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

www.dea.gov

The General Public
and the Registrant Community

Dear Registrant Community:

In light of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 (COVID-19) and the determination by the World Health Organization on March 11, 2020 that the global COVID-19 outbreak constitutes a pandemic, the Drug Enforcement Administration (DEA) has received inquiries from health care practitioners, pharmacists, and patients with regard to early refills on prescriptions for controlled substances.

The Controlled Substances Act and DEA's implementing regulations prohibit the refilling of schedule II controlled substances. 21 USC 829(a), 21 CFR 1306.12(a). However, pursuant to 21 CFR 1306.12(b) "an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance, subject to specific conditions are met. These conditions include, among other things, that the practitioner must sign and date the multiple prescriptions as of the date issued, (21 CFR 1306.05(a)); and, write on each separate prescription the earliest date on which the prescription can be filled (21 CFR 1306.12(b)(ii)). A pharmacy filling such prescription has no authority to change this date, or dispense the controlled substance to the patient prior to that date. This does not prohibit the practitioner from issuing one prescription for a 90-day supply if allowed by state law and regulation that otherwise comport with 21 CFR 1306.04(a).

With respect to schedule III through V controlled substances, which can be refilled under the CSA, some states have issued orders allowing pharmacies to dispense early refills of prescriptions. Subject to the provisions of 21 CFR 1306.06, requiring a pharmacy only to dispense controlled substances in the usual course of professional pharmacy practice, and if the prescription meets the requirements of 21 CFR 1306.04(a), this practice may be permitted if the early dispensing is allowed by state law and regulation. In all cases, it bears repeating that every prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and that a pharmacist bears a corresponding responsibility for the proper dispensing of controlled substances. *See* 21 CFR 1306.04(a). All prescriptions must also comply with applicable state laws.

Guidance documents, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implementing memoranda, the Department will not cite, use, or rely on any guidance document that

is not accessible through the Department's guidance portal, or similar guidance portals for other Executive Branch departments and agencies, except to establish historical facts. To the extent any guidance document sets out voluntary standards (e.g., recommended practices), compliance with those standards is voluntary, and noncompliance will not result in enforcement action. Guidance documents may be rescinded or modified in the Department's complete discretion, consistent with applicable laws.

We hope this information is helpful. Please do not hesitate to contact this office, or your local DEA Field Office, if you seek additional assistance regarding this or any other matter.

Sincerely,

THOMAS PREVOZNIK

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Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

DEA065/DEA-DC-17 – March 20, 2020