



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

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[Submitted electronically to commission@ondcp.eop.gov]

President's Commission on Combating Drug Addiction and the Opioid Crisis: Interim Report Comments from the American Pharmacists Association

Dear Members of the Commission on Combating Drug Addiction and the Opioid Crisis:

The American Pharmacists Association (APhA) appreciates the opportunity to provide our perspective on the draft interim report (hereinafter "Interim Report") of the President's Commission on Combating Drug Addiction and the Opioid Crisis (hereinafter "President's Commission"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 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 offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA is committed to working with the President's Commission and other health professionals and stakeholders to identify ways to curb opioid abuse. We believe solutions will take everyone working together, including health care professionals, patients, and federal, state and local governments. As the President's Commission works towards solutions, we reiterate the importance of considering the possible effects any policy change might have on legitimate patient access to prescription drugs, in addition to the opioid abuse and misuse epidemic. The Institute of Medicine (IOM) estimates there are 100 million Americans living with chronic pain--a number that does not include the additional 46 million individuals the Centers for Disease Control and Prevention (CDC) estimates suffer from acute pain due to surgery. Given the sheer number of Americans impacted, policy changes directly or indirectly restricting legitimate patient access to prescription drugs for pain will have far-reaching consequences. APhA offers the following suggestions to enhance the President's Commission's recommendations to President Trump.

I. Mandatory Education

The Interim Report recommends mandating prescriber education initiatives with the assistance of medical and dental schools and to make such education a requirement for Drug Enforcement Agency (DEA) licensure. APhA notes other health care professionals, including pharmacists in some states, are eligible to prescribe controlled substances. Since only medical and dental schools are noted in the Interim Report, APhA strongly recommends the President's Commission modify report language to clarify the health care practitioners they intend to receive mandatory education and to better include those professions in any educational initiatives or mandates.

In addition, consistent with recommendations made to the Food and Drug Administration regarding mandatory education, APhA suggests studying the impact and effectiveness of an education mandate prior to creating a mandate. Subsequent education policy should consider the outcomes of such a study. Several states have implemented mandatory education requirements for various health care practitioners, including pharmacists. Information may be gleaned from state experiences to better inform a policy related to mandatory education. In addition, APhA highlights the need to also consider any negative implications of a mandatory education policy, including whether practitioners forgo other education more relevant to their practice and the impact to patients who have a legitimate need for medications to treat their pain. Lastly, APhA notes any mandatory education policy initiated by the DEA should be coordinated with the FDA, state governments and various state boards regulating health care practitioners to limit redundancy and improve efficiency.

II. Medication-assisted treatment

APhA appreciates the President's Commission's recognition of the value of medication-assisted treatment (MAT) and the recommendation to increase funding for MAT. However, APhA is concerned the recommendation to require all modes of MAT be offered at every licensed MAT facility may have a significant, negative impact on patient access and oppose current efforts to expand access to MAT. While APhA supports efforts to increase the scope of MAT services available to patients and agrees with the President's Commission regarding prioritizing the treatment option best for the patient, we have concerns with requiring all authorized providers to offer all FDA-approved MAT.

APhA's is concerned because there are many different ways to provide MAT. Access the types of services that may be included in MAT also vary widely, especially when considering the availability of different health care practitioners. In addition, not all entities providing MAT are registered with the Drug Enforcement Agency as an opioid treatment program (OTP) because they are able to provide MAT with schedule III medications per the Drug Addiction Treatment Act of 2000 (DATA 2000). Therefore, requiring all facilities to offer a broad scope of MAT would directly conflict with the intent of DATA 2000, which enables certain health care practitioners operating in nontraditional setting to use schedule III medications, such a buprenorphine, in the provision of MAT without having to register as an OTP.

In addition, as researchers and drug developers work to enhance treatment options for opioid use disorder, it is important to recognize not all treatments used in MAT will necessarily be a controlled substance and could be costly and cost prohibitive for some facilities to provide. Given access to treatment options is currently a problem from some, additional mandates may only discourage practitioners from providing MAT.

Lastly, in regards to MAT, APhA suggests the President's Commission recommend including pharmacists in the pool of practitioners eligible to obtain a DATA 2000. Currently, 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements¹ with physicians and other prescribers to provide advanced care to patients, which may include components of MAT. APhA is aware of at least five states² that allow pharmacists to prescribe Schedule III, IV and V controlled substances under a collaborative practice agreement. The Comprehensive Addiction and

¹ Collaborative practice agreements create a formal practice relationship between a pharmacist and another health care provider and specify what patient care services – beyond the pharmacist's typical scope of practice- can be per

² States that allow pharmacists to prescribe controlled substances when working under a collaborative practice agreement: California, Massachusetts (hospital only), Montana, New Mexico, and Washington.

Recovery Act (CARA) of 2016 expanded the law to allow nurse practitioners and physicians assistants to obtain a DATA waiver and provided SAMHSA with authority to modify eligibility requirements for a DATA waiver. Pharmacist involvement in MAT for opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.^{3,4} Pharmacists' capabilities are recognized by the Food & Drug Administration (FDA)⁵ and in SAMSHA's 2015 Federal Guidelines for Opioid Treatment Programs.⁶ Allowing pharmacists to obtain a DATA-waiver will increase access to MAT and address treatment gaps.

III. Model Naloxone Dispensing Legislation and Requiring Prescribing of Naloxone with High-Risk Opioid Prescriptions

APhA agrees with the President's Commission's goal of expanding access to naloxone and encourages the President's Commission to recommend states who have not already done so⁷, expand access to pharmacist-prescribed naloxone via state-wide standing orders, state-wide protocols and other mechanisms. APhA strongly recommends the President's Commission consider naloxone legislation from California, North Dakota and Connecticut which expands access to naloxone by utilizing the pharmacist.

In addition, while pharmacist-prescribed naloxone is one tool that can significantly improve patient access to naloxone, APhA highlights the need for both public and private payers to consistently cover naloxone prescribed by a pharmacist. Many payers do not cover naloxone, and of those that do, there may be a requirement for the prescription to come from a physician. As a result, the benefits of pharmacist-prescribed naloxone may not be fully realized. APhA recommends the President's Commission considers outreach to payers to encourage coverage of naloxone and other related policies to improve access.

IV. Prescriptions Drug Monitoring Programs

APhA applauds the President's Commission for recommending additional federal funds and technical support to states to enhance interstate data sharing among state-based prescription drug monitoring programs (PDMP). APhA is aware of several technology solutions already in existence which enable interstate data sharing which could be utilized to further enhance this goal. In addition, when considering impact of PDMP policies and future grants to strengthen this tool, it's important for the President's Commission to remember that pharmacists are important contributors to and reviewers of PDMPs.

The Interim Report envisions the PDMP helping the clinician determine whether their patient has had an overdose and summarizing other relevant information into categories of high to low risk to help inform the clinical prescribing decision. APhA notes that 42 CFR Part 2 regulations may limit the

³ 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.

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

⁵ 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).

⁶ 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.

⁷ See, National Alliance of State Pharmacy Associations, *Naloxone Access in Community Pharmacies*, last updated June 1, 2017, available at: <https://naspa.us/resource/naloxone-access-community-pharmacies/>, for a complete showing of different types of legislation states have adopted to increase naloxone access in community pharmacies.

content of information shared in a PDMP. In addition, while it is important clinicians, including pharmacists, be made aware of a patient's potential risk, it is also important for the clinician to have access to the data the PDMP uses to quantify risk so practitioner can better exercise clinical judgment.

V. Privacy Laws and Jessie's Law

APhA is pleased that patient privacy has been addressed in the Interim Report. Since Jessie's Law (S. 2866) was recently included in the Food and Drug Administration Reauthorization Act of 2017 which was signed into law by the President, APhA recommends other enhancements related to the appropriate sharing of critical information of at-risk patients. Specifically, Jessie's Law directs the Secretary of Health and Human Services, to disseminate standards to provide information on a patient's history of opioid addiction to "hospitals and physicians". As worded, the language may be interpreted to mean that opioid addiction information would only will be disseminated to hospitals and the physicians working within those systems. Thus, other settings, such as outpatient surgical centers and clinics, and professionals, like pharmacists, may still have limited access to opioid addiction information. Limiting access to such information may negatively impact current care trends that encourage team-based care and innovate delivery beyond the hospital setting. Thus, APhA recommends expanding the scope of settings and professionals by treating pharmacies and pharmacists like hospitals and physicians as described in §2(a) of the S. 581.

In addition §2(b)(3) of Jessie's Law highlights the need for information about past opioid addiction to be prominently displayed when a physician or medical professional is prescribing a medication. While this is an important first step, the role of dispensing is equally important in the appropriate management of opioid use. In the testimony provided when this bill was introduced, Jessie Grubb's parents were quoted as saying "Please, we want you to notify anybody who handles, anyone who dispenses, anyone who is working with Jessie."⁸ While Section 2(b)(4) of Jessie's Law considers other practitioners' needs by requiring the standards to take into account the need for pharmacists and other medical professionals to have access to opioid addiction information in the medical records (including electronic health records), APhA notes pharmacists often do not have access to medical records, such as electronic health records. Therefore, to achieve the intent of Jessie's Law, APhA requests the President's Commission recommend funding health information exchanges that enable and enhance communications between pharmacists and other members of the care team.

VI. Alternative Solutions

a. Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S. 109)

APhA urges the President's Commission to recommend passage of the bipartisan, Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S. 109). The bill aims to improve patient access to health care through pharmacists and their patient care services. Pharmacists are involved in pain management programs may provide include medication tapering services, medication assisted treatment, and naloxone, among other services. Pharmacists are the medication experts on care teams and the most accessible health care practitioner, it is of the utmost importance that patients are able to access pharmacist services, which can help prevent prescription drug abuse and misuse, in addition to improve treatment outcomes.

⁸ 163 Cong. Rec. S1691-S1692 (statement of Sen. Manchin) available at: <https://www.congress.gov/congressional-record/2017/03/08/senate-section/article/S1691-1>

b. Improved Communication and Access to Information

APhA strongly supports better collaboration and communication between pharmacists, physicians and other health care providers to identify potential substance abuse problems. PDMPs represent one tool helping prescribers and pharmacists identify and prevent drug misuse, abuse, and/or diversion. However, communication between providers remains a significant barrier, especially because pharmacists do not often have access to a patient's medical record. APhA encourages the President's Commission to recommend providing additional funds to facilitate interoperable exchange of information with all practitioners, including pharmacists. The capability for interoperable data exchange of critical clinical information between pharmacists and prescribers is important to having meaningful systems to combat prescription drug abuse and misuse while decreasing heavy administrative burdens on busy health care professionals.

c. Increase Disposal

APhA suggests increasing the public's awareness of disposal options and access to prescription drug take back opportunities to decrease the likelihood of controlled substance use by persons other than the person to whom they were prescribed. Often an abuser's initial exposure to controlled substance prescription drugs comes from a family member or friend's prescription in their medicine cabinet. Additional education and opportunities for disposal may make individuals more likely to dispose of these unwanted drug products rather than storing them indefinitely. Therefore, we suggest considering ways to increase disposal.

Thank you for your leadership and work on addressing prescription drug abuse. We appreciate the opportunity to advocate for the role of the pharmacist, the medication expert on the patient's health care team, in discussions on ways to help combat prescription drug abuse and misuse. APhA look forward to the final report and working with the Administration to implement recommendations to address the opioid epidemic once the report is finalized. If you have any questions please contact Jenna Ventresca, Director of Health Policy, by email at jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,



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