



February 5, 2018

The Honorable Alex M. Azar II  
Department of Health and Human Services  
HHS Office of the Secretary

Sent via email to: [Secretary@hhs.gov](mailto:Secretary@hhs.gov)

**RE: Pharmacist Provision of Medication-Assisted Treatment for Opioid Use Disorders**

Dear Secretary Azar:

Congratulations on your confirmation as the Secretary of Health and Human Services (HHS). The American Pharmacists Association (APhA) looks forward to working with you to utilize evidence-based research regarding pharmacists' roles in helping advance patient care, including those with mental health and substance use disorders. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 64,000 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, community health centers, physician office practices, managed care organizations, hospice settings, and the uniformed services.

Medication-assisted treatment (MAT) is an area within your purview which we believe offers an opportunity for you to make progress toward your stated desire to "tackle the scourge of the opioids epidemic that is destroying so many individuals, families, and communities."<sup>i</sup> APhA views MAT as an important component of a multipronged approach to addressing opioid abuse and improving treatment. APhA supports efforts to expand access to MAT, such as increasing Drug Addiction Treatment Act of 2000 (DATA)-waivered physician's prescribing caps and allowing additional practitioners to obtain a DATA waiver. However, to further expand access to needed treatment, APhA urges you to use your secretarial authority granted in the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) to revise the "qualifying other practitioner"<sup>ii</sup> requirements to allow for pharmacists to be able to provide MAT services, in addition to physicians, nurse practitioners and physician assistants.

APhA made similar requests to SAMHSA and Assistant Secretary McCance-Katz but was advised the agency is not engaging in rulemaking on the topic. HHS/SAMHSA's regulatory agenda indicates there is forthcoming regulations related to opioid treatment programs. The regulations will rely on legal authority granted in CARA, specifically 21 U.S.C. 823(g) which establishes procedures for determining whether a health care practitioner can dispense opioid drugs for the purpose of treating opioid use disorders.<sup>iii</sup> Consequently, APhA believes upcoming

rulemaking regarding opioid treatment programs presents as an opportunity for HHS/SAMHSA to make pharmacists eligible for a DATA-waiver. Such a change is also consistent with intent of the White House and federal agencies' deregulatory efforts because federal, opposed to state, regulations are hindering pharmacists' ability to improve care by preventing them from increasing patient access to needed treatment.

APhA reiterates that pharmacists are often an underutilized health care resource despite their medication expertise and accessibility. Pharmacists today graduate with a Doctorate 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. Pharmacist involvement in MAT for opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.<sup>iv,v</sup> Currently, 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements<sup>vi</sup> with physicians and other prescribers to provide advanced care to patients, which may include components of MAT. In addition, according to the Drug Enforcement Agency, pharmacists are mid-level practitioners like PAs and NPs, and six states<sup>vii</sup> allow pharmacists to prescribe Schedule II-V controlled substances under a collaborative practice agreement.<sup>viii</sup> Consequently, under certain states' scope of practice laws, pharmacists are eligible to prescribe Schedule III controlled substances but are unable to prescribe certain Schedule III medications, such as buprenorphine, because federal laws and regulations do not allow their eligibility for a DATA waiver.

When pharmacists partner with physicians and other health care professionals to provide MAT, they streamline and improve care. Pharmacists' responsibilities may include treatment plan development, dispensing, patient communication, care coordination, adherence monitoring and improvement activities, among others. Allowing pharmacists to obtain a DATA-waiver will increase patients' access to MAT and address treatment gaps.

Thank you for the opportunity to provide our recommendation regarding an important opportunity to increase patients' access to substance use treatment programs by utilizing pharmacists. If you have any questions or require additional information, please contact Jenna Ventresca, Director, Health Policy, at [jventresca@aphanet.org](mailto:jventresca@aphanet.org) or by phone at (202) 558-2727.

Sincerely,



Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA  
Executive Vice President and CEO

cc: Stacie Maass, BSPHarm, JD, Senior Vice President, Pharmacy Practice and Government Affairs

The Honorable Elinore McCance-Katz, Assistant Secretary for Mental Health and Substance Use

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<sup>i</sup> Alex Michael Azar II, Opening Statement, Nominee for Secretary of Health and Human Services, available at: <https://www.help.senate.gov/imo/media/doc/Azar.pdf>.

<sup>ii</sup> P.L. 114-198, Sec. 303, stating in regards to the definition “qualifying other practitioner” the law states “The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.” and “the term ‘qualifying other practitioner’ means a nurse practitioner or physician assistant who satisfies each of the following...”

<sup>iii</sup> See Office of Information and Regulatory Affairs, HHS/SAMHSA, Certification of Opioid Treatment Programs (RIN: 0930-AA27), available at: <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0930-AA27>.

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

<sup>vi</sup> See Centers for Disease Control and Prevention (2017), *Advancing Team-Based Care Through Collaborative Practice Agreements*, available at: <https://www.cdc.gov/dhdsppubs/docs/CPA-Team-Based-Care.pdf> (last accessed: August 14, 2017).

<sup>vii</sup> States that allow pharmacists to prescribe controlled substances when working under a collaborative practice agreement: California, Massachusetts (hospital only), Montana, New Mexico, North Carolina, Ohio, and Washington.

<sup>viii</sup> See Drug Enforcement Agency, Mid-Level Practitioners Authorization by 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), last accessed: October 18, 2017.