DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1228A]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2024 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act. Additionally, as DEA announced in an April 29, 2024 letter to DEA-registered manufacturers, procurement quotas for commercial manufacturing of a schedule II controlled substance will be calculated on a semi-annual basis, except for injectable drug products containing schedule II controlled substances, which will be calculated on an annual basis.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(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 2024 adjusted aggregate production quotas for schedule I and II controlled substances, and an adjusted assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as relevant.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–1228A'' 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/DRW, 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 and Background

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas (APQ) for each basic class of controlled substance 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.

DEA established the 2024 APQ for substances in schedules I and II and the assessment of annual needs (AAN) for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on January 3, 2024.[1] That order stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all APQ and AAN are subject to adjustment. DEA published a Final Order revising the 2024 lisdexamfetamine and d-amphetamine (for conversion) APQ on September 5, 2024.[2]

[1] 89 FR 407.

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

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

DEA proposes to adjust the established 2024 APQ for certain schedule I and II controlled substances and the AAN for certain list I chemicals to be manufactured in the United States in 2024 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

Factors for Determining the Proposed Adjustments

In determining the proposed adjustments, the Administrator has taken into account the factors in 21 CFR 1303.13 (adjustment of APQ for controlled substances) and 21 CFR 1315.13 (adjustment of the AAN for ephedrine, pseudoephedrine, and phenylpropanolamine). The Administrator is authorized to increase or reduce the APQ and the AAN at any time.[3]

DEA determined whether to propose an adjustment of the APQ for 2024 by considering the factors found at 21 CFR 1303.13(b):

(1) Changes in the demand for that class, changes in the national rate of net disposal of the class, changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class, and changes in the extent of any diversion in the class;

(2) Whether any increased demand for that class, the national and/or individual rates of net disposal of that class are temporary, short term, or long term;

(3) Whether any increased demand for that class can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to [21 CFR] 1303.24(b);

(4) Whether any decreased demand for that class will result in excessive inventory accumulation by all persons registered to handle that class (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to [21 CFR] 1303.24(b) or abandoned pursuant to [21 CFR] 1303.27;

(5) 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 which are 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.

DEA also considered updated information obtained from 2023 year-end inventories, 2023 disposition data submitted by quota applicants, changes in estimates of the medical needs of the United States, export requirements, and other information made available to DEA after the initial APQ and AAN had been established. Additional factors the Administrator considered in calculating the APQ, but not the AAN, include product development requirements of both bulk and finished dosage form manufacturers.

After considering the changes in the extent of diversion of all controlled substances, as required by 21 CFR 1303.13(b)(1), DEA has determined that any changes from the initial calculations are slight and not statistically significant from the estimates of diversion that DEA applied to the initial APQ valuations.

DEA determined whether to propose an adjustment of the AAN for 2024 by considering the factors found at 21 CFR 1315.13(b) and summarized below:

(1) Changes in the demand for that chemical, changes in the national rate of net disposal of the chemical, and changes in the rate of net disposal of the chemical by registrants holding individual manufacturing or import quotas for that chemical;

(2) Whether any increased demand for that chemical, the national and/or changes in individual rates of net disposal of that chemical are temporary, short term, or long term;

(3) Whether any increased demand for that chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the assessment of annual needs, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to [21 CFR] 1315.24(b);

(4) Whether any decreased demand for that chemical will result in excessive inventory accumulation by all persons registered to handle that chemical (including manufacturers, distributors, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to [21 CFR] 1315.24(b) or abandoned pursuant to [21 CFR] 1315.27;

(5) Other factors affecting medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemical or the substances that are 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.

In evaluating whether there is a need for adjustment of the 2024 AAN for list I chemicals, DEA used the calculation methodology previously described in the 2010 and 2011 AAN.[4] DEA considered the total net disposals of the list I chemicals for the current and preceding two years, actual and estimated inventories, projected demand, industrial use, and export requirements from data provided by DEA registered manufacturers and importers on the relevant quota application forms.[5]

Additional Considerations Applicable to Covered Controlled Substances

When setting APQ, the Administrator must estimate the amount of diversion of any substance that is considered a ''covered controlled substance.''[6] The covered controlled substances are fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone.[7] DEA is required to ''make appropriate quota reductions, as determined by the [Administrator], from the quota the [Administrator] would have otherwise established had such diversion not been considered.''[8] When estimating diversion, the Administrator ''shall consider information'' that she, in consultation with the Secretary of Health and Human Services, ''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 ''may take into consideration'' whatever other sources of information she determines reliable.[9]

DEA sent letters to the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the states in March, April, and May 2024 requesting overdose death and overprescribing data that could be considered in estimating diversion. DEA received information from the CDC in May 2024, the FDA in June 2024, and has begun receiving Prescription Data Monitoring Program

[3] 21 CFR 1303.13(a), 1315.13(a).

[4] 74 FR 60294 (Nov. 20, 2009); 75 FR 79407 (Dec. 20, 2010).

[5] 74 FR 60294 (Nov. 20, 2009); 75 FR 79407 (Dec. 20, 2010).

[6] 21 U.S.C. 826(i)(1)(A).

[7] 21 U.S.C. 826(i)(1).

[8] All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b); 21 U.S.C. 826(i)(1)(C).

[9] 21 U.S.C. 826(i)(1)(B).

(PDMP) data from the states. DEA considered this information in developing the estimates of diversion for the five covered controlled substances for this proposed adjustment.

DEA also aggregated data for each covered controlled substance from Drug Theft and Loss Reports to determine the estimates of diversion. DEA gathered data involving employee theft, break-ins, armed robberies, and material lost in transit. DEA calculated the metric weight in grams of each active pharmaceutical ingredient (API) of the controlled substances being diverted as identified in these reports. In calculating the estimates of diversion, DEA utilized the same methodology as published in the Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2024.[10] Below, DEA provides an updated chart showing estimations of diversion for each of the covered controlled substances.

DIVERSION ESTIMATES FOR 2024 (g)

Fentanyl	112
Hydrocodone	124,170
Hydromorphone	1,137
Oxycodone	263,236
Oxymorphone	165

Implementation of Semi-Annual Quota Allotment

For the 2024 quota year, DEA announced that it intended to allocate procurement quotas to DEA-registered manufacturers of schedule II controlled substances on a quarterly basis, in order to help DEA prevent shortages and be more nimble in its administration of the quota program. After the announcement, DEA met with several manufacturers to discuss the impact of that change. Numerous manufacturers asked DEA to consider allocating quotas semi-annually to assist with production planning and execution. DEA understands and appreciates the complexities of the supply chain. In light of the discussions with manufacturers, as well as meetings with FDA discussing their statutory obligations for drug availability to meet legitimate patients' needs, input from health associations in foreign countries, and consideration of the continuing issues with the supply chain in the aftermath of the COVID–19 pandemic, DEA determined that it would and will allocate procurement quotas for schedule II controlled substances on a semi-annual basis, except that it would and will allocate procurement quotas for 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 that are manufactured domestically.

Proposed Adjustments for the 2024 Aggregate Production Quotas and Assessment of Annual Needs

DEA is proposing increases to the APQ for the following schedule I substances: psilocybin and psilocyn. These proposed increases are to support research and clinical trials by DEA-registered schedule I researchers. These proposed increases demonstrate DEA's support for research with schedule I controlled substances. The proposed increases reflect research and development needs as part of the process for seeking the FDA approval of new drug products.

DEA is proposing increases to the APQ for the following schedule II substances: noroxymorphone (for conversion), oripavine, and oxymorphone (for conversion). These proposed increases are necessary to meet manufacturing needs and increased consumption of naloxone products as standard treatment for opioid overdose. These substances are part of the synthesis pathway to manufacture naloxone products. On March 13, 2024, the ''White House Challenge to Save Lives from Overdose'' was announced in support of the Administration's Unity Agenda efforts to address the opioid overdose crisis.[11] The challenge is a nationwide initiative to increase training, awareness, and access to lifesaving opioid overdose reversal medications. The FDA has approved two over the counter (OTC) naloxone products for the emergency treatment of opioid overdose.[12] As a result of the White House Challenge and efforts by the Department of Health and Human Services to help recipients of State and Tribal Opioid Response Grants increase distribution of opioid overdose reversal agents, DEA is expecting medical usage of naloxone to continue to rise in 2024. The proposed increase to the APQ of noroxymorphone (for conversion), oripavine and oxymorphone (for conversion) reflects this increasing medical usage of naloxone.

DEA is proposing decreases to the following APQ: fentanyl, hydrocodone (for sale), hydromorphone, and oxycodone (for sale). These proposed decreases are based on adjustments to the diversion estimates for calendar year 2024.

DEA established the 2024 APQ for substances in schedules I and II on January 3, 2024.[13] Subsequent to that publication, DEA published in the **Federal Register** a final rule to permanently schedule 2-methyl AP-237 under the CSA.[14] As a result, this substance is subject to CSA schedule I controls and DEA is proposing to assign an individual APQ for this substance pursuant to 21 U.S.C. 826 and 21 CFR part 1303.

The Administrator, therefore, proposes to adjust the 2024 APQ for the schedule I and II controlled substances noroxymorphone (for conversion), oripavine, oxymorphone (for conversion), psilocybin, psilocyn, and 2-methyl AP–237. The proposed adjusted APQ and AAN, as expressed in grams of anhydrous acid or base, are as follows:

Basic class	Established 2024 quotas (g)	Proposed revised 2024 quotas (g)
New Temporary Controlled Schedule I Substances		
4F-MDMB-BUTICA	30	no change

[10] 88 FR 75312 (November 2, 2023).

[11] *https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/13/fact-sheet-biden-harris-administration-launches-the-white-house-challenge-to-save-lives-from-overdose/.*

[12] *https://www.fda.gov/news-events/press-announcements/fda-approves-second-over-counter-naloxone-nasal-spray-product.*

[13] 89 FR 407.

[14] 89 FR 18793 (March, 15, 2024).

Basic class	Established 2024 quotas (g)	Proposed revised 2024 quotas (g)
5F-EDMB-PICA	30	no change
ADB-4en-PINACA	30	no change
Clonazolam	30	no change
CUMYL-PEGACLONE	30	no change
Diclazepam	30	no change
Etizolam	30	no change
Flualprazolam	30	no change
Flubromazolam	30	no change
MDMB-4en-PINACA	30	no change
MMB-FUBICA	30	no change
Schedule I		
-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20	no change
1-(1-Phenylcyclohexyl)pyrrolidine	30	no change
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10	no change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30	no change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
2′-fluoro 2-fluorofentanyl	30	no change
1-Benzylpiperazine	25	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	10	no change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	no change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	no change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	no change
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30	no change
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	100	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30	no change
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25	no change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	no change
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30	no change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change
2,5-Dimethoxyamphetamine	25	no change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30	no change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30	no change
2-Methyl AP-237	0	30
3,4,5-Trimethoxyamphetamine	30	no change
3,4-Methylenedioxyamphetamine (MDA)	12,000	no change
3,4-Methylenedioxymethamphetamine (MDMA)	12,000	no change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-N-methylcathinone (methylone)	5,200	no change
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change
3-FMC; 3-Fluoro-N-methylcathinone	25	no change
3-Methylfentanyl	30	no change
3-Methylmethcathinone	30	no change
3-Methylthiofentanyl	30	no change
4,4′-Dimethylaminorex	30	no change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30	no change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	5,100	no change
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25	no change
4-CN-Cumyl-Butinaca	25	no change
4-Fluoroisobutyryl fentanyl	30	no change
4F-MDMB-BINACA	30	no change
4-FMC; Flephedrone	25	no change
4-MEC; 4-Methyl-N-ethylcathinone	25	no change
4-Methoxyamphetamine	150	no change
4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (alpha-PiHP)	30	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-N-methylcathinone (mephedrone)	45	no change
4-Methyl-alpha-ethylaminopentiophenone (4-MEAP)	25	no change
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25	no change
4′-Methyl acetyl fentanyl	30	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25	no change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50	no change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40	no change
5F-AB-PINACA; (1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25	no change

Basic class	Established 2024 quotas (g)	Proposed revised 2024 quotas (g)
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	25	no change
5F-CUMYL-P7AICA; 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboximide	25	no change
5F-CUMYL-PINACA	25	no change
5F-EDMB-PINACA	25	no change
5F-MDMB-PICA	25	no change
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	25	no change
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	25	no change
5-Fluoro-PB-22; 5F-PB-22	25	no change
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1Hindol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25	no change
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change
5-Methoxy-N,N-diisopropyltryptamine	25	no change
5-Methoxy-N,N-dimethyltryptamine	11,000	no change
AB-CHMINACA	30	no change
AB-FUBINACA	50	no change
AB-PINACA	30	no change
ADB-BUTINACA	30	no change
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30	no change
Acetorphine	25	no change
Acetyl Fentanyl	100	no change
Acetyl-alpha-methylfentanyl	30	no change
Acetyldihydrocodeine	30	no change
Acetylmethadol	25	no change
Acryl Fentanyl	25	no change
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50	no change
AH-7921	30	no change
All other tetrahydrocannabinol	1,166,130	no change
Allylprodine	25	no change
Alphacetylmethadol	25	no change
alpha-Ethyltryptamine	25	no change
Alphameprodine	25	no change
Alphamethadol	25	no change
alpha-Methylfentanyl	30	no change
alpha-Methylthiofentanyl	30	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	25	no change
alpha-pyrrolidinoheptaphenone (PV8)	25	no change
alpha-pyrrolidinohexabophenone (alpha-PHP)	25	no change
alpha-Pyrrolidinopentiophenone (α-PVP)	25	no change
Amineptine	30	no change
Aminorex	25	no change
Anileridine	20	no change
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25	no change
Benzethidine	25	no change
Benzylmorphine	30	no change
Betacetylmethadol	25	no change
beta-Hydroxy-3-methylfentanyl	30	no change
beta-Hydroxyfentanyl	30	no change
beta-Hydroxythiofentanyl	30	no change
beta-Methyl fentanyl	30	no change
beta′-Phenyl fentanyl	30	no change
Betameprodine	25	no change
Betamethadol	4	no change
Betaprodine	25	no change
Brorphine	30	no change
Bufotenine	15	no change
Butonitazene	30	no change
Butylone	25	no change
Butyryl fentanyl	30	no change
Cathinone	40	no change
Clonitazene	25	no change
Codeine methylbromide	30	no change
Codeine-N-oxide	192	no change
Crotonyl Fentanyl	25	no change
Cyclopentyl Fentanyl	30	no change
Cyclopropyl Fentanyl	20	no change
Cyprenorphine	25	no change
d-9-THC	1,523,040	no change
Desomorphine	25	no change
Dextromoramide	25	no change
Diapromide	20	no change
Diethylthiambutene	20	no change

Basic class	Established 2024 quotas (g)	Proposed revised 2024 quotas (g)
Diethyltryptamine	25	no change
Difenoxin	9,300	no change
Dihydromorphine	639,954	no change
Dimenoxadol	25	no change
Dimepheptanol	25	no change
Dimethylthiambutene	20	no change
Dimethyltryptamine	11,000	no change
Dioxyaphetyl butyrate	25	no change
Dipipanone	25	no change
Drotebanol	25	no change
Ethylmethylthiambutene	25	no change
Ethylone	25	no change
Etodesnitazene	30	no change
Etonitazene	25	no change
Etorphine	30	no change
Etoxeridine	25	no change
Eutylone	30	no change
Fenethylline	30	no change
Fentanyl carbamate	30	no change
Fentanyl related substances	600	no change
Flunitazene	30	no change
FUB-144	25	no change
FUB-AKB48	25	no change
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25	no change
Furanyl fentanyl	30	no change
Furethidine	25	no change
gamma-Hydroxybutyric acid	29,417,000	no change
Heroin	150	no change
Hydromorphinol	40	no change
Hydroxypethidine	25	no change
Ibogaine	150	no change
Isobutyryl Fentanyl	25	no change
Isotonitazine	25	no change
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35	no change
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45	no change
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45	no change
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30	no change
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30	no change
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35	no change
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30	no change
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30	no change
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30	no change
Ketobemidone	30	no change
Levomoramide	25	no change
Levophenyacylmorphan	25	no change
Lysergic acid diethylamide (LSD)	1,200	no change
MAB-CHMINACA; ADB-CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30	no change
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
MMB-CHMICA-(AMB-CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25	no change
Marijuana	6,675,000	no change
Marijuana extract	1,000,000	no change
Mecloqualone	30	no change
Mescaline	1,200	no change
Mesocarb	30	no change
Methaqualone	60	no change
Methcathinone	25	no change
Methiopropamine	30	no change
Methoxetamine	30	no change
Methoxyacetyl fentanyl	30	no change
Methyldesorphine	5	no change
Methyldihydromorphine	25	no change
Metodesnitazene	30	no change
Metonitazene	30	no change
Morpheridine	25	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-N-oxide	150	no change
MT-45	30	no change

Basic class	Established 2024 quotas (g)	Proposed revised 2024 quotas (g)
Myrophine	25	no change
NM2201: Naphthalen-1-yl 1-(5-fluorpentyl)-1H-indole-3-carboxylate	25	no change
N,N-Dimethylamphetamine	25	no change
Naphyrone	25	no change
N-Ethyl-1-phenylcyclohexylamine	25	no change
N-Ethyl-3-piperidyl benzilate	10	no change
N-Ethylamphetamine	24	no change
N-Ethylhexedrone	25	no change
N-Ethylpentylone, ephylone	30	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Nicocodeine	25	no change
Nicomorphine	25	no change
N-methyl-3-piperidyl benzilate	30	no change
N-Pyrrolidino Etonitazene	30	no change
Noracymethadol	25	no change
Norlevorphanol	2,550	no change
Normethadone	25	no change
Normorphine	40	no change
Norpipanone	25	no change
Ocfentanil	25	no change
ortho-Fluoroacryl fentanyl	30	no change
ortho-Fluorobutyryl fentanyl	30	no change
Ortho-Fluorofentanyl,2-Fluorofentanyl	30	no change
ortho-Fluoroisobutyryl fentanyl	30	no change
ortho-Methyl acetylfentanyl	30	no change
ortho-Methyl methoxyacetyl fentanyl	30	no change
Para-Chlorisobutyrl fentanyl	30	no change
Para-flourobutyryl fentanyl	25	no change
Para-fluorofentanyl	25	no change
para-Fluoro furanyl fentanyl	30	no change
Para-Methoxybutyrl fentanyl	30	no change
Para-methoxymethamphetamine	30	no change
para-Methylfentanyl	30	no change
Parahexyl	5	no change
PB-22; QUPIC	20	no change
Pentedrone	25	no change
Pentylone	25	no change
Phenadoxone	25	no change
Phenampromide	25	no change
Phenomorphan	25	no change
Phenoperidine	25	no change
Phenyl fentanyl	30	no change
Pholcodine	5	no change
Piritramide	25	no change
Proheptazine	25	no change
Properidine	25	no change
Propiram	25	no change
Protonitazene	30	no change
Psilocybin	20,000	30,000
Psilocyn	24,000	36,000
Racemoramide	25	no change
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45	no change
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30	no change
Tetrahydrofuranyl fentanyl	15	no change
Thebacon	25	no change
Thiafentanil	25	no change
Thiofentanyl	25	no change
Thiofuranyl fentanyl	30	no change
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30	no change
Tilidine	25	no change
Trimeperidine	25	no change
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25	no change
U-47700	30	no change
Valeryl fentanyl	25	no change
Zipeprol	30	no change
Schedule II		
1-Phenylcyclohexylamine	15	no change
1-Piperidinocyclohexanecarbonitrile	25	no change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	937,874	no change

Basic class	Established 2024 quotas (g)	Proposed revised 2024 quotas (g)
Alfentanil	5,000	no change
Alphaprodine	25	no change
Amobarbital	20,100	no change
Bezitramide	25	no change
Carfentanil	20	no change
Cocaine	60,492	no change
Codeine (for conversion)	942,452	no change
Codeine (for sale)	19,262,957	no change
d-amphetamine (for sale)	21,200,000	no change
d,l-amphetamine	21,200,000	no change
d-amphetamine (for conversion)	23,688,235	no change
Dexmethylphenidate (for sale)	6,200,000	no change
Dexmethylphenidate (for conversion)	5,374,683	no change
Dextropropoxyphene	35	no change
Dihydrocodeine	115,227	no change
Dihydroetorphine	25	no change
Diphenoxylate (for conversion)	14,100	no change
Diphenoxylate (for sale)	770,800	no change
Ecgonine	60,492	no change
Ethylmorphine	30	no change
Etorphine hydrochloride	32	no change
Fentanyl	731,360	731,341
Glutethimide	25	no change
Hydrocodone (for conversion)	1,250	no change
Hydrocodone (for sale)	27,143,545	27,121,498
Hydromorphone	1,951,801	1,951,508
Isomethadone	30	no change
L-amphetamine	30	no change
Levo-alphacetylmethadol (LAAM)	25	no change
Levomethorphan	30	no change
Levorphanol	20,000	no change
Lisdexamfetamine	32,736,000	no change
Meperidine	681,184	no change
Meperidine Intermediate-A	30	no change
Meperidine Intermediate-B	30	no change
Meperidine Intermediate-C	30	no change
Metazocine	15	no change
Methadone (for sale)	25,619,700	no change
Methadone Intermediate	27,673,600	no change
d,l-Methamphetamine	150	no change
d-methamphetamine (for conversion)	485,020	no change
d-methamphetamine (for sale)	47,000	no change
l-methamphetamine	587,229	no change
Methylphenidate (for sale)	53,283,000	no change
Methylphenidate (for conversion)	19,975,468	no change
Metopon	25	no change
Moramide-intermediate	25	no change
Morphine (for conversion)	2,393,200	no change
Morphine (for sale)	20,805,957	no change
Nabilone	62,000	no change
Norfentanyl	25	no change
Noroxymorphone (for conversion)	22,044,741	24,756,979
Noroxymorphone (for sale)	1,000	no change
Oliceridine	25,100	no change
Opium (powder)	250,000	no change
Opium (tincture)	530,837	no change
Oripavine	33,010,750	37,721,950
Oxycodone (for conversion)	437,827	no change
Oxycodone (for sale)	53,658,226	53,584,449
Oxymorphone (for conversion)	28,204,371	31,773,105
Oxymorphone (for sale)	464,464	no change
Pentobarbital	40,000,000	no change
Phenazocine	25	no change
Phencyclidine	35	no change
Phenmetrazine	25	no change
Phenylacetone	100	no change
Piminodine	25	no change
Racemethorphan	5	no change
Racemorphan	5	no change
Remifentanil	3,000	no change
Secobarbital	172,100	no change

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.