DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1568P]

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 2026

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2026 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 [INSERT 15 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. 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 his 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 2026 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. **1568P**" 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 2026 Aggregate Production Quotas and Assessment of Annual Needs

The proposed 2026 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 2026 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 2026 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 & 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 data from the HHS agency FDA in March 2025 and from the states in April 2025, pursuant to 21 CFR part 1303. DEA did not solicit input from CMS for reasons discussed in previous notices.[1] While DEA is requesting data from CDC, this request has been inadvertently delayed. Data received from the CDC that is relevant to the 2026 APQs will be considered in finalizing and/or adjusting the APQs. DEA requested information on trends in the legitimate use of select schedule I and II controlled substances from FDA. 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).

[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).

Assessment of Annual Needs

In similar fashion, in determining the proposed 2026 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 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 2026 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. In July 2025, FDA provided DEA with the predicted estimates of domestic medical usage for selected controlled substances for 2026, which DEA considered in developing the proposed 2026 APQ.

DEA observed an average of a 10.56 percent decrease in the medical usage of the schedule II opioids codeine, morphine, fentanyl, hydrocodone, hydromorphone, oxycodone and oxymorphone for the United States in 2024 compared to 2023. DEA projects that the medical usage of these controlled substances will continue to decline in 2026 based on a review of domestic usage data from IQVIA. DEA also considered the potential for diversion of these opioids, as required by 21 CFR 1303.11(b)(5). Additionally, DEA has observed a significant decline in requests for product development quotas to support manufacturing towards FDA approval of drug products containing oxycodone. Accordingly, the APQs for codeine (for sale), morphine (for sale), fentanyl, hydrocodone (for sale), hydromorphone, oxycodone (for sale), and oxymorphone (for sale) are being proposed as reductions from their 2025 established APQ value.

DEA is proposing a slight increase to the remifentanil APQ from the 2025 established APQ. Remifentanil is a schedule II synthetic opioid analgesic that is primarily administered intravenously to manage pain during and after surgical procedures. DEA reviewed the most recently available domestic usage data from IQVIA

and export data from DEA's internal database. Domestic medical usage of remifentanil has been increasing every year since 2020. Additionally, exports of this active pharmaceutical ingredient (API) have also increased from 2022 to 2024. Thus, DEA is proposing a higher APQ of remifentanil for 2026 than DEA initially established for 2025, to support increasing domestic medical use and export requirements.

DEA is also proposing an increase to the noroxymorphone (for sale) APQ from the 2025 established APQ to accommodate a manufacturer's request to manufacture reference standards, and to evaluate and identify unknown impurities in the manufacturing process. This additional APQ will also accommodate the manufacturer's need to conduct additional product development manufacturing activities to optimize the synthesis of noroxymorphone (for sale).

DEA observed an average of a 6.74 percent increase in domestic medical use of the schedule II stimulants amphetamine, methylphenidate (including dexmethylphenidate), and lisdexamfetamine in 2024 compared to 2023. Medications containing one of these controlled substances are commonly prescribed to treat patients with attention deficit hyperactivity disorder (ADHD). In 2025, dosage form manufacturers reported shortages of specific ADHD medications containing amphetamine, lisdexamfetamine, and methylphenidate to FDA. The stated reasons for these specific shortages include increases in product demand, supply chain issues, manufacturing and quality issues, lack of active ingredients, and business decisions of manufacturers. DEA considered drug shortage concerns when determining the proposed APQs for these substances.

In proposing the APQs for d-amphetamine (for sale), d,l-amphetamine, and methylphenidate, DEA considered manufacturers' reported inventories for amphetamine and methylphenidate-based products and determined that the 2026 APQs should be proposed at their 2025 adjusted APQ levels. DEA believes the inventories, when

combined with the proposed 2026 APQs, will be sufficient to support the estimated increases in domestic medical use and export requirements of amphetamine and methylphenidate-based products.

With respect to lisdexamfetamine, DEA is proposing an increase from the 2025 established lisdexamfetamine APQ to address increased prescribing, export requirements, and to ensure sufficient inventory for domestic manufacturers of FDA-approved lisdexamfetamine drug products. DEA recognizes that global consumption is increasing with almost 30 countries approving the use of lisdexamfetamine drug products to treat specific medical conditions. DEA reviewed the most recently available domestic usage data from IQVIA and export data from DEA's internal database and Multi International Data Analysis System (MIDAS). Extrapolation of the data predicts domestic use will increase 8.94 percent and export requirements will increase 14.85 percent in 2026. This double-digit increase in export requirements follows from the brand name product, Vyvanse, successfully being approved to treat patients suffering from attention-deficit/hyperactivity disorder (ADHD) in 29 countries in addition to the United States. Furthermore, Vyvanse is expected to launch in additional foreign countries between 2025 and 2027. Additional U.S. dosage form manufacturers have also begun exporting lisdexamfetamine finished dosage-form products according to the data extracted from DEA's internal databases. Reviewing internal databases, DEA determined that bulk manufacturers started 2025 with less than the 40% inventory allowance permitted by 21 CFR 1303.24. Increasing the lisdexamfetamine APQ in 2026 would allow the manufacturers to maintain the 40% inventory allowance permitted by 21 CFR 1303.24 while meeting the estimated increasing legitimate domestic and global demands. Thus, DEA is proposing a higher lisdexamfetamine APQ for 2026 than DEA initially established for 2025.

DEA is also proposing a corresponding increase to the APQ of d-amphetamine

(for conversion) over the 2025 level. The synthesis route to manufacture lisdexamfetamine requires the manufacturing of a controlled substance intermediate, d-amphetamine (for conversion). In most synthesis pathways, lisdexamfetamine cannot be manufactured without synthesizing d-amphetamine (for conversion) as an intermediate step, thus the APQ of d-amphetamine (for conversion) is proposed to increase commensurately to the lisdexamfetamine APQ increase.

DEA Projected Trends for Certain Schedule I Controlled Substances

DEA is proposing a higher APQ than the 2025 established APQs for the following schedule I controlled substances: 3,4-methylenedioxy-N-methylcathinone, 5-methyoxy-N-N-dimethyltryptamine, psilocybin and psilocyn to support manufacturing activities related to the increased level of research and clinical trials. Research and clinical trials are being conducted with these substances for potential treatment of conditions such as post-traumatic stress disorder (PTSD) and depression.

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.[2] 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

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

substances from 2024 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).

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."[3]

[3] 21 U.S.C. 826(i)(1)(C).

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 2025, 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 2022-2024. 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.[4] 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.[5] Certain state regulations now include red flag circumstances as potential indicators of illegitimate prescriptions, and thus of potential abuse and diversion of controlled substances.[6] *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

[4] 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.
[5] 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).
[6] 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.

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, 2025. 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-one states and three territories provided DEA with summarized PDMP data as of July 2025, utilizing the standardized report developed by NASCSA.[7] 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. Commonwealth of Northern Mariana Islands
6. Connecticut
7. Delaware
8. District of Columbia
9. Idaho
10. Indiana
11. Iowa
12. Kansas
13. Kentucky
14. Louisiana
15. Maine

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

16. Maryland
17. Michigan
18. Minnesota
19. Mississippi
20. Missouri
21. Montana
22. Nevada
23. New Jersey
24. New Mexico
25. North Carolina
26. Ohio
27. Oregon
28. Pennsylvania
29. Puerto Rico
30. South Carolina
31. South Dakota
32. Texas
33. Utah
34. Virginia

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.[8]

- 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.[9] States also provided the number of prescriptions paid entirely with cash as a percentage of the total prescriptions for the

[8] 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).
[9] This total does not include insurance co-payments made with cash.

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.[10]

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 2022-2024. 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 2021-2024, DEA analyzed trends in the data to predict the estimated

[10] 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).

percentage of patients who would be expected to be included in these red-flag metrics for 2026.

DEA also reviewed aggregate sales data for each of the covered controlled substances, which it extracted from IQVIA's National Sales Perspective.[11] 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 2025, in order to predict the estimated national sales for 2026.

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 2026 by the forecasted sales data from IQVIA for 2026. 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 2026 Based on State PDMP Data for Covered Controlled Substances from 2022-2024.

Controlled Substance	(g)
Fentanyl	27
Hydrocodone	124,656
Hydromorphone	477
Oxycodone	302,819
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

[11] 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.

diverted. Additional data was provided by a DEA field office based on the conclusion of a regulatory inspection. In January 2025, DEA Diversion Investigators conducted an inspection at a DEA-registered pharmaceutical company and discovered a significant quantity of oxycodone medications missing from various production stages. DEA fined the company who surrendered their DEA registration license at the conclusion of the investigation. 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	78
Hydrocodone	18,765
Hydromorphone	1,653
Oxycodone	43,978
Oxymorphone	97

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 2026 APQs

Controlled Substance	(g)
Fentanyl	105
Hydrocodone	143,421
Hydromorphone	2,130
Oxycodone	346,797
Oxymorphone	97

Continuing Efforts to Anticipate and Prevent Drug Shortages

DEA remains committed to monitoring drug shortages, limiting their impact, and resolving them as quickly as possible. DEA continues to seek additional information that will assist in accurately forecasting domestic medical usage and export requirements of

schedule I or II substances. In February 2024, DEA began utilizing IQVIA's foreign (non-U.S.) sales tracking data module, MIDAS, which provides valuable insight into the growing export markets for schedule II stimulants. In March 2025, DEA sent a letter requesting approximately 700 DEA-registered manufacturers and distributors to voluntarily switch their DEA ARCOS database reporting from a quarterly to monthly basis.

On April 29, 2024, DEA announced to DEA-registered manufacturers that procurement quotas for the purpose of commercial manufacturing of schedule II-controlled substances will be allocated on a semi-annual basis, except that procurement quotas relating to injectable drug products will be allocated annually. In a continuing effort to prevent drug shortages and be more agile in its administration of the quota program, DEA will continue to administer applicable procurement quotas on a semi-annual basis. DEA remains committed to ensuring that all patients with legitimate medical need can access appropriately prescribed medications.

The Administrator, therefore, proposes to establish the 2026 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	**Established 2026 Quotas (g)**
Schedule I	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	30
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(4-Methoxyphenyl)-N-methylpropan-2-amine (Para-methoxymethamphetamine)	30
1-(5-Fluoropentyl)-3-(1-naphthoyl) indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole (AM694)	30

1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2'-Fluoro 2-fluorofentanyl	30
2,5-Dimethoxy-4-Ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-[N]-Propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-(2,5-Dimethoxy-4-(N)-propylphenyl)ethanamine (2C-P)	30
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-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)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Ethoxybenzyl)-5-Nitro-1-(2-(Piperidin-1-yl)Ethyl)-1H-Benzimidazole (N-Piperidinyl Etonitazene)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(Ethylamino)-2-(3-Methoxyphenyl)Cyclohexan-1-One (Methoxetamine)	30
2-Methyl AP-237	30
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-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	30,000
3,4-Methylenedioxymethamphetamine (MDMA)	12,000
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
3-Methylmethcathinone	30
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
4′-Methyl acetyl fentanyl	30
4'-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4,4′-Dimethylaminorex	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	5,100

4-CN-Cumyl-Butinaca	25
4-Fluoroisobutyryl fentanyl	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methyl-alpha-ethylaminopentiophenone (4-MEAP)	25
4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP)	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methylaminorex	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
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	30,000
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-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
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
A-PIHP; 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (alpha-PiHP)	30
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25

ADB–4en–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
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
alpha-Ethyltryptamine	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
Alphacetylmethadol	25
Alphameprodine	25
Alphamethadol	25
Amineptine	30
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Beta hydroxy-3-methylfentanyl	30
Beta hydroxyfentanyl	30
Beta-hydroxythiofentanyl	30
Beta-Methyl fentanyl	30
Beta′-Phenyl fentanyl	30
Betacetylmethadol	25
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
CUMYL–PEGACLONE	30
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
Delta-9-Tetrahydrocannabinol	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	20,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Ethylphenidate	30
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
Marijuana	6,675,000
Marijuana extract	1,000,000
MDMB–4EN–PINACA	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
Mecloqualone	30
Mescaline	1,200
Mesocarb	30
Methaqualone	60
Methcathinone	25
Methiopropamine	30
Methoxyacetyl fentanyl	30
Methyl 2-(1-(4-fluorobutyl)-1h-indazole-3-carboxamido)-3,3-dimethylbutanoate (4F–MDMB–BINACA)	30
Methyldesorphine	5
Methyldihydromorphine	25
Metodesnitazene	30
Metonitazene	30
MMB-CHMICA; (AMB-CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
MMB–FUBICA	30
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5

Morphine-N-oxide	150
MT-45	30
Myrophine	25
N,N-Dimethylamphetamine	25
N-Ethyl-1-phenylcyclohexylamine; N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1h-benzimidazol-1-yl)ethan-1-amine; N-Desethyl Isotonitazene	30
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
N-Methyl-3-piperidyl benzilate	30
N-Pyrrolidino Etonitazene	30
Naphyrone	25
Nicocodeine	25
Nicomorphine	25
NM2201: Naphthalen-1-yl 1-(5-fluorpentyl)-1H-indole-3-carboxylate	25
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-Chloroisobutyrl fentanyl	30
Para-Flourobutyryl fentanyl	25
Para-Fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyrl fentanyl	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	40,000
Psilocyn	48,000
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
U-47700	30
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
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)	19,262,516
d-Amphetamine (for conversion)	29,171,447
d-Amphetamine (for sale)	26,450,000
d-Methamphetamine (for conversion)	485,020
d-Methamphetamine (for sale)	47,000
d,l-Amphetamine	21,200,000
d,l-Methamphetamine	150

Dexmethylphenidate (for conversion)	5,374,683
Dexmethylphenidate (for sale)	6,200,000
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	731,236
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	26,978,077
Hydromorphone	1,949,378
Isomethadone	30
l-Amphetamine	30
l-Methamphetamine	587,229
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	20,000
Lisdexamfetamine	42,057,460
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
Methamphetamine	150
Methylphenidate (for conversion)	19,975,468
Methylphenidate (for sale)	58,283,000
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,393,200
Morphine (for sale)	20,689,632
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	24,756,979
Noroxymorphone (for sale)	2,500
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	37,721,950
Oxycodone (for conversion)	437,827
Oxycodone (for sale)	50,237,652

Oxymorphone (for conversion)	31,773,105
Oxymorphone (for sale)	464,367
Pentobarbital	40,000,000
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	100
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	4,000
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 2026 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 2026 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 2026 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 November 25, 2025, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

[FR Doc. 2025-21509 Filed: 11/25/2025 4:15 pm; Publication Date: 11/28/2025]