May 31, 2016

Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
ATTN: Jinhee Lee, SAMHSA
5600 Fishers Lane
Room 13E21C
Rockville, MD 20857

RE: Medication Assisted Treatment for Opioid Use Disorders – RIN 0930-AA22

Dear Dr. Lee:

On behalf of the American Pharmacists Association ("APhA"), the National Community Pharmacists Association ("NCPA") and the Academy of Managed Care Pharmacy ("AMCP"), we appreciate the opportunity to provide input on the Substance Abuse and Mental Health Services Administration's ("SAMHSA") proposed rule, Medication Assisted Treatment for Opioid Use Disorders ("Proposed Rule").

APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 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. NCPA represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $81.4 billion health care marketplace and employ more than 314,000 individuals on a full or part-time basis. AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

APhA, NCPA and AMCP support medication-assisted treatment ("MAT") as an important component of a multipronged approach to addressing abuse of opioid medications.

We encourage legislative, regulatory, and private sector efforts that include pharmacists addressing our Nation's substance use disorder epidemic, however, we also believe it is important to balance those efforts with the legitimate needs of the millions of patients living with pain. We are committed to working with the SAMHSA, and other federal agencies, Congress, state agencies and officials, health professionals and stakeholders to identify ways to curb opioid misuse and abuse and provide treatment options. We believe solutions will require the unified and coordinated efforts of many diverse stakeholders, including health care professionals, patients and caregivers, community-based organizations, and federal, state, and local governments. APhA, NPCA and AMCP, like SAMHSA, agree that MAT is a valuable tool in helping patients overcome addiction.

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 to complete, and have more medication-related training than any other health care professional. Advancement of the pharmacist's role in MAT for opioid use disorders can help improve access and outcomes, while reducing the risk of relapse.[1,2] APhA, NCPA and AMCP encourage SAMHSA to include and support in its policies the role of the pharmacist in treatment programs like MAT as such a position aligns with SAMHSA's desire to increase access to MAT for opioid addiction. We offer recommendations to further this goal.

A. Support expanding practitioner eligibility for DATA waivers

The Proposed Rule intends to improve access to MAT that qualifies under the Drug Addiction Treatment Act (DATA) by increasing the treatment capacity for qualified physicians from 100 to 200 patients when certain criteria are met. While we understand that SAMHSA currently lacks authority to expand the scope of practitioners who are eligible to receive a DATA waiver through rulemaking, we encourage SAMHSA to support making the DATA waiver available to other health care practitioners, such as pharmacists. This is especially relevant as a bill (H.R. 4981) recently passed in the House of Representatives expands the pool of eligible practitioners to include nurse practitioners and physician assistants and gives the Secretary the authority to modify the eligibility requirements for a DATA waiver. Like nurse practitioners and physician assistants, in some states pharmacists can prescribe schedule III controlled substances when working under a collaborative practice agreement.

Currently, 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements with physicians and other prescribers to provide advanced care to patients. We are aware of at least five states[3] that allow pharmacists to prescribe Schedule III, IV and V controlled substances. In addition, pharmacists are already partnering with physicians to provide MAT. When such relationships form, pharmacists have taken the lead in developing treatment plans, communicating with patients, improving adherence, monitoring patients,

[1] 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.
[2] Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy*, 36(2), 312-321.
[3] States that allow pharmacists to prescribe controlled substances when working under a collaborative practice agreement: California, Massachusetts (hospital only), Montana, New Mexico, and Washington

identifying treatment options and performing tasks to alleviate the physician' burden. Thus pharmacists have both the knowledge and experience to provide MAT but treatment is limited because of regulatory barriers. Since approximately 86 percent of Americans live within 5 miles of a pharmacy, allowing pharmacists to obtain a DATA waiver would help connect patients to care and increase access in areas with limited treatment options, consistent with the intent of the Proposed Rule.

Considering SAMHSA's goal to expand access, it is of utmost importance to remember that pharmacists are the most accessible health care professionals who has expertise is in medications and patient care. As the Food & Drug Administration ("FDA") noted specifically concerning suboxone and subutex, "pharmacists will play a role in the delivery of opiate addiction treatment…"[4]. Additionally, SAMSHA's 2015 Federal Guidelines for Opioid Treatment Programs considers pharmacists' role in providing MAT by stating, "Some aspects of medication-assisted treatment services may be provided by an authorized health care professional other than a physician such as an advanced practice nurse, physician assistant, or advanced-practice pharmacist."[5] Given the opportunity to further advance the goals of the Proposed Rule and the potential to increase access to treatment, we encourage SAMHSA to actively support access solutions that include pharmacists as practitioners eligible for a DATA waiver.

B. Increased prescribing cap

While APhA, NCPA and AMCP support increasing the prescribing cap to 200 as described in the Proposed Rule, we are concerned that the increase is not sufficient. Just as there is no cap for prescribing opioids, our members do not believe that there should be a cap for MAT. Recent research shows that 48 states and the District of Columbia have opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates.[6] Although only 27.5 percent of DATA-waivered physicians have increased their patient limit capacity to 100, the finding that 82 percent of opioid treatment programs are operating at capacity clearly indicates the need for additional treatment options.[7] We believe that by increasing the prescribing cap, physicians and health care professionals will be able to reach more patients but many patients will still be left behind. For example, physicians may decide not to increase their treatment capacity or provide MAT even if waivered and prospective patients may lack a primary care provider or be unable to identify a waivered physician that is convenient.

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[4] Food & Drug Administration, *Information for Pharmacists SUBOXONE® (buprenorphine HCl/naloxone HCl dihydrate, sublingual tablet) and SUBUTEX® (buprenorphine HCl, sublingual tablet)*, available at: http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM191533.pdf (last accessed November 16, 2015).

[5] Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services, (March 2015), *Federal Guidelines for Opioid Treatment Programs*, available at: http://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf, last accessed: May 18, 2016.

[6] Jones, Christopher M., Campopiano, M., Baldwin, G. & McCance-Katz, Elinore. (2015). National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment, *American Journal of Public Health*, 105(8), e55-e63.

[7] Jones, Christopher M., Campopiano, M., Baldwin, G. & McCance-Katz, Elinore. (2015). National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment, *American Journal of Public Health*, 105(8), e55-e63, e59.

We appreciate SAMHSA's recognition of the value of other practitioners' services (i.e. nurse practitioners, physician assistants) and that leveraging such services may increase efficiencies of care, ultimately incentivizing physicians to increase their prescribing capacity. Since pharmacists were not listed as an example of other practitioner like physician assistants and nurse practitioners[8], we recommend that SAMHSA specifically highlight pharmacists, the medication expert on a care team, to help increase their utilization, add proficiencies to the care team, and ease workflow. In addition, given pharmacists' experience in helping curb drug diversion, the pharmacist can be a valuable addition to a MAT team when satisfying the Proposed Rule's requirement for a drug diversion plan.[9] Thus, SAMHSA should urge physicians, especially those at the highest treatment capacity, to include pharmacists in their MAT models to increase access and the provision of comprehensive care.

C. Information exchange

As noted above, we support expanding access to MAT by increasing the number of patients a practitioner can treat under the DATA waiver. While we appreciate that the process to request a patient limit of 200 includes a requirement that the physician will provide appropriate releases of information, we believe that pharmacists should be clearly included in the pool of practitioners to which a release should be considered.[10] For pharmacists to assess appropriateness of prescribed medications and to assist in the prevention of diversion, it is essential that pharmacists have access to the patient's relevant health information and be able to exchange pertinent clinical information using health information technologies. Therefore, in an effort to deliver more comprehensive and coordinated care, SAMSHA should explicitly address information exchange between waivered physicians and pharmacists and provide pharmacists access to appropriate information in the electronic health record.

D. Education

APhA, NCPA and AMCP appreciate SAMHSA's interest in expanding access to MAT and efforts to address opioid abuse and misuse, including updating 42 CFR Part 2. As opioid use and misuse and substance abuse is being addressed by governmental agencies and other entities, we believe it is of the utmost importance to educate health care professionals, patients and their families regarding these developments and new care expectations. Robust education is an essential component to ongoing and lasting improvements and will help each stakeholder adjust to the shift that is taking place regarding the prescribing and use of opioids. We recommend that SAMHSA work with other local, state and federal entities, including the Centers for Medicare and Medicaid Services, FDA, and Drug Enforcement Agency to develop education that is both comprehensive and targeted to address the knowledge gaps of relevant stakeholders.

[8] 42 CFR Part 8, 17652
[9] 42 CFR Part 8, 17661, §8.620(5) requiring adherence to a diversion control plan in the process to request a patient limit of 200.
[10] 42 CFR Part 8. 17661, §8.620(3) requiring physicians to provide appropriate released of information to permit the coordination of care with behavioral health, medical and other service practitioners.

Thank you for the opportunity to provide comments on the Proposed Rule and helping to identify ways to increase access to substance use treatment programs. As you move forward, please do not hesitate to use APhA, NCPA and AMCP as resources. We look forward to working with SAMHSA to expand access to MAT and help patients with substance use disorder.

Sincerely,

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