Published on *The National Law Review* https://natlawreview.com

Deadline Looms for Responding to DEA's Proposed Aggregate Production Quotas for 2021

Article By:

Health Care and Life Sciences Practice Group

Bailey N. Wendzel

On Tuesday, September 1, 2020, the Drug Enforcement Agency ("DEA") proposed 2021 aggregate production quotas (APQs) for controlled substances in schedules I and II of the Controlled Substances Act ("CSA") and an Assessment of Annual Needs ("AAN") for the List I Chemicals pseudoephedrine, ephedrine, and phenylpropanolamine. This marks the second year that DEA has issued APQs pursuant to Congress's changes to the CSA via the SUPPORT Act. After assessing the diversion rates for the five covered controlled substances, DEA reduced the quotas for four: oxycodone, hydrocodone, hydromorphone and fentanyl.

DEA recently increased the APQ to allow for the additional manufacture of certain controlled substances in response to the COVID-19 pandemic and the need to provide greater access to these medications for patients on ventilator treatment. According to DEA, that increased demand has been factored into the proposed APQs for 2021.

Comments are due by October 1, 2020. Because DEA's APQs determine the amount of quota DEA can allocate to individual manufacturers in 2021, adversely impacted parties should file comments soon.

Background on APQs

The CSA requires the establishment of 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. These aggregate quotas limit the quantities of these substances to be manufactured – and with respect to the listed chemicals, imported – in the United States in a calendar year, 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.

Changes in Setting APQs Under The SUPPORT Act

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients

and Communities Act (“SUPPORT Act”) signed into law October 24, 2018, provided significant changes to the process for setting APQs. First, under the CSA, aggregate production quotas are 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 SUPPORT Act provides an exception to that general rule by giving the 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.

Additionally, the SUPPORT Act changed the way the DEA establishes APQs with respect to five “covered controlled substances”: fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone. Under the SUPPORT Act, when setting the APQ for any of the “covered controlled substances,” DEA must estimate the amount of diversion. The SUPPORT Act requires DEA to make appropriate quota reductions “as determined by the [DEA] from the quota the [DEA] would have otherwise established had such diversion not been considered.” Furthermore, when estimating the amount of diversion, the DEA must consider reliable “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 other sources of information the DEA determines reliable.

Estimating Diversion

In accordance with this mandate under the SUPPORT Act, in setting the proposed APQs for 2021 DEA requested information from various agencies within the Department of Health and Human Services (“HHS”), including the U.S. Food and Drug Administration (“FDA”), Centers for Disease Control and Prevention (“CDC”), and the Centers for Medicare and Medicaid Services (“CMS”), regarding overdose deaths, overprescribing, and the public health impact of covered controlled substances. DEA also solicited information from each state’s Prescription Drug Monitoring Program (“PDMP”), and any additional analysis of prescription data that would assist DEA in estimating diversion of covered controlled substances.

After soliciting input from these sources, DEA extracted data on drug theft and loss from its internal databases and seizure data by law enforcement nationwide. DEA then calculated the estimated amount of diversion by multiplying the strength of the active pharmaceutical ingredient (“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.

Comparison to 2020 Quotas

In 2019, the DEA issued its quotas for 2020 – its first APQs issued pursuant to the changes made in the SUPPORT Act. Subsequently, in April 2020 in response to the COVID-19 pandemic, DEA increased the 2020 APQs as a proactive measure to ensure that the United States had an adequate and uninterrupted supply of these substances throughout the public health emergency. In doing so, DEA consulted with HHS and determined that the utilization rates for selected medications, required to implement the treatment regimens for ventilator patients stricken with COVID-19, had substantially increased compared to the previously estimated annual consumption rates. These temporary increases in 2020 will be displaced by the APQs DEA finalizes for 2021.

Below is a comparison of the proposed 2021 APQs and the original 2020 APQs for the five “covered controlled substances”:

Drug	Increase or	Proposed 2021	Original 2020

	Decrease in Proposed 2021 APQ?	APQ (g)	APQ (g)
Fentanyl	Decrease	666,249	813,005
Oxycodone	Decrease	57,110,032	67,593,983
Hydrocodone	Decrease	30,821,224	34,836,854
Oxymorphone	Increase[1]	28,204,371	24,525,540
Hydromorphone	Decrease	2,827,940	3,054,479

Most notably, in 2021, DEA proposes to decrease quotas for all covered controlled substances (with the exception of oxymorphone) compared to the original APQs set in 2020. This proposed decrease in APQs for 2021 is influenced in part by the diversion estimates DEA considered when determining quotas.

Previously, in setting the 2020 quotas, DEA considered diversion estimate data from 2018. Importantly, in 2018, DEA diversion estimates were lower compared to the diversion estimates in 2019, which DEA used in setting the APQs for 2021. The 2019 diversion estimates show an increase in estimated diversion for oxycodone, hydrocodone, oxymorphone, and hydromorphone.[2] Clearly, the increased diversion estimates for these covered controlled substances influenced DEA's proposal to decrease the APQs for these substances in 2021. The increase in diversion rates for four of the covered controlled substances also suggests that the decreases in quotas to date have not had a demonstrable impact on decreasing the rate of diversion of these substances.

A comparison of the diversion estimates follows:

Drug	Diversion Estimate Increase or Decrease in 2019?	2019 Diversion Estimates (kg) (used to determine proposed 2021 APQs)	2018 Diversion Est (kg) (used to determ APQs)
Fentanyl	Decrease	0.090	0.109
Oxycodone	Increase	60.959	57.051
Hydrocodone	Increase	30.294	24.259
Oxymorphone	Increase	1.311	1.157
Hydromorphone	Increase	1.424	1.219

Notably, although the estimated diversion for fentanyl decreased from 2018 to 2019, DEA proposes to lower the APQ for fentanyl in 2021, compared to the APQ in 2020.[3] This suggests that although DEA takes the diversion estimates into account when setting quotas, DEA still maintains a level of discretion, and considers other sources of information the DEA determines reliable in establishing APQs.

Other Reliable Sources

It is not entirely clear what other sources of information DEA relied on in setting the proposed 2021 APQs. For instance DEA found problematic that "FDA's predicted level of medical need for the United States was calculated by FDA at the beginning of the Coronavirus Disease 2019 (COVID-19) pandemic and, therefore, did not take into account changes in usage that are necessary to treat patients who require schedule II controlled substances."

Also, although DEA did recognize the importance of overdose deaths in understanding the Nation's opioid epidemic, DEA found CDC's overdose data to be largely unhelpful. With respect to fentanyl,

DEA found, based on "data presented to DEA by the CDC, which did not differentiate between licit fentanyl and illicit fentanyl and its analogues, as well as analyzed seizure data from law enforcement activities, DEA believes that the vast majority of deaths involving fentanyl were not from products that were lawfully manufactured and distributed pursuant to the CSA but were from unlawfully manufactured and distributed fentanyl and fentanyl related substances." However, DEA still proposes to reduce the APQ for this covered controlled substance.

In addition, DEA found the PDMP data it received from states AG's was incomplete and ultimately determined to be "inapplicable at the national level." DEA made note that several states confirmed receipt of DEA's request for PDMP data, yet only a small percentage provided that information to DEA.

Also, the proposed rule indicates that DEA was informed by CMS, which maintains Medicare Part D prescription data, that CMS may have information related to diversion, such as reliable rates of overprescribing (doctor shopping and being prescribed significantly more medicine than is medically necessary). However, CMS informed DEA that it does not have the ability to systematically distinguish between appropriate and inappropriate prescriptions without investigations. Thus, DEA indicated that it will attempt to solicit the raw data from CMS to determine overprescribing rates based on CDC prescription guidance for schedule II substances and DEA's own parameters for doctor shopping.

Thus, it appears the DEA has largely relied on its own internal data in setting the proposed APQs for 2021. Nonetheless, the SUPPORT Act's mandate requiring the DEA to estimate the amount of diversion for the covered controlled substances clearly influenced DEA's adjustments made to the proposed 2021 APQs.

Request for Comment

Written comments related to DEA's 2021 proposed APQs must be submitted or postmarked, on or before October 1, 2020. Because DEA's APQs impact how much quota DEA can allot to individual manufacturers, we strongly encourage manufacturers that will be adversely affected to file comments timely to ensure their needs, and their customers' needs, are adequately met for 2021.

---

[1] Although there is an increase proposed for the 2021 APQ for oxymorphone, the increase to 28,204,371g is identical to the adjusted APQ for oxymorphone issued in April. *See* 85 Fed. Reg. 20302 (Apr. 10, 2020).

[2] *Proposed 2021 APQs*, 85 Fed. Reg. 54407 at Table 3 – Estimate of Diversion for Covered Controlled Substances, Diversion Estimates for 2019 (Sept. 1, 2020).

[3] The 2020 APQ for fentanyl was 813,005 grams, based in part on a 2018 diversion estimate 0.109 kilograms. By contrast, the 2021 APQ for fentanyl is set at 666,249 grams, despite a lower 2019 diversion estimate of .090 kilograms.

National Law Review, Volume X, Number 269

aggregate-production-quotas-2021