American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

February 26, 2016

**U.S. Senate Committee on Finance: "Examining the Opioid Epidemic: Challenges and Opportunities**

**Statement of the American Pharmacists Association**

On behalf of the American Pharmacists Association (APhA), and our more than 62,000 members, we appreciate the opportunity to provide feedback on S.1913, "Stopping Medication Abuse and Protecting Seniors Act of 2015" and other efforts to address the opioid abuse epidemic. 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, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with the Committee 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 Committee works toward a solution we urge the Committee to consider the possible effects that any policy change might have on legitimate patient access to prescription drugs. The Institute of Medicine (IOM) estimates that 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 that directly or indirectly restrict legitimate patient access to prescription drugs for pain will have far-reaching consequences.

APhA supports education for health care professionals, including pharmacists and student pharmacists, to address issues of pain management, palliative care, and appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders. APhA proposes the following recommendations regarding S. 1913 and opioid use and abuse.

## I. S. 1913: Stopping Medication Abuse and Protecting Seniors Act of 2015

### A. Selection process for prescribers and pharmacies

APhA is a long-time advocate for making certain patient choice is included in health care policy. While we appreciate that S. 1913 requires prescription drug plans (PDPs) to ask for and consider beneficiaries' preferences when limiting at-risk patients to a particular prescriber and pharmacy, APhA remains concerned that the administration of these drug management programs and

the final selection of providers is by PDPs. While the legislation provides patient safeguards such as notices and rights to appeal, health care is complex and many patients do not understand the vast array of information that is provided to them.

APhA is a strong supporter of the benefit of patients receiving their prescriptions by a single pharmacy of their choice. Research has demonstrated, and CMS has recognized, that trusted relationships between patients and pharmacists are important, including in mental health-related care.[1] Given the relationship between mental health, chronic pain and substance abuse, being sensitive to the provider preferences of at-risk patient becomes even more important. APhA is concerned that the legislation's section discussing reasonable access may be interpreted to allow PDPs to minimize the importance of patient choice when selecting an at-risk beneficiary's prescriber and pharmacy.[2] This section states that a PDP sponsor's selection take into account "geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time."

Because PDPs can have a financial interest in steering beneficiaries to certain pharmacies (e.g., better contracted rates, ownership interest), we recommend that choices related to restricting patients to a particular prescriber and pharmacy are not granted to the PDPs. However, if it is decided that PDPs will be the entity to make such decisions, we recommend that patient choice be the default and any deviation from a patient's choice of prescriber and pharmacy must be justified in writing and allowed only upon approval by the Secretary.

B. Pharmacists role in at-risk determinations

APhA is pleased that pharmacists are explicitly included in the list of stakeholders tasked with identifying criteria that will be used to distinguish beneficiaries who are at-risk for prescription drug abuse. While APhA believes the language requiring PDPs to verify with "providers" that the beneficiary is at-risk includes pharmacist, we recommend "including pharmacists" be added to remove any ambiguity. Pharmacists play a unique role in the care continuum as they are medication experts, and often the health care professional that a patient will see most often. Pharmacists advise patients on drug-drug interactions, review medication dosages for appropriateness, and have the ability to more frequently observe behaviors that may be of concern. In addition, the vast majority of states allow providers to engage in collaborative practice agreements with pharmacists for certain services, such as medication therapy management. Some pharmacists in team-based care settings are engaged in pain management with prescribing authority for opioid therapy when working with physicians under collaborative practice agreements. Since pharmacists play such an integral role in pain management, they possess valuable knowledge that can be critical in determining whether a beneficiary is at-risk.

C. Clinical Contact

APhA has concern with the provision of the bill requiring PDP's to contact the at-risk beneficiary's physicians regarding whether prescribed medications are appropriate for the medical condition. Such a requirement without additional criteria related to risk would be overly broad, hinders the health professional's judgement and could cause delay in treatment for patients with a legitimate need.

[1] Mey, A., Know K., Kelly, F., Davey, A.K., Fowler, J., Hattingh, L., Fejzic, J., McConnell, D. & Wheeler, A.J. (2013). Trust and Safe Spaces: Mental Health Consumers' and Carers' Relationship with Community Pharmacy Staff, *The Patient – Patient-Centered Outcomes Research,* 6(4), 281-289.

[2] S. 1913, 114th Cong. Sec. 2(a)(1) adding "(5)(D) Selection of Prescribers" to Section 1860D-4(c) of the Social Security Act.

D. Patient privacy

APhA is pleased that patient privacy has been addressed in the bill. However, we feel the need to highlight that the Substance Abuse and Mental Health Services Administration (SAMHSA) is currently in the process of modernizing 42 CFR Part 2 which dictates confidentiality of substance use disorder patient records. Generally, 42 CFR Part 2 gives patients who suffer from substance use disorders greater privacy protections than the Health Insurance Portability and Accountability Act. Since PDPs will be exchanging sensitive patient information, we recommend considering adherence to 42 CFR Part 2.

E. Education

APhA supports comprehensive efforts to educate health care professionals, including prescribers and pharmacists about prescription drug abuse, and mechanisms to prevent it. As drafted, the bill requires the Secretary to provide education only to enrollees and providers regarding the drug management program. Although it is not clear which health care professionals are included in the term "providers", we support improving the training and education of all health professionals related to prescription drug abuse, misuse and treatment and encourage that such efforts incorporate ways to identify patients susceptible to addiction, and behaviors of addiction, abuse, misuse or diversion. In addition, the training should also educate health care professionals on various ways prescription drugs are diverted, and the different ways abusers are manipulating and administering the drugs.

Further, APhA supports incentivized patient education focused on prescription drug abuse beyond education limited to the drug management program. Pharmacists are accessible providers who are able to provide targeted patient education on the risks and benefits associated with taking prescription drugs with a potential for abuse.

## II. Alternative Policy Considerations

A. Naloxone

Making naloxone more widely available beyond hospitals/ emergency rooms and emergency medical transport is a relatively recent occurrence and precipitated in part by the Substance Abuse and Mental Health Services Administration SAMHSA recommendations (2013-14). Due to the expansion of sites providing naloxone, there needs to be a corresponding growth in training related to the appropriate use and administration of naloxone. State pharmacy associations and other pharmacy stakeholders have already begun to develop naloxone educational programs for pharmacists. We encourage the development, dissemination, and incentivization of naloxone-related education to patients and caregivers as well as to all members of the health care team.

For many patients, cost can be a significant barrier in accessing naloxone. In order to encourage patients and caregivers to obtain naloxone products, it is essential that payer policies allow for coverage of this potentially lifesaving product. Insurance coverage of naloxone varies, but some plans have implemented prior authorization requirements, limiting immediate access even with a prescription. On the supply side, pharmacies that want to stock naloxone may be required to purchase a large quantity of the product – resulting in a large amount of waste if the local demand is low and the excess product expires. Even if naloxone were to be made available over-the-counter, as some stakeholders have suggested, cost would continue to be a potential barrier for patients, especially because many insurers do not cover over-the-counter medications.

Several states have looked to increase patient access to naloxone by allowing pharmacist prescribing of naloxone. Some states have taken the approach of instituting a statewide protocol while others have implemented programs that use existing pharmacist collaborative practice authority. Still others have authorized pharmacists to dispense naloxone without a prescription. It is important to note that changes in scope may not automatically mean patients will have coverage by government and private payers; therefore, while a pharmacist may be able to prescribe or otherwise provide naloxone, a patient's insurance may not cover it. APhA advocates for pharmacists, an important member of the patient's health care team, to be able to furnish opioid reversal agents to help prevent opioid-related deaths and insurance policies that cover naloxone prescriptions, from all providers, for patients and caregivers who need it.

B. Improved Communication and Access to Information

APhA strongly supports better collaboration and communication between pharmacists and physicians to identify potential substance abuse problems. Prescription drug monitoring programs (PDMPs) represent one tool that helps prescribers and pharmacists to identify and prevent drug misuse, abuse, and/or diversion. However, integrated PDMPs that can be accessed by health care professionals' nationwide in a seamless manner with their workflow is necessary. In addition, there needs to be better communication between providers, states and their system so health care professionals can have access to real-time information regardless of state lines. Every state should have a PDMP which is interoperable with those of other states.

Expanding electronic prescribing (e-prescribing), which is the secure electronic transmission of prescriptions from prescribers to pharmacies, is also a means to combat prescription drug abuse, misuse, and diversion. The direct transmission of a prescription using electronic prescribing standards and technology reduces the potential for hard copy prescriptions in the patients' possession to be altered, forged, reproduced, or otherwise misused for unlawful purposes. Additionally, 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. Lastly, APhA would like to emphasize the importance of considering the role of pharmacists in policies regarding health information technology, and access to information.

C. Increase Prescription Drug Take Back Programs

APhA suggests increasing the public's access to prescription drug take back opportunities to decrease the likelihood that controlled substances will be used by persons other than the person to whom they were prescribed. According to a Drug Enforcement Agency press release, by May, 2014, seven take back days had been organized by DEA and an astonishing 4.1 million pounds (2,123 tons) of unwanted, unused and expired prescription medications had been removed from the public domain.[3] Often an abuser's initial exposure to controlled substance prescription drugs comes from a family member or friend's prescription in their medicine cabinet. If take back programs were more publically accessible, individuals will be more likely to dispose of these unwanted drug products rather than storing them indefinitely. Therefore, we look suggest considering ways to increase participation in and effectiveness of take back programs.

[3] Drug Enforcement Agency, (May 8, 2014), *DEA's National Prescription Drug Take-Back Days Meet a Growing Need for Americans,* available at: http://www.dea.gov/divisions/hq/2014/hq050814.shtml, last accessed: February 24, 2016.

Thank you for your leadership and work on addressing prescription drug abuse. We appreciate the inclusion of pharmacists in several portions of the bill and strongly advocate for continuing to include pharmacists, the medication experts on the patient's health care team, in discussions on ways to help combat prescription drug abuse and misuse. We look forward to supporting your efforts as the legislation moves through the process. If you have any questions please contact our Senior Lobbyist, Michael Spira, by email at mspira@aphanet.org or phone (202) 429-7507.

Sincerely,

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