U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, Illinois 60056

Dear Mr. Carter:

This is in response to your letter dated October 24, 2025, to then Assistant Administrator Thomas W. Prevoznik. In your letter, you requested a response to the following question: "How do [Drug Enforcement Administration] DEA formal or informal policies, regulations, or the federal Controlled Substances Act (CSA) affect the numerical thresholds set by drug distributors for purchasers of controlled substances?" Specifically, your letter concerns buprenorphine for treatment of patients with opioid use disorder. DEA appreciates the opportunity to address your question.

As a general matter, it is DEA's longstanding policy not to provide legal advice to regulated entities, government partners, or the general public. To comply with the Administrative Procedure Act and ensure fairness, DEA's interpretations of the law and regulations, as well as its guidance materials, are published in the *Federal Register* and/or on DEA's website, which allows all members of the general public to have equal access to such information. DEA's response to your inquiry must be limited to directing your attention to the pertinent provisions of the law, regulations, or other publicly disseminated documents issued by DEA.

As a preliminary matter, neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including Medications for Opioid Use Disorder (MOUD), that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits. It is important to note that, in 2022, the nation's three largest pharmaceutical distributors—McKesson, Cardinal Health, and AmerisourceBergen (now Cencora)—entered into a nationwide legal settlement to resolve opioid litigation brought by states and local government subdivisions. The settlement agreement required those distributors to create thresholds for the volume of controlled substances, including buprenorphine, that chain and independent retail pharmacies may purchase.

The CSA, as amended by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, Pub. L. 115-271) 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. DEA-DC-065, EO-DEA258, January 20, 2023

In a 2023 Letter to Registrants, DEA and U.S. Department of Health and Human Services emphasized our commitment to ensuring safe and ready access to MOUD and jointly advised that:

> As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. DEA recognizes that there have been recent increases in demand for certain schedule III MOUD controlled substances as compared to years prior to the Opioid Public Health Emergency, and that there may be a corresponding increase in prescriptions for these medications from medical providers. DEA supports collaboration amongst all DEA registrants to ensure there is an adequate and uninterrupted supply of MOUD products when these products are appropriately prescribed. Distributors should carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay.

I trust this letter adequately addresses your inquiry. For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

CHERYL OZ Digitally signed by CHERYL OZ Date: 2025.12.11 21:15:54 -07'00'

Cheri Oz
Assistant Administrator
Diversion Control Division