demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77 FR 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 Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33738, 33746 (2021).

When a respondent declines to testify and ''neither [takes] responsibility for his misconduct nor provid[es] any assurances that he has implemented remedial measures to ensure such conduct is not repeated,'' the respondent's silence weighs against registration. *Zvi H. Perper, M.D.,* 77 FR 64131, 64142 (2012) (citing *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008)); *see also Jeanne E. Germeil,* M.D., 85 FR 73786, 73803 (2020). Such silence also warrants an adverse inference against the respondent. *MacKay* v. *Drug Enf't Admin,* 664 F.3d 808, 820 (10th Cir. 2011) (upholding the Agency's finding that a respondent's failure to testify warranted an adverse inference because there was ''no evidence that [respondent] recognized the extent of his misconduct and was prepared to remedy his prescribing practices''); *T.J. McNichol, M.D.,* 77 FR 57133, 57153–54 (2012) (stating that ''it is appropriate to draw an adverse inference from Respondent's failure to testify'').

Here, Respondent has failed to accept responsibility or offer any basis for the Agency to trust him, despite his past misconduct, with the responsibility of a registration. RD, at 21. In light of Respondent's silence, he has not sufficiently demonstrated that he can be entrusted with a DEA registration. *See id.; MacKay,* 664 F.3d at 820; *Jeanne E. Germeil, M.D.,* 85 FR at 73803; *Zvi H. Perper, M.D.,* 77 FR at 64142.

In addition to acceptance of responsibility, the Agency looks to the egregiousness and extent of the misconduct, *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases), and considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74810 (2015). Here, Respondent's blatant and repeated disregard for the laws relating to controlled substances warrants a sanction. Respondent's inappropriate and unlawful prescribing of controlled substances placed multiple patients, and the public, at risk of harm. In this case, the Agency believes that denial of Respondent's application would deter Respondent and the general registrant community from disregarding controlled substance laws and engaging in the pattern of misconduct that permeated Respondent's actions as a registrant. *See* RD, at 22. As the Chief ALJ noted, ''[t]he misconduct established was sufficiently egregious that a denial is strongly supported.'' RD, at 22. Further, there is no evidence that Respondent's behavior is unlikely to recur in the future such that the Agency can entrust him with a registration.

In sum, the public interest factors weigh in favor of denial as a sanction; accordingly, the Agency shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the DEA registration application of Osmin A. Morales, M.D. (Control No. W20125906C) and any other pending application of Osmin A. Morales, M.D., for a DEA registration in Florida. This Order is effective December 4, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 25, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–24151 Filed 11–1–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1228P]

Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2024

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2024 aggregate production quotas (APQ) for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs (AAN) for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. For the 2024 quota year, DEA intends to allocate procurement quotas to DEA-registered manufacturers of schedule II controlled substances on a quarterly basis. In order to address domestic drug shortages of controlled substances, procurement quota allocations will be divided between quantities authorized for domestic sales and quantities authorized for export sales.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before December 4, 2023. Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the **Federal Register** a final order establishing the 2024 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–1228P'' on all correspondence, including any attachments. DEA encourages 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 *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *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. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority

Section 306 of the Controlled Substances Act (21 U.S.C. 826) requires the Attorney General to establish production quotas for each basic class of controlled substances listed in schedules I and II, and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2024 Aggregate Production Quotas and Assessment of Annual Needs

The proposed 2024 aggregate production quotas (APQ) and assessment of annual needs (AAN) represent those quantities of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States (U.S.) in 2024 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

Aggregate Production Quotas

In determining the proposed 2024 APQ, the Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1303.11, including the following seven factors:

(1) Total net disposal of the class by all manufacturers during the current and two preceding years;

(2) Trends in the national rate of net disposal of the class;

(3) Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;

(4) Projected demand for such class as indicated by procurement quotas requested pursuant to [21 CFR] 1303.12;

(5) The extent of any diversion of the controlled substance in the class;

(6) Relevant information obtained from the Department of Health and Human Services (HHS), including from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), and relevant information obtained from the states; and

(7) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

21 CFR 1303.11(b)

DEA formally solicited input from FDA and CDC in February of 2023 and from the states in April 2023, as required by 21 U.S.C. 826 and 21 CFR part 1303. DEA did not solicit input from CMS for reasons discussed in previous notices.[1] DEA requested information on trends in the legitimate use of select schedule I and II controlled substances from FDA and rates of

[1] Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021, 85 FR 54414 (Sept. 1, 2020) and Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021, 85 FR 54407 (Sept. 1, 2020).

overdose deaths for covered controlled substances from CDC. DEA's request for information from the states was made directly to the Prescription Drug Monitoring Program (PDMP) Administrators in each state as well as through the National Association of State Controlled Substances Authorities (NASCSA).

Assessment of Annual Needs

In similar fashion, in determining the proposed 2024 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, the Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1315.11, including the five following factors:

(1) Total net disposal of the chemical by all manufacturers and importers during the current and two preceding years;

(2) Trends in the national rate of net disposal of each chemical;

(3) Total actual (or estimated) inventories of the chemical and of all substances manufactured from the chemical, and trends in inventory accumulation;

(4) Projected demand for each chemical as indicated by procurement and import quotas requested pursuant to [21 CFR] 1315.32; and

(5) Other factors affecting medical, scientific, research, and industrial needs in the United States, lawful export requirements, and the establishment and maintenance of reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemicals or the substances manufactured from them, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

21 CFR 1315.11(b)

In determining the proposed 2024 AAN, DEA used the calculation methodology previously described in the 2010 and 2011 assessments of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

Estimates of Medical Need for Schedule II Opioids and Stimulants

In accordance with 21 CFR part 1303, 21 U.S.C. 826, and 42 U.S.C. 242, HHS continues to provide DEA with estimates of the quantities of select schedule I and II controlled substances and three list I chemicals that will be required to meet the legitimate medical needs of the United States for a given calendar year. The responsibility to provide these estimates of legitimate domestic medical needs resides with FDA. FDA provides DEA with predicted estimates of domestic medical usage for selected controlled substances based on information available to them at a specific point in time in order to meet statutory requirements.

FDA predicts that levels of medical need for schedule II opioids in the United States in calendar year 2024 will decline on average 7.9 percent from calendar year 2023 levels. These declines are expected to occur across a variety of schedule II opioids including fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone. DEA considered the potential for diversion of schedule II opioids, as required by 21 CFR 1303.11(b)(5), as well as a potential increase in demand for certain opioids identified as being necessary to support the previously postponed elective surgeries now that the COVID–19 public health emergency has ended, pursuant to 21 CFR 1303.11(b)(7), in developing the proposed 2024 APQ.

FDA predicted an average of a 3.1 percent increase in domestic medical use of the schedule II stimulants amphetamine, methylphenidate (including dexmethylphenidate), and lisdexamfetamine, which are prescribed to treat patients with attention deficit hyperactivity disorder (ADHD) and more recently prescribed off-label to treat patients diagnosed with long-COVID symptoms commonly known as brain fog where fatigue and cognitive impairment persist 4 to 12 weeks after a COVID infection.[2] FDA also raised concerns over drug shortage notifications it received from patients for specific ADHD medications containing methylphenidate and amphetamine. FDA's stated reasons for these specific shortages include increased prescribing potentially related to the growth in telemedicine, supply chain issues, manufacturing and quality issues, and business decisions of manufacturers. DEA considered FDA's concerns when determining the APQ for these substances. DEA believes that manufacturers will be able to meet the increase in domestic medical need with the APQs proposed in this notice.

DEA Projected Trends for Certain Schedule I Controlled Substances

There has been a significant increase in the use of schedule I hallucinogenic controlled substances for research and clinical trial purposes. DEA has received and subsequently approved new registration applications for schedule I researchers and new applications for registration from manufacturers to grow, synthesize, extract, and prepare dosage forms containing specific schedule I hallucinogenic substances for research and clinical trial purposes. DEA supports regulated research with schedule I controlled substances, as evidenced by the higher APQ proposed for 2024 as compared with APQ for these substances in 2023. Further, DEA published the final rule, ''Controls to Enhance the Cultivation of Marihuana for Research in the United States'' in December 2020, and the Medical Marijuana and Cannabidiol Research Expansion Act (Pub. L. 117–215) was enacted in December 2022. The agency continues to review and approve applications for schedule I manufacturers of marihuana that conform to the federal requirements contained in the CSA. *See* 21 CFR part 1318.

Thus, DEA is proposing APQ for ibogaine, psilocyn, psilocybin, delta-9-tetrahydrocannabinol (d-9-THC), and all other tetrahydrocannabinols to support manufacturing activities related to the increased level of research and clinical trials with these schedule I controlled substances. Additionally, DEA proposes APQs for d-9-THC and all other tetrahydrocannabinols for 2024 to reflect the relocation of manufacturing of these controlled substances from abroad to the United States.

Information Received for Consideration of the Remaining Factors

For the factors listed in 21 CFR 1303.11(b)(3) and (4), DEA registered manufacturers of controlled substances in schedules I and II provide information such as inventory, distribution, manufacturing, sales forecasts and quota requests to the DEA database systems. *See* 21 CFR 1303.12, 1303.22, and part 1304.

The regulation at 21 CFR 1303.11(b)(5) requires DEA to consider the extent of diversion of controlled substances.[3] Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than legitimate medical purposes. In order to

[2] New Long-Haul COVID Clinics Treat Mysterious and Ongoing Symptoms, Scientific American, June 30, 2021; Successful Treatment of Post-COVID–19 ADHD-like Syndrome-A case Report, J Atten Disord., 2023 Aug; 27(10): 1092–1098.

[3] The estimates of diversion for five ''covered controlled substances'' as required by 21 U.S.C. 826(i) are discussed later in the document.

consider the extent of diversion, DEA analyzed reports of diversion of controlled substances from 2022 submitted to its Theft Loss Report database. This database is comprised of DEA registrant reports documenting diversion from the legitimate distribution chain, including employee thefts, break-ins, armed robberies, and material lost in transit. The data was categorized by basic drug class, and the amount of active pharmaceutical ingredient (API) in the dosage form was delineated with an appropriate metric for use in proposing aggregate production quota values (*i.e.,* weight).

In this proposed 2024 APQ, DEA also considered the lingering effects of the COVID–19 pandemic on the global supply chain, pursuant to 21 CFR 1303.11(b)(7), and specifically the continued impacts on the availability of raw materials for use in the domestic manufacturing process. Additionally, DEA considered the impact of the demand for surgical care for elective surgeries that were deferred during the COVID–19 public health emergency.

Estimates of Diversion of Covered Controlled Substances

In establishing any quota . . . , or any procurement quota established by [DEA] by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a ''covered controlled substance''), [DEA] shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

21 U.S.C. 826(i)(1)(A)

In estimating diversion under that provision, DEA:

(i) shall consider information . . . , in consultation with the Secretary of Health and Human Services, [it] determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(ii) may take into consideration whatever other sources of information [it] determines reliable.

21 U.S.C. 826(i)(1)(B)

The statute further mandates that DEA ''make appropriate quota reductions, as determined by [DEA], from the quota [it] would have otherwise established had such diversion not been considered.'' [4]

In estimating the amount of diversion of each covered controlled substance that occurs in the United States, DEA considered information from state PDMP Administrators and from legitimate distribution chain participants.

Consideration of Information From Certain State PDMPs and From National Sales Data

Pursuant to 21 CFR 1303.11(b)(6), DEA requested state PDMP data for the purpose of establishing its APQ. DEA believes state PDMPs to be an essential, reliable source of information for use in effectively estimating diversion of the five covered controlled substances. In April 2023, DEA sent a letter to NASCSA requesting its assistance in obtaining aggregated PDMP data for the five covered controlled substances from each state covering the years 2020–2022. The letter indicated that DEA was specifically interested in an analysis of prescription data from each state's PDMP that would assist DEA in estimating diversion and setting appropriate quotas in compliance with 21 U.S.C. 826(i). In its request, DEA provided specific questions, discussed in detail below, based on common indicia of potential diversion known as ''red flags'' by physicians, pharmacists, manufacturers, distributors, and federal and state regulatory and law enforcement agencies.[5] DEA investigators and administrative prosecutors also rely on Agency case law in which these red flags of diversion have been upheld as indicia of potential diversion.[6] Certain state regulations now include red flag circumstances as potential indicators of illegitimate prescriptions, and thus of potential abuse and diversion of controlled substances.[7] *See* The Pharmacy Place Order, 86 FR 21008, 21012 (Apr. 21, 2021) (citing 22 Tex. Admin. Code 291.29(c)(4), specifying the geographical distance between the practitioner and the patient or between the pharmacy and the patient as a red flag).

DEA requested responses from state PDMP Administrators by June 15, 2023. NASCSA disseminated DEA's request to its PDMP Administrators and provided them with a report tool to ensure that responses to DEA's questions were extracted consistently across all responsive states. Thirty states and two territories provided DEA with summarized PDMP data between May 3, and June 15, 2023, utilizing the standardized report developed by NASCSA.[8] See Table 1a below.

TABLE 1a—STATES/TERRITORIES THAT RESPONDED TO DEA'S DATA REQUEST

State/territory
1. Alabama
2. Alaska
3. Arizona
4. Arkansas
5. Connecticut
6. Delaware
7. District of Columbia
8. Hawaii
9. Idaho
10. Indiana
11. Iowa
12. Kansas
13. Kentucky
14. Louisiana
15. Maine
16. Maryland
17. Michigan
18. Minnesota
19. Mississippi
20. Montana
21. Nevada
22. New Jersey
23. North Carolina
24. North Dakota
25. Ohio
26. Oklahoma
27. Puerto Rico
28. Rhode Island
29. South Carolina
30. South Dakota
31. Texas
32. Utah

Pharmacies are required by state law to enter controlled substance dispensing data into the state's PDMP database, including the prescriber's name, registered address and DEA number; prescription information (such as drug name); dispensing date; dosage dispensed; pharmacy registered address; and patient name and address. DEA considers PDMP data to be an accurate representation of dispensing activities in states. DEA received data for the following red-flag metrics:

- The total number of patients who saw three or more prescribers in a 90-day period and were dispensed an opioid following each visit. For this metric, DEA requested and was provided the number of prescriptions for the five covered controlled substances dispensed to these patients, as a percentage of the total prescriptions dispensed for that particular covered controlled substance, as well as the corresponding quantity of the covered

[4] 21 U.S.C. 826(i)(1)(C).

[5] National Association of Boards of Pharmacy (NABP) coalition consensus document ''Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances'' (2015). *www.nabp.pharmacy/resources/reports.*

[6] The Medicine Shoppe, 79 FR 59504, 59507, 59512–13 (2014); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (Oct. 12, 2012).

[7] The mere indicia of red flags alone is not proof of violation of 21 U.S.C. 824 or any other provision of the CSA. This rule discusses only their use by DEA as an analytical tool to estimate diversion.

[8] NASCSA formatted DEA's request into an analytics model developed by one of its associates, Appriss Inc.

controlled substance dispensed. This metric (patients being prescribed covered controlled substances from three or more prescribers in a 90-day period) is used to identify potential doctor shopping, a common technique to obtain a high number of controlled substances, which may lead to abuse or diversion of controlled substances. DEA has long considered doctor shopping to be an indicator of potential diversion.[9]

- The number of patients that were dispensed prescriptions for each of the five covered controlled substances that exceeded 240 morphine milligram equivalents (MME) daily. States provided the raw number of such prescriptions dispensed, the number of prescriptions as a percentage of the total covered controlled substance prescriptions dispensed, and the corresponding quantity of the covered controlled substance dispensed. DEA believes that accounting for quantities in excess of 240 MME daily allows for consideration of oncology patients with legitimate medical needs for covered controlled substance prescriptions with high MME. Higher dosages place individuals at higher risk of overdose and death. Prescriptions involving dosages exceeding 240 MME daily may indicate diversion, such as illegal distribution of controlled substances or prescribing outside the usual course of professional practice.

- The number of patients that paid cash for covered controlled substance prescriptions, without submitting for insurance reimbursement.[10] States also provided the number of prescriptions paid entirely with cash as a percentage of the total prescriptions for the five covered controlled substances dispensed, as well as the corresponding quantity of the covered controlled substances dispensed. When investigating potential diversion, cash payments are one element considered in identifying prescriptions filled for nonmedical purposes. Unusually high percentages of cash payments made to a prescriber or pharmacy for controlled substances may indicate diversion.[11]

[9] Frank's Corner Pharmacy, 60 FR 17574 (1995); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (Oct. 12, 2012).

[10] This total does not include insurance co-payments made with cash.

[11] Suntree Pharmacy and Suntree Medical Equipment, LLC, 85 FR 73753 (2018) (finding that the pharmacy filled prescriptions despite the presence of multiple unresolved red flags, including cash payments); Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy, 83 FR 10876 (Mar. 13, 2018) (revoking pharmacy's registration for filling prescriptions that raised the red flag of customers paying cash for their prescriptions, among other red flags).

DEA received PDMP data from the states in a standardized format that allowed DEA to aggregate the data. The PDMP data sample represents a population of approximately 150.7 million people, which is approximately 45 percent of the U.S. population. DEA believes this sample is sufficient to derive a reasonable nationwide estimate.

While PDMP data is useful in estimating diversion, it is not conclusive. Further investigation would be required before concluding that any of the subject prescriptions were actually diverted. DEA continues to evaluate its methodologies in estimating diversion in an effort to adjust quotas more efficiently. State participation is crucial to accurate data analysis, and DEA anticipates working closely with states, as well as other federal and state entities, in future quota determinations.

To calculate a national diversion estimate for each of the covered controlled substances from the responses received from state PDMP Administrators, DEA relied upon the number of individuals who received a prescription for a covered controlled substance that met any of the three red-flag metrics for each of calendar years 2020–2022. Using the population of the states responding to DEA's request, DEA then calculated the percentage of the population issued a prescription with a red flag. Using this estimated percentage for 2020–2022, DEA analyzed trends in the data to predict the estimated percentage of patients who would be expected to be included in these red-flag metrics for 2024.

DEA also reviewed aggregate sales data for each of the covered controlled substances, which it extracted from IQVIA's National Sales Perspective.[12] IQVIA sales data was selected to help quantify diversion at the national level because it reflects the best national estimate for all prescriptions written and filled, including the total quantity available for diversion or misuse. DEA analyzed trends in IQVIA sales data from January 2020—April 2023, in order to predict the estimated national sales for 2024.

To estimate diversion for each of the covered controlled substances, DEA multiplied the forecasted percentage of patients likely to receive a prescription for a covered controlled substance that meet any of the three red-flag metrics in 2024 by the forecasted sales data from IQVIA for 2024. The resulting estimate of diversion from data submitted by state PDMP Administrators is summarized below in Table 1b. This data contributed to the final diversion estimate set forth in Table 3.

[12] DEA has purchased this data from IQVIA for decades and routinely uses this information to administer several regulatory functions, including the administration of DEA's quota program.

TABLE 1B—DIVERSION ESTIMATES FOR 2024 BASED ON STATE PDMP DATA FOR COVERED CONTROLLED SUBSTANCES FROM 2020–2022

Controlled substance	(g)
Fentanyl	18
Hydrocodone	83,823
Hydromorphone	356
Oxycodone	150,684
Oxymorphone	0

Consideration of Registrant Reported Diversion in the Legitimate Distribution Chain

DEA extracted data from its Theft Loss Report database and categorized it by each basic drug class. DEA calculated the estimated amount of diversion by multiplying the quantity of API in each finished dosage form by the total amount of units reported stolen or lost to estimate the metric weight in grams of the controlled substance being diverted. This estimate of diversion from the legitimate supply chain for each of the covered controlled substances is displayed in Table 2. This data contributed to the final diversion estimates set forth in Table 3.

TABLE 2—DIVERSION ESTIMATES BASED ON SUPPLY CHAIN DIVERSION DATA FOR COVERED CONTROLLED SUBSTANCES

Controlled Substance	(g)
Fentanyl	74
Hydrocodone	12,454
Hydromorphone	481
Oxycodone	31,698
Oxymorphone	252

In accordance with 21 U.S.C. 826(i), DEA's estimate of diversion for the five controlled substances was calculated by combining the values in Tables 1b and 2. DEA reduced the APQ for each covered controlled substance by the quantities listed in Table 3.

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES TO BE APPLIED TO THE 2024 APQS

Controlled substance	(g)
Fentanyl	92
Hydrocodone	96,277
Hydromorphone	838

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES TO BE APPLIED TO THE 2024 APQS—Continued

Controlled substance	(g)
Oxycodone	182,382
Oxymorphone	252

Forthcoming Regulatory Changes and Administration of Individual Quotas for 2024

DEA is committed to ensuring that all Americans can access appropriately prescribed medications. As part of this commitment, DEA undertook work to understand the supply chain dynamics for controlled substances subject to quotas over the last year and a half, especially in highly genericized markets. Based on that review, DEA observed various challenges in the quota allocation process stemming from the lack of real-time inventory and sales data accessible to DEA, the lack of information on manufacturers' production lead times, and issues of timeliness in ARCOS reporting.

Relatedly, beginning in the latter half of 2022, the DEA and FDA observed an increase in the number of drug shortages reported by manufacturers of schedule II stimulants including mixed-salt amphetamine products starting in April 2022 and lisdexamfetamine and methylphenidate starting in July 2023. As DEA and FDA stated in their open letter,[13] we remain committed to doing all we can to prevent stimulant drug shortages, limit their impact, and resolve them as quickly as possible.

DEA commissioned two reports by IQVIA [14] in order to understand the demographic shifts impacting the prescribing of schedule II stimulants. The reports provided valuable insights. Chief among those insights was the observed increase in prescriptions dispensed for mixed-salt amphetamine products to adults between the ages of 31–40 years, particularly women, and older patients (71–80 years old), particularly during the COVID–19 pandemic (*i.e.* 2020 and 2021). In contrast, during 2022, dispensed prescriptions for products containing methylphenidate HCl and dexmethylphenidate HCl had a higher annual increase in 2022 (than in 2021) as compared to mixed-salt amphetamine products which may be indicative of product switching from amphetamine to methylphenidate and dexmethylphendiate. Neither DEA nor FDA anticipated these changes.

In addition to these demographic shifts in prescribing, DEA also evaluated inventory, manufacturing, and sales data submitted by manufacturers through ARCOS and through reports submitted to DEA's Quota Management System. That analysis revealed that dosage manufacturers of amphetamine did not utilize the full extent of their authorized quotas. DEA authorized amphetamine medication dosage form manufacturers across the entire market to purchase and use 38,418 kilograms of amphetamine but those manufacturers initially [15] reported the purchase of only 31,539 kg. Of that quantity, dosage manufacturers only shipped 26,953 kg of amphetamine medications.

This ongoing work has led DEA to conclude that changes to its regulations likely will be useful in developing more precise quotas that will provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks, while also reducing opportunities for diversion. For instance, DEA believes that changes to reporting requirements are necessary to improve both the type of data collected and the timeliness of that data, allowing DEA to be more nimble in its administration of the quota program. Future regulatory changes may seek to address the lack of real-time inventory and sales data accessible to DEA, the lack of information on production lead times, and issues of timeliness in ARCOS reporting, by considering, for example, requiring manufacturers to provide anticipated production timelines and monthly ARCOS reporting. DEA is not seeking comments on these concepts through this notice, but will publish detailed proposals for comment in the future.

DEA also will seek additional information that will assist the agency to more accurately forecast export requirements, especially for those substances that are not controlled internationally.[16] DEA understands that manufacturers have contractual obligations that dictate business decisions regarding the quantities of finished dosage forms they will produce under a single DEA-issued quota, which applies to products manufactured with an active ingredient, whether for domestic or foreign markets. DEA also is exploring the purchase of third-party data to improve its understanding of the dynamic changes in foreign markets. Building off the recently issued quota management rule,[17] DEA also intends to add new subcategories to individual manufacturing quotas and procurement quotas, to distinguish between domestic requirements and export requirements.

DEA also is considering methods by which it might increase transparency in its quota setting process. Future regulatory proposals may define additional steps, including such concepts as public notification and an opportunity for public input when prescribing rates for controlled substances deviate substantially from FDA's estimate of future use. Furthermore, DEA is considering regulatory changes which will authorize it to reduce a manufacturer's individual manufacturing or procurement quota in order to apportion it to another manufacturer. As with the regulatory changes mentioned above, DEA will welcome comment on detailed proposals in the future, and is not requesting comment on these general concepts in this notice.

The abovementioned regulatory changes will take time. In the meantime, for the 2024 quota year, DEA intends to allocate procurement quotas to DEA-registered manufacturers of schedule II controlled substances on a quarterly basis. In order to address domestic drug shortages of controlled substances, procurement quota allocations for schedule II controlled substances will be divided between quantities authorized for domestic sales and quantities authorized for export sales. DEA will be sending a letter to each manufacturer with instructions on the data that will be necessary to allow DEA to process subsequent quarterly procurement quota allocations. DEA may publish or post how many companies have been allocated quota in

[13] Both DEA and FDA released this letter on Aug. 1, 2023. It is available at: *https://www.dea.gov/sites/default/files/2023-08/DEA%20and%20FDA%20Issue%20Joint%20Letter%20to%20the%20Public.pdf.*

[14] Both reports are available at: *https://www.deadiversion.usdoj.gov/drug_chem_info/stimulants/.*

[15] In July 2023, several manufacturers who—according to their reporting to DEA—had failed to use their full amphetamine procurement quotas in 2022 received correspondence from DEA and FDA asking them to confirm that they would use their full 2023 procurement quotas. Upon receiving that correspondence—approximately seven months after the close of calendar year 2022—one such manufacturer then revised its 2022 reporting to DEA to reflect that it had, in fact, used nearly all of its 2022 amphetamine procurement quota.

[16] While amphetamine and methylphenidate are currently recognized as schedule II controlled substances under the Convention on Psychotropic Substances of 1971, lisdexamfetamine is not. Additional details may be found at: *https://www.incb.org/incb/en/psychotropics/1971_convention.html.*

[17] Management of Quotas for Controlled Substances and List I Chemicals, 88 FR 60117 (Aug. 31, 2023) (effective Nov. 29, 2023).

a given calendar year, and how many of those companies have utilized their allocated quota. Further, DEA may publish or post the names of the companies that have been allocated quota.

The Administrator, therefore, proposes to establish the 2024 APQ for certain schedule I and II controlled substances and AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Proposed 2024 quotas (g)
Schedule I	
-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	30
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2′-fluoro 2-fluorofentanyl	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C–P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	12,000
3,4-Methylenedioxymethamphetamine (MDMA)	12,000
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	5,200
3,4-Methylenedioxypyrovalerone (MDPV)	35
3–FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4,4′-Dimethylaminorex	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	5,100
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
4–CN-Cumyl-Butinaca	25
4-Fluoroisobutyryl fentanyl	30
4F–MDMB–BINACA	30
4–FMC; Flephedrone	25
4–MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-alpha-ethylaminopentiophenone (4–MEAP)	25
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4′-Methyl acetyl fentanyl	30
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog)	40
5F–AB–PINACA; (1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F–ADB; 5F–MDMB–PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	25
5F–CUMYL–P7AICA; 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboximide	25
5F–CUMYL–PINACA	25
5F–EDMB–PINACA	25
5F–MDMB–PICA	25
5F–AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	25
5F–APINACA; 5F–AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	25
5-Fluoro-PB–22; 5F–PB–22	25
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1Hindol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25

Basic class	Proposed 2024 quotas (g)
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	11,000
AB–CHMINACA	30
AB–FUBINACA	50
AB–PINACA	30
ADB–FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH–7921	30
All other tetrahydrocannabinol	790,010
Allylprodine	25
Alphacetylmethadol	25
alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-pyrrolidinoheptaphenone (PV8)	25
alpha-pyrrolidinohexabophenone (alpha-PHP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Amineptine	30
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
beta-Hydroxy-3-methylfentanyl	30
beta-Hydroxyfentanyl	30
beta-Hydroxythiofentanyl	30
beta-Methyl fentanyl	30
beta′-Phenyl fentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Brorphine	30
Bufotenine	15
Butonitazene	30
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
d-9–THC	900,610
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,300
Dihydromorphine	639,954
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	3,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25

Basic class	Proposed 2024 quotas (g)
Ethylone	25
Etodesnitazene	30
Etonitazene	25
Etorphine	30
Etoxeridine	25
Eutylone	30
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
Flunitazene	30
FUB–144	25
FUB–AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	29,417,000
Heroin	150
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	150
Isobutyryl Fentanyl	25
Isotonitazine	25
JWH–018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH–019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH–081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenyacylmorphan	25
Lysergic acid diethylamide (LSD)	1,200
MAB–CHMINACA; ADB–CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
MDMB–CHMICA; MMB–CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB–FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB–CHMICA-(AMB–CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Mesocarb	30
Metodesnitazene	30
Metonitazene	30
Marijuana	6,675,000
Marijuana extract	1,000,000
Mecloqualone	30
Mescaline	1,200
Methaqualone	60
Methcathinone	25
Methiopropamine	30
Methoxetamine	30
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT–45	30
Myrophine	25
NM2201: Naphthalen-1-yl 1-(5-fluorpentyl)-1H-indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Nicocodeine	25
Nicomorphine	25

Basic class	Proposed 2024 quotas (g)
N-methyl-3-piperidyl benzilate	30
N-Pyrrolidino Etonitazene	30
Noracymethadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
ortho-Fluoroacryl fentanyl	30
ortho-Fluorobutyryl fentanyl	30
Ortho-Fluorofentanyl,2-Fluorofentanyl	30
ortho-Fluoroisobutyryl fentanyl	30
ortho-Methyl acetylfentanyl	30
ortho-Methyl methoxyacetyl fentanyl	30
Para-Chlorisobutyrl fentanyl	30
Para-flourobutyryl fentanyl	25
Para-fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyrl fentanyl	30
Para-methoxymethamphetamine	30
para-Methylfentanyl	30
Parahexyl	5
PB–22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Protonitazene	30
Psilocybin	15,000
Psilocyn	24,000
Racemoramide	25
SR–18 and RCS–8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR–19 and RCS–4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrofuranyl fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
Thiofuranyl fentanyl	30
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
UR–144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U–47700	30
Valeryl fentanyl	25
Zipeprol	30
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	866,746
Alfentanil	5,000
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	942,452
Codeine (for sale)	19,262,957
d-amphetamine (for sale)	21,200,000
d,l-amphetamine	21,200,000
d-amphetamine (for conversion)	20,000,000
Dexmethylphenidate (for sale)	6,200,000

Basic class	Proposed 2024 quotas (g)
Dexmethylphenidate (for conversion)	4,200,000
Dextropropoxyphene	35
Dihydrocodeine	115,227
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	60,492
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	676,062
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	27,143,545
Hydromorphone	1,951,801
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	20,000
Lisdexamfetamine	26,500,000
Meperidine	681,184
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
d,l-Methamphetamine	150
d-methamphetamine (for conversion)	485,020
d-methamphetamine (for sale)	47,000
l-methamphetamine	587,229
Methylphenidate (for sale)	53,283,000
Methylphenidate (for conversion)	19,975,468
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,393,200
Morphine (for sale)	20,805,957
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	1,000
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	437,827
Oxycodone (for sale)	53,658,226
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	464,464
Pentobarbital	33,843,337
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	100
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	10,390,226
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	41,100
Ephedrine (for sale)	3,933,336
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	170,360,314

The Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

These proposed 2024 quotas reflect the quantities that DEA believes are necessary to meet the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements; and the establishment and maintenance of reserve stocks. DEA remains committed to conducting continuous surveillance on the supply of schedule II controlled substances and list I chemicals necessary to treat patients with COVID–19, and, pursuant to her authority, the Administrator will move swiftly and decisively to increase any 2024 APQ that she determines is necessary to address an unforeseen increase in demand, should that occur.

In accordance with 21 CFR 1303.13 and 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2024 APQ and AAN as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will issue and publish in the **Federal Register** a final order establishing the 2024 APQ for controlled substances in schedules I and II and establishing an AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as directed by 21 CFR 1303.11(c) and 1315.11(f).

Signing Authority

This document of the Drug Enforcement Administration was signed on October 30, 2023, 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–24282 Filed 11–1–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–17]

Isaac Sved, M.D.; Decision and Order

On December 8, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Isaac Sved, M.D. (Respondent) of Buford, Georgia. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, Control No. BS4103610, 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 has ''committed such acts as would render [his] registration inconsistent with the public interest.'' *Id.* at 1, 4 (citing 21 U.S.C. 823(g)(1),[1] 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Teresa A. Wallbaum (the ALJ) who, on June 20, 2023, issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 27. 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, credibility findings,[2] findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD.

I. Findings of Fact

Georgia Standard of Care

DEA hired Dr. Lobel to testify as an expert in the standard of care for the practice of medicine and the prescribing of controlled substances in the state of Georgia, with a focus on pain management. RD, at 4; Tr. 105.[3] Dr. Lobel defined ''standard of care'' as a ''minimum level of competence or care so as not to harm the patient,'' and described how the Georgia standard of care requires a practitioner to, prior to prescribing controlled substances, obtain a patient's prior medical records; obtain a medical history, including family medical history and mental health history; conduct an appropriate physical examination; obtain a urine drug screen; check the PDMP; obtain informed consent from the patient; and document all information. RD, at 11; Tr. 120, 128–129, 134, 136. Further, the physical examination must be appropriate to the complaint, and for patients who have spinal pain, the practitioner should also conduct a complete neurologic exam. RD, at 11; Tr. 129–130. In addition, the Georgia standard of care requires that a practitioner determine and document the severity of pain. RD, at 11; Tr. 135–136.

Dr. Lobel testified that under the Georgia standard of care, opioids ''are not first-line treatment for chronic pain,'' so a practitioner must ''weigh the risks and benefits at every visit,'' as well as look out for adverse effects, side effects, and aberrant behavior. RD, at 11; Tr. 132–133, 136–137. According to Dr. Lobel, under the Georgia standard of care, a practitioner should consider taking a patient off of opioids when there is a ''lack of functional benefit, toxic effects of the medicine where they're having end organ damage, . . . [or] someone [] showing any signs or symptoms of addiction,'' and patients

[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 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 3–17. The Agency agrees with the ALJ that the Diversion Investigator's testimony, which was focused on the uncontroversial introduction of documentary evidence and her contact with the case, was credible in that it was sufficiently detailed, plausible, and internally consistent. *Id.* at 4. Further, the Agency agrees with the ALJ that the testimony from the Government's expert witness, Dr. Steven Lobel, M.D., which was focused on the Georgia standard of care and Respondent's prescribing to the patients listed in the OSC/ISO, was credible in that it was consistent with Georgia statutes governing the prescribing of controlled substances, especially in the pain management context, and was clear, direct, substantial, and consistent with regards to the individual patients. *Id.* at 4–5. Finally, the Agency agrees with the ALJ that although Respondent's testimony was credible as to general facts, including Respondent volunteering information regarding prior disciplinary actions, on the issue of whether his prescriptions were within the usual course of professional practice and for a legitimate medical purpose, Respondent's testimony was not fully credible in that his interpretations of the Georgia standard of care were inconsistent with the Georgia state statutes. *Id.* at 9–10.

[3] During the hearing, both Government counsel and Dr. Lobel initially referenced a national standard of care established by the CDC Guidelines, *see* RD, at 10, but Dr. Lobel ultimately testified that the Georgia standard of care, upon which this decision is based, is grounded in the state medical board's publications and Georgia state statutes, with the CDC Guidelines incorporated to the extent that they deal with the prescriptions of opioids. RD, at 10; Tr. 114–115, 119, 125.