Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2026–02914 Filed 2–12–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1654]

Bulk Manufacturer of Controlled Substances Application: Scottsdale Research Institute

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Scottsdale Research Institute has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before April 14, 2026. Such persons may also file a written request for a hearing on the application on or before April 14, 2026.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on January 8, 2026, Scottsdale Research Institute, 12815 North Cave Creek Road, Phoenix, Arizona 85022, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to bulk manufacture the listed controlled substances to support clinical trials and distribution to their customers. No other activities for these drug codes are authorized for this registration.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2026–02908 Filed 2–12–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

John Bender, M.D.; Decision and Order

On October 17, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to John Bender, M.D., of Fort Collins, Florida (Respondent). OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificates of Registration Nos. BB3697577 and FB3064831, alleging that Respondent's continued registration is ''an imminent danger to the public health or safety.'' *Id.* (quoting 21 U.S.C. 824(d)). The OSC also proposed the revocation of Respondent's registration because Respondent has committed such acts as would render his registration inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(g)(1); 824(a)(4)).

More specifically, the OSC alleges that between April 25, 2022, and June 11, 2024, Respondent filled approximately 4,244 controlled substance prescriptions issued by practitioners at his clinic without possessing a state pharmacy license or a DEA pharmacy registration, in violation of state and federal law. *Id.* at 4 (citing 21 CFR 1306.04 and 1306.06, and Colo. Rev. Stat. 12–280–120(1) and 12–280–129(1)(d)).[1] [2] The OSC further alleges that the two office locations where Respondent dispensed controlled substances operated as unregistered pharmacies. *Id.* (citing 21 U.S.C. 823(g)(1), 21 CFR 1301.11(a), 1301.13(e), Colo. Rev. Stat 12–280–120(1), 12–280–129(1)(d)).

After conducting a hearing, Administrative Law Judge, Paul E. Soeffing issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Recommended Decision or RD) on June 2, 2025. The RD recommended that the Agency revoke Respondent's registration. RD, at 32. Respondent filed untimely exceptions to the RD.[3] The Agency adopts and hereby incorporates by reference the ALJ's credibility findings,[4] findings of fact, sanctions analysis, and recommended sanction, and summarizes and clarifies portions

[1] The Government further alleges that Respondent violated 21 CFR 1307.11 but does not reference this provision in its Post-Hearing Brief. *See* OSC, at 4. The OSC also alleges that Respondent failed to report prescriptions to the Colorado Prescription Monitoring Program but the Government does not reference these allegations in its Post-Hearing Brief. *Id.* at 3. Accordingly, the Agency considers these allegations as abandoned and does address them.

[2] The Agency need not adjudicate the criminal violations alleged in the OSC/ISO. *Ruan* v. *United States,* 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

[3] Respondent's Exceptions were filed on July 28, 2025, over a month after the regulatory deadline of June 22, 2025. *See* 21 CFR 1316.66 (requiring Exceptions to be filed ''[w]ithin twenty days after the date upon which a party is served a copy of the report of the presiding officer''); June 30, 2025 Transmittal Letter from the Chief ALJ (stating that the ALJ's Recommended Decision was sent to the parties on June 2, 2025). Respondent states in its Motion for Leave to File Exceptions Out of Time that ''[u]nder 21 CFR 1316.66, a party may be granted leave to file exceptions out of time when it serves the interests of justice and the other party is not prejudiced.'' This is a misstatement of 21 CFR 1316.66, which outlines the foregoing standard for assessing whether a party may file a *response* to the opposing party's Exceptions after the 20-day deadline has lapsed. Here, the Government did not file Exceptions.

In the absence of a more specific standard for assessing the timeliness of Respondent's Exceptions, the Agency considers whether Respondent has provided good cause for the untimely filing, and finds that Respondent has not. Respondent did not provide any explanation for why his Exceptions were over a month late, why he did not request an extension from the ALJ, or why the late filing should be excused. July 17, 2025 Motion for Leave. Respondent simply argued that the interests of justice require his Exceptions to be considered because the ALJ's recommendations were incorrect, unsupported, and infringed upon his constitutional rights. *Id.* at 1–2. In other words, Respondent's justification for the late filing was that he disagreed with the Recommended Decision.

Notwithstanding Respondent's failure to demonstrate good cause, the Agency exercises its discretion to consider Respondent's untimely Exceptions, in part because the Agency has not adopted the ALJ's legal analysis and finds that addressing Respondent's Exceptions provides important guidance to the registrant community on DEA's interpretations of the relevant provisions of the CSA. Ultimately, the Agency rejects Respondent's Exceptions and agrees with the ALJ's recommended sanction.

[4] 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 3–10.

thereof herein. The Agency does not adopt the ALJ's conclusions of law, but ultimately agrees with the ALJ that revocation is the appropriate sanction.

I. Applicable Law

As the Supreme Court stated in *Gonzales* v. *Raich,* 545 U.S. 1 (2005), ''the main objectives of the [Controlled Substances Act (CSA)] were to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances.'' 545 U.S. at 12. *Gonzales* explained that:

> Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA . . . . The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.

Id. at 12–14. Here, the OSC's allegations concern the CSA's ''strict requirements regarding registration[,] . . . [and] drug security'' and, therefore, go to the heart of the CSA's ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'' *Id.*

A. The Allegation That Respondent Unlawfully Filled Controlled Substance Prescriptions Without a Pharmacy State License or Pharmacy Registration

The CSA requires ''[e]very person who dispenses, or proposes to dispense, any controlled substance'' to obtain a registration according to DEA regulations, unless exempted. 21 U.S.C. 822(a)(2). The CSA defines ''dispense'' as ''to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery.'' 21 U.S.C. 802(10). Registrants are authorized to dispense controlled substances ''to the extent authorized by their registration and in conformity with other provisions of [title 21 of the United States Code].'' 21 U.S.C. 822(b).

There are two primary categories of dispensing: (1) filling prescriptions and (2) dispensing or administering medications directly to patients without a prescription. Pursuant to the CSA's implementing regulations, only a pharmacist ''acting in the usual course of his [or her] professional practice'' may fill a prescription for a controlled substance. 21 CFR 1306.06. The regulations define a prescription as:

> an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (*e.g.,* an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

21 CFR 1300.01.

A practitioner may not fill a prescription. 21 CFR 1306.06. However, a practitioner may dispense or administer a controlled substance directly to the ultimate user, without a prescription, in the usual course of his professional practice. *See supra* Section II.B. (discussing 21 U.S.C. 829(a), (b); 21 CFR 1306.11; 21 CFR 1306.21).

I. Findings of Fact

Respondent is a licensed physician in Colorado. Tr. 214–16, 241–42, 381, 408, 449; GX 2; RX 3; RD, at 17. Respondent has two DEA practitioner registrations in Fort Collins, Colorado, and Parker, Colorado. Tr. 70–71; GX 1; RD, at 4.

The Miramont Wellness Clinic (MWC)

Respondent has an ownership interest in Miramont Wellness Clinic (MWC), which has three office locations in Colorado, including two in Fort Collins (the Drake Road and Snow Mesa locations) and one in Parker (the Parker location). Tr. 79; RD, at 4. Each office has a retail store. Tr. 39–40, 78; GX 5. As of April 24, 2024, MWC employed several mid-level practitioners and physicians, including Dr. K.L., who was identified as a top ten recipient of controlled substances in Colorado. Tr. 31; RD, at 3. Dr. K.L. was the principal practitioner at the Drake Road location, while Respondent was the principal practitioner at the Snow Mesa and Parker locations. Tr. 79; RD, at 4. MWC also employed administrative staff and pharmacy technicians who were not practicing under a pharmacist's license. Tr. 58–59, 407;[5] GX 7; RD, at 5. Respondent does not possess, and has never possessed, any pharmacy registrations for MWC with DEA or the State of Colorado. Tr. 75–76, 381; GX 69; RD, at 4–5, 16.

[5] Respondent testified that MWC ''did hire people who had degrees in pharmacy technician, but they weren't practicing under a pharmacist's license. When they come to work for me, they're practicing under a medical doctor license.'' Tr. 407. Respondent further testified that one of MWC's employees, Ms. J.T., was trained as a Certified Pharmacy Technician, but she was not licensed by the Colorado Board of Pharmacy. *Id.* at 442.

MWC's Dispensing of Controlled Substances

On April 25, 2024, the Diversion Investigator (DI) assigned to this case inspected MWC's Drake Road location during an investigation of Dr. K.L. Tr. 31; RD, at 3. DI observed that this location appeared to be operating like a retail pharmacy. Tr. 35–36. There was a drive-thru for patients to fill their prescriptions and an area inside the office identified with a sign ''Dispensary Rx,'' that contained a pharmacy counter, a cash register, a retail waiting area, and a prescription vending machine, called VendRx, that dispensed medications. Tr. 35–39, 54–55; GX 7, at 5–7; GX 71, at 3; RD, at 3, 5. MWC's website includes a picture of the VendRx machine and states, ''We also offer low-cost Prescription Dispensing, with 24 hour* prescription refills at our DirectRX vending machines.'' Tr. 43; GX 5, at 1. The asterisk language states ''*24 Hour dispensing available at our Miramont Drake Location.'' Tr. 43–44; GX 5, at 2. Each MWC location has a VendRx machine that fills prescriptions issued by MWC's practitioners. Tr. 242; RD, at 7.

Respondent prepared a video demonstrating how the VendRx machine works. RX 7. The practitioner first generates an electronic prescription through the VendRx software by clicking on the ''Write Rx'' tab and entering the patient's name, gender, and date of birth, and then adding the drug type, strength, quantity, usage instructions, days' supply, number of refills, and practitioner's signature. *Id.* The practitioner then hits the ''prescribe'' button, and the prescription can be filled by the patient at the VendRx machine. *Id.*

The record includes video from MWC's website showing how the VendRx machine operates from the patient's perspective. Tr. 44–47, 51; GX 6. The video contains a spoken narrative that informs patients that MWC ''pioneered a robotic prescription dispensing machine . . . calle[d] DirectRX . . . [that] allows [MWC's] doctors to prescribe your medications quickly during your office visits.'' GX 6; GX 70. It instructs patients to ''simply walk up to the machine, type in your last name, follow the prompt, pay with your credit card, and you will receive your prescription and your receipt.'' GX 6; GX 70. As the patient begins typing in her last name, the machine auto generates a list of patients with last names containing those letters. For example, in Respondent's demonstrative video, a woman types in ''M–A,'' and the machine offers two individuals with

a last name beginning with those letters. RX 7. After the woman selects the correct name and enters the patient's date of birth, a screen pops up that reads, ''retrieving prescription data,'' followed by a screen that lists the prescription(s) that will be filled and asks for the patient's signature. *Id.*

Respondent testified that the VendRx machine cannot dispense any medications that are in a box or in small or large bottles. Tr. 389. Because of these limitations, the VendRx can only fill about 10% of the controlled substance prescriptions filled at MWC. *Id.* When medications cannot be dispensed by the machine, the machine generates a receipt, which the patient takes to the retail manager, who confirms the identity of the patient, that the patient's signature is present, and that payment has been made. *Id.* at 397. The retail manager confirms that the medication on the claim ticket matches what is in the system, prepares a label, and dispenses the medication. *Id.*

Respondent testified that even when VendRx does not dispense the medication, its inventory control system keeps a permanent log of all medications dispensed at MWC. *Id.* at 248, 389, 399. Respondent testified that MWC does not fill prescriptions for individuals who are not patients of MWC. *Id.* at 399.

Respondent's Purchases of Controlled Substances From Suppliers

DEA maintains an internal system called ARCOS (Automated Reporting and Consolidated Ordering System) that contains reports of all controlled substances that a supplier has sold to an entity. Tr. 81; RD, at 5. Suppliers are required to report to ARCOS what they have sold to DEA registrants. Tr. 83; RD, at 5. ARCOS contains the name of the supplier, the name, quantity, and strength of the controlled substance, the size of the bottles or packaging, and the National Drug Code numbers for the controlled substance. Tr. 81–82; RD, at 5. DI searched ARCOS for all practitioners at MWC, including Respondent, for the two-year period from April 24, 2022, through April 24, 2024. Tr. 83–84, 94; RD, at 5. The ARCOS information for Respondent returned numerous orders, consistent with his ranking as the fourth highest recipient of controlled substances in Colorado. Tr. 95–96, 104; GX 8–9; RD, at 5. DI testified that, in contrast, the ARCOS information for the other practitioners at MWC (aside from Dr. K.L., who ordered controlled substances for the Drake location) showed that they ordered little or no controlled substances for MWC. Tr. 96–97, 104, 208; GX 10–22; RD, at 5.

DI served administrative subpoenas on three of Respondent's suppliers, as well as VendRx, the Colorado Board of Pharmacy, and Walgreens to authenticate the ARCOS information for Respondent. Tr. 105–11; GX 23, 25, 31, 33, 35, 37, 39, 41, 43, 58, 62, 64, 66, and 68; RD, at 5. The subpoena responses showed, and Respondent admits, that Respondent purchased the vast majority of the controlled substances that were dispensed at the Snow Mesa and Parker locations. Tr. 112–13, 116–17, 125–26, 156, 159, 208, 428–29; GX 24, 26–30, 32, 34, 36, 38, 40, 42, 67, 69; Resp. Post-hearing brief, at 24 (''[Respondent] does not dispute, that he ordered many of the medications, including controlled substances, that were dispensed at the Miramont Snow Mesa and Parker offices.''); RD, at 5; *but see* Tr. 325 (Respondent's testimony that he did not begin ordering controlled substances for the Parker location until June 2023).

Dispensing of Controlled Substances at MWC

From April 25, 2022 to April 25, 2024, MWC filled approximately 4,244 controlled substance prescriptions that were issued by practitioners other than Respondent at the Snow Mesa and Parker locations. Tr. 158–61; GX 40, 42, 67; RD, at 5. These prescriptions were filled by the VendRx machines and by unlicensed employees, and they were filled with controlled substances that Respondent had purchased. *Id.* Tr. 112–13, 116–17, 125–26, 156, 159, 208; GX 24, 26–30, 32, 34, 36, 38, 40, 42, 67, 69; Resp. Post-hearing brief, at 24; RD, at 5. The controlled substances dispensed included a schedule II opioid (hydrocodone-acetaminophen); a schedule III hormone (testosterone-cypionate); schedule IV benzodiazepines, sedatives, painkillers, and weight loss drugs (lorazepam, diazepam, alprazolam, clonazepam, zolpidem, carisoprodol, tramadol, eszopiclone, and phentermine); and a schedule V opioid (codeine-guaifenesin). Tr. 161–63; GX 40, 42, 67; RD, at 2–3, 5, 14, 23. The practitioners who issued these prescriptions included physicians, nurse practitioners, and physician assistants. Tr. 201–02; GX 3.

For example, Dr. P.M.J. is a physician at MWC's Snow Mesa location. Tr. 382; RX 21, 22; RD, at 9. Dr. P.M.J. is a primary care physician who primarily serves diabetic patients, but she dispenses some controlled substances, including alprazolam, lorazepam, clonazepam, phentermine, tramadol, testosterone, and zolpidem. Tr. 385–866, 445; GX 40, at 36–37; RD, at 9. The dispensing data for the VendRx machine shows that approximately 50 controlled substance prescriptions issued by Dr. P.M.J. were filled from ''staff storage'' at the Snow Mesa location. GX 40, at 36–37. Dr. P.M.J.'s data shows that she did not purchase any controlled substances for any of the MWC locations, GX 13; these prescriptions were filled from Respondent's stock. Respondent admitted on cross-examination that he purchased the phentermine that Dr. P.M.J. dispensed. Tr. 446; RD, at 9.

Government Exhibits 40 and 42 list the additional prescriptions that were filled at MWC for patients of MWC's practitioners from the stock of controlled substances that Respondent purchased.

Accordingly, the Agency finds based on substantial evidence that Respondent allowed thousands [6] of prescriptions [7] issued by MWC's practitioners to be filled from the stock of controlled substances that Respondent purchased. The Agency finds based on substantial evidence that these prescriptions were filled by a machine or by unlicensed individuals and that neither Respondent nor the prescribing practitioner was involved in filling them. Finally, the Agency finds based on substantial evidence that MWC did not possess a pharmacy license with DEA or the State of Colorado.

II. Public Interest Determination

A. Legal Background on Public Interest Determinations

When the CSA's requirements are not met, the Attorney General ''may deny, suspend, or revoke [a] registration if . . . the [registrant's] registration would be 'inconsistent with the public interest.' '' *Gonzales* v. *Oregon,* 546 U.S.

[6] Respondent testified that he did not begin ordering controlled substances for the Parker location until June 2023. Tr. 325. Government Exhibit 42 shows that approximately 1,000 prescriptions were filled at the Parker location before or during June 2023. GX 42, at 1–13. Thus, out of the 4,244 prescriptions filled at the Parker and Snow Mesa locations from April 25, 2022 to April 25, 2024, approximately 1,000 were not filled using controlled substances that Respondent purchased. The Agency is not considering these 1,000 as part of its decision in this matter.

[7] The orders submitted by MWC's practitioners through the VendRx software were prescriptions under 21 CFR 1300.01 because they were ''order[s] for medication which [were] dispensed to or for an ultimate user,'' and they were not for ''immediate administration to the ultimate user.'' Respondent's video demonstration of the VendRx software showed the practitioner generate an electronic prescription by clicking on the ''Write Rx'' tab and entering the details required for the prescription, including the patient's identifying details, the medication details and instructions, and the practitioner's signature. RX 7. The practitioner then hit the ''prescribe'' button, and the prescription was filled by the patient at the machine. *Id.*

243, 251 (2006) (quoting 21 U.S.C. 824(a)(4)). In the case of a ''practitioner,'' Congress directed the Attorney General to consider five factors in making the public interest determination. *Id.;* 21 U.S.C. 823(g)(1)(A–E).[8]

The five factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. at 292–93 (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' quoting *In re Arora,* 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *see Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 181 (D.C. Cir. 2005) (describing the Agency's adjudicative process as ''applying a multi-factor test through case-by-case adjudication,'' quoting *LeMoyne-Owen Coll.* v. *N.L.R.B.,* 357 F.3d 55, 61 (D.C. Cir. 2004)). Any one factor, or combination of factors, may be decisive, *David H. Gillis, M.D.,* 58 FR at 37508, and the Agency ''may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied.'' *Morall,* 412 F.3d. at 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.,* 70 FR 33207, 33208 (2007)); *see also Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007).

Moreover, while the Agency is required to consider each of the factors, it ''need not make explicit findings as to each one.'' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44(e).

B. Registrant's Registration Is Inconsistent With the Public Interest

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case is confined to Factors B and D. OSC, at 3–4. Evidence is considered under Factors B and D when it reflects compliance or non-compliance with laws related to controlled substances and experience dispensing controlled substances. *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022).

Here, as found above, the Agency finds that Respondent allowed thousands of prescriptions issued by MWC's practitioners to be filled at MWC from a stock of controlled substances that Respondent had purchased. The controlled substances were dispensed by a machine and by unlicensed employees, and neither Respondent nor the prescribing practitioner was involved in the process of filling them. MWC did not have a pharmacy registration that would permit Respondent or MWC to fill controlled substance prescriptions. Accordingly, the Agency finds substantial record evidence that Respondent violated 21 CFR 1306.06, which provides that ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . . .''

Respondent's Exceptions

In his Exceptions, Respondent quotes various statutes and regulations out of context to imply that a practitioner may fill a controlled substance prescription for another practitioner. *See* Respondent's Exceptions, at 6–9 (''Hence, regulations permit delivery to a patient by the practitioner, *or* by another individual pursuant to the practitioner's lawful order.'') This interpretation is clearly contradicted by the plain language of the pertinent statutes and regulations. The CSA's definitions of ''dispense'' and ''dispenser,'' along with corresponding statutes and regulations, delineate a clear distinction between lawful direct dispensing of controlled substances by practitioners and lawful filling of prescriptions by pharmacists. The CSA defines dispense as:

> to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.

21 U.S.C. 802(10). The conjunction ''or'' signals that dispensing may be done ''by . . . a practitioner'' *or* ''pursuant to the lawful order of, a practitioner.'' When read together with 21 CFR 1306.06's mandate that only pharmacists may fill prescriptions, the CSA creates two categories of permissible dispensing: (1) delivery/dispensing of a controlled substance *by a practitioner* ''to an ultimate user,'' and (2) delivery/dispensing of a controlled substance *by a pharmacist* ''to an ultimate user . . . pursuant to the lawful order of, a practitioner.'' In other words, a practitioner may dispense a controlled substance to the ultimate user without a prescription, and a pharmacist may dispense a controlled substance to the ultimate user pursuant to a prescription issued by a practitioner.

The CSA and its implementing regulations further clarify that practitioners may only dispense controlled substances ''*directly* . . . to an ultimate user'' in the usual course of their professional practice. 21 U.S.C. 829(a), (b) (''Except when dispensed directly by a practitioner . . . to an ultimate user, no controlled substance in schedule[s II through IV], . . . may be dispensed without the written prescription of a practitioner . . . .''); 21 CFR 1306.11 (''An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription''); 21 CFR 1306.21 (''An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to'' regulations pertaining to narcotic drugs.). The CSA defines ''ultimate user'' as ''a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household . . . .'' *Id.*

Neither the CSA nor its implementing regulations provides further guidance on what it means for a practitioner to dispense a controlled substance ''directly . . . to an ultimate user.'' However, the word ''directly'' leaves

[8] The five factors 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.

21 U.S.C. 823(g)(1)(A–E).

little ambiguity as to Congress's intent. Representative definitions of the words ''direct'' and ''directly'' from various dictionaries include: ''without anyone or anything else being involved or between,'' [9] ''[i]n a straight line or course,'' [10] ''immediately,'' [11] ''in immediate physical contact,'' [12] and ''to cause to turn, move, or point undeviatingly or to follow a straight course.'' [13] These definitions support the Agency's plain language reading that when a practitioner dispenses a controlled substance without a prescription, the practitioner must personally deliver the controlled substance to his patient without using an intermediary.[14]

This plain language reading is clearly consistent with Congress's intent when considered in the context of the CSA's implementation of a ''closed regulatory system'' with ''strict requirements'' intended to ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'' *Gonzales* v. *Raich,* 545 U.S. at 12–14. The manner in which Respondent permitted controlled substances to be dispensed at MWC could have led to the abuse and diversion of the controlled substances that Respondent purchased. Because the controlled substances were dispensed by the VendRx machine or unlicensed employees, no licensed practitioner or pharmacist physically handled the medication to ensure that the correct medication was dispensed or that it was dispensed in the correct quantity or dosage. Nor did a practitioner confirm that a patient who received a controlled substance from the machine was the same patient to whom the prescription was issued. As Respondent's video exhibit demonstrates, a prescription can be filled at the VendRx machine by any individual who knows the name and date of birth of an individual prescribed a controlled substance at MWC, with no photo identification required.[15] GX 7; Tr. 393, 436–37, 444; *but see* Tr. 436–37 (Respondent's testimony that his employees ''are watching the area and on guard in their control of the lobby''), 444–45. Thus, the controlled substances that Respondent dispensed exited the closed regulatory loop established by Congress when they were dispensed by individuals not trained to assess the legitimacy of prescriptions or ensure that prescriptions were filled in accordance with applicable state and federal laws and regulations. *See* 21 CFR 1306.04 (''The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.''); *see also Trinity Pharmacy II,* 83 FR 7304, 7331 (2018) (The corresponding responsibility requires ''pharmacists to identify and resolve suspicions that a prescription is illegitimate . . . before 'knowingly filling such a purported prescription.' '').

DEA's interpretation of the CSA in this context is not new or unexpected. The Agency has previously sanctioned practitioners for filling prescriptions issued by other practitioners. For example, in *Margy Temponeras, M.D.,* the Agency revoked a physician's registration who—despite not holding a pharmacy registration—operated a dispensary out of which she dispensed ''thousands of controlled substance prescriptions which were issued by her father, who was not registered at the location of [the respondent's] practice.'' [16] 77 FR 45675, 45676 (2022); RD, at 15. The respondent's dispensary was located at the same address as her medical practice. *Id.* at 45,677; RD, at 15. The Administrator held that the

[9] Cambridge Online Dictionary, available at *https://dictionary.cambridge.org/us/dictionary/english/direct.*

[10] Black's Law Dictionary (12th ed. 2024).

[11] Black's Law Dictionary (12th ed. 2024).

[12] Merriam-Webster Online Dictionary, available at *https://www.merriam-webster.com/dictionary/directly.*

[13] Merriam-Webster Online Dictionary, available at *https://www.merriam-webster.com/dictionary/direct.*

[14] Respondent argues in his Exceptions that ''[n]either the ALJ's Decision nor DEA's Order cites a statute or regulation requiring that the ordering practitioner physically deliver a controlled substance to the patient,'' and asserts that courts have interpreted 1306.04(a) ''to prohibit a provider from dispensing a controlled substance for an *illegitimate* purpose outside the usual course of medical practice—*not* to require that the provider personally deliver the medication to the patient.'' Resp. Exceptions, at 7. However, none of the cases that Respondent cites involves a physician who authorized unlicensed employees to dispense controlled substances purchased by that physician, and Respondent has not identified any language in these cases that contradicts the Agency's reasonable interpretation of the relevant statutes and regulations discussed herein. Respondent's assertion that ''[i]t is undisputed that [Respondent] dispensed controlled substances for legitimate medical purposes in the course of professional practice'' is not supported by the record. Respondent's Exceptions, 8. Respondent's dispensing of controlled substances violated the CSA's implementing regulations, which require that a practitioner directly dispense controlled substances to the ultimate user.

Respondent also asserts that ''[t]here is no evidence that [he] committed a knowing or intentional violation.'' Resp. Exceptions, at 3, 8. The Agency, however, has repeatedly held that ''misconduct need not be intentional to revoke a registrant's registration,'' and that ''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and could justify revocation or denial.'' *See, e.g., Peter Dashkoff, M.D.,* 90 FR 19313, 19316 n.9 (2025) (citing *Paul J. Caragine,* 63 FR 51592, 51601 (1998)).

[15] Respondent's video also demonstrated that the VendRx machine begins populating a list of names after the user types in only two letters. RX 7. For example, when the user types in ''M–A,'' the machine provides two names where the letters ''M–A'' begin the patient's first or last name. *Id.* With the breadth of personal information currently available on the internet, a user could quickly type a few sets of letters that are common in first or last names, select a name, and conduct a quick internet search using the patient's name and general location to potentially find the patient's date of birth. The user could then purchase a controlled substance that was not prescribed for him.

[16] Respondent attempts to distinguish *Temponeras* because the physician whose prescriptions were filled by the respondent in *Temponeras* was not registered at the office where the respondent filled his prescriptions, whereas the practitioners in this case were registered where Respondent filled their prescriptions. Resp. Exceptions, at 10–11. However, 1306.06 clearly mandates that prescriptions may only be filled by registered pharmacists, without any exceptions for practitioners registered at the same office location, and Respondent does not cite to any authority suggesting that the registered address of the prescribing practitioner is relevant.

Respondent further argues that the *Temponeras* decision ''is the primary cited basis for findings that [Respondent] violated federal law,'' and this decision ''is not binding and would not even be entitled to judicial deference.'' *Id.* (citing *Loper Bright Enterprises* v. *Raimondo,* 603 U.S. 369, 412–13 (2024)). Although Respondent is correct that *Loper Bright* instructs federal courts to independently interpret statutes rather than relying on an Agency's interpretation, an Agency is still charged with enforcing and interpreting the statutes that it implements, and may reference prior Agency decisions in doing so. *Temponeras,* and this Decision, are based on a logical, plain language interpretation of federal regulations that state that only pharmacists may fill controlled substance prescriptions, and that practitioners must dispense controlled substances directly to the ultimate user. Moreover, the *Temponeras* decision is also relevant to show that Respondent had notice of the Agency's reasonable interpretation of the applicable statutes and regulations.

Finally, Respondent argues that *Temponeras* involved an Ohio law that required prescribing physicians to personally furnish drugs to the patient, whereas the ALJ in this case found that Colorado law did not require personal dispensation by the prescribing practitioner. Resp. Exceptions, at 11. As discussed throughout this Decision, the Agency does not adopt the ALJ's legal analysis and, accordingly, does not adopt his conclusions regarding Colorado law. The Agency need not make findings regarding Colorado state law, because the CSA's mandate that practitioners dispense controlled substances directly to their patients requires practitioners to personally deliver controlled substances to their patient without an intermediary. Federal law supersedes any state law that does not require direct dispensation.

The Agency notes, however, that the language of the applicable Colorado law is very similar to the Ohio law cited in *Temponeras.* The Ohio law exempts a physician from the unauthorized practice of pharmacy if he ''personally furnish[es] . . . [his] patients with drugs, within [his] scope of professional practice.'' Temponeras, 77 FR at 45678 (citing Ohio Rev. Code Ann.§ 4729.29(A)(1)). Similarly, the pertinent Colorado law states that ''[a] practitioner may personally compound and dispense for any patient under the practitioner's care any drug that the practitioner is authorized to prescribe and that the practitioner deems desirable or necessary in the treatment of any condition being treated by the practitioner.'' Colo. Rev. Stat. §§ 12–280–120(6).

respondent violated 21 CFR 1306.06 ''because she exceeded the authority granted by her registration when she dispensed controlled substance prescriptions issued by her father without holding a pharmacy registration.'' *Id.* (citing 21 U.S.C. 822(b)). The Agency also held in *Fred Samimi, M.D.,* that a physician's practice of allowing his office staff to dispense controlled substances violated the CSA and its regulations, and articulated the Agency's concerns about the heighted risk of abuse and diversion from this practice:

> [T]he unsupervised dispensing of controlled substances by unlicensed individuals creates a heightened risk that those individuals will divert the drugs. . . . So too, allowing unlicensed persons, who likely have no training in identifying persons engaged in drug abuse or diversion, to dispense controlled substances without supervision, increases the opportunity for those persons who are self-abusing or engaged in diversion to obtain controlled substances.

79 FR 18698, 18710 (2014) (citing *Temponeras* 77 FR at 45677–78; *Gonzales* v. *Oregon,* 546 U.S. at 274).[17]

Although Respondent tries to muddy the distinction between filling prescriptions and dispensing controlled substances, Respondent was unable to avoid referring to MWC's dispensing activities as ''filling prescriptions.'' *Cf.* Tr. 242 (''[W]e don't fill outside prescriptions. We only dispense and fill medication orders.''); Respondent's Post-Hearing Brief, at 7 (stating that ''[the medical office] does not fill prescriptions for patients issued by providers outside of [the medical office]''). Nevertheless, MWC's distribution of controlled substances was clearly unlawful whether considered under the standards applicable to practitioners dispensing controlled substances or pharmacists filling prescriptions.

In the RD, the ALJ sustained violations of 21 CFR 1306.06 (requiring that prescriptions be filled by pharmacists) and 21 CFR 1306.04 (providing that ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription''). Respondent argues that the ALJ erred in finding that he violated 21 CFR 1306.04, and espouses two primary arguments in support: First, that the way in which the ALJ phrased the 1306.04 violation was different than what the Government alleged in the OSC, therefore raising a notice issue; and second, that the Government has not proven the requisite elements of 21 CFR 1306.04.

The Agency does not adopt the ALJ's legal analysis in this Final Order and does not sustain a violation of 21 CFR 1306.04. Thus, Respondent's notice concerns are moot. The Agency finds that Respondent's dispensing activities are more accurately portrayed as ''filling prescriptions'' than ''dispensing controlled substances,'' which makes 21 CFR 1306.06 the more pertinent regulation. The Agency need not find violations of both 21 CFR 1306.04 and 1306.06 where 21 CFR 1306.06 more directly addresses Respondent's unauthorized filling of prescriptions. However, the Agency notes that 21 CFR 1306.04 does not support Respondent's defense. In fact, the error of Respondent's dispensing practices is evident from a close examination of 21 CFR 1306.04, which states 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. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

This regulation reinforces the distinction between filling prescriptions and dispensing controlled substances and makes clear that a licensed professional—either a pharmacist or a practitioner—must be responsible for ensuring that dispensing is ''proper.'' *Id.* Here, Respondent delegated the responsibility for proper dispensing to an unlicensed employee (and/or a machine), which clearly contravenes the structure outlined by 21 CFR 1306.04. Thus, while the Agency does not sustain a violation of 21 CFR 1306.04 because the nature of his misconduct is more accurately captured under 21 CFR 1306.06, Respondent's attempt to use 21 CFR 1306.04 as a defense fails.

Respondent also argues that he did not violate 21 CFR 1306.06. Respondent argues that 21 CFR 1306.06 ''addresses requirements that a pharmacist be properly registered and acting in the usual course of professional practice when filling a prescription,'' and here, Respondent argues that ''controlled substances were dispensed to patients pursuant to lawful practitioner orders, as authorized by federal and state law.'' Respondent's Exceptions, at 9. Respondent argues that the ALJ made conflicting findings that on the one hand he violated 1306.06 because the prescriptions were not filled by a pharmacist, and on the other hand that he was not required to have a pharmacy registration because he was not operating a pharmacy. As stated above, the Agency does not adopt the ALJ's legal analysis in this case. The Agency finds that MWC's staff was filling prescriptions issued by MWC's practitioners, which is an activity that may only be done by a pharmacist.[18] The only lawful way for Respondent, a practitioner, to distribute the large quantity of controlled substances that he purchased would have been for him to dispense them directly to his own patients.[19]

[17] While Respondent correctly observes in its Exceptions that the CSA permits agents or employees of registrants to possess controlled substances, they may only do so while ''acting in the usual course of [their] business or employment,'' which does not include performing activities that they are not trained or registered to do, such as dispensing controlled substances, which must be done by registered pharmacists or practitioners. *See* Resp. Exceptions, at 7; 21 CFR 1306.04, 1306.06.

[18] The ALJ did not sustain the Government's allegations that MWC's locations were operating as unregistered pharmacies. RD, at 24–25. The Agency agrees with the ALJ that the Government did not prove that Respondent violated Colorado law by ''falsely assum[ing] the title of or falsely represent[ing] that [he was] a pharmacist'' or by ''falsely represent[ing]'' that MWC was a ''registered outlet.'' *Id.* at 26 (declining to find a violation of Colo. Rev. Stat. 12–280–129(1)(d)). Although MWC did advertise that it dispensed medications, there is no evidence that Respondent or MWC falsely represented that MWC was a pharmacy, and MWC did not fill prescriptions of outside patients. The Agency also agrees with the ALJ that the Government did not prove that Respondent violated 21 CFR 1301.13(e), which requires that any person engaging in more than one group of ''independent activities'' obtain a separate registration for each group of activities, because 21 CFR 1301.13(e) does not distinguish among different dispensing activities (*e.g.,* pharmacists filling prescriptions versus practitioners dispensing medications) in its definition of ''independent activities.'' RD, at 22. The Agency further finds that the Government did not adequately develop its arguments as to why the other provisions cited—including 21 U.S.C. 823(g)(1), which governs registration requirements for practitioners, Colo. Rev. Stat. 12–280–120(1), which requires that controlled substances be dispensed only in accordance with that section, and 21 CFR 1301.11(a), which requires that every person who dispenses controlled substances obtain a DEA registration—support the allegation that Respondent was operating unregistered pharmacies. OSC/ISO, at 4.

However, the Agency notes that MWC's unlicensed staff filled prescriptions, which is an activity that may only be done by a pharmacist. Respondent's practitioner registration did not authorize him to allow unlicensed staff to fill prescriptions for controlled substance or dispense controlled substances that he purchased. In other words, Respondent exceeded the authority granted by his practitioner registration.

[19] Respondent argues that Colorado law permits mid-level practitioners to dispense controlled substances purchased by their supervising physician. *See, e.g.,* Resp. Exceptions, at 17. The Agency does not make any findings related to Colorado law, because Respondent's conduct clearly violated the CSA and its implementing regulations. However, the Agency notes that even if Colorado law permitted mid-level practitioners to

Respondent further argues that the ALJ improperly weighed the public interest factors by failing to consider positive evidence under factors B and D and failing to consider that factors A, C, and E weigh in his favor. However, as previously stated, federal courts have repeatedly affirmed that ''the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant.'' *Jayam Krishna-Iyer,* 74 FR at 462. Because the public interest inquiry ''focuses on protecting the public interest[,] what matters is the seriousness of the registrant's misconduct,'' *id.,* and findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Here, the Agency finds that the Government has presented substantial evidence of Respondent's non-compliance with federal law (factor D) and negative experience dispensing controlled substances (factor B), which weighs strongly against Respondent under factors B and D. Respondent allowed thousands of prescriptions for controlled substances to be filled outside of the CSA's closed regulatory system, which could have led to abuse and diversion.

Respondent argues that the Agency should consider under factor B that only a small portion of the medications dispensed at MWC were controlled substances, that the amount of controlled substances dispensed was appropriate considering the number of patients and practitioners at MWC, that only 10% of controlled substances were dispensed through the VendRx machine, that only 10% of the prescriptions issued to MWC patients were filled at MWC, that the only schedule II controlled substance dispensed at MWC was hydrocodone, and that any patient receiving hydrocodone was subject to a urine drug screen and controlled substance contract. Respondent's Exceptions, at 16. Respondent also argues that it is relevant to factor B that he has been licensed as a physician since July of 1993, and that he has supervised and consulted with numerous physician assistants and nurse practitioners who issue prescriptions for controlled substances.[20] *Id.* Finally, Respondent notes that he and all MWC providers stopped dispensing while this matter has been pending. *Id.*

The Agency does not find that these facts influence its factor B analysis. The Government's allegations focused on the large volume of controlled substance prescriptions that MWC filled unlawfully, not whether prescriptions at MWC were issued lawfully or whether the percentage or volume of controlled substances was appropriate given the number of patients and practitioners.[21] The Government need not prove generally that all operations at MWC were unlawful to demonstrate that revocation is warranted. The Agency has repeatedly held that ''the public interest inquiry is not a numbers game in which the Government must prove a certain number of violations,'' and has revoked registrations even where the Government has demonstrated only a few instances of unlawful prescribing or dispensing. *See Larry Daniels,* 82 FR at 14984 (collecting cases). Here, the Government proved that MWC unlawfully filled thousands of prescriptions for controlled substances, including at least 400 hydrocodone prescriptions, which weighs strongly against Respondent under Factors B and D.

Moreover, Respondent's implementation of urine drug screens and opioid contracts does not negate the unlawfulness of MWC's dispensing procedures, nor does the fact that hydrocodone was the only schedule II substance dispensed mitigate the Agency's concerns about potential abuse and diversion of the more than 400 hydrocodone prescriptions filled unlawfully. Additionally, the fact that only 10% of controlled substances were dispensed through the VendRx machine is immaterial because the remainder were dispensed by Respondent's unlicensed employees, which is also unlawful. Finally, Respondent's and MWC's cessation of dispensing does not weigh in Respondent's favor, because the immediate suspension of Respondent's registration made it unlawful for Respondent to prescribe or dispense controlled substances.

With respect to Factor D, ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances,'' Respondent notes that the ALJ did not find any violations of Colorado law, that Respondent reasonably believed he was in compliance with Colorado and federal law, that Respondent had communicated with Colorado officials regarding ''his understanding of governing Medical Board Rules [ ] that Physician Assistants and Nurse Practitioners can carry out delegated work for a physician's patients including medication dispensing,'' that DEA did not take action against Respondent in 2017 when it previously audited Respondent's dispensing practices.[22] Respondent's Exceptions, at 17.

As discussed throughout this Decision, the Agency does not adopt the ALJ's legal analysis or his conclusions regarding state law, and the Agency does not make any findings regarding Respondent's compliance with state law because Respondent's practice of allowing unlicensed staff to fill prescriptions clearly violated federal law. Respondent's belief that he was operating in compliance with federal law was not reasonable because MWC's dispensing practices conflicted with a

dispense the controlled substances that Respondent purchased, the CSA required them to dispense the controlled substances directly to their patients. As found above, neither Respondent nor the prescribing practitioner was involved in dispensing the controlled substances to the patients. The prescribing practitioners issued prescriptions in the VendRx software that were then filled by the VendRx machine or by MWC's employees.

[20] Respondent's lengthy tenure as a physician and his supervision of mid-level practitioners is not persuasive considering the substantial evidence of noncompliance with the CSA. The factor B analysis focuses on the registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. *Kansky J. Delisma, M.D.,* 85 FR 23845, 23852 (2020) (citing *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012)).

[21] In the absence of evidence of illegality, the Agency assumes that controlled substances at MWC were prescribed legitimately. *See, e.g., Larry C. Daniels, M.D.,* 86 FR 61630, 61611 (2021) (''With respect to consideration given to a practitioner's positive experience in prescribing, the DEA assumes that all of the prescriptions a registrant has issued were issued lawfully, except for those prescriptions that the Government alleges were issued unlawfully.'') (citing *Wesley Pope, M.D.,* 82 FR 14944, 14984 (2017). DEA gives no more than nominal weight to evidence that a practitioner has engaged in lawful dispensing to thousands of patients. *Syed Jawed Akhtar-Zaidi, M.D.,* 80 FR 42962, 42968 (2015) (citing *Krishna-Iyer,* 74 FR at 463); *see also Medicine Shoppe-Jonesborough,* 73 FR 364, 386 n.56 (2008) (ruling that no amount of lawful conduct could outweigh ''flagrant violations'' and make the misconduct somehow consistent with the public interest), aff'd *Medicine Shoppe-Jonesborough* v. *DEA,* 300 F. App'x 409 (6th Cir. 2008).

[22] Because the Government's allegations in this case range from April 25, 2022, to June 11, 2024, an audit in 2017 is irrelevant. OSC/ISO, at 4. Respondent argues that MWC's ''ordering and dispensing practices were functionally the same before and after 2017,'' but there is no evidence on the record regarding Respondent's 2017 practices, and Respondent acknowledges that the VendRx was not added until after DEA's 2017 audit. Resp. Exceptions, at 17. It was not reasonable for Respondent to assume that a successful audit in one year portended a successful audit in later years, especially when MWC incorporated a new dispensing machine into its practice. *See, e.g., Svetlana Burtman, N.P.,* 90 FR 16881, 16882 n.3 (2025) (''Further, the Agency rejects Respondent's theory that, if a registrant's 'storage and record-keeping practices' are compliant in one year, the registrant may maintain a 'reasonable belief' that she will remain compliant going forward regardless of changes in the registrant's practices or without the registrant continuously monitoring for required changes.''). Moreover, even if Respondent's practices were identical in 2017, DEA is not precluded from enforcing the CSA simply because it did not do so in the past.

plain language reading of federal regulations governing dispensing and with prior Agency decisions espousing that interpretation. *See Temponeras,* 77 FR at 45677; *Samimi,* 79 FR at 18710. Thus, the Agency finds that factor D weighs strongly against Respondent's continued registration, as Respondent permitted thousands of controlled substances to be dispensed unlawfully over an extended time.

Although the Agency agrees with Respondent that the remaining factors do not weigh against his continued registration, the Agency need not find that each factor weighs against a registration to find that a registration is inconsistent with the public interest. *See, MacKay,* 664 F.3d at 821. Regarding factor A, although there is no record evidence of disciplinary action against Registrant's state medical license, 21 U.S.C. 823(g)(1)(A), state authority to practice medicine is ''a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011). As to factor C, there is no evidence in the record that Registrant has been convicted of any federal or state law offense ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). As to factor E, the Government's evidence fits squarely within the parameters of factors B and D and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E).[23] Accordingly, factor E does not weigh for or against Registrant.

Accordingly, the Agency has fully considered Respondent's Exceptions and still finds that after considering the factors of 21 U.S.C. 823(g)(1), Respondent's continued registration is ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). The Agency further finds that the Government satisfied 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). The Agency also finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in spite of the public interest determination, Respondent can be trusted with a registration.

III. Sanction

Where, as here, the Government has met the burden of showing that Registrant's continued registration is inconsistent with the public interest, the burden shifts to Registrant to show why he 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, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *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, the Agency requires that a registrant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *See Jones Total Health Care Pharmacy,* 881 F.3d at 833; *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.,* 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.,* 83 FR 29569, 29573 (2018); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 830–31. In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *See Jones Total Health Care Pharmacy,* 881 F.3d at 830–31; *Hoxie,* 419 F.3d at 483–84. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *See Jones Total Health Care Pharmacy,* 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by a Registrant and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Here, the Agency agrees with the ALJ that Respondent did not accept responsibility for his conduct. RD, at 30. Respondent repeatedly testified that he believed that MWC's dispensing practices complied with federal and state law, *e.g.,* Tr. 306–07, 423, and he continued to defend MWC's conduct in his Post-hearing brief.[24] Respondent testified that he is very familiar with physician dispensing practices across Colorado and that MWC was ''simply doing what physicians have done for 150 years in the state of Colorado, which is dispense meds.'' [25] Tr. 306–07.

[23] Respondent argues that his career accomplishments—such as his service of thousands of patients over 30 years of medical practice and his service in the army and navy—should weigh in his favor under factor E. Respondent's Exceptions, at 15. While the Agency appreciates that Respondent is a highly-qualified and hardworking physician who has made substantial contributions to his community, community impact evidence is considered to be irrelevant to DEA revocation proceedings. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,771 n.70 (2021) (citing *Frank Joseph Stirlacci, M.D.,* 85 FR 45,229, 45,239 (2020)).

[24] Respondent cites two cases where the Agency determined that registrants accepted responsibility for overbilling Medicaid even though they offered an explanation for why they overbilled. Respondent's Exceptions, at 20 (citing *Melvin N. Seglin, M.D.,* 63 FR 70431, 70433 (1998); *Anibal P. Herrera, M.D.,* 61 FR 65075, 65078 (1996). These cases are not relevant here, because Respondent did not acknowledge that his conduct was unlawful as these registrants did. Moreover, these cases are more than two decades old and apply an outdated sanctions analysis. *See infra* n.26.

[25] Respondent testified at the hearing that MWC operated in a similar manner to urgent care and health clinics where one physician orders controlled substances for the whole office. Tr. 307, 422. Although there are circumstances where practitioners who are agents or employees of another practitioner or institution may dispense using the DEA registration of that practitioner or institution, MWC operations did not comply with regulations governing affiliated physicians. Pursuant to 21 CFR 1301.22, which governs a practitioner using the registration of another practitioner:

> An individual practitioner who is an agent or employee of another practitioner . . . registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

This regulation is not applicable to MWC's dispensing practices because MWC's practitioners used their own DEA registrations (not Respondent's) and they issued prescriptions, which is expressly disallowed under this provision. *See, e.g.,* GX 13 (DEA registration for Dr. P.J.); GX 40, at 36 (Dispensing data for Snow Mesa showing that Dr. P.J. issued prescriptions under her DEA registration). Similarly, 21 CFR 1301.22(c), which governs practitioners using the registration of a hospital or other institution, requires the institution to designate a specific internal code number for each individual practitioner, and the practitioner prescribes or dispenses using the hospital's registration. By contrast, MWC's practitioners issued prescriptions under their own DEA registrations, and the prescriptions were filled from Respondent's stock of controlled substances. Thus, MWC's dispensing practices can be distinguished from urgent care facilities and hospitals that are operating in compliance with 21 CFR 1301.22.

Respondent argues in his post-hearing brief that the Government's expectation that each practitioner order his own controlled substances is impracticable and will lead to waste and stockpiling of medications. Resp. Post-Hearing Brief, at 27. However, as demonstrated above, the CSA has developed a framework for members of an affiliated medical group to dispense from a common

Respondent testified that in 25 years of private practice he has never heard of limitations within a practice group of providers dispensing from a stock of controlled substances purchased by another member of the group. *Id.* at 423.

Respondent also attempted to minimize his conduct, which further suggests that the Agency cannot trust him with a registration. *See, e.g., Rachel Kientcha-Tita, M.D.,* 90 FR 45811, 45812 (2025) (citing *Michael A. White* v. *Drug Enf't Admin.,* 626 F. App'x 493, 496–97 (5th Cir. 2015)). For example, Respondent testified that only a fraction of the medications dispensed at MWC were controlled substances and that hydrocodone was the only schedule II drug dispensed at MWC. Tr. 249. However, any controlled substance dispensed outside of the CSA's closed regulatory system can result in abuse and diversion, and Respondent permitted thousands of controlled substance prescriptions, including more than 400 hydrocodone prescriptions, to be dispensed in this manner. GX 40, 42.

Respondent argues in his Exceptions that ''[he] is entitled to explain why he believed the challenged conduct was permitted, while making clear that he respects the agency's interpretation and will not engage in alleged improper conduct.'' Resp. Exceptions, at 20. Respondent argues that there would be ''significant due process implications'' if the Agency ''interpret[ed] acceptance of responsibility as requiring that he *also* admit premeditated wrongdoing,'' because it ''would nullify his right to defend against the government's [case].'' *Id.* at 21. However, DEA has long held that ''[w]hen a registrant has committed acts inconsistent with the public interest, [he] must both accept responsibility and demonstrate that [he] has undertaken corrective measures.'' *Janet S. Pettyjohn, D.O.,* 89 FR at 82641. Federal courts have affirmed that ''DEA may properly consider a registrant's acceptance of responsibility in determining if registration should be revoked.'' *Jones Total Health Care Pharmacy,* 881 F.3d at 830. According to the eleventh circuit, ''[i]f a [registrant] has failed to comply with its responsibilities in the past, it makes sense for the agency to consider whether the [registrant] will change its behavior in the future.'' *Id.*

Here, Respondent's assertions that he reasonably believed that MWC's dispensing practices complied with federal law suggest that the Agency cannot trust Respondent to comply with the CSA in the future. The CSA and its implementing regulations clearly state that prescriptions may only be filled by pharmacists, and DEA has published two decisions informing the registrant community that it is unlawful for practitioners to allow unlicensed employees to fill controlled substance prescriptions.

Respondent also argues that he ''t[ook] responsibility for the underlying conduct'' because he testified that ''the buck stops with him'' at MWC and he has ''the ultimate responsibility'' for MWC's patients and employees. Resp. Exceptions, at 19–20 (citing Tr. 294, 426–27, 393, 447–48). However, these statements were vague and did not address the legality of MWC's dispensing practices. Respondent maintained at the hearing and in post-hearing filings that MWC's dispensing practices were legal under federal and state law. *See, e.g.,* Tr. 306–07, 423; Resp. Post-Hearing Brief, at 17 (''[Respondent] reasonably believed that practices at [MWC] were in compliance with state and federal law.''); Resp. Exceptions, at 6–19. Accordingly, the Agency rejects Respondent's Exceptions and agrees with the ALJ that Respondent failed to unequivocally accept responsibility for his misconduct.

Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74810 (2015); *OakmontScript Limited Partnership,* 87 FR 21546, 21545 (2022). Here, the Agency agrees with the ALJ that the egregiousness of Respondent's conduct favors revocation. RD, at 31. As the ALJ stated, ''Respondent's violations were not limited to a single instance or a single type of violation, but consisted of widespread violations involving numerous practitioners at his medical offices and thousands of controlled substance prescriptions.'' *Id.* Respondent was the fourth highest purchaser of controlled substances in Colorado, tr. 95–96, and authorized MWC's staff to fill thousands of prescriptions without a pharmacy registration. Over 400 of these prescriptions were for a dangerous and highly-abused schedule II opioid. GX 40.

Furthermore, considerations of specific and general deterrence in this case militate in favor of revocation. RD, at 31. Although Respondent testified that he will respect DEA's interpretation of the CSA and cease filling controlled substance prescriptions going forward, Respondent's failure to accept responsibility suggests that he does not appreciate the registrant's obligation to be knowledgeable of the CSA and DEA's plain language interpretations of the CSA, and, therefore, may not be deterred from violating the CSA in the future.[26] Interests of general deterrence

stockpile of controlled substances if they comply with the requirements of the regulations.

[26] Respondent argues that it would be improper for DEA to revoke his registration because ''[t]here is no evidence that any alleged improper practice would recur,'' and Respondent has implemented ''remedial systems that preclude recurrence.'' Resp. Exceptions, at 18. While the Agency is not required to consider remedial evidence when a Respondent has not accepted responsibility, *see Salman Akbar, M.D.,* 86 FR 52181, 52195 (2021), Respondent's only evidence of remediation appears to be the cessation of MWC's unlawful dispensing practices. Cessation of unlawful behavior after Government action is not remedial evidence, especially here, where the ISO stripped Respondent of all authority to dispense, prescribe, or handle controlled substances. OSC/ISO, at 1, 5. The Agency has determined that revocation is the appropriate remedy in this case based on the extent and egregiousness of Respondent's misconduct and his failure to accept responsibility.

Respondent argues that ''[t]his case is markedly distinct from others in which DEA has imposed revocation or a lesser sanction,'' and references several cases that are more than two decades old. Resp. Exceptions, at 18. As the Agency recently stated in *Mary A. Vreeke, M.D.,* the opioid epidemic has surged in the past decade, and ''[t]he Agency has [ ] departed from some of its more lenient sanction policies, citing the need to protect the public from abuse and diversion.'' 89 FR 75567, 75572 (2024). For example, the Agency has repeatedly reaffirmed that an unequivocal acceptance of responsibility is critical for a registrant to regain the Agency's trust and maintain a registration. *See, e.g., Jones Total Health Care Pharmacy,* 881 F.3d at 833 (rejecting respondent's argument that its conduct was not egregious enough to warrant a sanction of revocation and highlighting the Agency's historical focus on acceptance of responsibility: ''The DEA decisions Petitioners rely on are distinguishable because, in each of the decisions, the agency found that the registrant had rebutted the government's case by, among other things, admitting fault or expressing remorse. . . . Petitioners . . . do not cite any decision in which the DEA has continued a registration despite finding that the registrant did not fully accept responsibility''); *MacKay,* 664 F.3d at 822 (finding that ''because [the respondent] ha[d] not accepted responsibility for his conduct, revocation of his registration [was] entirely consistent with DEA policy''); *Jeffery J. Becker, D.D.S.,* 77 FR 72387, 72408 (2012) (''Agency precedent has firmly placed acknowledgement of guilt and acceptance of responsibility as conditions precedent to merit the granting or continuation of status as a registrant.''); *Jayam Krishna-Iyer,* 74 FR at 464 (''even where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct'').

Not only do the decisions Respondent references use an outdated sanctions framework, but they are factually distinguishable from this case. Resp. Exceptions, at 19–20. Several of these cases involve registrants with substance abuse issues, which raise distinct considerations, and the Agency has occasionally shown leniency towards registrants who accept responsibility and demonstrate that they have undergone successful treatment for substance abuse. For example, although the registrant in *Karen A. Kruger, M.D.,* unlawfully

Continued

also support a sanction of revocation. Any sanction less than revocation would signal to the registrant community that allowing unlicensed employees to fill thousands of prescriptions for schedule II through V controlled substances may be excused, even where Respondent has failed to accept responsibility. *See Joseph Gaudio, M.D.,* 74 FR 10083, 10095 (2009). Distributing such a large volume of controlled substances outside of the closed regulatory system poses a significant risk to the public, and the Agency bears the responsibility of deterring misconduct that endangers the public. *David A. Ruben, M.D.,* 78 FR 38363, 38385 (2013). Therefore, the Agency finds that the egregiousness of the Respondent's behavior and the interests of specific and general deterrence support a sanction of revocation.

In sum, Respondent has not offered sufficient credible evidence on the record to rebut the Government's case for revocation and Respondent has not demonstrated that he 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) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificates of Registration Nos. BB3697577 and FB3064831 issued to John Bender, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of John Bender, M.D., to renew or modify this registration, as well as any other pending application of John Bender, M.D., for registration in Colorado. This Order is effective March 16, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on January 30, 2026, by Administrator Terrance C. Cole. 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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prescribed diethylpropion to herself using fictitious names, she accepted responsibility, testified that she was addicted, and underwent successful treatment for her addiction. 69 FR 7016 (2004). The Agency highlighted the importance of the respondent's acceptance of responsibility in its decision not to revoke, and noted that ''[t]he Acting Deputy Administrator finds significant the Respondent's ready willingness to cooperate with law enforcement authorities when questioned about allegations of her improperly prescribing.'' *Id.* at 7017–18. In *Theodore Neujahr, D.V.M.,* the Agency likewise noted that much of the respondent's unlawful behavior was a result of his addiction, and because the respondent had been sober for at least a decade when the decision was issued, the Agency determined that there was a low likelihood of relapse. 65 FR 5680, 5681 (2000). Similarly, the allegations against *Jeffrey Martin Ford, D.D.S.,* largely concerned self-abuse of controlled substances, and the respondent had successfully undergone treatment and been sober for over a decade at the time of the decision, which largely mitigated the Agency's concerns. 68 FR 10750, 10753 (2003). Finally, in *Paul W. Sexton,* the Agency did not sustain the majority of the Government's allegations but found that the respondent had unlawfully prescribed anabolic steroids and failed to keep complete and accurate records of controlled substances. 64 FR 25073, 25079 (1999). The Agency felt that revocation was too harsh of a sanction because the respondent accepted responsibility for the unlawful prescribing and recordkeeping deficiencies and demonstrated that he had remedied both. *Id.* By contrast, the Respondent in this case failed to accept responsibility for his misconduct and therefore failed to restore trust with the Agency.

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–373 and 50–374; NRC–2026–0727]

Constellation Energy Generation, LLC; LaSalle County Station, Units 1 and 2; License Amendment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Opportunity to comment, request a hearing and to petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Renewed Facility Operating Licenses (RFOLs) No. NPF–11 and NPF–18, issued to Constellation Energy Generation, LLC (Constellation, the licensee) for LaSalle County Station, Units 1 and 2 (LaSalle). The proposed license amendments, if granted, would temporarily revise the Technical Specification (TS) Limiting Condition for Operation (LCO) 3.3.7.1, ''Control Room Area Filtration (CRAF) System Instrumentation,'' until December 31, 2027. The Atomic Energy Act of 1954, as amended, (the Act) grants the Commission authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person. For this amendment request, the NRC proposes to determine that it involves NSHC.

DATES: Submit comments by March 16, 2026. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Requests for a hearing or petition for leave to intervene must be filed by April 14, 2026.

ADDRESSES: You may submit comments by any of the following methods however, the NRC encourages electronic comment submission through the Federal rulemaking website.

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2026–0727. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: *Bridget.Curran@nrc.gov*. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–5–A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Robert Kuntz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3733; email: *Robert.Kuntz@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2026–0727 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods: