



**Via Electronic Submission to:** [www.regulations.gov](http://www.regulations.gov)

January 4, 2021

Drug Enforcement Administration  
Attn: DEA Federal Register Representative/DPW  
Diversion Control Division  
8701 Morrissette Drive  
Springfield, VA 22152

**Re: RIN 1117–AB55 Docket No. DEA–499**

Dear Sir or Madam:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Drug Enforcement Administration (DEA) on the *Interim final rule with request for comments: Implementation of the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018: Dispensing and Administering Controlled Substances for Medication Assisted Treatment*, published in the Federal Register on November 2, 2020 (85 FR 69153). Founded in 1852, APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA is pleased that DEA is implementing the SUPPORT Act provisions relating to dispensing and administering controlled substances for medication-assisted treatment (MAT) for opioid use disorder (OUD).

### **The COVID-19 Pandemic has Exacerbated the Opioid Epidemic**

On October 7, 2020, Health and Human Services (HHS) Secretary Azar renewed the opioid public health emergency (PHE) under Section 319 of the Public Health Service (PHS) Act.<sup>1</sup> Unfortunately, the opioid epidemic has been further exacerbated by the COVID-19 pandemic. According to the Overdose Detection Mapping Application Program (ODMAP), suspected drug overdoses increased 18% in March 2020 compared with March 2019, 29% in April, and 42% in

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<sup>1</sup> See Renewal of Determination That A Public Health Emergency Exists, available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-8Oct20.aspx>

May.<sup>2</sup> Pharmacists stand ready to use our patient care knowledge and experience, as medication experts, to help reduce overdose and addiction.

### **The Pharmacist's Role in Medication-Assisted Treatment (MAT) for Opioid Use Disorder**

Pharmacists are often an underutilized health care resource despite their extensive medication expertise and widespread accessibility. Pharmacists today graduate with a Doctor of Pharmacy degree, which requires six to eight years of higher education to complete, and have more medication-related training than any other health care professional.

Pharmacists' involvement in MAT for OUD helps improve patient access and outcomes, while reducing the risk of relapse.<sup>3 4</sup> Pharmacists' MAT-related services may include assisting with treatment plan development, dispensing and administering MAT medications, patient communication, care coordination, and medication monitoring, including adherence, among others.

**In order to further expand access to MAT and address treatment gaps for OUD, APhA respectfully requests that DEA confirm APhA's understanding that Section 3204(a) of the SUPPORT Act, which amended the Controlled Substances Act (CSA) by adding section 309A (21 U.S.C. §829a), allows pharmacists to administer buprenorphine to patients by injection or implantation for the purpose of maintenance or detoxification treatment, as long as they:**

- (1) have a DEA registration; and**
- (2) are authorized to administer under state law.**

Specifically, 21 U.S.C. §829a states that "in accordance with a prescription that meets the requirements of this subchapter," pharmacies may deliver a controlled substance "to the prescribing practitioner or the *practitioner administering the controlled substance*, as applicable, at the location listed on the practitioner's certificate of registration" (emphasis added). In addition, §829a(2)(B) specifies that the controlled substance must be administered by injection or implantation, and §829a(2)(3) requires that "the pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which such activities take place."

§829a makes a clear distinction between the "prescribing practitioner" (who must be a "qualifying practitioner" under 21 U.S.C. § 823(g)), and the "practitioner administering the controlled substance," who need not be a "qualifying practitioner." §829a(6) requires both the

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<sup>2</sup> 'Cries for help': Drug overdoses are soaring during the coronavirus pandemic. <https://www.washingtonpost.com/health/2020/07/01/coronavirus-drug-overdose/> July 1, 2020

<sup>3</sup> DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, *Journal of the American Pharmacists Association*, 55(2), 187-192.

<sup>4</sup> Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy*, 36(2), 312-321.

prescribing practitioner and the practitioner administering the controlled substance to “maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations of the Attorney General.”

APhA appreciates DEA codifying the language in Section 3204 of the SUPPORT Act in this Interim Final Rule. However, since “practitioner administering the controlled substance” is not specifically defined under the CSA, regulations, or DEA’s recent guidance entitled “Q&A Pharmacy Delivery of Buprenorphine Products under the SUPPORT Act,”<sup>5</sup> APhA believes that DEA should take this opportunity to confirm and clarify that a “practitioner administering the controlled substance,” including a pharmacist, does not need to be a “qualifying practitioner (e.g., DATA-waived).” Pharmacists and their patients would greatly benefit from DEA providing this clarity.

### **Pharmacists are Well-Positioned to Administer Buprenorphine to Patients for Purposes of Maintenance or Detoxification Treatment**

DEA recognizes pharmacists as midlevel providers, and eight states have pharmacists with DEA numbers: CA, ID, MA, MT, NM, NC, OH and WA.<sup>6</sup> In addition, in all states except MD, NY, NC, RI, and DC, pharmacists can administer long acting injectables (LAI) pursuant to an individual prescription, however in twelve additional states the authority is restricted to a collaborative practice agreement (CPA).<sup>7</sup>

Some states, such as Ohio, are proactively taking steps to address the opioid epidemic by authorizing pharmacists to administer buprenorphine. Ohio H.B. 341, which became effective on December 16, 2020, authorizes pharmacists to administer by injection physician-prescribed “addiction treatment drug[s] administered in a long-acting or extended-release form.”<sup>8</sup> DEA’s confirmation of pharmacists’ authority to administer buprenorphine to patients under Section 3204(a) of the SUPPORT Act/21 U.S.C. §829a would go a long way towards increasing the number of pharmacists in Ohio and across the nation who are ready, willing, and able to furnish this important treatment option for OUD.

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<sup>5</sup> DEA Diversion Control Division, DATA-Waived Guidance Document, Q&A Pharmacy Delivery of Buprenorphine Products under the SUPPORT Act, Sept. 18, 2020, available at [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-045\)\(EO-DEA220\)\\_QA\\_Pharmacy\\_Del\\_buprenorphine\\_Products\\_under\\_SUPPORT\\_\(Final\)\\_9-28-20.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-045)(EO-DEA220)_QA_Pharmacy_Del_buprenorphine_Products_under_SUPPORT_(Final)_9-28-20.pdf)

<sup>6</sup> DEA, MID LEVEL PRACTITIONERS - Controlled Substance Authority by Discipline within State, available at [https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp\\_by\\_state.pdf](https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf)

<sup>7</sup> National Alliance of State Pharmacy Associations (NASPA), Pharmacist Authority to Administer Long-Acting Antipsychotics (updated Nov. 2019), available at <https://naspa.us/wp-content/uploads/2017/07/Pharmacists-Authority-to-Administer-Medications.pdf>

<sup>8</sup> Ohio H.B. 341, available at [file:///C:/Users/kbolte/Downloads/hb341\\_05\\_EN%20\(1\).pdf](file:///C:/Users/kbolte/Downloads/hb341_05_EN%20(1).pdf)

Thank you for your consideration of APhA's comments on this important issue. If you have any questions or require additional information, please contact Karin Bolte, Director, Health Policy, at [kbolte@aphanet.org](mailto:kbolte@aphanet.org) or by phone at (301) 648-0673.

Sincerely,

A handwritten signature in cursive script that reads "Ilisa BG Bernstein".

Ilisa BG Bernstein, PharmD, JD, FAPhA  
Senior Vice President, Pharmacy Practice and Government Affairs