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

DEA Publishes Proposed Rule Regarding Quota Processes

Article By:

Karen Owen Gibbs

On April 19, 2018, the US Drug Enforcement Administration (DEA) issued a Notice of Proposed Rule Making (NPRM) proposing various changes to DEA's process for setting Aggregate Production Quotas (APQ) and Individual Procurement Quotas (IPQ). These quotas, which are set substantially in advance, govern the amount of legal manufacture of certain drugs (including opioids) in the United States each year.

The NPRM is of particular interest in a few respects. First, it reflects the Trump administration's ongoing "war on opioids" in the sense that it requires additional factors—including diversion—to be considered in setting the quotas. It also reflects the increased voice of the states on such issues, allowing for hearings to resolve states' objections to APQ changes.

The NPRM also comes—probably coincidentally—on the heels of concerns raided by hospital trade groups and others regarding the *shortages* of certain opioids used in hospitals, including opioid injectables. Earlier this year, some hospital systems had to "ration" certain narcotics, resulting in some delays of patient care, particularly of elective surgeries. Very recently, the DEA raised some production quotas for drug manufacturers who produce the products most often needed by hospitals.

The NPRM calls for consideration of information from government agencies, such as the Food and Drug Administration, the Centers for Disease Control and others, in setting the quotas. In theory, these entities would help achieve a healthy balance that would both address diversion concerns and allow sufficient production for legitimate patient needs.

Given the competing interests and the attention focused on this issue, we will likely see more legislative, regulatory and sub-regulatory attention paid to opioid issues, including quotas, in the near future.

National Law Review, Volume VIII, Number 110