U. S. Department of Justice
Drug Enforcement Administration
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NOV 14 2016

Jeffrey Fudin, PharmD, DAAPM, FCCP, FASHP
357 Delaware Avenue #214
Delmar, New York 12054

Dear Dr. Fudin:

This responds to your letter, dated August 18, 2016, to the Drug Enforcement Administration (DEA). Within your letter, you asked questions about the legal requirements relating to the prescribing of drug products containing buprenorphine for the treatment of pain.

Initially, please be advised that DEA cannot provide you with a private legal opinion. Consistent with the laws governing federal agencies and basic principles of fairness, any statements by DEA interpreting the law as applied to specific factual scenarios must be disseminated in a public manner. Accordingly, our response to your inquiry must be limited to reiterating general legal principles that are germane to your inquiry.

Buprenorphine is a schedule III controlled substance. 21 CFR § 1308.13(e)(2)(i). As with all controlled substances, buprenorphine may only be prescribed, administered, or dispensed for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice and otherwise in accordance with the Controlled Substances Act (CSA) and DEA regulations. The general registration requirement applicable to all practitioners (registration under 21 U.S.C. § 823(f)) applies to a practitioner who dispenses buprenorphine for the legitimate treatment of pain in the usual course of professional practice. No additional DEA registration is required for such purpose.

By way of comparison, in contrast to the requirements for dispensing narcotic drugs to treat pain, the CSA generally requires a practitioner who dispenses narcotic drugs for maintenance treatment or detoxification treatment to be separately registered for that purpose, 21 U.S.C. § 823(g)(1). However, this separate registration requirement is waived in the case of dispensing (including the prescribing) by a practitioner of narcotic drugs in schedule III, IV, or V if the practitioner and the drug meet the conditions specified in 21 U.S.C. § 823(g)(2). Because buprenorphine is a schedule III narcotic drug, this waiver applies to the dispensing of drugs containing buprenorphine that have been approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for use in maintenance or detoxification (provided the other requirements of subsection 823(g)(2), as well as the requirements of 21 CFR §§ 1301.28 and 1306.05(b), are satisfied). Among other things, as set forth in 21 CFR § 1306.05(b), a prescription for buprenorphine for use in maintenance or detoxification must include the identification number that DEA issues to the practitioner under 21 CFR § 1301.28(d).

In your letter, you refer to "buprenorphine products specifically FDA approved for the treatment of pain," and you mention several buprenorphine products by name. DEA cannot address whether

these assertions are correct as any questions you may have about FDA-approved uses – or any possible consequences under the FD&C Act for dispensing for unapproved (off-label) uses – must be submitted directly to the FDA.

Finally, please note that, in addition to the above-summarized requirements under federal law, practitioners who dispense buprenorphine must also comply with any additional requirements that may be imposed by the states in which they practice. 21 C.F.R. § 1307.02. Therefore, it is recommended that you check with the board of pharmacy or board of medicine in your state to determine if that state imposes any restrictions or additional requirements for prescribing buprenorphine drug products for the treatment of pain.

To access an electronic version of the laws and regulations cited within this letter, please visit www.DEAdiversion.usdoj.gov. If you have additional questions regarding this issue, please contact the Diversion Control Division Liaison and Policy Section at (202) 307-7297.

Sincerely,

Louis J. Milione
Assistant Administrator
Diversion Control Division