

June 6, 2017

Senator Amy Klobuchar
302 Hart Senate Office Building
Washington, DC 20510

Senator Joe Manchin
306 Hart Senate Office Building
Washington, DC 20510

Senator Robert Portman
448 Russel Senate Office Building
Washington, DC 20510

Senator Angus King
133 Hard Senate Office Building
Washington, DC 20510

RE: Prescription Drug Monitoring Act of 2017

Dear Sens. Klobuchar, Portman, Manchin and King,

The American Pharmacists Association and National Community Pharmacists Association appreciates the opportunity to provide input on the Prescription Drug Monitoring Act of 2017. As the medication experts on the patient's health care team, pharmacists play an important role in preventing prescription drug misuse and abuse while helping patients obtain access to medications they need. APhA and NCPA emphasize that pharmacists are a key health care professional that needs to be included in the development of policies to address this important public health need. APhA and NCPA are supportive of ongoing efforts at the local, state and federal levels to address the opioid epidemic, including those that aim to better utilize and enhance prescription drug monitoring programs (PDMPs). However, we are concerned some of the new requirements being placed on health care providers in a condensed time frame may not meaningfully impact the problem and actually detract from progress already made. Accordingly, we offer the following comments in effort to further evidence-based solutions that will help patients, families and communities combat prescription drug abuse and misuse.

I. Reporting requirements

Sec. 3, Prescription Drug Monitoring Program Requirements, makes grant funding contingent on a state's compliance with five (5) requirements, including mandating PDMP consultation and reporting, providing proactive notification to a practitioner when patterns indicative of controlled substance misuse are detected, make available quarterly de-identified data sets and an annual report and that the data contained in the PDMP be made available to other states. We are concerned that several of the funding prerequisites, in particular the mandatory reporting requirements for dispensers within twenty-four hours, will be overly burdensome to implement and disrupt patient care. APhA and NCPA recommend changing each reporting requirement to a recommendation.

a. 24-hour reporting requirement

In the case of many pharmacies, PDMP systems are not integrated into pharmacy systems and the act of reporting may require entry into multiple states' systems. Because PDMP systems are not integrated into pharmacists and other health care professionals' workflow, the 24-hour reporting requirement may be onerous for many pharmacists and other practitioners at this time. For example, some pharmacies purchase technology or pay vendors to enable seamless reporting

at the time of dispensing. Others mail-in data, log onto the state's PDMP to upload reports to the PDMP or designate one individual to report to the PDMP as not all pharmacists may be trained in PDMP reporting. It is also important to note that different states have exempted practitioners working in certain entities from reporting to the PDMP. Technology malfunctions at the state level or within the pharmacy may also impede reporting. Moreover, because of state laws, their PDMP processes and data-sharing agreements with other states, imposing a 24-hour requirement may not affect when the reported information is actually available. Before mandating a 24-hour reporting period for all dispensers, APhA and NCPA recommend researching whether the 24-hour reporting requirement can be easily and effectively implemented by states and practitioners, whether any exceptions or modifications are necessary, and the benefit of such a requirement in the current environment. Such research should include pharmacists' and other stakeholders' perspectives and consider cost, workflow and different capabilities of each state's PDMP. Until such research is performed, APhA and NCPA suggest changing the 24-hour reporting requirement to a recommendation.

b. Proactive notification to a practitioner when patterns indicate controlled substance misuse

The bill requires the PDMP to provide proactive notification to a practitioner when patterns indicative of controlled substance misuse are detected. However, the bill does not detail how patterns indicative of controlled substance misuse will be determined. APhA and NCPA emphasize the need to have pharmacists, due to their medication expertise and patient-care experience, included in the development of any processes or clinical decision support tools used to proactively identify patients who may be misusing controlled substance. Further, APhA and NCPA recommend clarifying that such tools do not replace clinical decision-making and should not be used against a practitioner in any kind of claim or legal proceeding. In addition, we recommend requiring that the methodology relied upon for such tools be explained and made available to health care practitioners.

II. Two-Year Implementation Period

The bill currently requires that each state satisfy a set of five requirements within two years of enactment to receive funding for the state's PDMP. We believe that this short timeline will prevent states from being able to effectively and meaningfully comply, putting needed state funding at-risk. Sec. 3 makes significant demands on states that would require additional investments and staff resources, effectively excluding those states who may benefit most greatly from a grant. APhA and NCPA suggest removing the two year implementation period to provide states with additional flexibility and encourages a criteria be added that would weight selection based on state need or benefit.

III. Data-sharing Single Hub

To help facilitate access to and sharing of PDMP information and data between states, the bill requires the Attorney General to award a grant to an eligible entity to establish and maintain an inter-State data-sharing single hub. While we are strong advocates for interoperable PDMPs, we are aware of existing efforts to facilitate interstate data sharing and reporting. Therefore, to

prevent duplicating efforts and wasting resources, including funds already spent and future grants, we recommend prior to the creation of a hub, the current PDMP landscape, including policies facilitating data sharing, be analyzed. This will help ensure future policies augment, not supplant or disrupt, the successful work already underway. Furthermore, it is not clear from the bill's language the functionality of this single hub. While there is benefit to having a central location for this information, it still may require the practitioner to go into different PDMPs to report the information and whether practitioners could use the hub to check patient information.

IV. Team-based Care

Pharmacists are involved in pain management programs, including provisions of medication tapering services, work in medication assisted treatment programs, and furnishing naloxone where authorized. Depending on state authority, pharmacists working under collaborative practice agreements can initiate, monitor, modify, and discontinue medication therapy, including opioids, and order and interpret laboratory tests in collaboration with other members of the health care team. In addition, pharmacists are required by DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.¹

Since patients living with chronic conditions often have medications from multiple providers, pharmacists help bridge the communication gap between health care providers by coordinating and providing medication-related services. Pharmacists are part of the team helping patients with legitimate pain management needs achieve treatment goals. However, pharmacist-provided services are not consistently covered by payers. Thus, efforts to enhance prescription drug monitoring programs should consider making grants available to pharmacists to advance care by better utilizing pharmacists' capabilities in prescription drug abuse, misuse and treatment.

Thank you for your leadership and work on this issue. We look forward to supporting your efforts and working with you as the bill is refined. If you have any questions please contact Alicia Kerry Mica, at amica@aphanet.org or 202-429-7507 or Karry K. La Violette at karry.laviolette@ncpanet.org or 703-600-1180.

Sincerely,



Alicia Kerry J. Mica
American Pharmacists Association



Karry K. LaViolette
National Community Pharmacists Association

¹ United States Drug Enforcement Administration, Practitioner's Manual, 2006:30 "Federal courts have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the usual course of professional practice' in a way that will provide definitive guidelines to address all the varied situations physicians may encounter".