DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–22]

Midtown Specialty RX; Decision and Order

On January 25, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Midtown Specialty RX (Respondent) of Houston, Texas. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA Certificate of Registration, Control No. FM2396427, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest because, among other reasons, Respondent repeatedly dispensed controlled substance prescriptions to over sixty patients without resolving red flags of drug abuse and diversion. *Id.* (citing 21 U.S.C. 823(g)(1),[1] 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Paul E. Soeffing (the ALJ) who, on July 13, 2023, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 67. Respondent did not file exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings,[2] credibility findings,[3] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD and summarizes and expands upon portions thereof herein.

I. Findings of Fact

Standard of Care—Dispensing

Katherine Salinas, R.Ph., who is currently employed full-time as a Compliance Officer for the Texas State Board of Pharmacy, credibly testified for the Government as an expert in the standard of care and the professional responsibility required of a Texas pharmacy in its dispensing practices. RD, at 7–8, 21; Tr. 128, 131, 133–134; Government Exhibit (GX) 4, at 8.[4] According to Ms. Salinas, prior to dispensing a prescription for a controlled substance, Texas pharmacists are required to determine whether the prescription was issued in the usual course of professional practice and to make every reasonable effort to ensure that the prescription was issued for a legitimate medical purpose. RD, at 8, 9; Tr. 134, 135. Further, in making that determination, Texas pharmacists are required to exercise sound professional judgment, meaning that they must evaluate the prescription in its entirety and must contact the prescriber if the authenticity of the prescription is in question. RD, at 8–9; Tr. 134–135.

Ms. Salinas's testimony is consistent with Texas law which states that ''[a] pharmacist may not . . . dispense or deliver a controlled substance . . . except under a valid prescription and in the course of professional practice.'' Tex. Health & Safety Code section 481.074(a)(1). Texas law notes that ''[a] pharmacist may not . . . dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.'' *Id.* section 481.074(a)(2). Texas regulations require that a Texas pharmacist ''shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order'' and ''shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.'' 22 Tex. Admin. Code sections 291.29(a)–(b), 291.34(b)(1).

Ms. Salinas also testified that Texas pharmacists must check the Prescription Drug Monitoring Program (PDMP) and must attempt to resolve and document the resolution of any ''red flags''—warning signs or problematic patterns that indicate a potential for diversion—prior to dispensing controlled substances. RD, at 9–10; Tr. 135–136, 270.

In discussing red flags, Ms. Salinas testified that some of the known red flags include: the same doctor or group of doctors repeatedly prescribing the same strength and dosage of medication over a long period of time and/or for multiple patients (also called ''pattern prescribing''); prescriptions from a small group of doctors; patients traveling long distances to the pharmacy; multiple patients sharing the same address and receiving prescriptions for the same controlled substances from the same prescribers; [5] and ''non-therapeutic prescribing and dispensing'' where controlled substances are illegitimately prescribed or dispensed with other controlled and/or noncontrolled (including over-the-counter) substances.[6] RD, at 9, 10, 11, 14, 19; Tr. 136, 144, 146, 147, 159–160, 171, 173–174, 233–234, 281. Ms. Salinas testified that one red flag is sufficient to ''raise concern'' and that pharmacists have an ongoing responsibility to resolve red

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

[2] The only exception is with regards to allegations concerning the cash payment red flag, which this Decision and Order does not address due to the number and egregiousness of the rest of the allegations.

[3] The Agency adopts the ALJ's summary of each of the witnesses' testimonies as well as the ALJ's assessment of each of the witnesses' credibility. *See* RD, at 4–28. The Agency agrees with the ALJ that the testimony from the Government's expert witness, Ms. Katherine Salinas, R.Ph., which was focused on the Texas standard of care and Respondent's dispensing to the patients listed in the OSC/ISO, was credible in that it was internally consistent, logically persuasive, and presented an objective analysis. RD, at 21. The ALJ found that Ms. Salinas's testimony was credible and reliable, but ultimately gave her testimony less weight than he otherwise would have due to her prior interactions with Respondent during the course of her duties as a Compliance Officer. *Id.* at 21–22. Regarding the Respondent's case, the Agency agrees with the ALJ that the testimony from Respondent's former pharmacist-in-charge, E.W., which was focused on describing her process for filling prescriptions at Respondent, was generally credible and internally consistent, though, as noted by the ALJ, E.W.'s testimony was not specific to the prescriptions at issue and minimal evidence was offered in corroboration. *Id.* at 23. Finally, the Agency agrees with the ALJ that the testimony from Respondent's owner, S.M., which addressed Respondent's procedures for filling prescriptions, addressing red flags, keeping inventories, and securing controlled substances, was generally credible; however, minimal evidence was offered to corroborate her testimony and, as the ALJ noted, S.M. has a significant personal interest in the outcome of the proceedings. *Id.* at 28.

[4] For Ms. Salinas's full qualifications, *see* GX 43; RD, at 7–8.

[5] Ms. Salinas clarified that prescriptions issued within a month or two of each other that list the same address for the same controlled substance and written by the same prescriber would create a shared address red flag, whereas prescriptions issued and filled at a longer period apart with those same characteristics may not be caught or noticed by a pharmacist; a red flag determination would be ''diminished'' beyond the one-month timeframe. RD, at 11; Tr. 277–278.

[6] Ms. Salinas testified that receiving prescriptions for two opioids is uncommon and indicative of potential diversion; illegitimate prescriptions for schedule II controlled substances are commonly prescribed with other controlled and noncontrolled substances to give the illusion of legitimacy. RD, at 19; Tr. 233–234, 236. According to Ms. Salinas, the Texas State Board of Pharmacy rules and regulations warn pharmacists that a 1:1 ratio of controlled substances to noncontrolled or over-the-counter substances could indicate nontherapeutic dispensing and diversion. RD, at 19; Tr. 235. Ms. Salinas noted that these kinds of prescriptions are also referred to as ''cocktail'' or ''cocktail-like'' prescriptions. RD, at 19; Tr. 237.

flags—even if they are resolving the same red flags repeatedly—and to document their resolution. RD, at 9; Tr. 137–138, 143. Ms. Salinas also stated that if a pharmacist is unable to resolve a red flag, then he or she should not dispense the prescription. RD, at 9; Tr. 137, 247–248.

Similarly, the Texas Board of Pharmacy sets forth numerous operational standards for pharmacists filling prescriptions, requiring, firstly, that '' [f]or the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant . . . (III) reasonable dose and route of administration; . . . (VI) drug-drug interactions; . . . and (X) proper utilization, including overutilization or underutilization.'' *Id.* section 291.33(c)(2)(A)(i). Further, ''[u]pon identifying any clinically significant conditions . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.'' *Id.* section 291.33(c)(2)(A)(ii).

A Texas pharmacist must ensure that ''[p]rior to dispensing, any questions regarding a prescription drug order [] be resolved with the prescriber and written documentation of these discussions [be] made and maintained.'' *Id.* section 291.33(c)(2)(A)(iv). Such documentation must be made ''on the prescription or in the pharmacy's data processing system associated with the prescription . . . and shall include . . . (i) [the] date the prescriber was consulted; (ii) [the] name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) [the] initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.'' *Id.* section 291.33(c)(2)(C).

Finally, a Texas pharmacist must consider the various ''red flag factors'' in ''preventing the non-therapeutic dispensing of controlled substances,'' including, among others: pattern prescribing; prescriptions for controlled substances commonly known to be abused; prescriptions for controlled substances at the highest strength and/or in large quantities, indicating lack of individual drug therapy; multiple patients sharing the same address and obtaining similar controlled substance prescriptions from the same practitioner; and patients consistently paying for controlled substance prescriptions with cash rather than through insurance. *Id.* section 291.29(f).

Respondent's Inappropriate Dispensing

Pattern Prescribing

In reviewing the relevant PDMP data and patient profiles in the current matter, Ms. Salinas identified numerous instances and types of pattern prescribing. RD, at 10; Tr. 144–145. Specifically, Ms. Salinas noted that Respondent's most frequently dispensed controlled substances were oxycodone,[7] hydrocodone,[8] and promethazine with codeine.[9] RD, at 10; Tr. 144–145. Ms. Salinas explained that the opioids oxycodone and hydrocodone, the muscle relaxant carisoprodol, and promethazine cough syrup with codeine generate greater concern for diversion in instances of potential pattern prescribing because these drugs are commonly abused and diverted in the Houston area. RD, at 10–11; Tr. 141–142. Ms. Salinas also noted that prescriptions for ''strong opioids'' were written for and dispensed in ''at least'' a month's supply (over 100 tablets).[10] RD, at 10, 46; Tr. 144–145. Further, Ms. Salinas testified that 80 percent of the oxycodone prescriptions were written by the same three physicians, with a majority of these written by the same single physician, Dr. L.S.[11] RD, at 10; Tr. 144–145. Ms. Salinas testified that she reviewed the patient profiles, physician profiles, and the numerous prescriptions for oxycodone 30 mg, hydrocodone-acetaminophen 10–325 mg, and promethazine with codeine, and found no notations resolving any of the red flags, let alone the pattern prescribing red flag. RD, at 46; Tr. 147–230.

Moreover, Ms. Salinas testified regarding several examples of Respondent's dispensing that suggested a lack of individualization, another indicator of the pattern prescribing red flag. RD, at 47–48. For example, Patient M.B. always received a prescription for oxycodone along with a rotation of noncontrolled and over-the-counter substances such as a stool softener, ibuprofen, a muscle relaxant, vitamin D, and folic acid; meanwhile, Patient W.J. received prescriptions of oxycodone paired with a 300-day supply [12] of stool softener, which Ms. Salinas opined was particularly odd based on the number of tablets prescribed. RD, at 47; Tr. 234–239; *see also* GX 28, at 2, 7–8; GX 30, at 2–20.

In Ms. Salinas's unrebutted expert opinion, the red flag of pattern prescribing present in these prescriptions needed to be resolved before they were dispensed and such resolution needed to be documented; because there was no documented resolution of these red flags, Ms. Salinas found that Respondent failed to meet its corresponding responsibility. RD, at 11, 48; Tr. 146–147, 234, 239, 241–242. As such, the Agency agrees with the ALJ and finds that Respondent dispensed controlled substance prescriptions that presented the red flag of pattern prescribing and failed to properly document and resolve this red flag prior to dispensing; accordingly, Respondent filled these controlled substance prescriptions outside the usual course of professional practice in violation of the Texas standard of care. RD, at 49.

Shared Addresses

One of Texas' red flag factors is ''multiple persons with the same address present[ing] substantially similar controlled substance prescriptions from the same practitioner.'' 22 Tex. Admin. Code section 291.29(f)(11). Regarding the issue of shared addresses, Ms. Salinas provided many examples of Respondent's dispensing that raised the shared address red flag. RD, at 51–52. For example, Patients J.J. and S.B., who share an address, were both prescribed oxycodone 30 mg from Dr. L.S.; Respondent dispensed these prescriptions on January 6, 2022, and January 7, 2022, respectively. RD, at 51–52 n. 89; GX 44, at 20.[13] Dr. L.S. also issued prescriptions for 30 mg of oxycodone, all of which Respondent dispensed, to all of the following groups of patients with shared addresses: (1) G.V. on March 2, 2022, J.L. on March 10, 2022, and B.G. on April 21, 2022; (2) K.M. on August 4, 2021, and M.B. on August 20, 2021; (3) D.O. on August 18, 2021, and C.P. on August 19, 2021; and (4) C.B. and L.N. both on December 22, 2021. RD, at 52 n. 90, 92–95. Moreover, Respondent dispensed substantially

[7] *See* Tr. 148–159, 163–170, 195, 201–203, 219–220; GX 19, 26–28, 44 (Patients E.D., R.H., B.Y., D.S., J.J., S.B., G.V., J.L., B.G., D.G., B.J., K.M., M.B., D.O., C.P., T.P., Y.Y., C.B., L.N., B.B., D.P., J.C., M.H., L.M., R.T., T.M., D.A., R.P., S.S., T.C., C.H., E.H., L.S., R.J., W.J., and R.B.).

[8] *See* Tr. 170–171, 207; GX 31, 44 (Patients V.R., H.L., T.H., and B.B.).

[9] *See* Tr. 199; GX 22. (Patient J.A.).

[10] *See* Tr. 235–236; GX 31 (Patient B.B.).

[11] *See* Tr. 148–159; GX 44 (Patients E.D., R.H., B.Y., D.S., J.J., S.B., G.V., J.L., B.G., D.G., B.J., K.M., M.B., D.O., C.P., T.P., Y.Y., C.B., and L.N.).

[12] Without a documented explanation, Respondent filled only 100 of the tablets. RD, at 47 n. 84; Tr. 238–239.

[13] *See also* Tr. 148–159; GX 44 (Patients E.D., and B.Y.; Patients J.J. and S.B.; Patients G.V., J.L., and B.G.; Patients K.M. and M.B.; Patients D.O. and C.P.; and Patients C.B. and L.N.).

similar prescriptions for oxycodone 30 mg and other opioids issued by Drs. D.A., W.K., B.R., and M.Q. that were also prescribed to patients who shared the same address.[14] RD, at 12–13; Tr. 147–172; GX 44.

In Ms. Salinas's credible and unrebutted expert opinion, the red flag of shared addresses present in these prescriptions needed to be resolved before they were dispensed and such resolution needed to be documented; because there was no documented resolution of this red flag, Ms. Salinas found that Respondent failed to meet its corresponding responsibility. RD, at 14, 53; Tr. 162, 171–72, 279–280. As such, the Agency agrees with the ALJ and finds that Respondent dispensed controlled substances, issued less than two months apart, to patients who shared addresses and received prescriptions for the same controlled substances from the same prescriber. RD, at 54. Moreover, Respondent failed to properly resolve and document resolution of the shared address red flag prior to dispensing and, accordingly, filled these controlled substance prescriptions outside the usual course of professional practice in violation of the Texas standard of care. *Id.*

Long Distances

One of Texas' red flag factors is ''the geographical distance between the practitioner and the patient *or* between the pharmacy and the patient.'' 22 Tex. Admin. Code section 291.29(c)(4) (emphasis added). Ms. Salinas testified that Houston pharmacies generally use 30 miles as a guideline for when a distance traveled by a patient becomes a red flag. RD, at 16–17; Tr. 214. Ms. Salinas noted that the long-distance red flag can be resolved, but a pharmacist should have a conversation with the patient, document the specific issue or concern on the prescription, and document any reasonable explanation that resolves the red flag before dispensing the prescription. RD, at 17; Tr. 212–213, 229–230.

Regarding the red flag of long distances, Ms. Salinas testified that she calculated the distances traveled in the current matter based on the home addresses listed on the patients' prescriptions filled at Respondent. RD, at 18; Tr. 216–218. Based on her calculations, Ms. Salinas found that multiple patients traveled far beyond the guideline of 30 miles of their home addresses to fill prescriptions at Respondent.[15] For example, the following patients all traveled the following miles one way to fill prescriptions for oxycodone 30 mg at Respondent: E.H., 84.1 miles one way (Tr. 215–218); R.J., 92.5 miles one way (Tr. 220–221); R.B., 88.5 miles one way (Tr. 219–220); L.S., 74 miles one way (Tr. 222–223); W.J., 79.5 miles one way (Tr. 223–224); J.A., 167.5 miles one way (Tr. 224–225). RD, at 56–57. Ms. Salinas further testified that there was no documentation providing alternate addresses, distances, or explanations that documented a resolution of these red flags. RD, at 18, 57; Tr. 216–218, 225–229.

In Ms. Salinas's unrebutted expert opinion, the red flag of long distances present in these prescriptions needed to be resolved before they were dispensed and such resolution needed to be documented; because there was no documented resolution of this red flag, Ms. Salinas found that Respondent failed to meet its corresponding responsibility. RD, at 17, 20. Tr. 212–213, 241–242. As such, the Agency agrees with the ALJ and finds that Respondent dispensed controlled substances to patients who traveled long distances and failed to properly resolve and document resolution of the long-distance red flag prior to dispensing; accordingly, Respondent filled these controlled substance prescriptions outside the usual course of professional practice and in violation of the Texas standard of care. RD, at 59.

Respondent's Arguments Regarding Inappropriate Dispensing

Regarding Respondent's case, E.W. was the pharmacist-in-charge at Respondent at the time of the relevant events. RD, at 22; Tr. 304, 307. E.W. testified credibly, but with little corroborating evidence, regarding Respondent's general dispensing practices; however, she did not testify specifically regarding the prescriptions at issue in this case. RD, at 23. With regard to Respondent's general practice, E.W. testified that before dispensing prescriptions, she would get a phone number from the patient, discuss insurance with the patient, and then make a copy of the patient's driver's license. RD, at 22; Tr. 304. Next, after reviewing the full PDMP drug history of the patient, if ''everything check[ed] out,'' E.W. would enter the prescription, pull the medication, and ''go through the process.'' RD, at 22; Tr. 304–305. E.W. explained that she would check to make sure that prescribers were ''proper by law'' and Houston-based, adding that the pharmacy only filled prescriptions from Houston doctors ''in good standing.'' [16] RD, at 22; Tr. 305–307. E.W. testified that she never documented what she discovered through the verification process. RD, at 22 n.58, 23; Tr. 308, 310. Then, E.W. would fill the prescription, counsel the patient, and have him or her sign documentation affirming that he or she had been counseled. RD, at 22; Tr. 305. E.W. noted that the pharmacy has refused to fill prescriptions in the past, but admitted that she would not document her concerns or reasons for refusing to fill the prescription. RD, at 22–23; Tr. 308, 310–311. Again, E.W. did not testify specifically regarding the procedures followed with regard to the prescriptions at issue, but she did acknowledge that she knew that the PDMP data would have indicated that the same group of doctors was prescribing the same strength and quantity of medication to multiple patients. RD, at 22–23; Tr. 310.

As for Respondent's owner, S.M., she testified that though she is not a licensed pharmacist, she works as a pharmacy technician at Respondent. RD, at 23; Tr. 313–314. S.M.'s testimony was generally credible, but there was little corroborating evidence and the ALJ noted that she has a significant personal interest in the outcome of the proceedings. RD, at 28. S.M. testified generally regarding Respondent's process, stating that the pharmacy only fills prescriptions written by doctors in the Houston area. RD, at 23; Tr. 315. When asked whether Respondent ''check[ed] to make sure the prescriptions were legitimate,'' S.M. testified that Respondent ''hired a third party to go out to the doctors' offices to verify the doctors, check their licenses, [and] check to make sure that they were abiding by the red flag checklist.'' [17] Tr. 318; *see also* RD, at 23–24; Tr. 315–316, 321.[18] S.M. testified that when a patient

[14] *See* Tr. 163–171; GX 44 (Patients B.B. and D.P.; Patients L.M. and R.T.; Patients T.C. and R.P.; Patients H.L. and T.H.).

[15] *See* Tr. 215–225; RD, at 3–4, Stip. 12–17; GX 19, 22, 24, 26–28 (Patients E.H., R.B., R.J., L.S., W.J., and J.A.).

[16] E.W. testified that to verify ''good standing'' ''offices were called[,] . . . someone went out to check the doctors,'' or she would check the Texas Medical Board's website. RD, at 22 n.58, 23; Tr. 308, 310.

[17] The Agency notes that pharmacies have a ''corresponding responsibility'' to ensure proper dispensing of controlled substances that exists independent of a prescriber's responsibility. 21 CFR 1306.04(a). Nothing in Ms. Salinas's testimony suggests that making sure that prescribers are abiding by the red flag checklist is part of a pharmacy's corresponding responsibility. *See supra* Standard of Care—Dispensing.

[18] As evidence that Respondent generally took steps to identify red flags prior to dispensing, S.M. testified that she had sent at least one letter to the Texas Medical Board reporting physicians who

Continued

entered the pharmacy, either a pharmacist or herself would ask the patient for identification, take down the patient's allergy information and phone number, check the PDMP for ''anything that might stand out,'' and ''verify'' the prescription with the prescriber by calling the prescriber. RD, at 24; Tr. 330–331.[19] S.M. testified that if ''everything check[ed] out,'' Respondent would fill the prescription, at which time the pharmacist would ''counsel the patient about [the] medication'' and answer any questions. RD, at 24; Tr. 331.[20]

Regarding Respondent's procedure for addressing and resolving red flags, S.M. agreed that Texas pharmacies are to determine the legitimacy of prescriptions by resolving red flags and that resolution of red flags must be properly documented. RD, at 25; Tr. 370. S.M. testified that Respondent would ''check the patient, contact the doctor, verify the prescription[,] . . . [and] verify any information that [it] could from the patient.'' RD, at 24; Tr. 321. S.M. also testified that Respondent has refused to fill prescriptions in the past if, upon review of PDMP data, the pharmacist found that the patient was presenting for an early refill, the prescription was fraudulent, or the pharmacist did not think the prescription was legitimate. RD, at 24–25; Tr. 314. S.M. testified that if the pharmacist refuses to fill a prescription, the pharmacy keeps no record of that refusal and shreds the unfilled prescription; S.M. also asserted that ''[the pharmacy does not] have to document that [it] didn't fill the prescription.'' RD, at 25; Tr. 314–315.

S.M. testified that ''patient counseled'' written on prescriptions[21] reflects that the prescription was ''resolved to the pharmacist's satisfaction'' through the steps that S.M. testified Respondent takes prior to dispensing. RD, at 25; Tr. 363, 365. Notably, E.W. testified that she had written ''consult,'' not ''patient counseled,'' on the prescriptions at issue in this case to indicate that she had looked at the PDMP. RD, at 22; Tr. 306, 363. However, review of the prescription records at issue indicates that only ''counseled'' or ''patient counsel'' (and not ''consult'') were ever written on the prescriptions at issue, and review of both E.W. and S.M.'s full testimony suggests there is no distinction between the use of the words ''consult'' and ''counsel.'' This suggests an imprecise word choice by E.W. All that is relevant to this matter is that the prescriptions said ''counseled'' or ''patient counsel'' and S.M. testified that more detailed patient notes were unnecessary because Respondent conducts the same process for all patients and all prescriptions, including refill prescriptions. RD, at 25; Tr. 363–364.

Contrary to S.M.'s testimony, Ms. Salinas opined that the handwritten note to the effect of ''patient counsel'' present on the majority of the prescriptions at issue in the current matter does not constitute red flag resolution. First, she testified, patient counseling is a separate requirement under the Texas State Board of Pharmacy regulations, and ''counseling usually entails talking about what the medication is, how to take it, what to do if you miss a dose, side effects to watch out for . . . that sort of thing.'' RD, at 16, 18; Tr. 187–188, 209–210, 229–230. Second, even if Respondent writing ''patient counsel'' was meant to show red flag resolution, the notations in the current matter do not satisfy the requirement of documentation of red flag resolution because they ''[do not] tell the story.'' RD, at 16, 18; Tr. 187–188, 209–210, 229–230. The Agency credits Ms. Salinas's expert opinion that Respondent failed to adequately document resolution of the relevant red flags prior to dispensing each of the prescriptions at issue in this case. *See supra,* at Respondent's Inappropriate Dispensing; *see also* RD, at 28.

Regarding the various red flags at issue in the current matter, S.M. testified that the patients who traveled to Respondent from non-Houston addresses did so because the pharmacies near their homes do not carry controlled substances prescribed to treat pain. RD, at 26; Tr. 325.[22] Respondent did not present evidence to support this claim nor evidence that this information was documented in either patient profiles or on patients' prescriptions.[23]

Standard of Care—Inventory, Recordkeeping, and Storage

The CSA requires pharmacies to keep accurate and timely records of inventory and dispensing, including initial and biennial inventories. 21 CFR 1304.11(a)–(c). Texas law also requires pharmacies to keep and maintain records, including ''a perpetual inventory of any controlled substance listed in Schedule II.'' 22 Tex. Admin. Code section 291.75(a)(1), (c)(4)–(5).

Ms. Salinas testified that Texas pharmacies are required to keep and maintain accurate records of all prescriptions, invoices, signature logs for individuals participating in prescription processing, counseling documentation, and controlled substance inventories for at least two years. RD, at 10, 60; Tr. 138–139. Ms. Salinas also testified that Texas pharmacies are required by law to have inventories of all controlled substances available for inspection. RD, at 20–21; Tr. 243. Ms. Salinas noted that under the Texas standard of care, in the case of a disaster such as a flood, a pharmacy must notify the Texas State Board of Pharmacy within ten days and should immediately re-conduct an inventory. RD, at 21; Tr. 243–244.

The CSA requires that ''[c]ontrolled substances listed in Schedules II, III, IV, and V . . . be stored in a securely locked, substantially constructed cabinet.'' 21 CFR 1301.75(b); RD, at 60. Regarding storage, Ms. Salinas testified that Texas pharmacies must keep their controlled substances stored, locked, and secured at their registered location as well as have written security policies and procedures, motion sensors, and an alarm system with offsite monitoring. RD, at 10, 21, 61; Tr. 139, 245. Ms. Salinas testified that she was not aware

were writing questionable prescriptions. RD, at 24 n.60; Tr. 318–20; Respondent Exhibit (RX) 7, at 1–2. Even so, there is no evidence that respondent identified and resolved the relevant red flags prior to dispensing the controlled substances at issue in this case.

[19] S.M. agreed that PDMP data would show information pertaining to prescribers who write prescriptions for oxycodone 30 mg to multiple patients for multiple months. RD, at 25; Tr. 361–362.

[20] S.M. testified that if Respondent needed information on a patient's diagnosis or condition or any other additional information, someone working at Respondent would call the prescriber, who ''would let [Respondent] know at length about [the patient's] medical records, if [the patient was] in an accident or if [the patient] had some kind of other ailment going on,''; whoever called the prescriber would document the information by ''[writing] it down sometimes in the patient's profile and sometimes on the back of the prescription.'' RD, at 24; Tr. 328. S.M. testified that on the back of prescriptions, she would note ''if something changed with the prescription, if the quantity was incorrect or the doctor wrote the SIG wrong, things like that.'' RD, at 24; Tr. 329. However, there is no evidence of such documentation for the relevant prescriptions.

[21] When S.M. was first asked what ''counseled patient'' written on the back of a prescription meant, she testified that that it meant that the pharmacist had counseled the patient ''at length about [the] prescription.'' Tr. 329. This testimony is consistent with Ms. Salinas's testimony regarding the typical meaning of the notation. *See infra;* RD, at 16; Tr. 187–88; 209–10.

[22] S.M. testified that Respondent was ''never instructed to write . . . if the patient's address was far away'' and that ''[Respondent has] been inspected several times by Ms. Salinas, and . . . [has] never been directed by her to do that.'' RD, at 25; Tr. 364. Even if true, this does not relieve Respondent of its obligations under Texas law.

[23] *See, e.g., George Pursley, M.D.,* 85 FR 80162, 80171 n.28 (2020) (''Post hoc written or oral justifications . . . are not controlling.'').

of any exceptions to these requirements and that it would be concerning to her if a registrant was storing controlled substances at a personal residence; further, Ms. Salinas opined that there is no justification for removing controlled substances from the registered location and if drugs are ever moved, registrants are required to document the move. RD, at 21; Tr. 245–246.

Respondent's Case

S.M. admitted that Respondent did not have initial, ending, or biennial inventories at the time of DEA's June 1, 2022 inspection and that the last annual inventory that Respondent had on file was for 2020. RD, at 26, 60; Tr. 339, 344, 352–353. S.M. testified that in late 2021, a pipe burst in a neighboring business causing a flood that damaged Respondent's inventories. RD, at 26; Tr. 340–341, 344, 351. S.M. admitted that she ''should have immediately recreated'' the inventory and that not doing so was a mistake in judgment. RD, at 26–27; Tr. 348–349. S.M. testified that she has since taken remedial action by updating Respondent's perpetual inventory on a daily basis. RD, at 27; Tr. 349. S.M. acknowledged that Respondent's current inventory was initially generated on June 1, 2022, during the DEA inspection when Respondent's pharmacist-in-charge and DEA Diversion Investigators conducted a pill count upon return of the controlled substances from S.M.'s residence to Respondent's registered location. RD, at 27; Tr. 353. S.M. also acknowledged that at least six months had passed between the date that she asserts Respondent's inventories were damaged by flooding and the June 1, 2022 inspection, with S.M. testifying that she tried to recreate the inventory during that time but that it ''takes a lot to recreate an inventory.'' RD, at 27; Tr. 353–354. S.M. asserted that Respondent has since corrected the situation and that on the date that the OSC/ISO was issued in the current matter, Respondent had current inventories. RD, at 26; Tr. 345.

S.M. also admitted that without permission from DEA or the Texas State Board of Pharmacy, she removed controlled substances from Respondent's registered location and transported them to her personal residence on a daily basis. RD, at 27, 61; Tr. 111, 338. S.M. acknowledged that while she was transporting drugs to and from her home, there was a working safe at the pharmacy. RD, at 28; Tr. 360.[24] S.M. testified that she took the controlled substances home ''to ensure the safety of the drugs'' after there were burglaries and robberies in the neighborhood where Respondent is located, including two instances of attempted burglary at Respondent itself. RD, at 27, 61; Tr. 336–338, 355–358; RX 4–5.[25] S.M. also testified that she removed the controlled substances from Respondent because ''[w]hen the pandemic started, it was chaos[,] . . . [there was] no clear direction on what to do with anything[,] . . . [e]verybody was working from home . . . [and] [n]obody knew what to do . . . [because] [nobody could] get in contact with anyone.'' RD, at 27–28; Tr. 338–339. S.M. testified that she has since taken remedial action by keeping Respondent's controlled substances locked in the safe at the registered location and she has stopped transporting controlled substances to and from Respondent on a daily basis following the June 2022 inspection. RD, at 28; Tr. 349, 338–339.

Based on Respondent's admissions, the Agency agrees with the ALJ that Respondent did not take and/or keep initial or biennial inventories as of the date of DEA's June 2022 inspection and did not store its controlled substances in a securely locked and substantially constructed cabinet. RD, at 60, 61; ALJ Exhibit 7 (Respondent's Answer), at 2.

II. Discussion

A. The Five Public Interest Factors

Under the CSA, ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

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

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

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

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

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

21 U.S.C. 823(g)(1).

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case for revocation of Respondent's registration is confined to Factors B and D. RD, at 31–32; *see also id.* at 31 n.66 (finding that Factors A, C, and E do not weigh for or against revocation).

Having reviewed the record and the RD, the Agency agrees with the ALJ, adopts the ALJ's analysis, and finds that the Government's evidence satisfies its *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4); RD, at 31–62.

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Sualeh Ashraf, M.D.,* 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Respondent violated numerous Federal and State laws regulating controlled substances. OSC/ISO, at 2–10.[26] Specifically, Federal law requires that ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice,'' and that ''[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a), 1306.06;

[24] A DEA Diversion Investigator testified that during the June 2022 inspection, she retrieved controlled substances from S.M.'s home that were being kept in an unlocked suitcase in the closet. RD, at 61; Tr. 41–45; GX 41, at 1–2.

[25] S.M. testified that she had called both DEA and the Texas State Board of Pharmacy regarding the attempted burglaries but that neither entity ''did anything.'' RD, at 27 n.63; Tr. 338. S.M. testified that ''[she] thought [she] was doing the correct thing by taking the drugs and taking them away from an environment where [people] were breaking in and trying to rob[,] . . . [b]ut [she] [does] know now that [she] was not doing the right thing, and [she] would not do it again.'' RD, at 28; Tr. 348.

[26] The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan* v. *United States,* 142 S. Ct. 2,370 (2022) (decided in the context of criminal proceedings).

see also 21 U.S.C. 829. Federal law also emphasizes that although ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a).[27] Regarding recordkeeping, inventory, and storage, Federal law requires that ''[c]ontrolled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.'' *Id.* § 1301.75(b). In addition, pharmacies are required to keep and maintain accurate and timely records of dispensing and inventory, including initial and biennial inventories. *Id.* § 1304.11(a)–(c).[28]

As for State law, Texas regulations require that ''[a] pharmacist may not . . . dispense or deliver a controlled substance . . . except under a valid prescription and in the course of professional practice.'' Tex. Health & Safety Code section 481.074(a)(1).[29] The Texas Board of Pharmacy also sets forth numerous operational standards for pharmacists filling prescriptions, requiring, firstly, that pharmacists ''shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant . . . (III) reasonable dose and route of administration; . . . (VI) drug-drug interactions; . . . and (X) proper utilization, including overutilization or underutilization.'' *Id.* section 291.33(c)(2)(A)(i). Further, ''[u]pon identifying any clinically significant conditions . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.'' *Id.* section 291.33(c)(2)(A)(ii). A Texas pharmacist must also ensure that ''[p]rior to dispensing, any questions regarding a prescription drug order [ ] be resolved with the prescriber and written documentation of these discussions [be] made and maintained.'' *Id.* section 291.33(c)(2)(A)(iv).[30] Finally, a Texas pharmacist must consider the various ''red flag factors'' in preventing the non-therapeutic dispensing of controlled substances, including, among others: pattern prescribing; prescriptions for controlled substances commonly known to be abused; prescriptions for controlled substances at the highest strength and/or in large quantities, indicating lack of individual drug therapy; multiple patients sharing the same address and obtaining similar controlled substance prescriptions from the same practitioner; and patients consistently paying for controlled substance prescriptions with cash rather than through insurance. *Id.* section 291.29(f). ''The geographical distance between the practitioner and the patient *or* between the pharmacy and the patient,'' can present as an additional red flag factor under Texas regulations. 22 Tex. Admin. Code section 291.29(c)(4) (emphasis added). Regarding recordkeeping, inventory, and storage, Texas pharmacies are required to keep and maintain accurate and timely records of the inventory and distribution of controlled substances—including ''a perpetual inventory of any controlled substance listed in Schedule II''—and such documentation must be readily available upon request or inspection. *Id.* section 291.75(a)(1), (c)(4)–(5).

In the current matter, the Agency agrees with the ALJ's analysis that Respondent's dispensing fell below the Texas standard of care—and thus was outside the usual course of professional practice—because, as detailed above, Respondent repeatedly filled prescriptions for controlled substances for multiple patients without adhering to Texas' operational standards for pharmacists filling prescriptions and without addressing or resolving numerous and blatant red flags of abuse and/or diversion;[31] in addition, Respondent repeatedly failed in its obligations regarding recordkeeping, inventory, and storage.[32] *Id.* at 42–44, 49–50, 53–55, 59–62. As Respondent's conduct displays clear violations of the Federal and State regulations described above, the Agency agrees with the ALJ and hereby finds that Respondent repeatedly violated Federal and State law relating to controlled substances. *Id.* Accordingly, the Agency agrees with the ALJ and finds that Factors B and D weigh in favor of revocation of Respondent's registration and thus finds Respondent's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). *Id.* at 61–62.

III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Respondent's registration, the burden shifts to the registrant to show why it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, it must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the

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

[28] Registrants are required to take an ''initial inventory,'' meaning an ''inventory of all stocks of controlled substances on hand on the date [they] first engage[ ] in the manufacture, distribution, or dispensing of controlled substances . . . ''; ''[a]fter the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years'' and this ''biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.'' *Id.* § 1304.11(b)–(c).

[29] Texas law states that ''[a] pharmacist may not . . . dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.'' *Id.* section 481.074(a)(2). Further, it is unlawful in Texas for any ''registrant or dispenser'' to knowingly deliver a controlled substance in violation of sections 481.070–481.075 of the Texas Health and Safety Code. *Id.* section 481.128. Texas regulations require that a Texas pharmacist ''shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order'' and ''shall make every reasonable effort to ensure that any prescription drug order . . . has been issued for a legitimate medical purpose by a practitioner in the course of medical practice.'' 22 Tex. Admin. Code sections 291.29(a)–(b), 291.34(b)(1).

[30] Such documentation must be ''on the prescription or in the pharmacy's data processing system associated with the prescription . . . and shall include . . . (i) [the] date the prescriber was consulted; (ii) [the] name of the person communicating the prescriber's instructions; (iii) any applicable information pertaining to the consultation; and (iv) [the] initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.'' *Id.* section 291.33(c)(2)(C).

[31] Although Ms. Salinas opined that different apartment or unit numbers at the same address would be considered a shared address red flag under the Texas standard of care, *see supra,* the ALJ found that ''[w]hile different apartments in the same building or complex may share the same street number, the unit or apartment number that completes the address makes them unique addresses.'' RD, at 54. However, the Agency has previously agreed with Ms. Salinas and found that different apartment or unit numbers at the same address constituted the shared address red flag under the Texas standard of care when the patients in question were receiving prescriptions for the same controlled substances from the same prescribers. *Blue Mint Pharmacy,* 88 FR 75326, 75327–75328 (2023).

[32] The Agency also agrees with the ALJ's conclusions that none of Respondent's arguments to the contrary, as detailed above, refute this analysis. RD, at 42–44, 48–50, 57–60.

Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33738, 33746 (2021).

Here, and as noted by the ALJ, Respondent, through its owner, admitted fault for its failure to maintain adequate inventories and failure to properly store controlled substances at its registered location.[33] RD, at 63–64; Tr. 338–339, 348–349, 354. However, Respondent completely ''failed to acknowledge [its] errors in handling prescriptions with red flags'' and did not ''accept responsibility for failing to identify, resolve, and document red flags.'' RD, at 64–65. As such, the ALJ concluded, and the Agency agrees, that Respondent has not demonstrated unequivocal acceptance of responsibility for its actions. RD, at 64 (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79188, 79201–202 (2016)).

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 at 79202–303); *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801, 74810 (2015). Even so, in the current matter, Respondent did not provide any evidence of remedial measures related to its improper dispensing that demonstrate that Respondent would be able to spot, resolve, and document resolution of red flags in the future. The ALJ noted, and the Agency has considered, that Respondent's owner testified, without documentary corroboration, that since the June 2022 inspection, Respondent has updated its ''perpetual inventory'' on a daily basis and keeps its controlled substances locked in the registered location's safe. RD, at 65 n.120; Tr. 345, 349. However, ''remediation alone is not adequate to avoid a sanction and [ ] limited-to-no-weight is given to remedial measures when the effort is not made until after enforcement begins.'' *Morris & Dickson Co., LLC,* 88 FR 34523, 34540 (2023).[34] Moreover, because the Respondent has not presented evidence of any remedial measures for its egregious dispensing failures, the Agency cannot entrust Respondent with a registration.

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR at 74810. In this case, the Agency agrees with the ALJ that given that Respondent's pharmacist-in-charge filled every single prescription at issue and that Respondent's owner testified that she was present for and involved in all filling of prescriptions, yet both individuals failed to acknowledge that any red flags existed or required resolution, ''the interests of specific deterrence, even standing alone, motivate powerfully in favor of revocation.'' RD, at 66–67; Tr. 321, 328–331. Further, the Agency agrees with the ALJ that the interests of general deterrence also support revocation, as a lack of sanction in the current matter would send a message to the registrant community that the failure to properly address and document resolution of red flags, the failure to keep adequate inventories, and/or the failure to securely store controlled substances can be excused. RD, at 67.

Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious. *Id.* at 66. As stated by the ALJ, ''Respondent dispensed many controlled substances over a one-and-a-half-year period without any regard for its obligations to identify, resolve, or document any blatant red flags of potential diversion'' and with awareness of both its obligations and the existence of numerous red flags in the prescriptions that it was filling and dispensing. *Id.;* Tr. 310, 364–365, 367, 370. Further, regarding recordkeeping, inventory, and storage, Respondent not only failed to maintain proper inventories, thereby ''precluding the ability of DEA to conduct an accountability audit,'' but also failed to properly store controlled substances at its registered location, with Respondent's owner instead transporting and storing controlled substances at a personal residence in complete disregard of security requirements. RD, at 66.

In sum, Respondent has not offered any credible evidence on the record that rebuts the Government's case for revocation of its registration and Respondent has not demonstrated that it can be entrusted with the responsibility of registration. *Id.* at 67. 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. FM2396427 issued to Midtown Specialty RX. 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 Midtown Specialty RX to renew or modify this registration, as well as any other pending application of Midtown Specialty RX for additional registration in Texas. This Order is effective November 12, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 4, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Halowells Pharmacy; Decision and Order

On November 8, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Halowells Pharmacy (Registrant) of Pearland, Texas. Request for Final Agency Action (RFAA), Exhibit (RFAAX) A, at 1. The OSC/ISO informed Registrant of the immediate suspension of its DEA Certificate of Registration, Control No.

[33] While Respondent clearly violated both Federal and State law by failing to have inventories on hand during the June 2022 inspection, Respondent has accepted responsibility for and taken steps to remediate this particular violation. Respondent has also accepted responsibility, though perhaps not unequivocally, and attempted to remediate the improper storage of controlled substances at her home. However, acceptance of responsibility and remedial steps regarding these two violations does not lead the Agency to reduce the sanction here, because the evidence shows that Respondent has not unequivocally accepted responsibility nor taken any steps to remediate the egregious dispensing violations. *See infra.*

[34] Citing *Mireille Lalanne, M.D.,* 78 47750, 47777 (2013) (quoting *Liddy's Pharmacy, L.L.C.,* 76 FR 48887, 48897 (2011) (''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.'')); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36503 (2007) (giving no weight to respondent's ''stroke-of-midnight decision'' to cease supplying suspect pharmacies with controlled substances and to employ a compliance officer).