Basic class	Established 2024 quotas (g)	Proposed revised 2024 quotas (g)
Sufentanil	4,000	no change
Tapentadol	10,390,226	no change
Thebaine	57,137,944	no change
List I Chemicals		
Ephedrine (for conversion)	41,100	no change
Ephedrine (for sale)	3,933,336	no change
Phenylpropanolamine (for conversion)	14,878,320	no change
Phenylpropanolamine (for sale)	7,990,000	no change
Pseudoephedrine (for conversion)	1,000	no change
Pseudoephedrine (for sale)	186,617,466	no change

The Administrator further proposes that the APQ for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 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 any adjustment of the 2024 APQ for each basic class of controlled substances in schedules I and II and AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.[15]

Signing Authority

This document of the Drug Enforcement Administration was signed on September 20, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–21960 Filed 9–20–24; 4:15 pm]

BILLING CODE P

[15] 21 CFR 1303.13(c) and 1315.13(c).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1413P]

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 2025

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2025 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before October 25, 2024. 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 2025 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–1413P'' 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: Heather E. Achbach, 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 2025 Aggregate Production Quotas and Assessment of Annual Needs

The proposed 2025 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 in 2025 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 2025 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 2024 and from the states in April 2024, 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 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 2025 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 following five 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

[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 2020, 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).

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 2025 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 2025 will decline on average 6.6 percent from calendar year 2024 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 (PHE) has ended, pursuant to 21 CFR 1303.11(b)(7), in developing the proposed 2025 APQ.

FDA predicted an average of a 3.5 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 since 2022 from patients for specific ADHD medications containing amphetamine, lisdexamfetamine, and methylphenidate. FDA's stated reasons for these specific shortages include increased prescribing potentially related to the growth in telemedicine during and after the COVID–19 PHE, supply chain issues, manufacturing and quality issues, lack of active ingredients, and business decisions of manufacturers. DEA considered FDA's concerns when determining the APQ for these substances. Additionally, DEA considered manufacturer and distributor-reported data which shows inventories for both amphetamine and methylphenidate-based products have increased year-over-year throughout the supply chain. DEA believes these increases in inventories combined with the established APQs are adequate to address FDA's estimated increases in domestic medical use for amphetamine and methylphenidate. With respect to lisdexamfetamine, DEA recently increased the APQ pursuant to a final order published on September 5, 2024 to address reported shortages.[3] In sum, DEA believes that manufacturers will be able to meet the increase in domestic medical need for these three schedule II stimulants with the APQs proposed in this notice.

DEA Projected Trends for Certain Schedule I Controlled Substances

DEA is proposing a higher APQ for ibogaine than DEA granted for 2024 to support manufacturing activities related to the increased level of research and clinical trials with this schedule I controlled substance. Additionally, DEA proposes a higher APQ for gamma hydroxybutyric acid (GHB) to allow for an anticipated increase in domestic bulk manufacturing to meet forecasted and continued domestic market need due to the closure of a foreign manufacturing facility. Imports of the schedule III oxybate form of GHB from that manufacturing facility have supplied an estimated 78% of the domestic need. Their foreign plant closure will be approximately one year in duration. GHB (oxybate) products are used in the treatment of patients diagnosed with narcolepsy and cataplexy.

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 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.[4] Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than legitimate medical purposes. In order to consider the extent of diversion, DEA analyzed reports of diversion of controlled substances from 2023 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 2025 APQ notice, DEA continues to consider 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 PHE.

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

[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] Adjustment to the Aggregate Production Quota for Lisdexamfetamine and d-Amphetamine (for Conversion) for 2024, 89 FR 72424 (Sept. 5, 2024).

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

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.'' [5]

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 2024, 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 2021–2023. 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.[6] 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.[7] Certain state regulations now include red flag circumstances as potential indicators of illegitimate prescriptions, and thus of potential abuse and diversion of controlled substances.[8] *See, e.g.,* 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, 2024. 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. Twenty-nine states and three territories provided DEA with summarized PDMP data as of July 2024, utilizing the standardized report developed by NASCSA.[9] See Table 1a below.

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

State/territory
1. Alabama.
2. Alaska.
3. Arkansas.
4. Commonwealth of Northern Mariana Islands.
5. Connecticut.
6. Delaware.
7. District of Columbia.
8. Idaho.
9. Indiana.
10. Kansas.
11. Kentucky.
12. Louisiana.
13. Maryland.
14. Massachusetts.
15. Michigan.
16. Minnesota.
17. Mississippi.
18. Montana.
19. Nevada.
20. New Jersey.
21. New Mexico.
22. North Carolina.
23. Oklahoma.
24. Oregon.
25. Pennsylvania.
26. Puerto Rico.
27. South Carolina.
28. South Dakota.
29. Utah.
30. Vermont.
31. Virginia.
32. Washington.

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 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.[10]
- 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.[11] States also provided the number of prescriptions paid entirely with cash as a percentage

[5] 21 U.S.C. 826(i)(1)(C).

[6] 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.*

[7] The Medicine Shoppe, 79 FR 59504, 59507, 59512–13 (Oct. 2, 2014); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (Oct. 12, 2012).

[8] 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.

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

[10] Frank's Corner Pharmacy, 60 FR 17574 (Apr. 6, 1995); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (Oct. 12, 2012).

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

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.[12]

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 112.35 million people, which is approximately 34 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 set 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 2021–2023. 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 2021–2023, 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 2025.

DEA also reviewed aggregate sales data for each of the covered controlled substances, which it extracted from IQVIA's National Sales Perspective.[13] 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 2021–April 2024, in order to predict the estimated national sales for 2025.

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 2025 by the forecasted sales data from IQVIA for 2025. 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.

TABLE 1b—DIVERSION ESTIMATES FOR 2025 BASED ON STATE PDMP DATA FOR COVERED CONTROLLED SUBSTANCES FROM 2021–2023

Controlled substance	(g)
Fentanyl	26
Hydrocodone	90,396
Hydromorphone	699
Oxycodone	234,372
Oxymorphone	000

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	73
Hydrocodone	12,528
Hydromorphone	481
Oxycodone	30,265
Oxymorphone	165

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.

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES TO BE CONSIDERED IN THE 2025 APQS

Controlled substance	(g)
Fentanyl	99
Hydrocodone	102,924
Hydromorphone	1,180
Oxycodone	264,637
Oxymorphone	165

Continuing Efforts To Anticipate and Prevent Drug Shortages

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 an open letter in 2023,[14] we remain committed to doing all we can to prevent stimulant drug shortages, limit their impact, and resolve them as quickly as possible.

In particular, DEA continues to seek additional information that will assist the agency to more accurately forecast export requirements, especially for those substances controlled domestically in schedule I or II that are not controlled internationally. 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 has purchased third-party data to improve its understanding of the dynamic changes in foreign markets. In February 2024, DEA began utilizing IQVIA's foreign (non-U.S.) sales tracking

[12] Suntree Pharmacy and Suntree Medical Equipment, LLC, 85 FR 73753 (Nov. 19, 2020) (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).

[13] 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.

[14] 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.*

data module, MIDAS (Multi International Data Analysis System), which provides valuable insight into the growing export markets for schedule II stimulants. Building off the recently issued quota management rule,[15] DEA also intends to add new subcategories to individual manufacturing quotas and procurement quotas, to distinguish between domestic requirements and export requirements.

As part of DEA's continuing effort to prevent shortages and be more nimble in its administration of the quota program, DEA intends to continue to allocate procurement quotas to DEA-registered manufacturers of schedule II controlled substances on a semi-annual basis for the 2025 quota year, except that it will continue to allocate procurement quotas relating to injectable drug products containing schedule II controlled substances on an annual basis. DEA announced this change in a letter to DEA-registered manufacturers on April 29, 2024. No further change is being implemented at this time. DEA remains committed to ensuring that all patients with legitimate medical need can access appropriately prescribed medications.

The Administrator, therefore, proposes to establish the 2025 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 2025 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
2-Methyl AP-237	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-Methylmethcathinone	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-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (alpha-PiHP)	30
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

[15] Management of Quotas for Controlled Substances and List I Chemicals, 88 FR 60,117 (Aug. 31, 2023) (effective Nov. 29, 2023).

Basic class	Proposed 2025 quotas (g)
4′-Methyl acetyl fentanyl	30
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
4F-MDMB-BUTICA	30
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-PICA	30
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
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	11,000
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-BUTINACA	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-4en-PINACA	30
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	1,166,130
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
Clonazolam	30
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25

Basic class	Proposed 2025 quotas (g)
CUMYL-PEGACLONE	30
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
d-9-THC	1,523,040
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diclazepam	30
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,300
Dihydromorphine	639,954
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	11,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Etizolam	30
Etodesnitazene	30
Etonitazene	25
Etorphine	30
Etoxeridine	25
Eutylone	30
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
Flualprazolam	30
Flubromazolam	30
Flunitazene	30
FUB-144	25
FUB-AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	49,675,266
Heroin	150
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	210
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
Marijuana	6,675,000
Marijuana extract	1,000,000
MDMB-4en-PINACA	30
MMB-FUBICA	30
Mecloqualone	30
Mescaline	1,200
Mesocarb	30
Methaqualone	60

Basic class	Proposed 2025 quotas (g)
Methcathinone	25
Methiopropamine	30
Methoxetamine	30
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Metodesnitazene	30
Metonitazene	30
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-Desethyl isotonitazene	30
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
N-methyl-3-piperidyl benzilate	30
N-piperidinyl etonitazene	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	30,000
Psilocin	36,000
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

Basic class	Proposed 2025 quotas (g)
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)	937,874
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)	23,688,235
Dexmethylphenidate (for sale)	6,200,000
Dexmethylphenidate (for conversion)	5,374,683
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	731,341
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	27,121,498
Hydromorphone	1,951,508
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	20,000
Lisdexamfetamine	32,736,000
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)	24,756,979
Noroxymorphone (for sale)	1,000
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	37,721,950
Oxycodone (for conversion)	437,827

Basic class	Proposed 2025 quotas (g)
Oxycodone (for sale)	53,584,449
Oxymorphone (for conversion)	31,773,105
Oxymorphone (for sale)	464,464
Pentobarbital	40,000,000
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)	186,617,466

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

These proposed 2025 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.

In accordance with 21 CFR 1303.13 and 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2025 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 2025 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 September 20, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–21962 Filed 9–20–24; 4:15 pm]

BILLING CODE 4410–09–P