September 27, 2022

RE: SAMHSA Policy Priority Meeting on Buprenorphine Access and Availability in Pharmacy Settings

Dear Dr. Shah,

The American Pharmacists Association, National Alliance of State Pharmacy Associations, and National Community Pharmacists Association thank you for the opportunity to attend the recent *Policy Priority Meeting on Buprenorphine Access and Availability in Pharmacy Settings*. Overcoming access barriers to buprenorphine for treatment of opioid use disorder (OUD) is a priority for our organizations, and we are actively working to provide education to pharmacists and engage in advocacy efforts to address many of the barriers discussed during the meeting. We submit the following recommendations to address these barriers to buprenorphine access for medication assisted treatment (MAT).

Overarching requests to Federal Agencies:

1. **HHS: Create a centralized reporting mechanism to collect information and track data on all barriers to buprenorphine access.**

   Currently, there is not a centralized mechanism to collect data on buprenorphine access issues. With a goal of increasing access to this lifesaving medication, creating a centralized website for individuals and organizations to self-report buprenorphine-related issues would assist in collecting data that could be used to develop solutions. For example, in an effort to promote interoperability, the Office of the National Coordinator has created a website where individuals can report issues with individuals or entities that interfere with the exchange of electronic health information.

2. **HHS: Use PREP Act authority to issue a moratorium on the enforcement of distribution and dispensing actions of buprenorphine during the opioid crisis public health emergency (PHE).**

   The COVID-19 pandemic is an excellent example of the government's ability to rapidly respond to public health needs. PREP Act authority was used to temporarily waive federal requirements and implement authorities to meet health care needs across the country. Under the current opioid crisis public health emergency, a similar approach could be used to maximize enforcement discretion, issue federal waivers or use demonstration authorities to rapidly address federal barriers for the distribution and dispensing of buprenorphine.

3. **HHS: Use PREP Act authority to standardize telehealth provisions for prescribing and dispensing buprenorphine during the opioid crisis public health emergency.**

As discussed during the meeting, variations between state and federal telehealth provisions are causing barriers to buprenorphine access. Our organizations recommend that PREP Act authorities be used to implement standardized telehealth authorities to facilitate buprenorphine prescribing and dispensing, including across state lines. In addition, the HHS Secretary could also use authority under the Cares Act (P.L. 116-136) to enable beneficiaries to access telehealth from a broader range of providers under section 1834(m)—including pharmacists for this purpose.[1]

4. **HHS: Use PREP Act authorities to recognize pharmacists as DATA-waived providers during the PHE.**

   Many pharmacists work in team-based care models providing comprehensive medication management services to patients with OUD. They work under collaborative practice agreements (CPAs) with physicians and providers to monitor and manage medication therapies, including initiating buprenorphine, post-diagnosis, and making medication adjustments according to the terms of the CPA. They also perform various types of patient assessments. Recognizing pharmacists as DATA-waived providers would expand patient access to treatment services in the 10 states that permit pharmacists to prescribe controlled substances and remove administrative barriers that require the pharmacist to have the physician sign off on every prescription.

5. **HHS: Explore de-scheduling buprenorphine for medication assisted treatment (MAT).**

   Our organizations understand that this request is a long-term proposal and that work will need to be done to determine the pros and cons of such an action, but moving buprenorphine from a Schedule III to a Schedule IV or V medication when used for MAT could reinforce to providers its importance in treatment.

Requests to the Drug Enforcement Administration (DEA):

1. **Immediately disseminate written public guidance regarding DEA's position on enforcement of buprenorphine for MAT.**

   Absent clear, written DEA guidance on how prescribing, ordering, and dispensing of buprenorphine is enforced differently compared to other opioids, pharmacists' fears of DEA enforcement related to buprenorphine will continue. The public health need to increase access to buprenorphine is hampered by fears of DEA enforcement on pharmacies that dispense higher quantities of buprenorphine, especially as the number of prescribers and resulting prescriptions increases. While DEA representatives often state in public meetings that the DEA views buprenorphine differently, such verbal statements do not translate to federal guidance for pharmacies and/or actions or enforcement discretion by DEA agents at the local level. The following case has been circulated widely in the pharmacy community and contributes to these pharmacists' fears related to DEA actions: https://www.npr.org/sections/health-shots/2021/11/08/1053579556/dea-suboxone-subutex-pharmacies-addiction.

[1] The CARES Act eliminated requirements in the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (P.L. 116-123) and allows the HHS Secretary to waive telehealth restrictions under 1834(m) that normally apply only to a "qualified provider" or "practitioner" during the COVID-19 PHE, but this temporary authority is not applicable to opioid crises PHE.

Transparent information from DEA that is communicated to physicians, pharmacists and other providers would help significantly in overcoming fears of DEA action related to buprenorphine.

a) **Create publicly available information on red flags for controlled substances that also contrasts how buprenorphine for MAT is different from a "flags" perspective.**

Written and publicly available clarification from DEA via an FAQ or issue brief about enforcement policies related to red flags in general is needed, especially since recent court cases point to an expectation that pharmacists document resolution of potential red flags, an added administrative burden to already burdened pharmacy staff (See, https://www.pharmacytoday.org/article/S1042-0991(22)00385-1/fulltext#relatedArticles and https://www.thefdalawblog.com/2022/02/identifying-and-resolving-red-flags-dea-continues-to-run-it-up-the-flagpole/). There is also an urgent need for DEA to communicate the difference between red flags for controlled substances vs. how "flags" differ for buprenorphine when carrying out the pharmacist's corresponding responsibility. Buprenorphine should be removed from the red flags used for other opioids, and a new set of "flags" should be developed. The following table provides an example of some of the factors that could be addressed:

Examples	Pain Medicine Red Flag	Buprenorphine Red Flag
Patients travel in groups on the same day and have the same doctor	YES	NO Ex: group therapy day
DEA certification previously suspended or revoked	Possibly	Often No Ex: provider in recovery
Patients with needle marks/history of untruthfulness	YES	NO Ex: patient just started treatment
Prescriber writing prescriptions outside their primary specialty	Possibly	NO Ex: OB/GYN for pregnant patients
Paying in cash for RX	YES	NO Ex: Some MAT with onerous PA's

Ryan SA. Webinar presentation: Buprenorphine 101: Physicians and Community Pharmacists Collaborating to Improve Access to Medication Assisted Treatment. American Pharmacists Association and American Society of Addiction Medicine. March 20, 2020. Available at: https://apha.docebosaas.com/learn/course/internal/view/elearning/80/buprenorphine-101-physicians-and-community

2. **DEA: Partner with professional organizations to conduct local level education and training of DEA agents about use of buprenorphine for medication assisted treatment and how it is different than other opioids.**

   Regional education and training programs could be conducted by clinicians (pharmacists, physicians, others) and DEA officials and focus on use of buprenorphine for medication assisted treatment and DEA national policy related to enforcement of buprenorphine.

Requests to DEA and Wholesalers:

1. **Remove buprenorphine from the suspicious order monitoring program for controlled substances to remove barriers to pharmacy access to this medication.**

   Wholesaler "suspicious order" enforcement of obscure, but often fixed ratios of controlled substances to noncontrolled substances and buprenorphine to Suboxone ratios dispensed by pharmacies prevent, or limit access by pharmacies to these life-saving MAT medications. Pharmacists fear the unknown actions by wholesalers to limit or discontinue access to controlled substances. Thus, pharmacies will often either not stock MAT medications or turn patients away to avoid skewing their ratios. Wholesalers will not disclose formal ratios but will discuss preferences in the 20% controlled to 80% noncontrolled range. Other actions the pharmacy takes to maintain good patient care and prevent diversion are not taken into account in this program. DEA states they do not set ratios, yet the operating assumption of wholesalers is that ratios must not be exceeded for any reason.

   As prescribing of buprenorphine increases to meet gaps in treatment, pharmacies that fill increasing numbers of prescriptions face having their supplies cut off if they exceed their wholesaler's limits. Removing buprenorphine from the algorithms used for this program would remove a barrier to stocking buprenorphine. Overall, greater transparency in this program overall would help pharmacies in maintaining their supplies of controlled substances.

CMS and Other Payers

1. **CMS/Payers: Implement a federal government mandate to remove prior authorization requirements and formulary restrictions on buprenorphine products for MAT.**

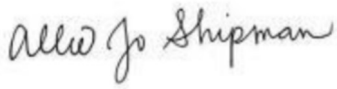
   Using PREP Act authorities, remove prior authorization requirements and formulary restrictions on buprenorphine products for MAT during the current opioid public health emergency to include Medicare, Medicaid and private sector programs. HHS has required no patient out of pocket costs for administering COVID-19 vaccines during the PHE. For buprenorphine, removing prior authorization requirements and formulary restrictions as a payer policy would remove a significant barrier to patient access.

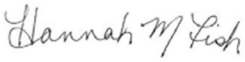
2. **CMS/Payers: Evaluate and address current reimbursement issues for pharmacies across payer types so pharmacies do not incur financial loss when they dispense buprenorphine products for MAT.**

   Many pharmacies have significant reimbursement issues for buprenorphine, often receiving reimbursement that does not cover the cost of medication. Current reimbursement levels also do not take into account, or cover, the extra time and effort for pharmacists to perform the additional necessary safety checks for this medication. Our organizations urge HHS and CMS to examine current reimbursement rates and address PBM reimbursement issues for buprenorphine. We also recommend that CMS issue a recommendation to Part D plans and other payers for an enhanced buprenorphine dispensing fee to account for the time and resources required to dispense buprenorphine. For example, CMS was successful in facilitating COVID-19 vaccine administration rates by providing an enhanced administration fee of $40 (geographically adjusted).

Thank you for the opportunity to provide these recommendations. Our organizations are committed to assist in expanding access to buprenorphine for MAT through community pharmacies. Please contact Anne Burns (aburns@aphanet.org), Allie Jo Shipman (ajshipman@naspa.us), or Hannah Fish (Hannah.fish@ncpanet.org) with any questions or requests for follow-up information.

Sincerely,





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