enf't Admin,* 2022 WL 444,357, *6 (11th Cir. Feb. 14, 2022) (''[T]he Administration 'has long interpreted [21 CFR 1306.04(a)] 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.'' *JM Pharmacy Grp., Inc., d/b/a Farmacia Nueva & Best Pharma Corp.,* 80 FR 28667, 28670 (May 19, 2015) (citation omitted and emphasis added); *see also* [*United States* v.] *Hayes,* 595 F.2d at 261 n.6 ('[A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.' ''); RD, at 33–34. Dr. Graham testified that an essential element of the corresponding responsibility is that a pharmacist must identify any red flags present with a prescription, resolve those red flags, and document their resolution prior to dispensing. RD, at 15–16; Tr. 110–13. Dr. Graham testified about the specific red flags that she identified for each patient, and she testified that there was no documentation in Respondent's files reflecting any attempt to address or resolve those red flags. RD, at 7 n.10; Tr. 96–122. Dr. Graham thus concluded that Respondent violated its corresponding responsibility and acted beneath the standard of pharmacy practice in Louisiana when it dispensed controlled substances to each patient. RD, at 7 n.10.; Tr. 132, 140, 146.[29] The Agency finds that Dr. Graham provided sufficient factual support for these conclusions.

Respondent also asserts that Dr. Graham ''did not address the detailed reasoning provided by [Ms.] Neumann regarding how she resolved the red flags for the subject prescriptions, nor did she address the data contained in the patient profiles that supported [Ms.] Neumann's decision to resolve the red flags and dispense the prescriptions as written.'' Exceptions, at 5–6. Dr. Graham did, in fact, address the data contained within the patient profiles. She testified that she reviewed the patient profiles and prescriptions for each patient and identified red flags for each patient for which no resolution was documented. Tr. 122. Respondent's contention that Dr. Graham should have addressed all of Ms. Neumann's undocumented, *post hoc* justifications reflects a misunderstanding of DEA's prior Agency decisions, which highlight the importance of documentation. As discussed throughout this decision, the Agency has long found that it will not credit a Respondent's undocumented, *post hoc* justifications for its prescribing or dispensing. *Pharmacy Doctors Enterprises Inc., d.b.a. Zion Clinic Pharmacy,* 789 F. App'x at 731 (A respondent pharmacy ''fail[s] to comply with its corresponding responsibility not to fill prescriptions written for illegitimate purposes'' when it fails to ''tak[e] and document[ ] steps to resolve . . . red flags or refusing to fill prescriptions with unresolvable red flags.''). This principle is critical to the Agency's ability to enforce against violations of the CSA, because enforcement would be impractical if the viability of the Government's case hinged on the plausibility of a Respondent's undocumented, *post hoc* justifications. Respondent's failure to document any resolution of the red flags in this case rendered its dispensing beneath the standard of care and outside the usual course of professional practice.

Exceptions 7–8

Respondent asserts that the ALJ erred in inferring that Respondent failed to resolve red flags from Respondent's failure to document their resolution, because Ms. Neumann testified that she did take steps to address and resolve each red flag. Exceptions, at 7–11. Respondent cites to *Superior Pharmacy,* 81 FR 31310, at 31335 n.55, as support for the assertion that ''a lack of documentation is not, on its own, sufficient evidence to prove that a red flag was not resolved.'' Exceptions, at 8.

However, *Superior Pharmacy* does not support this assertion. In *Superior Pharmacy,* the Agency found that the Government had not met its burden of demonstrating that Respondent had failed to document the resolution of red flags because the Government had only offered prescriptions (and not patient profiles) into evidence, and the Government's investigators had not asked respondent's pharmacists if there were other places, aside from the prescriptions, where they might have documented the resolution of the red flags. *Superior Pharmacy,* 81 FR 31335 n.55. *Superior Pharmacy* makes clear that in a case where the Government has provided sufficient evidence to establish that the red flags were not documented anywhere, ''it would be reasonable to draw an adverse inference that a pharmacist failed to resolve a red flag (or flags) from the failure to document the resolution . . . .'' [30] *Id.* at 31,335 (emphasis added); *see also Hills Pharmacy, LLC,* 81 FR 49816, 49836 (2016) (citing *Superior Pharmacy,* and finding that ''the absence of documentation on the prescriptions [was] not conclusive proof'' of a failure to document the resolution of the red flags because the respondent's PIC testified that his practice was to document red flags on a due diligence checklist, which was not admitted into evidence). Here, the Government admitted prescriptions and patient profiles into evidence, and Respondent has not asserted that there was any other location where Respondent documented the resolution of red flags.

Respondent also cites to several prior Agency decisions, including the Agency's recent decision in *Coconut Grove,* that purportedly show that the Government may not meet its burden of proof simply by demonstrating that a pharmacy failed to document the resolution of red flags. Exceptions, at 9–11 (''The only evidence the Government has offered in this matter is the absence of documentation. That alone is not enough to satisfy the Government's burden of proof.''). Respondent argues that these cases all involved ''additional evidence which pointed to wrongdoing,'' beyond a failure to document, which Respondent argues is further support that the Government did not meet its burden of proof. *Id.* at 9.

[29] *See also Holiday CVS, L.L.C.,* 77 FR 62341 (finding that the Government can prove that a registrant violated its corresponding responsibility by showing that: (1) the registrant dispensed a controlled substance, (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed, and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance).

[30] Respondent argues that it ''excepts to any negative inference drawn from any evidence which it did not introduce,'' because ''the Government has failed to meet its burden that the prescriptions were not written for a legitimate medical purpose.'' Exceptions, at 18–19. Respondent asserts that it is ''under no obligation to introduce evidence to strengthen its case'' because of the Government's failure to meet its burden. *Id.* However, Respondent does not cite to any particular findings in the RD that it objects to, and instead refers generally back to Exception 7. *Id.* This Exception lacks the level of specificity required under 21 CFR 1316.66, which provides that exceptions should be supported by ''specific and complete citations of the pages of the transcript and exhibits.'' Moreover, the Agency found that the Government did meet its prima facie burden of demonstrating that Respondent's registration was inconsistent with the public interest, which shifted the burden to Respondent to demonstrate that it could be entrusted with a registration. Respondent did not make that showing.

The Agency rejects these arguments. First, as discussed throughout this Decision, the Agency may infer from Respondent's failure to document that Respondent failed to address and resolve red flags, and the Agency has repeatedly held that it will not credit a registrant's undocumented, *post hoc* justifications. Second, the Agency regularly revokes registrations based on documentation failures. For example, in *Coconut Grove,* the Agency revoked a pharmacy's registration based on the pharmacy's failure to document resolutions of red flags in ways and for reasons that are very similar to this case. The pharmacy's expert in *Coconut Grove* argued that the pharmacy's PIC had resolved the relevant red flags ''over time in continuing conversations with the patients and the doctors,'' but the Agency rejected these arguments, because the pharmacy's only notation on the prescription was ''verified,'' which was not sufficient to resolve the red flag. 89 FR 50374. Based on the pharmacy's failure to document the resolution of the red flags, the Agency found that the pharmacy had failed to address and resolve those red flags. *Id.* The Agency further concluded that the pharmacy's dispensing was outside the usual course of professional practice and beneath the standard of care. *Id.* The Agency drew similar conclusions in *Heavenly Care Pharmacy,* 85 FR 53402 (2020), also cited by Respondent. Respondent is correct in observing that the prescriptions in *Heavenly Care* raised more red flags than the prescriptions in this case, and that there was an additional ground for revocation in that case. However, the Government need not identify multiple grounds for revocation, and the Agency has never tallied a registrant's legal violations and required the Government to meet a certain numerical threshold.

Here, the Government proved that Respondent filled numerous prescriptions without adequately addressing and resolving several red flags, which rendered Respondent's dispensing beneath the standard of care, outside the usual course of professional practice, and in violation of Federal and State law. The Government also proved that Respondent filled unlawful prescriptions that were written for Ms. Neumann by Ms. Neumann's father. These violations are sufficient to revoke a registration.

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. 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. FN4373293 issued to Neumann's Pharmacy, LLC. 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 Neumann's Pharmacy, LLC, to renew or modify this registration, as well as any other pending application of Neumann's Pharmacy, LLC, for additional registration in Louisiana. This Order is effective February 24, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on January 16, 2025, 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. 2025–01536 Filed 1–22–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed First Amended Consent Decree Under the Clean Water Act

On January 16, 2025, the Department of Justice lodged a proposed First Material Modification to the 2006 Consent Decree with the United States District Court for the District of Connecticut in the lawsuit entitled *United States et al.* v. *Metropolitan District of Hartford, Connecticut,* Civil Action No. 3:06–cv–00728.

In this action, the United States and the State of Connecticut sought civil penalties and injunctive relief for violations of the Clean Water Act, 33 U.S.C. 1251 *et seq.,* in connection with the Metropolitan District of Hartford, Connecticut's (''MDC's'') operation of its municipal wastewater treatment facility and sewer system. These claims were resolved in a Consent Decree, which was approved by the Court in August 2006. Under the Consent Decree, the MDC is required to, among other things, eliminate all sanitary sewer overflow (''SSO'') outfalls by a date certain and submit and implement control projects and schedules to reduce inflow and infiltration (''I/I''), which can dilute sanitary sewers and in turn, decrease treatment efficiency. Since 2006, the MDC has eliminated all but three of its SSO outfalls and has proposed several I/I reduction projects and schedules. The proposed modification extends the deadline for eliminating the remaining SSO outfalls by about 4 years and incorporates a schedule for implementing I/I reduction projects.

The publication of this notice opens a period for public comment on the proposed First Material Modification to the 2006 Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States et al.* v. *Metropolitan District of Hartford, Connecticut,* D.J. Ref. No. 90–5–1–1–08404. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* If you require assistance accessing the proposed Consent Decree, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Eric D. Albert,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2025–01559 Filed 1–22–25; 8:45 am]

BILLING CODE 4410–15–P