U. S. Department of Justice
Drug Enforcement Administration
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Springfield, Virginia 22202

www.dea.gov

Walter F. Wrenn, III, M.D.
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Dear Dr. Walter F. Wrenn, III

This is in response to your letter dated September 8, 2021, to the United States Attorney General Merrick Garland. You stated that the 2016 Center for Disease Control's (CDC) pain management guidelines made it difficult for practitioners to provide care for patients experiencing opioid addiction. The Drug Enforcement Administration (DEA) appreciates the opportunity to address your letter and apologizes for the delay in response.

The Controlled Substances Act (CSA) and its implementing regulations established a closed system of distribution to help prevent diversion of legitimate controlled substance medications into the illicit market. One of the most important principles underlying the CSA and its implementing regulations is that to be valid, every prescription for a controlled substance must be based on a determination by an individual practitioner that the dispensing of the controlled substance is for a legitimate medical purpose in the usual course of professional practice. *United States v. Moore, 423 U.S. 122 (1975)* and 21 CFR 1306.04(a). To satisfy this requirement, practitioners who dispense controlled substances must do so in accordance with a standard of medical practice that is generally recognized and accepted in the United States.

Although DEA is the agency responsible for administering the CSA, DEA does not act as the federal equivalent of a state medical board overseeing the general practice of medicine and lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine. DEA has not promulgated regulations regarding the treatment of pain. Federal law and DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that may be prescribed on a single prescription, or the duration of treatment intended with the prescribed controlled substance. DEA has consistently emphasized and supported the prescriptive authority of an individual practitioner under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards as outlined in the DEA's policy statement published in the *Federal Register* on September 6, 2006, titled *Dispensing Controlled Substances for the Treatment of Pain,* 71 FR 52715.

Regarding the 2016 publication of the *CDC Guideline for Prescribing Opioids for Chronic Pain,* the CDC issued a media statement[1] warning against one-size fits all misapplications of its guidelines, and advised doctors to evaluate pain management issues on a case-by-case basis using good medical

1 CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain | CDC Online Newsroom | CDC. This media statement was also published in an article in the New England Journal of Medicine dated April 24, 2019.

judgment. Please be advised that the CDC published on February 10, 2022 a notice with comment period titled "Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids." This notice, if finalized, will update and expand the 2016 Guideline. 87 FR 7838.

Furthermore, on April 9, 2019, the Food and Drug Administration (FDA) published a safety announcement on their website entitled: *FDA Identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering.*[2]

Additionally, DEA is a committed partner to HHS' Opioid Rapid Response Program (ORRP). ORRP is an interagency, coordinated federal effort to mitigate drug overdose risk among patients impacted by law enforcement actions that disrupt access to prescription opioids or medication assisted treatment/medication for opioid use disorder (MAT/MOUD). ORRP supports care continuity and risk reduction for patients by coordinating federal law enforcement actions and public health overdose risk mitigation. Today, ORRP supports all 50 US states and the District of Columbia. The program leverages relationships across federal, state, and local agencies, to include DEA, to facilitate timely communication, care coordination, risk reduction, and other overdose prevention interventions.

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, or any other, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

THOMAS PREVOZNIK

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Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

CC: DPM Philadelphia Division

[2] https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.