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APhA

December 2, 2016

Sent via email to: PARTDPOLICY@cms.hhs.gov

Attn: Chad Buskirk
Centers for Medicare & Medicaid Services
Mail Stop C1-24-23, 7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: Listening Session Regarding the Implementation of Certain Medicare Part D Provisions in the Comprehensive Addiction and Recovery Act (CMS-2016-0166)

Dear Sir/Madam:

On behalf of the American Pharmacists Association (APhA), and our more than 62,000 members, we appreciate the opportunity to provide feedback in response to, "Medicare Program: Listening Session Regarding the Implementation of Certain Medicare Part D Provisions in the Comprehensive Addiction and Recovery Act" (hereinafter, the "Listening Session"). 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, physician offices, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with the Centers for Medicare & Medicaid Services (CMS) and other federal agencies, health professionals, patients and stakeholders to curb opioid abuse and misuse through drug management programs (DMPs). We believe that DMPs can be effective when everyone works together, including health care professionals, patients, and federal, state and local governments. APhA supports education for health care professionals, including pharmacists and student pharmacists, and patients to address issues of pain management, palliative care, drug diversion, substance use disorders and appropriate use of opioid reversal agents in overdose situations.

As the CMS develops its policies on DMPs, we emphasize the importance of considering the possible effects that policy changes may have on 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, changes to care that directly or indirectly restrict the access of patients with

legitimate needs to practitioners, including pharmacists, and prescription drugs will have far-reaching consequences. APhA looks forward to working with CMS on ways to develop and efficiently implement effective and meaningful DMPs, and offers the below commentary in response to questions posed during the Listening Session.

I. Responses to the Listening Session

APhA recognizes that prescription drug abuse, misuse and treatment is a significant and ongoing problem for patients and communities. APhA believes that DMPs represent one prong of a multi-pronged approach to effectively address and prevent these issues. Identifying and utilizing a broad array of approaches, such as pharmacist-provided services and improved collaborative care, can optimize the impact of medications while minimizing patient risk of addiction. The prescription drug abuse epidemic cannot be solved by implementing one-size fits all policies, but rather, solutions tailored to the patient with practitioner involvement. To help towards this end, APhA advocates that CMS convene an expert panel of a wide variety of health care practitioners, including pharmacists, who routinely work with patients likely to be identified as at-risk, to provide recommendations on the development of DMPs and changes to respond to identified problems or needs.

1. Developing clinical guidelines that indicate misuse of frequently abused drugs.

1.1. Besides opioids, what other frequently abused scheduled drugs should be considered?

APhA's members indicated that the evidence demonstrates benzodiazipines, muscle relaxants (e.g., carisopridol), and in some cases, certain stimulants, pose a risk to patients for substance use or misuse. APhA recommends that decisions on any drugs for incorporation into the guidelines due to their risk of abuse or misuse should be based on strong evidence and consider the impact on patients with legitimate needs.

1.2. What are suggestions for developing the clinical guidelines for opioids and other considered frequently abused drugs?

Congress provided in the Comprehensive Addiction and Recovery Act (CARA) that at-risk beneficiaries will be identified, "through the use of clinical guidelines that indicate misuse or abuse of prescription drugs... that are developed by the Secretary…"[1] Because it is not practical to identify every clinical scenario or type of patient who may be at-risk of addiction, the guidelines should be flexible to accommodate an individual's legitimate needs and appropriate clinical judgement by pharmacists and other health care practitioners. Strict clinical guidelines may also negatively impact patient care if deviations are used to identify pharmacies or prescribers that are contributing to abuse or misuse. CARA allows a PDP sponsor[2] to change a DMP patient's selection of pharmacy or prescriber if the PDP sponsor believes the pharmacy or prescriber is contributing to abuse or misuse.[3] However, the methodology a PDP may use is not clear. If rigid guidelines are used in such a process, APhA

[1] P.L. 114-198.Sec. 704 (a) Drug Management program for at-risk beneficiaries

[2] Because CARA is applicable to both Medicare-Advantage Prescription Drug plans and Part D plans, we use the term "PDP sponsor" to include both a PDP sponsor offering a prescription drug plan to a part D eligible individual and, when applicable, MA organizations offering MA-PD plans to MA eligible individuals.

[3] P.L. 114-198. "In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under clause (iii)(II) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii)."

believes that practitioners may be limited in the care provided as operating outside of such guidelines could risk their relationship with a PDP sponsor.

APhA recommends that CMS convene workgroups that include pharmacists and other members of the care team with experience in patient care, medications, pain management, and substance use disorder and treatment, when developing clinical guidelines and other regulatory activity related to opioids, pain management, and other frequently abused drugs.

APhA anticipates that PDP sponsors will rely on guidelines when developing algorithms that identify beneficiaries for a DMP. APhA is concerned that PDP sponsors that use only on an algorithm to select patients for a DMP will over- and unnecessarily identify patients as being at-risk. Therefore, in line with CDC recommendations and policies of state Medicaid programs, APhA encourages CMS to require DMP enrollment decisions to "combine objective criteria with subjective review, based on clinical judgment."[4] APhA suggests requiring PDP sponsors to include subjective review, performed by health care clinicians, such as pharmacists, when selecting beneficiaries for a DMP.

CMS should also require that DMPs develop processes for patients to self-enroll and for clinicians to recommend patients that should or should not be enrolled in a DMP. Such opportunities for patients and clinicians should be available before a patient is identified as at-risk. In addition, we strongly encourage CMS to require that a DMP beneficiary's pharmacies and prescribers, including those not selected by the patient for the DMP, are notified of coverage changes and the at-risk determination. Doing so will enable the patient's health care team to make better informed clinical decisions, minimize any delay in treatment, and coordinate care.

1.3. <u>What are the standards for terminating a beneficiary's at-risk identification and/or maximum time period to be considered at-risk?</u>

APhA requests CMS clarify what is meant by "maximum time period to be considered at-risk," since it is not clear whether it signals the reassessment of the patient's at-risk determination, or if it leads to automatic removal from a DMP without clinical input. APhA does not support beneficiaries' automatic removal from a DMP based solely on an arbitrary time period and supports CMS requiring PDP sponsors to assess the appropriateness of at-risk patient's inclusion in a DMP.

As noted previously, APhA encourages CMS to develop a mechanism for pharmacists and other health care providers to recommend whether or not a patient should be enrolled in, or removed from, a DMP. In addition, the DMP framework needs to consider the impact medication changes, such as increases or decreases in dosage or number of prescriptions, will have on a patient's at-risk identification or imposed maximum time period. Also, APhA believes there should be automatic termination of patient enrollment in a DMP when patients are no longer prescribed frequently abused drugs.

In addition, should CMS decide to impose a maximum time period to be considered at-risk, APhA believes it is important that patients who view the DMP favorably have the option to remain on the program without limitation.

[4] Centers for Disease Control & Prevention (2012). Patient Review & Restriction Programs, CDC Expert Meeting Report.

2. The use of evidence-based prescribing guidelines for opiates.

2.1. What are the prescribing guidelines that CMS should consider?

APhA recommends that CMS consider many types of prescribing guidelines, not just those from government agencies or those that target only primary care practitioners. APhA emphasize the importance of incorporate ongoing evidence review into any guideline process.

3. Assessing the impact of drug management programs for at-risk beneficiaries on cost-sharing and accessibility to prescription drugs for enrollees who are considered at-risk.

3.1. What type of existing beneficiary education should be appropriate for the Secretary to provide with respect to drug management programs?

In response to the opioid epidemic, state pharmacy associations and other pharmacy stakeholders have developed educational programs for pharmacists on topics such as naloxone, pain management and recognizing signs and symptoms of addiction. APhA encourages the development, dissemination, and incentivization of pharmacist-provided education to patients and caregivers, as well as other member of the health care team. Like the aforementioned educational efforts, DMP education should address risks associated with taking opioids and other drugs of abuse, signs of addiction, opportunities to seek help, effective disposal practices, and patient options if there is an issue reaching their pharmacy or prescriber. Education should also clearly outline the patient's options, including appeals process(es) and suggestions to help beneficiaries select a pharmacy and prescriber. Information provided to beneficiaries should emphasize that significant weight will be given to the beneficiary's pharmacy and prescriber selection, and that the PDP sponsor will have authority to select a prescriber and pharmacy only if the patient provides no response. APhA members strongly recommended that a call center specific to DMP issues be made available to pharmacists, prescribers and patients to provide educational support, answer questions, and help coordinate care.

3.2. What types of existing public health resources are there for addressing prescription drug abuse?

While significant resources and efforts at the local, state and federal levels have been focused on prescription drug abuse, it continues to be a significant problem. It is evident that there is not one solution or an easy fix, accordingly, we all need to continue to work together on identifying and implementing targeted and effective ways to curb this epidemic. For our part, APhA encourages clinician participation in education and training resources that, like our organization's offerings, reflect the importance of preventing abuse and misuse while recognizing that there are patients with a legitimate need for these medications. APhA collaborates with other organizations on Generation Rx, an outreach program that increases awareness of prescription medication misuse & abuse, and encourages health care providers, community leaders, parents, elementary-aged students, teens and college students to actively work to prevent abuse (directly reached >130,000 people in 2015). APhA worked with CDC to develop a resource highlighting the pharmacist's role in curbing prescription drug abuse and misuse.[5] APhA also created a publicly accessible resource center (Opioid Use, Abuse and Misuse Resource Center), which connects pharmacists and pharmacy technicians to tools, educational materials, research, guidelines, and news.

[5] *See*, Centers for Disease Control and Prevention, Pharmacists: On the Front Lines, available at: https://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf, last accessed: December 2, 2016.

3.3. What type of data should be supplied to CMS for the purpose of identifying patterns of prescription drug utilization?

APhA has been a strong supporter of programs to optimize the impact of medications and eliminate waste, including drug utilization reviews. However, APhA is concerned about the unintended consequences of CARA's requirement that a PDP sponsor operating a DMP must provide data to inform drug utilization patterns. CARA states, "the Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for the purposes of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and that may indicate fraudulent medically unnecessary or unsafe use."[6] APhA believes that a DMP may significantly impact prescription drug utilization and potentially change what is considered a "normal" pattern. APhA recommends that CMS devote resources to research whether utilization patterns outside the norm are good indicators of fraud, unnecessary medical use or unsafe use.

In order to receive meaningful feedback on data needed for drug utilization patterns, APhA suggests CMS better describe what they consider "prescription drug utilization," including the scope of drugs to be monitored. APhA recommends that CMS also collect data to assess the impact of DMPs on beneficiary access, behavior and health outcomes to determine program effectiveness and to identify components of programs that enhance effectiveness.

3.4. What should be considered reasonable provider/pharmacy access standards for beneficiaries with regard to geographic location, cost-sharing impact, etc.?

APhA's community pharmacist members have repeatedly voiced concern about the substantial adverse impact of preferred networks on their businesses, patient access, and continuity of care. In some cases, pharmacists are forced to close pharmacy locations because they are shut out of the preferred network in a service area. When pharmacies close, patients lose access to health care through pharmacists and pharmacist-provided services. To provide adequate patient access, CMS should ensure that PDP sponsors do not limit pharmacy participation in preferred networks, especially when pharmacies are willing to meet network terms and conditions. This concern is exacerbated by language in CARA which mentions "in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select…" We do not believe it was the intent by Congress to disrupt the pharmacist-patient relationship for these vulnerable patients by limiting patient choice to in-network pharmacies. Moreover, such a requirement could drive at-risk patients to multiple pharmacies, which runs counter to the bill's underpinning concept that patient medication is best managed by a single physician and single pharmacy. To remedy this issue, we believe that the utmost deference should be given to a patient's preference, and should not be limited to in-network pharmacies or physicians.

Similarly, while APhA supports the concept of reducing costs to patients through mechanisms such as preferred cost-sharing pharmacies ("PCSPs"), patient access concerns exist. Pharmacy benefit managers create sub-networks of PCSPs, whereby plans or PBMs contract with selected pharmacies to offer reduced or no cost-sharing for beneficiaries. While APhA supports the concept of reducing costs through PCSPs, we have concerns about this approach when such arrangements are not offered to all pharmacies, or when the only PCSPs able to meet the terms and conditions for PCSP sub-network

[6] P.L. 114-198.

participation are pharmacies owned by the PBM. In the context of a DMP, patient choice of pharmacy may be unnecessarily limited by the cost to the drug plan, as opposed to offering access to the pharmacy preferred by the patient or that will provide the best care. Given the pharmacist's role as a medication expert and their proven ability to improve adherence and outcomes, APhA encourages CMS to continue to refine access standards and policies which focus on the patient and are not arbitrarily limited by contractual relationships which may not be in the patient's best interest. Also, evaluations of Part D and MA-PD plans need to include the performance of their DMPs, and this performance needs to be publicly reported.

3.5. What should be the exception criteria to a change in a beneficiary's provider and/or pharmacy choices?

Circumstances that may warrant an exception to a change in a beneficiary's prescriber and pharmacy include prescriptions written in emergency rooms and other urgent care situations, dental offices, and partial fills for patients when traveling. CMS should also consider exceptions when a pharmacy or prescriber is unable, or decides, to no longer provide services associated with the DMP. In addition, there should be a process for patients to request a change to their prescriber and/or pharmacy choices, with or without a significant change of circumstances. APhA recommends that a significant change of circumstances, such as change in health status, address, caregiver circumstances and financial constraints, warrant more immediate action.

APhA urges CMS to require that PDP sponsors consult the pharmacy and prescriber before a patient in a DMP prescriber and pharmacy is locked in. Our members strongly emphasized the importance of being able to evaluate a patient's medication requirements because pharmacies may not be able to obtain or maintain the necessary medications. APhA believes that patient care is optimized when a patient is seen regularly at a single pharmacy. However, because pharmacies have variable stock and different monthly limits set by wholesalers on shipments of controlled substances, not every pharmacy can necessarily satisfy these patients' medications needs. APhA members have expressed significant concerns that products containing controlled substances have been harder to obtain or maintain because of DEA diversion efforts. Thus, it is critical that the pharmacy be consulted prior to locking in the patient. Further, APhA encourages CMS, FDA and DEA work together to reconcile policies and strategies to combat prescription drug abuse, misuse and treatment. As patients are driven to a single pharmacy, a simple delay in shipment or temporary shortage could prevent patient access and receipt of needed and legitimate treatment.

4. How should the appeals process be used so that the enrollee may appeal or contest being identified as an at-risk beneficiary for prescription drug abuse?

4.1. How should beneficiary complaints related to a drug management program fit into existing Part D appeals and grievance process?

APhA believes beneficiaries should be able to make complaints about a DMP even if they do not pursue a formal appeal or file a grievance. If an appeal is filed, it should be adjudicated in a timely manner and beneficiary enrollment in the DMP should be delayed until the appeal or grievance is resolved. In addition, beneficiaries should be made aware of the appeals and grievance process regularly, after enrolling in a DMP.

4.2. What are the advantages and disadvantages of providing for automatic escalation of beneficiary appeals related to a drug management program to an independent review entity?

APhA is not providing comment on this section.

5. Which types of enrollees should be exempt from being considered at-risk (hospice and long-term care enrollees are already excluded)?

5.1. What other types of exemptions should be deemed necessary by the Secretary (by frequently abused drug)?

At this time, APhA does not have input on additional exemptions but will provide feedback to subsequent CMS outreach.

6. How should terms and definitions be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse?

To prevent variable application by PDP sponsors and encourage consistency between DMPs, APhA suggests that CMS specify how terms and definition should be applied when determining whether an enrollee is an at-risk beneficiary for prescription drug abuse. APhA encourages CMS to convene stakeholder panels that include pharmacists, when considering how terms and definitions should be applied.

7. What information should be included in the notices sent to the at-risk beneficiary?

APhA is a long-time advocate for including patient preference in medical decision-making and educating patients. Thus, CMS should consider both the methods of communication and content when developing DMP regulations. APhA beleive that PDP sponsors should be required to utilize different avenues of communications so that patients are more likely to receive and review information relevant to the DMP. APhA is concerned that if notice is not received and reviewed, patient access to prescribers and pharmacies may be unnecessarily limited and the pharmacist-patient relationship disrupted.

In regards to content, the notice should describe a patient's options for both pharmacies and physicians. The regulations and notice should also make clear that the utmost deference will be given to a patient's preference. Notices should explain why a beneficiary has been selected for the plan, outline next steps and requirements, and opportunities for appeals. PDPs should develop and make available resources, such as call centers with translators, to help beneficiaries understand the DMP and their options. Notices should also recommend that beneficiaries notify their prescriber and pharmacy that they have been identified to be enrolled in a DMP, and include additional information about opioid abuse and misuse and treatment. PDPs should clearly articulate that the DMP's purpose is to help prevent addiction and improve care, and is not meant to be viewed as a diagnosis or as a punishment. As previously discussed, because APhA believes that Congress did not intend to limit a patient's choice to in-network prescribers or pharmacies, the notice should include accurate cost-sharing information regarding in-network and out-of-network choices.

8. Explanation of point-of-sale notices to enrollees for why the at-risk beneficiary is prohibited from receiving a prescription outside of the designated pharmacy.

It is critical that beneficiaries understand the purpose of a DMP and how it functions, because of the impact it can have on patient care and confusion that can result from unexpected denial of claims. Since beneficiaries receive many notices, APhA is concerned that mailed notices will go unnoticed and patients will first learn of a DMP when a claim is denied at a pharmacy. APhA urges CMS to require that notice, prior to a patient being locked-in, is given to a patient's primary prescriber(s) and pharmacy(ies), so that they may help notify the patient. APhA suggests that CMS consider giving the pharmacist limited authority to override the DMP and provide a partial or complete fill of the medication, if the pharmacist believes the patient was unaware of their enrollment in a DMP.

In addition, APhA encourages CMS to consider other forms of communication, such as electronic point-of-sale messages that indicate a patient's enrollment status. Point-of-sale notification to the pharmacist should also identify the pharmacy and prescriber to which the patient is committed through the DMP. Point-of-sale notices directed to patients should clearly indicate that the pharmacy and pharmacist is not responsible for the decision to enter a patient into a DMP, and a number specifically for DMP issues should be provided so that the pharmacist and/or patient can contact the plan to learn more. The PDPs should provide notices in a variety of languages and suitable for persons with disabilities, as well as language assistance services to enhance communication and patient understanding of the DMP.

9. The responsibility for the implementation of the program of the PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under section 1860D-4(c)(5) of the Act.

9.1. <u>What are the key responsibilities for Part D sponsors to develop an unbiased, neutral drug management program in Part D?</u>

When developing an unbiased, neutral drug management program, APhA suggests implementing measures that prevent or restrict Part D sponsors from viewing DMPs as a direct or indirect cost-saving opportunity. For example, DMPs should not be used as leverage when negotiating contracts as a means to drive beneficiary behavior to certain medication, physicians or pharmacies. APhA believes that decisions related to DMPs should be based on evidence supporting improved patient outcomes and reduced risk of addiction. In addition, when selecting a pharmacy and prescriber, the utmost deference should be given to patient choice. When a patient has not provided any selections, the sponsor should select a pharmacy using information in their claims data, such as the pharmacy where the patient regularly fills medications for chronic care or receives additional services, unless there is evidence of fraud or risk to the patient. APhA also recommends that the sponsor be required to provide a justification for their selection to enhance transparency and help patients decide whether to appeal the decision.

As noted above, APhA suggests DMP enrollment decisions be based on a combination of objective criteria and subjective review, including review by a pharmacist or other health care provider. While APhA anticipates that sponsors will use software to initially identify patients who are potentially at-risk, a health care practitioner can play a crucial role in reviewing records and contacting providers to better understand a patient's circumstances. Such efforts may limit "at-risk" false-positives, lower appeal rates and enhance patient care. APhA encourages PDP sponsors to work with a

variety of stakeholders, including pharmacists and beneficiaries, when developing implementation efforts and plans to limit bias and encourage neutrality.

10. Sharing claims data from Part A and B with Part D sponsors.

10.1. What data is needed, how could Part D sponsors use the data, and could the data be used to improve other areas of the program?

APhA supports the sharing of Medicare data to better evaluate the effectiveness and outcomes of its services and programs. Because Medicare is a segmented program, it is hard to evaluate the effectiveness of services and offerings because while it may be an expense in one area, such as Part D, a service can produce savings in another area, such as Part A or Part B. APhA has been an advocate for the value of pharmacists and their services and the impact their medication expertise can have on Medicare far beyond Medicare Part D. We encourage CMS to use Medicare data to assess program components across the care continuum. For example, in alignment with the Department of Health and Human Services' National Action Plan for Adverse Drug Event Prevention,[7] adverse drug events can be better understood if comprehensive data is measured and shared (e.g., linking in-patient and out-patient data).[8]

10.2. What are the concerns with providing this data to stand-alone Part D sponsors?

While APhA supports the use of data to better evaluate programs and services, we have concerns with the unidirectional sharing of data to PDPs. We believe CMS is in a better position to analyze the data because of their responsibility across the Medicare program.

10.3. What other data could Part D sponsors supply to CMS for the purpose of identifying patterns of prescription drug abuse?

Part D sponsors could supply information to CMS regarding patient utilization of pharmacist-provided services, such as medication-therapy management, to facilitate research regarding such services and their impact on patients' risk for abuse and misuse. We encourage CMS to use such data to study the value and impact of pharmacist-provided services across Medicare, as currently, research can be limited to Part D or is based on less than ideal sample sizes.

II. Additional Concerns and Comments

1. Clinical contact and collaborative care

APhA supports the provision of CARA requiring plans to monitor the medications of patients enrolled in a DMP. We believe medication management is an important method to prevent and treat prescription drug abuse, optimize medications and improve adherence, among other potential benefits. The law also requires PDP sponsors to contact relevant prescribers of an enrolled beneficiary regarding the appropriateness of prescribed medications.[9] As described above, pharmacists are medication

[7] Department of Health and Human Services, National Action Plan for Adverse Drug Event Prevention, available at: https://health.gov/hcq/pdfs/ade-action-plan-508c.pdf, last accessed: December 2, 2016.
[8] Department of Health and Human Services, National Action Plan for Adverse Drug Event Prevention, available at: https://health.gov/hcq/pdfs/ade-action-plan-508c.pdf, last accessed: December 2, 2016.
[9] P.L. 114-198. "With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

experts on the patient's health care team who already review medications for appropriateness. Accordingly, we believe that CMS should consider a similar requirement to contact the beneficiary's pharmacy(ies) as part of the PDP's monitoring efforts.

To enhance patient care, APhA supports better collaboration and communication between pharmacists and physicians to identify potential substance abuse problems, monitor high-risk patients, and improve patient understanding and education about their medications. Since DMPs tie a patient to a single pharmacy and single physician, this may be viewed as an opportunity to enhance communication and access to health information, and facilitate coordinated, team-based care and information sharing.

2. Enrollment period

APhA is concerned that the time when a beneficiary is sent the first notice to the time that they are locked-in to a pharmacy and prescriber may be too brief. As patients may have many options of prescriber and pharmacy, to make a better informed decisions, they may need to time to meet with pharmacists and prescribers in advance of making their selections. Thus, patients should have an opportunity to request additional time before making their pharmacy and prescriber choices.

3. Patient privacy

APhA is pleased that patient privacy has been addressed in the bill. 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. We encourage CMS to work with SAMHSA to develop guidelines to help facilitate information sharing between stakeholders involved in a DMP so that relevant patient information, such as prescriptions for buprenorphine, can be communicated to pharmacists. It is important that PDPs make prescriber and pharmacist compliance with these laws and regulations seamless and straightforward to improve patient care.

4. 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 law requires the Secretary to provide education only to enrollees and providers regarding the drug management program. APhA supports more robust and incentivized patient and provider education focused on prescription drug abuse beyond education limited to the DMP. Pharmacists are accessible providers who are able to provide services related to substance use disorder and treatment, and can play a more significant role in addressing this serious public health concern.

APhA provides a broad array of resources and educational offerings, including continuing pharmacy education (CPE) to help maintain professional competencies and states' CPE requirements for licensure. APhA's educational library consists of home-study CPE activities, live activities, training programs, and ambulatory care review and recertification activities. In addition, APhA's annual meetings contained CPE sessions devoted to pain management. Our monthly publication, *Pharmacy Today*, frequently covers prescription drug abuse, pain management and treatment, and has given it more attention in recent years due to the concern over opioid use and misuse in the U.S. In

addition, *Pharmacy Today* publishes a special pain section annually and offers CPE with many of its articles.

5. Electronic Prescribing

Although the law does not make clear how prescriptions will be communicated, APhA suggests the CMS encourage the use of electronic prescribing. 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.

Thank you for your leadership and work on addressing prescription drug abuse. We appreciate the inclusion of pharmacists in CMS's efforts to obtain stakeholder feedback and are willing to serve as a resource for the agency as it develops regulations and guidelines. If you have any questions please contact Jenna Ventresca, Associate Director, Health Policy, by email (jventresca@aphanet.org) or phone (202) 558-2727.

Sincerely,

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