

Please note: This is the text of the final order as signed by the Acting Administrator, but the official version of the final order will be as it is published in the Federal Register.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-508A]

Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, In Response to the Coronavirus Disease 2019 Public Health Emergency

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice; Final order.

SUMMARY: The Drug Enforcement Administration is adjusting the 2020 aggregate production quotas for certain controlled substances in schedule II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine and pseudoephedrine. This increase is in response to the current nationwide COVID-19 public health emergency as declared by the Secretary of Health and Human Services on January 31, 2020.

EFFECTIVE DATE: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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 [INSERT 30 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.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-508A” on all correspondence, including any attachments. The Drug Enforcement Administration 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 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

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 for each basic class of controlled substance listed in schedule I and II and for the list I chemicals 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.

DEA established the 2020 aggregate production quotas and assessment of annual needs on December 2, 2019, (84 FR 66014) to 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 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 include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes. The order stipulated that all aggregate production quotas and assessments of annual needs are subject to adjustment, in accordance with 21 CFR 1303.13 and 1315.13.

Public Health Emergency

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person which can result in multi-organ failures, pneumonia, or death.¹ COVID-19 has rapidly spread through numerous countries, including the United States. COVID-19 poses a serious public health risk and all 50 states have reported cases of COVID-19.² On January 31, 2020, the Secretary of Health and Human Services

¹ <https://www.cdc.gov/coronavirus/2019-ncov/downloads/2019-ncov-factsheet.pdf>

² https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fsummary.html

(HHS) declared a public health emergency. DEA is closely collaborating with HHS to ensure an adequate and uninterrupted supply of controlled substances in order to meet 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.

Analysis for the Proposed Adjustments to the 2020 Aggregate Production Quotas and Assessment of Annual Needs

DEA is adjusting the established 2020 aggregate production quotas and assessment of annual needs for selected schedule II controlled substances and list I chemicals, to be manufactured in the United States to provide for the estimated needs of the United States. These adjustments are necessary to ensure that the United States has an adequate and uninterrupted supply of these substances as the country moves through this public health emergency. Although the existing 2020 quota level is sufficient to meet current needs, DEA is acting proactively to ensure that — should the public health emergency become more acute — there is sufficient quota for these important drugs.

Factors for Determining the Proposed Adjustments

In determining these adjustments, the Acting Administrator has taken into account the criteria in accordance with 21 CFR 1303.13 (adjustment of aggregate production quotas for controlled substances). The Acting Administrator is authorized to increase or reduce the aggregate production quota at any time. 21 CFR 1303.13(a). DEA regulations state that there are five factors that shall be considered in determining to adjust the aggregate production quota. 21 CFR 1303.13(b). Accordingly, the Acting Administrator has taken into account the following factors when determining to make the adjustments described below for 2020: (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; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Acting 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. 21 CFR 1303.13(b). The Acting Administrator has taken into consideration, in particular, the unforeseen emergency posed by COVID-19 and the effect the emergency is having on the need for certain controlled substances, particularly for patients who are on ventilators.

Considerations Based Upon the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

Pursuant to 21 U.S.C. 826(a)(1), “production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.” However, the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018 (SUPPORT Act), (Pub. L. 115-271), provides an exception to that general rule by now giving DEA the authority to establish quotas in terms of pharmaceutical dosage forms if the agency determines that doing so will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

In addition to the factors listed above, DEA must estimate the amount of diversion of any substance that is considered a “covered controlled substance,” as defined by the SUPPORT Act. 21 USC 826(i)(1)(A). The SUPPORT Act lists fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone as the “covered controlled substances.” Through the SUPPORT Act, DEA is also required to “make appropriate quota reductions, as determined by the [Administrator],³ from the quota the [Administrator] would have otherwise established had such diversion not been considered.” 21 U.S.C. 826(i)(1). When estimating diversion, the “[Administrator] (i) shall consider information the [Administrator], in consultation with the Secretary of [HHS], determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered

³ All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

controlled substance in the United States; and (ii) may take into consideration whatever other sources of information the [Administrator] determines reliable.”⁴ *Id.*

Information Considered to Satisfy the Factors for Determining the Adjustments

For the factors listed in 21 CFR 1303.13(b)(1) and (2), DEA consulted with HHS and determined that the utilization rates for selected medications required to implement the treatment regimens for ventilator patients stricken with the COVID-19 virus have substantially increased compared to the previously estimated annual consumption rates. There is a substantial range in the number of patients that will require ventilation treatment due to COVID-19, as the United States is still in the early stages of modeling best-case/worst-case scenarios for infection and hospitalization rates. Although DEA has considered this crisis to be a short-term increase in rate of disposal, the unknown factor is the estimated number of patients requiring a ventilator regimen in addition to the patients with other medical conditions that already require ventilator assistance.

For the factors listed in 21 CFR 1303.13(b)(3) and (4), DEA has already waived the requirement for manufacturers to suspend their manufacturing capacity pursuant to 1303.24(b) and cannot foresee any decrease in demand for the selected classes of controlled substances as currently modeled by HHS. DEA has considered the current requirements for social distancing that have been implemented by manufacturers which may lead to increases in production delays. DEA will monitor the individual manufacturing and procurement quotas granted in an effort to prevent excessive inventory accumulation by all persons registered to handle the classes. By monitoring

⁴ DEA intends to finalize amendments to the Agency’s regulations that will implement the amendments to the CSA made by the SUPPORT Act. Although these amendments to the regulations have not yet been issued, the statutory requirements stated above became effective upon enactment of the SUPPORT Act, and DEA is therefore obligated to adhere to them in issuing these adjusted aggregate production quotas.

individual manufacturing and procurement quotas, DEA will insure that the increase in APQ will be utilized primarily for the manufacturing of medications identified by the FDA as involved in the sedation, intubation, and pain relief of patients being treated for COVID-19. With respect to factor 21 CFR 1303.13(b)(5), the Acting Administrator has determined that the COVID-19 pandemic constitutes an unforeseen emergency supporting the increase in the aggregate production quotas and assessments of annual needs for the substances set forth below.

Setting APQ in terms of Pharmaceutical Dosage Form and the Estimation of Diversion as Established by the SUPPORT Act

While DEA is now allowed to issue quotas in terms of pharmaceutical dosage form, it is not required to do so. DEA will not be utilizing this authority at the aggregate production quota level, but will be doing so at the individual dosage-form manufacturing level where it will have a greater impact on averting potential shortages. Because quotas set at the individual dosage-form manufacturing level are more directly connected to distributions of current and new FDA-approved drug products, they allow DEA to manage manufacturing quotas to alleviate any potential shortage in a more timely manner than with quotas set at the aggregate production quota level. This is also true because the aggregate production quota is initially established prior to the start of the quota calendar year.

To estimate diversion as is required by the SUPPORT Act, DEA aggregated the active pharmaceutical ingredient (API) of each covered controlled substance by metric weight where the data was available in internal databases. Based on the individual entries into the aforementioned databases, DEA calculated the estimated amount of

diversion by multiplying the strength of the API listed for each finished dosage form by the total amount of units reported to estimate the metric weight in kilograms of the controlled substance being diverted. The estimate of diversion for each of the covered controlled substances is reported below.

Diversion Estimates for 2019 (kg)	
Fentanyl	.090
Hydromorphone	1.288
Oxymorphone	N/A

Additional Legal Considerations

The procedures by which DEA adjusts aggregate production quotas are set forth in the DEA regulations. As stated in 21 CFR 1303.13, the Acting Administrator, upon determining that an adjustment of the aggregate production quota of any basic class of controlled substance is necessary, shall publish in the Federal Register general notice of an adjustment in the aggregate production quota for that class. Any interested person may file comments or objections to these adjusted aggregate production quotas within the time specified by the Acting Administrator in this notice.

Section 1303.13 further provides that, “[a]fter consideration of any comments or objections . . . the Acting Administrator shall issue and publish in the Federal Register his final order determining the aggregate production quota for the basic class of controlled substance.” The Acting Administrator has determined, however, that because of the nationwide public health emergency declared by the Secretary of HHS on January 31, 2020, in response to the COVID-19 public health emergency, the public interest requires that this final order be effective immediately. Accordingly, pursuant to 21 CFR 1307.03, the Acting Administrator hereby waives the provision of 21 CFR 1303.13 which requires

consideration of any comments or objections prior to the publication of this final order. The Acting Administrator will, however, consider any comments or objections filed in response to this final order in determining whether any further adjustment to the aggregate production quota for calendar year 2020 is necessary. The Acting Administrator has made the same determination with respect to the adjustment of the assessment of annual need for ephedrine and pseudoephedrine.

Determination of 2020 Adjusted Aggregate Production Quotas and Assessment of Annual Needs

In determining the adjustment of 2020 aggregate production quotas and assessment of annual needs, DEA has taken into consideration the factors set forth in 21 CFR 1303.13(b) and 21 CFR 1315.13(b), in accordance with 21 U.S.C. 826(a) and (i), and the current public health emergency due to COVID-19. Based on all of the above, the Acting Administrator is adjusting the 2020 aggregate production quotas for 4-Anilino-N-Phenethyl-4-Piperidine (ANPP), Codeine (for sale), Fentanyl, Hydromorphone, Methadone (for sale), Methadone Intermediate, Morphine (for sale), Noroxymorphone (for conversion), Oripavine, and Oxymorphone (for conversion); as well as the 2020 annual assessment of needs for ephedrine (for sale) and pseudoephedrine (for sale). Based upon DEA's consultations with federal partners at HHS, drug manufacturers, drug distributors and hospital associations, DEA understands that products containing Fentanyl, Hydromorphone, Morphine, Codeine, Pseudoephedrine and Ephedrine, are often used to treat patients in intensive care units and those on ventilators or for individuals who may have conditions which impact their breathing. In order to produce those products, DEA must also increase the aggregate production quota

for the following controlled substance intermediates: ANPP, Noroxymorphone (for conversion), Oripavine and Oxymorphone (for conversion).

The Acting Administrator hereby adjusts the 2020 aggregate production quotas for the following schedule II controlled substances and the 2020 assessment of annual needs for the list I chemicals ephedrine and pseudoephedrine, expressed in grams of anhydrous acid or base, as follows:

Controlled Substance	Current APQ (g)	Adjusted APQ (g)
Schedule II		
4-Anilino-N-Phenethyl-4-Piperidine (ANPP)	813,005	934,956
Codeine (for sale)	30,731,558	35,341,292
Fentanyl	813,005	934,956
Hydromorphone	3,054,479	3,512,651
Methadone (for sale)	22,278,000	25,619,700
Methadone Intermediate	24,064,000	27,673,600
Morphine (for sale)	29,353,655	33,756,703
Noroxymorphone (for conversion)	19,169,340	22,044,741
Oripavine	28,705,000	33,010,750
Oxymorphone (for conversion)	24,525,540	28,204,371
List I Chemicals		
Ephedrine (for sale)	4,136,000	4,756,400
Pseudoephedrine (for sale)	174,246,000	200,382,900

The aggregate production quotas for all other schedule I and II controlled substances included in the 2020 established aggregate production quotas and the 2020 assessment of annual needs for the list I chemical phenylpropanolamine remain at this time as previously established.

Dated:

Electronically Signed: 04-06-2020

Uttam Dhillon,
Acting Administrator.

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