DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–25]

Rayford ACP; Decision and Order

On June 15, 2021, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, collectively OSC) to Rayford ACP [1] (hereinafter, Respondent) of Rayford, Texas. OSC, at 1 (citing 21 U.S.C. 823(f) and 824(a)(4), (d)).

A hearing was held before DEA Administrative Law Judge Teresa A. Wallbaum (hereinafter, the ALJ). On January 25, 2022, the ALJ issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, ''RD''), which recommended revocation of Respondent's registration. RD, at 69. Respondent filed Exceptions to the RD [2] and the Government filed a response. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, findings of fact, conclusions of law, and recommended sanction in the RD and summarizes and expands upon portions thereof herein.

I. Findings of Fact

Pursuant to 21 U.S.C. 823(f), 824(a)(4), the Government seeks revocation of Respondent's DEA registration because Respondent allegedly committed acts rendering its continued registration inconsistent with the public interest, including repeatedly filling prescriptions for controlled substances for seventeen patients in the face of unresolved red flags of abuse and diversion in violation of 21 CFR 1306.04(a) and 1306.06, and Tex. Health & Safety Code 481.074(a). OSC, at 2, 7.

A. Summary of the Proceeding and Relevant Facts

The Government presented its case through records and testimony from two witnesses, a DEA Diversion Investigator (hereinafter, DI), Tr. 33–63, and Dr. DiGi Graham, D.Ph., Tr. 64–573, 1494–1552, who testified as an expert witness in retail pharmacy, hospice pharmacy care, and the practice of pharmacy in the State of Texas. RD, at 15–18.

Respondent presented its case through testimony from four witnesses; including two experts, Ms. Jenna Head, RPh., BCGP (qualified as an expert in Texas pharmacy law, hospice pharmacy, and a pharmacy's corresponding obligation), Tr. 585–1029, and William C. Yarborough, III, Pharm.D, J.D. (qualified as an expert in Texas and federal law and retail pharmacy), Tr. 1406–1430; Tronown Thomas, Respondent's owner and Pharmacist-in-Chief (PIC), Tr. 1032–1402, 1485–1492; and Shawn Stevens, RN, a fact witness regarding early refills, Tr. 1480–1485. RD, at 18–25.[3]

B. Corresponding Responsibility

The Agency credits Dr. Graham's testimony that both federal and Texas law impose an independent, corresponding responsibility on pharmacists to ensure that a prescription is issued for a legitimate medical purpose and within the usual course of professional practice before dispensing.[4] RD, at 26–27; Tr. 97–98; Tex. Health & Safety Code 481.074(a). Further, the Agency finds, based on Dr. Graham's credible expert testimony and Texas law, that the independent corresponding responsibility requires a pharmacist to resolve red flags and document their resolution. RD, at 27; Tr. 98–100, 128, 317; *see* 22 Tex. Admin. Code § 291.29(f). Specifically, the Agency finds, as Dr. Graham credibly testified, a pharmacist fulfilling his or her corresponding responsibility and acting within the usual course of professional practice in Texas must review controlled substance prescriptions for red flags, such as cocktail prescriptions,[5] clinically significant therapeutic duplication,[6] [7]

[1] Respondent holds a DEA Certificate of Registration No. FL1670341 at the registered address of 440 Rayford Road, Suite 155, Rayford, Texas 77386. OSC, at 1–2.

[2] The Agency has reviewed and considered Respondent's Exceptions and finds them to be without merit as further addressed herein.

[3] The Agency adopts the ALJ's summary of each of the witnesses' testimonies and her assessment of the witnesses' credibility. RD, at 15–25. The Agency agrees with the ALJ that Dr. Graham's testimony was persuasive and consistent with Texas statutes regarding the standard of care. *Id.* at 18. It further agrees that Ms. Head and Mr. Thomas repeatedly relied on presumptions and their testimony therefore offered limited value. *Id.* at 21, 24–25. Ms. Head's testimony is illustrative: ''I know that the nurse and the physician are already monitoring for opioid-induced neurotoxicity . . . [be]cause I know that's hospice and what they have to do, then I don't see that that is a red flag, and I don't see I need to call to ask them if they're doing their job.'' Tr. 741. Respondent and its experts espouse a position that the prescriptions at issue do not raise red flags because the prescriber presumably had a legitimate reason for issuing the prescriptions. This position is not supported in the law or the record. *See infra* n.4.

[4] The Agency agrees with the RD that the record evidence supports a finding that ''there is only one standard, applicable to both retail and hospice patients, . . . [as] described by Dr. Graham.'' RD, at 30. Ms. Head testified that there were key distinctions between a hospice and a non-hospice pharmacy, *see* Resp Exceptions, at 2–5, and that due to these distinctions, most, if not all, of the red flags at issue in this case were never triggered because the prescriptions were stamped ''hospice patient'' or ''terminally ill.'' RD, at 20–21, 32; Tr. 684, 689, 888, 969, 991. Respondent's position directly conflicts with Texas law and the notion that a pharmacist has a corresponding responsibility that is separate and independent of the prescriber in 21 CFR 1306.04. *See infra* n.11 and Discussion. Further, the importance of this corresponding responsibility to ensure the legitimacy of prescriptions is exemplified in Patient J.T., who had multiple prescriptions that presented red flags and were incorrectly stamped ''terminally ill.'' RD, at 33–34. Respondent's position in this case undermines the CSA's purpose of preventing diversion and abuse of controlled substances. Therefore, I reject Respondent's argument because it conflicts with a core principle of the CSA—the establishment of a closed regulatory system devised to ''prevent the diversion of drugs from legitimate to illicit channels.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13–14, 27 (2005); *see Jennifer St. Croix, M.D.,* 86 FR 19,010, 19,024 (2021). Additionally, Respondent notably does not point to any regulation or law exempting pharmacies dispensing to hospice patients from the requirements to resolve red flags, which are specifically set forth in the relevant Texas law. Dr. Graham credibly testified that, although the objective red flags listed in the law apply regardless of the situation, the red flags are often more easily resolved for hospice patients. Tr. 119–21, 175–76, 239–40, 249, 1519–20, 1527–28; RD, at 29. Respondent, however, did not maintain documentation of its resolution of red flags and continued to argue that the prescriptions did not present any red flags at all. The law and the record evidence do not support Respondent's arguments.

[5] As further explained herein, 22 Tex. Admin. Code § 291.29(f)(3) defines one relevant red flag factor as ''controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants . . . or any combination of these drugs,'' and the Agency credits Dr. Graham's testimony in accordance with this law that a pharmacist acting within the usual course of professional practice and exercising his or her corresponding responsibility must resolve and document this red flag without exception. *Compare* ALJX 30, at 3 (Respondent arguing that certain symptoms (pain, shortness of breath, and anxiety) are ''universal symptoms of the end-of-life process'' such that ''a reasonable hospice pharmacist following the standard of care would not consider the combination of an opioid and a benzodiazepine an automatic red flag''), *with* Tr. 109, 111–12, 136–37, 400–01, 1494–95, 1499–1503, 1523–24 (Dr. Graham opining that cocktail prescribing in hospice is still a red flag because hospice patients are often dehydrated and at a greater risk of dangerous accumulation of drugs in their systems). *See also* RD, at 28; Tex. Admin. Code § 291.29(f)(3). Texas law does not exempt hospice pharmacies from this requirement.

[6] Dr. Graham testified that therapeutic duplication is defined as medications in the same category that ''work on the same receptor site that alleviates the same symptoms.'' RD, at 28; Tr. 112–14; *see also* Tr. 255–56, 330–31, 337–38, 1516. The Agency rejects Respondent's Exceptions regarding therapeutic duplication. Resp Exceptions, at 12–21. Dr. Graham testified that anything that could harm the patient was clinically significant and explicitly testified to the potential harm that could be caused by the duplications presented in the subject prescriptions. Tr. 570; RD, at 61; *see, e.g.,* Tr. 116, 173, 205 (Dr. Graham's testimony addressing the harms of therapeutic duplication). Dr. Graham's testimony was focused on the pharmacological impact that the cited duplicative therapies would have on the body, rather than the intended use of the medication. Tr. 111–16. The Agency finds limited value in Ms. Head's speculative opinions that certain liquid morphine prescriptions were

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early refills,[8] and distance; [9] and resolve those red flags prior to dispensing and document their resolution. RD, at 30; Tr. 100, 183–84, 340–41, 343, 400–01, 407–08, 1499–1502, 1523–24; *see also* Tr. 141–397. According to Dr. Graham, documentation of the resolution of red flags does not need to be complex. RD, at 27; Tr. 99, 163–64, 335, 356, 403–04. Respondent produced no documentation of its resolution of the relevant red flags for the subject prescriptions. *See* RD, at 62.

C. The Subject Prescriptions

The Agency agrees with and incorporates the findings of the RD and, based on the evidence in the record, finds that Respondent's dispensing of each of the subject controlled substance prescriptions to each of the relevant patients was outside of the usual course of professional practice of pharmacy in Texas and in violation of Respondent's corresponding responsibility. Respondent dispensed controlled substances on numerous occasions without documenting the resolution of the following red flags: cocktail prescribing for patients J.C., C.G., D.M., M.I., M.W., D.H., I.G., M.M., B.H., T.T., and M.J.; therapeutic duplication for patients D.M., M.I., M.W., D.H., I.G., J.L., M.G., B.H., T.T., M.J., K.B., and L.F.; early refills for patients D.M., and J.L.; and long distances for Patient J.G. and J.T. RD, at 34–54. For example, the Government established that Respondent dispensed at least thirty-nine prescriptions to Patient D.M. without documenting the resolution of multiple red flags, including combination prescribing, therapeutic duplication, and/or early refills. *Id.,* at 38–41. Regarding retail patients, J.C. and C.G., Respondent conceded that it ''did not appropriately exercise its corresponding responsibility,'' because it dispensed controlled substances without documenting the resolution of red flags for combination prescribing. Tr. 1087, 1091; RD, at 15. The Government also established that Respondent dispensed at least nineteen prescriptions for controlled substances to another retail patient, Patient J.T., who lived approximately sixty miles from Respondent without documenting the resolution of the traveling a long distance red flag. RD, at 37–38; Tr. 390–92.[10]

In accordance with Dr. Graham's credible expert testimony, the ALJ's analysis, and the records as a whole, the Agency finds that in dispensing the subject controlled substance prescriptions without documenting the resolution of the applicable red flag(s), Respondent's pharmacists did not fulfill their corresponding responsibility and Respondent did not dispense the subject prescriptions in the usual course of professional practice and within the applicable standard of care.

II. Discussion

Section 304(a) of the Controlled Substances Act (hereinafter, CSA) provides that ''[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 the case of a practitioner, which includes a pharmacy, the CSA requires the Agency consider the following factors in determining whether Respondent's registration would be inconsistent with the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

The DEA 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 proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). When the Government has

being used to treat breathing problems. *See, e.g.,* Tr. 684–87. Furthermore, Texas law specifically states that clinically significant duplicative therapies present a red flag, and further requires that red flags be resolved and documented. 22 Tex. Admin. Code § 291.33(c)(2)(A); *see* Discussion *infra*. There is no evidence that Respondent identified and resolved the red flags of clinically significant therapeutic duplication and documented their resolution as required by Texas law. Tr. at 99, 163, 335, 356, 403–04. Therefore, because the evidence does not establish that Respondent resolved the red flag in any manner, both Dr. Graham's testimony, Tr. 115, 331, and Ms. Head's testimony about how this red flag could theoretically be resolved is largely irrelevant.

[7] Mr. Thomas testified that Respondent used software that would alert the pharmacist when a prescription was potentially duplicative and the pharmacist would have to exercise his or her judgment in dismissing the alert. Tr. 1073–74. Respondent argues, without support, that the dismissal of this alert demonstrates that there was no red flag. Resp Exceptions, at 12–13. Contrary to Respondent's argument, the system appears to be alerting the pharmacist to a red flag. As already established, a pharmacist exercising his or her corresponding responsibility must resolve red flags and is required to document such resolution under Texas law. There is no such evidence of documentation in this case.

[8] Respondent presented testimony that early refills were permissible for hospice agencies at a much lower threshold than the threshold identified by Dr. Graham. *Compare* Tr. 120, 439–40, 1519–20, 1527, *with* Tr. 651–54, 1070–71, 1225; *see also* RD, at 29. Dr. Graham credibly testified that Respondent's low threshold would not fulfill the goal of identifying suspicious patterns. Tr. 1520; *see also* RD, at 29; Tr. 240, 243. Respondent further argued that a particular hospice agency set a lower refill threshold through policy, Resp. Exceptions, at 22, and Dr. Graham rationally and credibly testified that if that were the case, the early refill red flag could easily be resolved with a notation documenting that hospice agency's refill policy. RD, at 29; Tr. 1528. The Agency agrees with the RD that Dr. Graham's testimony on the issue was more compelling and more credible and has given it controlling weight. *See* RD, at 29–30. Early refills of a prescription must be identified and resolved under 22 Texas Admin. Code § 291.33(c)(2)(A)(i)(X); *see infra* Discussion. Respondent failed to document the resolution of this red flag.

[9] Texas law states that ''[r]easons to suspect that a prescription may have been authorized in the absence of a valid patient-practitioner relationship or in violation of the practitioner's standard of practice include: . . . the geographical distance between the practitioner and the patient or between the pharmacy and the patient.'' *See* 22 Tex. Admin. Code § 291.29(c)(4); RD, at 29–30; *see also* Tr. 122–23; 380–385 (Dr. Graham's testimony that travelling long distances to a pharmacy triggers the pharmacist's responsibility). The Agency rejects Respondent's arguments and Exceptions that are contrary to the plain language of Texas law, including Respondent's argument that the dispensing to Patient J.T. was proper because the prescriber's office was only 3.9 miles from Respondent. RD, at 37; Tr. 1423–27. The Agency also rejects Respondent's argument that Rayford's contract with Patient J.G.'s hospice agency, resolved any long distance concerns, because Respondent did not produce the contract on the record or otherwise demonstrate documentation of the resolution of the red flag. *See* Resp Exceptions, at 23–24 (*citing* Tr. 1350). Dr. Graham testified that a hospice agency's policy can resolve the distance concern if documented, Tr. 381, 383–84, 387, 405–06; RD, at 30, but there is no evidence that Respondent resolved the distance concern prior to dispensing and documented that resolution in this case. *See, e.g., George Pursley, M.D.,* 85 FR 80,162, (2020) (''Post hoc written or oral justifications . . . are not controlling.'') Tr. 381, 383–84, 387, 405–06.

[10] Respondent objected to the ALJ's characterization of Dr. Yarborough's testimony regarding the distance red flag. (Tr. 1426–27). Resp Exceptions, at 25 (*citing* RD, at 37). Texas law is clear that long distances travelled to a practitioner or a pharmacy indicates a potential invalid patient-practitioner relationship, therefore, the Agency fully credits Dr. Graham's testimony regarding the existence of the red flag and the requirement to resolve it and finds it unnecessary to address Respondent's Exception regarding the wording of the RD. *See supra* n. 9. RD, at 37–38; Resp Exceptions, at 25.

met its *prima facie* case, the burden then shifts to the Respondent to show that revoking its registration would not be appropriate, given the totality of the facts and circumstances on the record. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008). Having reviewed the record and the RD, the Agency agrees with the ALJ, adopts her analysis, and finds that the Government has proven by substantial evidence that Respondent committed acts which render its continued registration inconsistent with the public interest. RD, at 54–64.

While the Agency has considered all of the public interest factors, the Government's case invoking the public interest factors of 21 U.S.C. 823(f) seeks revocation of Respondent's registration based solely under Public Interest Factors Two and Four. *See* RD, at 55, n.53 (finding that factors 1, 3, and 5 do not weigh for or against revocation).

A. Factors Two and Four

Factors 2 and 4 are often analyzed together. *See, e.g., Fred Samimi, M.D.,* 79 FR 18,698, 18,709 (2014). Under Factor 2, the DEA analyzes a registrant's ''experience in dispensing . . . controlled substances.'' 21 U.S.C. 823(f)(2). Factor 2 analysis focuses on a registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012) (explaining that ''every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [the registrant's] professional career''). Similarly, under Factor 4, the DEA analyzes a registrant's compliance with federal and state controlled substance laws. 21 U.S.C. 823(f)(4). Factor 4 analysis focuses on violations of state and federal laws and regulations. *Volkman* v. *DEA,* 567 F.3d 215, 223–24 (6th Cir. 2009).

As the Agency found above, as supported by credible, expert testimony, both federal and Texas law impose an independent, corresponding responsibility on pharmacists to ensure that a prescription is issued for a legitimate medical purpose and within the usual course of professional practice. Texas Health & Safety Code § 481.074(a); 21 CFR 1306.04; RD, at 26–27, 57; Tr. 97–98. ''The language in 21 CFR 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990). Further, the record testimony and state law demonstrate that a pharmacist who exercises his or her corresponding responsibility in filling a controlled substance prescription is required to resolve red flags and document the resolution.[11] RD, at 27; Tr. 98–100, 128, 317; *see* 22 Tex. Admin. Code 291.29(f).

To prove a pharmacist violated his or her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such 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.'' *Bertolino,* 55 FR at 4730 (citations omitted). Thus, when a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008).

Specifically, the Agency has found based on credible expert testimony and Texas law that a Texas pharmacy exercising its corresponding responsibility and acting within the standard of care must review for cocktail prescriptions, therapeutic duplication, early refills, and distance; must resolve these red flags prior to dispensing; and must document their resolution. RD, at 30; Tr. 100, 183–84, 340–41, 343, 400–01, 407–08, 1499–1502, 1523–24; *see also* Tr. 141–397.

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation for each of the patients at issue in this matter by ''repeatedly dispens[ing] controlled substances without addressing or resolving clear red flags.'' Gov Prehearing, at 16; *see also* Gov Posthearing, at 2. Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g., Morning Star Pharmacy,* 85 FR 51,045, 51,061 (2020) (relevant red flags include distance, drug cocktails, and therapeutic duplication); *Gulf Med Pharmacy,* 86 FR 72,694, 72,728 (2021) (relevant red flags include distance, drug cocktails, and therapeutic duplication); *Pharmacy 4 Less,* 86 FR 54,550, 54,573–76 (2021) (relevant red flags include distance); *East Main Street Pharmacy,* 75 FR 66,149, 66,163–65 (2010) (relevant red flags included long distances; lack of individualized therapy or dosing; drug cocktails; and early fills/refills).

Moreover, Texas law explicitly states that ''the geographical distance between the practitioner and the patient or between the pharmacy and the patient'' is a reason to suspect that a prescription may have been authorized in violation of the practitioner's standard of practice. 22 Tex. Admin. Code § 291.29(c)(4); *see also Morning Star Pharmacy,* 85 FR at 51,051 (applying 22 Tex. Admin. Code § 291.29(c)(4)); RD, at 61. It further states that early refills must be identified, resolved, and that resolution documented prior to dispensing under 22 Texas Admin. Code § 291.33(c)(2)(A)(i)(X), which requires a pharmacist to review for ''proper utilization, including overutilization or underutilization,'' *Id.; see also* Tr. 566 (Dr. Graham testifying that overutilization review includes early refills); RD, at 61. When red flags are identified, a pharmacist must resolve and document the resolution of any red flag or consultation. 22 Texas Admin. Code § 291.33(c)(2)(A)(ii) (''[u]pon identifying any clinically significant conditions [or] situations . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner''); *id.* § 291.33(c)(2)(C) (a pharmacist has an obligation to document any consultation); RD, at 61. Therefore, Respondent's failure to document the resolution of a red flag violated Texas law. *Id.* at §§ 291.33(c)(2)(A)(ii), 291.33(c)(2)(C).

The Agency agrees with the RD that Respondent dispensed controlled substances on numerous occasions without documenting a resolution of red flags for cocktail prescribing, therapeutic duplication, early refills,

[11] The Agency agrees with the RD that Texas law and ''the record evidence [do] not support an assumption that hospice care is so highly-regulated and so closely-monitored that it alters a pharmacy's independent, corresponding responsibility to dispense only lawful prescriptions . . . .'' RD, at 34 (citing 21 CFR 1306.04(a) and *The Pharmacy Place,* 86 FR 21,008, 21,013 (2021)).

and long distances. RD, at 62–64; *supra,* at Findings of Fact C. For many of these patients, the prescriptions filled contained multiple unresolved red flags at once. *See, e.g.,* RD 38–40 (Patient D.M. on January 23, 2019, Respondent dispensed two short-acting opioids along with a benzodiazepine, which raised red flags for both therapeutic duplication and cocktail prescribing, and on March 20, 2020, Respondent dispensed hydrocodone six days early along with alprazolam, which raised red flags for both early refills and cocktail prescribing). Accordingly, the Agency agrees with the RD that the Government has established by substantial evidence that Respondent filled numerous prescriptions to seventeen patients outside the usual course of professional practice and without fulfilling its corresponding responsibility in violation of 21 CFR 1306.04(a) and 1306.06. Further, the Government established by substantial evidence that Respondent acted in violation of Texas law as set forth in 22 Texas Admin. Code §§ 291.29 and 291.33 and Texas Health & Safety Code § 481.074(a). *See* RD, at 64. The Government has made a *prima facie* case that the Respondent has committed acts that render its registration inconsistent with the public interest, and its misconduct supports the revocation of its registration. RD, at 64.

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent's registration, the burden shifts to the respondent 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 LLC 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, Respondent has failed to unequivocally accept responsibility. Respondent did admit that it violated its corresponding responsibility with respect to retail patients J.C. and C.G., Tr. 1087, 1091, but then proceeded to deny that retail patient J.T.'s prescriptions presented a red flag based on distance in spite of clear Texas law to the contrary. RD, at 66 (internal citations omitted). Respondent also consistently denied that the controlled substance prescriptions for its hospice patients presented any red flags. Tr. 1377–78; ALJ Ex. 30, at 2–5; *see also, e.g.,* Tr. 1093–94, 1097, 1120–21, 1124–28, 1130, 1132–34, 1140, 1142–46, 1148–50, 1204–23, 1273–76, 1279–80, 1290, 1293; RD, at 66. For example, PIC Thomas denied that Patient D.M.'s prescriptions presented red flags, despite his own expert testifying to the contrary. *Compare* Tr. 1105–06 (PIC Thomas), *with* Tr. 725–29, 731–32 (Ms. Head). A registrant's acceptance of responsibility for misconduct is not adequate when the registrant does not understand what the law requires. *See Zion Clinic Pharmacy,* 83 FR 10,876, 10,903 (2018).[12]

Furthermore, Respondent's misconduct was far from a one-time occurrence. Respondent filled multiple prescriptions for Schedule II controlled substances presenting numerous red flags. *See Noah David, P.A.,* 87 FR 21,165, 21,174 (2022); *see also Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases) (''The egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction.'')

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR at 8248. The Agency finds that considerations of both specific and general deterrence weigh in favor of revocation in this case. A sanction less than revocation would send a message to the current and prospective registrant community that compliance with core controlled-substance legal principles is not a condition precedent to receiving and maintaining a DEA registration. Further, there is simply no evidence that Respondent's behavior is not likely to recur in the future such that the Agency can entrust it with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction. Accordingly, the Agency shall order the sanctions the Government requested, as contained in the Order below.

[12] When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ahuja,* 84 FR at 5498 n.33; *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,801, 74,810 (2015); *see also Jones Total Health Care Pharmacy, LLC, SND Healthcare, LLC,* 881 F.3d 823, 833 (11th Cir. 2018) (upholding DEA's refusal to consider pharmacy's remedial measures given lack of acceptance). The Agency agrees with the ALJ that even if the Agency were to consider Respondent's remedial measures, they would not affect the ultimate decision in this matter. RD, at 67. Here, Respondent has made no showing of remedial measures as to the hospice patients, because it denies any error that requires remediation. *Id.* As to the retail patients, Respondent's PIC testified that he does in-house training, including ''ten-minute huddles'' on a daily basis to emphasize the need for documentation. Tr. 1379–80; RD, at 67. He also testified that the pharmacy has a new software system that allows pharmacists to scan and attach documents to the electronic patient file. Tr. 1074, 1253; RD, at 67. The Agency does not find such measures to be adequate in addressing the nature of the violations found here. *See* RD, at 67.

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 FL1670341 issued to Rayford ACP. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of Rayford ACP for registration in Texas. This order is effective October 17, 2022.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 8, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Reginald James Newsome, M.D.; Decision and Order

On March 16, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government)