

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders

Summary: This guidance document clarifies that neither the Controlled Substance Act (CSA) nor the Drug Enforcement Administration (DEA) regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can order and dispense. This document also reminds all DEA registrants of the requirement to establish systems to identify and report suspicious orders of controlled substances to include Medication for Opioid Use Disorder (MOUD).

Activity: Reporting Suspicious Orders of Controlled Substances Including MOUD

To Whom it Applies: DEA Registrants

Question: Are DEA-registered manufacturers or distributors required by the CSA or DEA regulations to establish limits (quantitative thresholds) on the amounts of controlled substances, including MOUD, that another DEA registrant can order or dispense?

Answer: No. Neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits.

The CSA, as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act) requires each DEA registrant to: 1) design and operate a system to identify suspicious orders for the registrant; 2) ensure that the system complies with applicable Federal and State privacy laws; and 3) upon discovering a [suspicious order](#) or series of orders, notify the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business. [21 U.S.C. 832\(a\)](#). Suspicious orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [21 U.S.C. 802\(57\)](#). Furthermore, all applicants and registrants must maintain effective controls and procedures to guard against theft and diversion. [21 CFR 1301.71\(a\)](#).

To comply with these statutory and regulatory requirements, many DEA-registered manufacturers and distributors establish controlled substance monitoring systems that set thresholds that may limit the amount of a customer's controlled substance purchases and may prompt a report of a [suspicious order](#) to DEA. However, whether to set such thresholds (if any) and at what levels are decisions that each manufacturer or distributor may make in the design and implementation of its controlled substance monitoring system. DEA does not have a role in establishing or revising thresholds for controlled substances that manufacturers or distributors may set for their customers as part of the required monitoring systems.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies.

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