CFR 1308.11 and 1308.12 remain at zero.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 13, 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. 2024–30019 Filed 12–16–24; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1413E]

Established 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: Final order.

SUMMARY: This final order establishes the initial 2025 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective December 17, 2024.

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, VA 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

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

II. Background

The 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 that may be manufactured in the United States in 2025, in order to provide for the estimated medical, scientific, research, and industrial needs of the U.S., 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.

On September 25, 2024, a notice titled ''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'' was published in the **Federal Register**.[1] This notice proposed the 2025 APQs for each basic class of controlled substance listed in schedules I and II and the 2025 AANs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed APQs and the proposed AANs on or before October 25, 2024.

III. Comments Received

Within the public comment period, DEA received 1,882 comments from DEA registrants, chronic pain patients, patients with attention deficit/hyperactivity disorder (ADHD), pain advocacy associations, U.S. professional associations, U.S. doctors and nurses, and others. The comments included concerns about potential domestic opioid drug shortages due to further quota reductions; patient difficulty filling authorized opioid prescriptions; increases in drug overdose deaths despite a continued decrease in production quotas; requests for an extension to the comment period; stimulant drug shortages in the United States; concerns that medical professionals might be impeded from exercising their medical expertise regarding opioid prescriptions; requests for a public hearing; and comments not pertaining to DEA-regulated activities. While all comments were posted to regulations.gov, DEA restricted the attachments to 10 comments from public view due to confidential business information and/or confidential personal identifying information.

Opioid Adequacy

Issue (National Production Levels of Proposed APQs for Opioids Compared to 2024 levels): DEA received a significant number of comments from pain advocacy groups, hospital associations, health professionals, and others who raised concerns over the proposed APQs for certain opioids in 2025, which were proposed at a level lower than the established production levels for 2024. The commenters suggested that the proposed APQ levels could exacerbate shortages experienced in 2024.

DEA Response: DEA considers numerous factors in determining an APQ, including total net disposal of the class by all manufacturers during the current and two preceding years, trends in the national rate of net disposal of the class, total actual or estimated inventories of the class and of all substances manufactured from the class, information obtained from the Food and Drug Administration (FDA), and changes in the currently accepted medical use in treatment. 21 U.S.C. 826(a); 21 CFR 1303.11(b). Additional factors considered can be found in 21 CFR 1303.11(b). After considering all of the relevant factors, DEA has determined that the proposed APQs for the five covered controlled substances—fentanyl, hydrocodone, hydromorphone, oxycodone and oxymorphone—are sufficient to meet the forecasted legitimate domestic and foreign needs and allow for maintenance of reserve stocks. These considerations also lead DEA to conclude that U.S. manufacturers will need to manufacture approximately the same amount of those opioids in 2025 as in 2024 in order to meet legitimate needs.

Accordingly, DEA proposed the 2025 APQs for those five substances at the same level as in DEA's proposed revised APQs for 2024 published on September

[1] 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, 89 FR 78772 (September 25, 2024).

25, 2024.[2] In that publication, DEA proposed minor reductions to the 2024 APQs for 4 of the 5 substances to reflect DEA's updated calculations of diversion, as required by Congress. Specifically, Congress requires DEA to make appropriate quota reductions ''from the quota [DEA] would have otherwise established had such diversion not been considered.'' [3] DEA applied the same estimates of diversion in proposing and finalizing the 2025 APQs and has reduced the 2025 APQs accordingly. The APQs for those five controlled substances are lower than the initial 2024 established APQs by approximately 0.1% combined. These decreases in the APQs will not affect the ability of the APQs to provide all material necessary for the estimated medical, scientific, research, and industrial needs of the U.S., lawful export requirements, and the establishment and maintenance of reserve stocks.

Issue (Medication Out of Stock at Pharmacy Level): DEA received comments questioning whether the 2025 proposed APQs for Schedule II opioids will be adequate to meet legitimate medical needs of patients. Commenters said that because of decreases in APQs for specific opioids, they have had difficulty filling legitimate prescriptions at pharmacies. These issues have negatively impacted their quality of life and caused mental health-related issues, including the possibility of suicide.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet legitimate medical, scientific, and export needs of the United States. DEA sets the APQs for controlled substances based on the available data and information received at that specific point in time; however, subsequent factors outside of DEA's control, including changes to manufacturers' business practices may emerge afterwards and potentially contribute to a temporary lack of inventory of controlled substances at the point of dispensation. In recent years, these factors have included labor shortages and a lack of production capacity. In such circumstances, DEA, in coordination with FDA, can utilize tools under the CSA to try to prevent or alleviate drug shortages so that patients are able to fill legitimate prescriptions for controlled substances without undue delay. Additionally, if patients are faced with a delay in receiving their medications, the patients may request a one-time transfer of initial dispensing of an electronic prescription for Schedules II—V controlled substances from one retail pharmacy to another retail pharmacy if authorized under state law.[4] If the medication is a controlled substance in Schedules III—V and includes authorized refills, the refills can also be transferred with the initial prescription to the receiving pharmacy.

Issue (Nationwide Opioid Shortages): DEA received many comments stating there is a nationwide shortage of opioid medication because the commenters' local pharmacies were often out of stock, forcing the commenters to spend significant time contacting additional pharmacies, and traveling further to get prescriptions filled. Commenters stated that many times they were unsuccessful in their attempts to fill the prescription.

DEA Response: Drug shortages may occur due to factors outside of DEA's control such as manufacturing and quality problems, processing delays, supply chain disruptions, or discontinuations. In such circumstances, if the drug manufacturer notifies the FDA Drug Shortage Staff, FDA will coordinate with DEA to address and minimize the impact of drug shortages if both agencies believe action is warranted. Currently, FDA has not issued notice of any nationwide shortages of the types of opioid medications mentioned by these commenters.

Issue (Failure to Acknowledge Drug Shortages): One commenter expressed that DEA is failing to acknowledge and address opioid drug shortages that are complicating access to prescribed medications, effectively creating conditions such as ''pharmacy deserts.''

DEA Response: DEA is aware of specific product shortages of pain medicines and works with FDA and DEA-registered manufacturers to alleviate them. Patients and medical professionals may notice specific drug products are out of stock in particular areas; however, DEA cannot dictate DEA registrants' distributions of drug products. If a drug manufacturer notifies FDA of a manufacturing-related shortage, FDA and DEA can take additional steps to help alleviate the shortage if action is warranted.

Issue (Patients Switching to Illicit Fentanyl or Medications Obtained from Illegal Sources): Several commenters expressed concerns that because of DEA's reduction of quotas for pain relieving controlled substances, chronic pain sufferers who were unable to fill their legitimate prescriptions eventually turned to illegal fentanyl or medications obtained from illegitimate sources as a substitute relief that could increase the risk of overdose death. These commenters stated that overdose deaths in the United States continue to rise because of illegal fentanyl or illegitimate medications, not from pharmaceutical medications prescribed to chronic pain patients.

DEA Response: While overdose deaths may occur because of use of illicit substances, DEA's quota regulations have been implemented to prevent misuse and diversion of pharmaceutical controlled substances. In this way, these quotas can reduce the occurrence of overdose and death from the use of legitimate controlled substances. Patients should work closely with their providers to utilize other FDA-approved medications for their conditions and fill their prescriptions only from DEA-registered pharmacies. The only safe medications containing controlled substances are ones prescribed by a trusted, DEA-registered medical professional and dispensed by a licensed pharmacist at a DEA-registered pharmacy. The medications received from unregistered internet sources may, in fact, be manufactured or laced with illicit substances including illicit fentanyl, which contributes to rates of overdose deaths.

Issue (Opioid Prescribing Hesitancy): Many commenters, mostly self-identified chronic pain patients, expressed that the goal of the 2016 Centers for Disease Control and Prevention Guidelines was to decrease opioid overdoses, but instead there has been an increase in overdoses nationwide of over 400 percent due to illegal fentanyl or illegally manufactured pain pills. Commenters stated that many chronic pain patients have been harmed, and some have died by suicide, due to the inability to get prescriptions because of the APQ reductions made by DEA. Many commenters also stated that restrictions imposed by DEA have caused opioid medications to be under-prescribed due to fear of prosecution. Commenters said doctors should have latitude in making treatment decisions to prescribe opioid pain medications based on individual patient needs.

DEA Response: Pursuant to 21 U.S.C. 826(i), DEA is mandated to estimate diversion for 5 controlled substances—

[2] *See* 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, 89 FR 78764 (Sept. 25, 2024).

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

[4] *See Revised Regulation Allows DEA-Registered Pharmacies to Transfer Electronic Prescriptions at a Patient's Request,* DEA.gov (Sept. 1, 2023), *https://www.dea.gov/stories/2023/2023-09/2023-09-01/revised-regulation-allows-dea-registered-pharmacies-transfer.*

fentanyl, hydrocodone, hydromorphone, oxycodone and oxymorphone—and this estimation includes the consideration of rates of overdose deaths. While overdose deaths may occur as a result of the use of illegal fentanyl or illegally manufactured pain medications, quotas are being set by DEA to prevent misuse and diversion of pharmaceutical controlled substances, and thus reduce the occurrence of overdose and death from the use of legitimate controlled substances. Additionally, DEA's regulations do not impose restrictions on the amount and the type of medication that licensed practitioners can prescribe. DEA has consistently emphasized and supported the authority of individual practitioners under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards, as outlined in DEA's policy statement published in the **Federal Register** on September 6, 2006, titled ''Dispensing Controlled Substances for the Treatment of Pain.'' [5]

Attention Deficit/Hyperactivity Disorder (ADHD) Medication

Issue (Shortage): DEA received comments expressing general concerns regarding the ongoing drug shortages for stimulant medications used in the treatment of ADHD.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the estimated legitimate medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. DEA sets the APQs to provide for all legitimate medical purposes and for anticipated foreign demand. Additionally, DEA and FDA coordinate efforts to prevent or alleviate drug shortages. Such efforts may include the adjustment of the APQs and individual domestic manufacturers' quotas, FDA's approval of additional market competitors, and coordination between the agencies to allow importation of foreign-manufactured drug products that meet FDA approval. If the actual prescribing rates of these substances are significantly higher than the 2025 estimates of medical needs, the Administrator has the authority to increase the aggregate production quota at any time. 21 CFR 1303.13(a).

Insufficient Gamma Hydroxybutyric Acid (GHB)

Issue (GHB APQ Insufficient to Support New FDA-Approved Generic Medications Entering the Market as well as Existing Branded Drug Products): DEA received one comment from a law firm that voiced concern that the proposed 2025 GHB APQ will be insufficient to provide for existing branded products on the market as well as emerging generic products with anticipated FDA-approval dates near the end of calendar year 2025. The commenter noted that FDA has expanded the conditions for which the branded products can be prescribed as part of an effective treatment.

DEA response: DEA is aware of the current FDA-approved GHB branded drug products and their exclusivity timelines as well as the numerous generic drug applications that are pending before FDA for approval. The 2025 APQ for GHB is being finalized at 49,675,266 grams, which is 20,258,266 grams higher than the 2024 APQ. This equates to an almost 70 percent increase in the amount of bulk active pharmaceutical ingredient (API) that can be made available in 2025 to provide for legitimate medical need, as compared to 2024. This additional API can be utilized in the manufacture of existing drug products on the market, product development activities leading to FDA-approved generic drugs, as well as inventory necessary to begin calendar year 2026 without shortages. The 2025 APQ is based on all available data including company-submitted information, U.S. export data, U.S. import data, and FDA drug data highlighting emerging and changing drug products containing GHB prescribed to the relevant patient population.

Diversion Estimates

Issue (Impact of Diversion Estimate on Opioids): Commenters voiced concern with the ''red flags'' associated with diversion data gathered from state Prescription Drug Monitoring Program (PDMP) data, which DEA uses to estimate diversion for the five covered controlled substances. Commenters worried that repeated attempts to fill prescriptions would be shown in the state PDMP data and result in concerns that they were engaged in ''doctor shopping,'' and their conduct could be misperceived as a ''red flag'' of actively seeking prescribed covered controlled substances from three or more prescribers in a 90-day period. Commenters were concerned that such misperceptions could render them unable to fill validly issued prescriptions.

DEA Response: In the event that a patient's general pharmacy does not have sufficient stock of a particular drug, a patient visiting multiple pharmacies to fill a single prescription would not be included in the ''red flag'' metric of patients actively seeking prescribed covered controlled substances from three or more prescribers in a 90-day period. The state PDMP data submitted was adequate to allow DEA to draw reliable inferences regarding the state and U.S. populations. The sample is large enough to allow DEA to accurately generalize the data to the whole population of the United States for use in the calculation of estimated national levels of diversion of the covered controlled substances. DEA developed the metric of patients prescribed covered controlled substances from three or more prescribers in a 90-day period to identify potential doctor shopping, a common technique used to obtain large amounts of controlled substances for the purpose of abuse or diversion. Federal administrative and criminal case law demonstrates that multiple prescriptions from multiple prescribers in a short timeframe is a reliable indicator of diversion.[6] In addition, DEA did not consider prescriptions written for the five covered controlled substances in quantities lower than 240 morphine milligram equivalents (MME) daily because some patients, including oncology patients in particular, have legitimate medical needs for covered controlled substance prescriptions in excess of 90 MME daily. DEA did not wish to inadvertently include legitimate prescriptions for these patients in its calculation of diversion. Daily dosages higher than 240 MME place individuals at a higher risk of overdose and death, and correlate with a heightened risk of diversion. DEA received aggregated data from state PDMPs that reflected only individual filled prescriptions.

Data Collection and Analysis

Issue (Data Accuracy): Several commenters stated that FDA's estimation of medical needs and DEA's data collection process are flawed and inaccurate.

DEA Response: FDA utilizes a variety of data sources in developing its estimates of domestic medical needs. When determining the 2025 APQs, DEA considered the estimation of domestic medical needs data provided by FDA,

[5] Dispensing Controlled Substances for the Treatment of Pain, 71 FR 52716 (September 6, 2006).

[6] The Medicine Shoppe, 29 FR 59504, 59507, 59512–13 (2014); Holiday CVS, LLC, d/b/a CVS Pharmacy Nos. 219 and 5195, 57 FR 62316 (2012).

and also considered other data sources including prescriptions dispensed in prior and current years reported in IQVIA, research and clinical trial information from DEA-registered researchers and manufacturers, information provided in quota applications from DEA-registered manufacturers, as well as historic and current year export data and future estimations of export requirements. DEA is actively reevaluating and improving the data collection process to ensure that the APQs are set at an adequate level to meet legitimate medical, scientific, research, and export needs while establishing and maintaining reserve stocks.

Issue (Lack of Data Transparency): Two commenters stated that there is a lack of transparency in the quota setting process.

DEA Response: DEA is considering methods that might increase transparency in its quota setting process. Future regulatory proposals may include steps such as public notification and an opportunity for public input when prescribing rates for controlled substances substantially deviate from FDA's estimate of medical needs. DEA must strike a balance between increasing transparency and complying with the applicable laws and regulations aimed at protecting confidential business and patient information.

Comments and Quota Applications From DEA-Registered Manufacturers

Issue: DEA received additional quota applications as well as comments from DEA-registered manufacturers regarding a specific schedule I controlled substance, requesting the APQs be established at a sufficient level to allow for their manufacturing to meet medical and scientific needs.

DEA Response: DEA considered the additional quota applications and comments from DEA-registered manufacturers and determined that DEA's APQ for dimethyltryptamine (DMT) should be increased to support legitimate research and scientific efforts toward an FDA-approved drug product. The increase is reflected below in the section titled, ''Determination of 2025 Aggregate Production Quotas and Assessment of Annual Needs.''

Request for Hearing and Extension of Comment Period

Issue: Several individual commenters suggested that DEA consider holding a public hearing regarding the APQs and AANs.

DEA Response: The decision whether to grant a hearing on the issues raised by the commenters lies solely within the discretion of the Administrator.[7] While hearings are required when requested by states in certain situations, these requests were not submitted by states. These requests did not include any evidence that would lead to the conclusion that a hearing is necessary or warranted. DEA has addressed specific points raised by the commenters in the issues and responses above.

Issue: DEA received three comments requesting an extension of the comment period so the commenters can better research the issues and submit additional comments.

DEA Response: DEA declines to extend the comment period. The number and scope of comments indicate that the provided 30 days was adequate. Additionally, DEA may propose to adjust these established APQs and AANs at any time after they have been established, at which time additional comments will be accepted.[8]

Out of Scope Comments

DEA received comments that are outside the scope of this order. The comments were general in nature and raised issues with respect to specific medical illnesses, medical treatments and medication costs. These comments do not impact the analysis involved in establishing the 2025 APQs.

IV. Determination of 2025 Aggregate Production Quotas and Assessment of Annual Needs

In determining the established 2025 APQs and AANs, DEA has considered the above comments along with the factors set forth in 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a). These factors include, but are not limited to, the 2024 manufacturing quotas, current 2024 sales and inventories, anticipated 2025 export requirements, industrial use, additional applications for 2025 quotas, and information on research and product development requirements.

On October 25, 2024, DEA published a final rule placing ethylphenidate in schedule I of the CSA,[9] making all regulatory controls pertaining to schedule I controlled substances applicable to the manufacture of these substances, including the requirement to establish an aggregate production quota pursuant to 21 U.S.C. 826 and 21 CFR part 1303. This final order establishes an aggregate production quota for this substance.

Estimates of Diversion

As specified in the proposal, and as required by 21 U.S.C. 826(i), DEA calculated a national diversion estimate for each of the five covered controlled substances. This data, which remains unchanged, was 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 2025.*[10]

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2025 APQs for the following schedule I and II controlled substances and the 2025 AANs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

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[7] 21 CFR 1303.11(c).

[8] 21 CFR 1303.13.

[9] Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule I, 89 FR 84281 (October 22, 2024).

[10] 89 FR 78772 (Sept. 25, 2024).

Basic Class	Established 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
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
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	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
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-CHMCA); 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

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
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
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

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The Administrator also establishes APQs for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 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 2025 APQ and AAN as needed.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 11, 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. 2024–30023 Filed 12–16–24; 8:45 am]

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