

Controlled Substance Ordering Thresholds Listening Session Background and Questions

PURPOSE

Since the fourth quarter of 2022, patient calls to the Pennsylvania Department of Health's Patient Advocacy Program have increased regarding controlled substance availability. Patients have reported that controlled substance ordering thresholds are impacting their ability to fill prescriptions for controlled substances--particularly opioids for pain management, benzodiazepines, and medications for opioid use disorder (MOUD)--at their regular retail pharmacies. Patients also have reported having to call and/or visit multiple retail pharmacies to find one that had their medication in-stock, and have reported experiencing issues with dosage, receiving lower doses than their scripts called for.

Patients' access to medication is a top priority of the Department and its Office of Drug Surveillance and Misuse Prevention. Thus, the Department is launching a series of Listening Sessions to capture information from the various stakeholders impacted by these controlled substance ordering thresholds.

BACKGROUND

On July 1, 2022, a court-ordered injunctive relief began as part of opioid settlement agreements with AmeriSource Bergen, McKesson, and Cardinal Health pharmaceutical distributors. As described in letters issued by [Amerisource Bergen](#) and [Cardinal Health](#), the following controlled substance threshold terms apply to retail pharmacies as required by the injunction:

1. Ordering Thresholds and Suspicious Order Reporting: Under the injunctive relief terms, pharmaceutical distributors will use statistical, model-based thresholds to set controlled substance order limits. Orders from retail pharmacies that exceed a threshold will be blocked, not shipped, and reported as suspicious.
2. A pharmaceutical distributor's Controlled Substance Monitoring Program personnel are responsible for decisions related to whether controlled substances are distributed to a particular retail pharmacy and adjusting controlled substance threshold limits, including buprenorphine, the first FDA approved medication to treat opioid use disorder.

On January 20, 2023, the United States Drug Enforcement Agency (DEA) released a [memo](#) clarifying that restrictive controlled substance ordering and dispensing thresholds are not required by the DEA or the Controlled Substances Act (CSA). The DEA only requires pharmaceutical distributors to establish systems to identify and report suspicious orders of controlled substances. The distributors response to this requirement was to establish the aforementioned thresholds. Retail pharmacies were advised that threshold limit increases are available through their individual distributor websites, though it is uncertain how many retail pharmacies across the Commonwealth requested an ordering threshold increase.

QUESTIONS

The Department seeks to better understand the ways the July 2022 court-ordered injunctive relief and subsequent controlled substance ordering thresholds are impacting stakeholders across the Commonwealth.

In the listening sessions, we hope to discuss such topics as:

1. How are patients being impacted?
2. How are providers being impacted?
3. How widespread is this problem?
4. Do you have any suggestions on how to resolve this issue?