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[Submitted electronically to www.WMOpioidSubmissions@mail.house.gov]

Rep. Kevin Brady
Chairman
Committee on Ways and Means

Richard Neal
Ranking Member
Committee on Ways and Means

Peter J. Roskam
Chairman
Committee on Ways and Means
Subcommittee on Health

Sander Levin
Ranking Member
Committee on Ways and Means
Subcommittee on Health

Re: Committee on Ways and Means and the Committee's Subcommittee on Health Request for Feedback Regarding Response to the Opioid Epidemic

Dear Chairman Brady, Chairman Roskam, Ranking Member Neal, and Ranking Member Levin:

The American Pharmacists Association (APhA) is pleased to respond to your request for feedback from stakeholders across the continuum of care to inform the development of future legislation. Founded in 1852 as the American Pharmaceutical Association, APhA 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 would like to provide feedback on the following topics included in the request.

I. Overprescribing/Data Tracking

1. Perverse Incentives in Medicare

Currently, pharmacists' services are not covered under Medicare Part B. As a result, beneficiaries' access to the health care practitioner with the most medication-related education and training is limited, and restricted mainly to services related only to the dispensing of medications. By not including pharmacists among other Part B providers whose services are covered, Medicare also effectively makes it more difficult for other members of the health care team and patients to work with pharmacists as a part of a coordinated, team-based approach to care.

2. Second-Fill Limits

As with first-fill limits, APhA has concerns that requirements to limit second-fills of opioids replaces practitioner judgement and counters efforts to utilize advancements in technology and science to optimize outcomes through individualized care. APhA cautions against the use of population-level data by payors to make broad policy determinations for individual patients. APhA is concerned each payor will use its own limited data to develop policies to create variable and inconsistent requirements not based on evidence. APhA believes patient care could not only be negatively impacted by the substance of these policies, which is based on limited data, but compliance with variable payor requirements is an administrative burden on providers that takes away time from patient care activities.

3. Tools to Prevent Opioid Abuse

As mentioned above, current federal statutes and corresponding regulations restrict Medicare beneficiaries' access to pharmacists' services. Pharmacists can help fight against the opioid epidemic by managing and optimizing the impact of medications, reviewing medications to help prevent overprescribing, tailoring care plans to patient needs, providing recommendations for non-opioid pain management alternatives, and educating patients regarding opioids. APhA urges the Ways and Means Committee to advance the *Pharmacy and Medically Underserved Areas Enhancement Act* (H.R. 592/ S. 109) to help prevent opioid abuse and misuse, increase treatment options and better manage patients' pain through pharmacist-provided care.

In addition, APhA encourages the Ways & Means Committee to consider legislative solutions that would facilitate nationwide integration of prescription drug monitoring programs (PDMPs). Although some states have data-sharing agreements in place, not all states share data with one another. Facilitating the national integration of PDMPs would help pharmacists better fulfill their corresponding responsibility by providing more information relevant to their dispensing decision.

APhA anticipates stakeholders will advocate for many different tools and policies in effort to combat the opioid epidemic. As the Ways & Means Committee considers these tools and policies, APhA emphasizes the importance of relying on evidence-based research and carefully considering the feedback from different stakeholders, especially from patients and providers. APhA recognizes the immediate need to address the opioid epidemic. However, it is crucial evaluation of efforts, particularly those recently implemented, occur to prevent unintended consequences or requiring burdensome, ineffective strategies.

4. Medication Therapy Management (MTM)

APhA strongly encourages the Committee to allow Part D beneficiaries at-risk of opioid use disorder to receive the benefit of pharmacists' services, either through some expansion of the MTM benefit or through another mechanism. Research has demonstrated the effectiveness of pharmacists providing care to chronic pain patients. In one study, adult patients with an appointment for chronic pain who were prescribed >50 morphine milligram equivalents

(MMEs)/day had charts reviewed by a pharmacist before each appointment and the pharmacist's recommendations were sent electronically to the provider before the appointment.[1] Results indicated the mean MMEs/day decreased by 14% with no change in pain scores and there were statistically significant improvements in multiple other secondary opioid safety outcomes. APhA uses this study as an example of a pharmacist-provided services that could help address the opioid epidemic but generally would not be covered under current Medicare Part D, or Part B, policies. APhA appreciates the Committee's request for feedback regarding MTM but believes the Committee should do more to expand access to pharmacist-provided care beyond only focusing on the Part D MTM program.

5. Electronic Prior Authorization

APhA supports efforts to increase use of electronic prior authorization as a means to help improve and streamline care and reduce administrative burdens. However, reduced administrative burdens associated with electronic prior authorization should not serve as justification to require or encourage more plans to implement additional prior authorization policies; any prior authorization requirements should be evidence-based and undergo regular review to identify therapies that no longer warrant prior authorization due to, for example, minimal impact on utilization or low prior authorization denial rates. In addition to making use of electronic prior authorization, APhA believes prior authorization programs can be enhanced through improved communication of prior authorization determinations and greater transparency, including better access for contracted health care providers and patients to prior authorization requirements, criteria, rationale, and program changes.

6. Prescription Drug Monitoring Programs

PDMPs were developed to help inform health care providers' clinical decision-making related to the prescribing and dispensing of controlled substances. While APhA does not have a position regarding CMS and other health care entities' access to PDMP data, we support the use of interprofessional advisory boards that include pharmacists, to coordinate collaborative efforts, including the compiling, analysis and use of PDMP data trends related to controlled substance misuse, abuse and/or fraud. APhA would need to understand the purpose of sharing PDMP data with CMS and other entities, as well as the type or level of data that would be shared before commenting on this area.

II. Communication and Education

1. Beneficiary Notifications

APhA agrees patient education must be enhanced to help curb the opioid epidemic. Currently, FDA has taken significant steps to help improve patient awareness, including use of black box warnings which are visible to patients. While these warnings are helpful, it is important that patients are also made aware of alternative treatment options that are covered by payers. Insurer involvement in education and communication related to opioids and treatment

[1] Cox, N., Tak, C.R., Cochella, S.E., Leishman E., & Gunning, K. (2018). Impact of Pharmacist Previsit Input to Providers on Chronic Opioid Prescribing Safety. *J Am Board Fam Med,* 31(1): 15-112.

options is critical because providers informing patients of alternative treatment options will be of little value to those who are unable to receive the care because it is not covered by their insurer.

Clearly, pharmacists also serve an important role in educating patients, particularly because they are the most accessible health care practitioner with 89% of Americans living within five miles of a community pharmacy. Although pharmacists currently spend time educating patients regarding their medications, policy changes to provide more time and reimbursement to pharmacists for necessary, comprehensive education is crucial.

2. Prescriber Notification and Education

APhA believes education for prescribers and other health care professionals, such as pharmacists, is best provided by associations and professional organizations that can tailor education to intra- and inter-profession needs. In addition, FDA's newly finalized education blueprint[2] aims to educate health care professionals by identifying the components of an effective treatment plan and encourages team-based care. APhA believes such tools and education can help guide and better inform care provided by health care practitioners without dictating specific thresholds or stigmatizing health care professionals operating outside norms.

As the Committee looks for effective ways to notify providers regarding outlier prescribing practices, we could suggest it look at successful practices which consider factors beyond prescribing patterns in a PDMP. For example, the Department of Veterans Affairs utilizes an Opioid Therapy Risk Report (OTRR), which is a "patient-focused, actionable, and provider-specific report." This tool helps inform prescribing decisions by considering different factors, including patient-specific information and perspectives of other members of the care team, such as pharmacists.[3,4]

III. Treatment

1. Opioid Treatment Programs (OTPs) and Medication Assisted Treatment (MAT)

As the health care provider patients usually see last before receiving their medications, pharmacists can provide valuable information and services to patients regarding appropriate medication use. Research has demonstrated pharmacists can help improve outcomes by screening patients and facilitating an intervention.[5,6,7] Our members are interested in helping

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[2] Food and Drug Administration (January 2018). FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain, available at: https://www.regulations.gov/document?D=FDA-2017-D-2497-0683

[3] Department of Veterans Affairs, VHA Pain Management, Opioid Therapy Risk Report, available at: https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp

[4] *See* Department of Veterans Affairs, VA Accelerates Deployment of Nationwide Opioid Therapy Tool, available at: https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2681

[5] *See* Marra, C.A., Cibere, J., Grubisic, M., Grindrod, K.A., Gastonguay, L., Thomas, J.M., Embley, P., Colley, L., Tsuyuki, R.T., Khan, K.M. & Esdaile, J.M. (2012). Pharmacist-initiated intervention trial in osteoarthritis: A multidisciplinary intervention for knee osteoarthritis, *Osteoarthritis,* 42(12), 1837-1845.

[6] *See* Rosser, S., Frede, S., Conrad, W.F. & Heaton, P.C. (2013). Development, implementation, and evaluation of a pharmacist-conducted screening program for depression, *Journal of the American Pharmacists Association,* 53(1), 22-29.

[7] *See* Peterson, J.F., Kripalani, S., Danciu, I,m Harrell, D. Marvanovam M., Mixon, A.S., Rodriguez, C. & Powers, J.S. (2014). Electronic surveillance and pharmacist intervention for vulnerable older inpatients on high-risk medication regimens, *American Geriatrics Society,* 62(11), 2148-2152.

patients who may be suffering from substance use disorders (SUD). However, in many areas, treatment services or information about treatment options is not readily available. Therefore, APhA appreciates the Committee's help in identifying ways to increase patients' access to and information about SUD treatment, including considering alternative treatment and reimbursement models.

In addition to our request for the Committee's support for the *Pharmacy and Medically Underserved Areas Enhancement Act* (S. 109 / H.R. 592), APhA urges the Committee to advance legislation that enables pharmacists to obtain a Drug Addiction and Treatment Act of 2000 (DATA 2000) waiver. Although pharmacists in some states can enter into collaborative practice agreements and other like arrangements with other health care practitioners to initiate naltrexone, a schedule II medication, the same cannot be done for buprenorphine, a schedule III medication. Consequently, patient access to buprenorphine can be more difficult than naltrexone because the DATA 2000 limits the types of providers that can prescribe buprenorphine to physicians, nurse practitioners (NPs) and physician assistants (PAs). Although pharmacists, NPs, and PAs are considered "mid-level practitioners" by DEA,[8] pharmacists, who are authorized under some states' scope of practice laws to prescribe schedule III controlled substances, are unable to prescribe buprenorphine, a schedule III controlled substance, under DATA 2000 because they are not enumerated in the law alongside PAs and NPs as an eligible provider.

Despite the aforementioned legislative barriers, pharmacists are playing a growing role in MAT and other SUD treatment services as part of team-based care. For example, in Kentucky, a protocol to allow a pharmacist to initiate and administer naltrexone, a schedule II drug used to treat SUDs, was recently approved by the Board of Pharmacy.[9] Pharmacists in several other states and systems are bridging the gaps in care by serving as sites for naltrexone administration, joining care teams, and entering into collaborative practice agreements[10] to expand patient access to certain MAT services (other than prescribing), including Baltimore residents, American

[8] Drug Enforcement Agency, Mid-level Practitioners Authorization by State, available at: https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf, last accessed: March 9, 2018.
[9] *See* Kentucky Board of Pharmacy, Opioid Use Disorder Naltrexone Therapy Protocol, available at: https://pharmacy.ky.gov/Board%20Authorized%20Protocols/Opioid%20Use%20Disorder%20Protocol%20Approved%201%2017%202018.pdf
[10] A collaborative practice agreement creates a formal practice relationship between pharmacists and prescribers. CPAs identify what functions – in addition to the pharmacist's scope of practice – are delegated to the pharmacist by the collaborating prescriber, under negotiated conditions outlined in the agreements. These patient care services can include modification of current drug therapy, initiation of new therapy, ordering of labs, and/or physical assessment of the patient. For more information, *see* American Pharmacists Association, Collaborative practice agreements: NASPA workgroup releases recommendations, available at: http://www.pharmacist.com/article/collaborative-practice-agreements-naspa-workgroup-releases-recommendations

Indians and Alaska Natives, among many others in need.[11,12,13,14,15,16,17] However, admittedly, pharmacists' potential to optimize the benefits of different treatment programs and services is unnecessarily limited by current statutory barriers. Pharmacists are well-suited to help meet SUD treatment needs but legislative changes are needed to further enhance patient access. Accordingly, APhA urges the Ways and Means Committee to support and advance the *Expanded Access to Opioid Abuse Treatment Act of 2017 (H.R. 3991)*[18] and the *Pharmacy and Medically Underserved Areas Enhancement Act* (H.R. 592).

2. Reimbursement

As reiterated above, pharmacists are not reimbursed under Medicare Part B for their patient care services. APhA urges the Ways and Means Committee to prioritize passing the *Pharmacy and Medically Underserved Areas Enhancement Act (S. 109 / H.R. 592)* to advance this commonsense policy. America is in the midst of an opioid epidemic. Therefore, it is crucial that patients and other health care providers can utilize the medication experts on a care team as efforts to enhance prevention, patient education, prescribing, tapering, and treatment of substance use disorder are implemented.

3. Alternative Options for the Treatment of Pain

As stated previously, pharmacists have been filling gaps in care related to prevention, pain treatment and opioid use disorder. Currently, 48 states allow pharmacists to enter into a collaborative practice agreement with a prescriber to obtain authority to perform a broader scope services. While APhA supports the Ways and Means Committee efforts to identify alternative treatment options, it is important that attention also be paid to methods to optimize treatments that are currently available, including those involving medications. Patients will likely continue to use medications as part of their pain treatment plan, in which pharmacist-provided care services would remain a critical component.

Lastly, APhA requests the Committee when developing policies to weigh the benefit against any cost or burden, including negative impacts to patients. APhA notes that well-intentioned policies can negatively impact patient care. For example, prior authorization policies

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[11] DiPaula BA, Menachery E. Physician-Pharmacist Collaborative Care Model for Buprenorphine-maintained Opioid-dependent Patients. J Am Pharm Assoc. 2015; 55: 187-192.
[12] Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. Journal of the American Pharmacists Association. 57 (2017), S135-S140.
[13] Lagisetty, P., Klasa, K., Bush, C., Heisler, M., Chopra, V. & Bohnert, A. Primary care models for treating opioid use disorders: What actually works? A systematic review. PLOS One, https://doi.org/10.1371/journal.pone.0186315.
[14] Gilmore Wilson, C. & Fagan, B. Providing Office-Based Treatment of Opioid Use Disorder. Annals of Family Medicine. 2017; 15(5).
[15] Grgas, M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program, Mental Health Clinicam, 2013, 3(6), 290-291.
[16] Suzuki et al., Implementation of a collaborative care management program with buprenorphine in primary care: A comparison between opioid-dependent patients and chronic pain patients using opioids non-medically, Journal of Opioid Management, 10(3), 159-168.
[17] McCarty et al., Training rural practitioners to use buprenorphine: Using The Change Book to facilitate technology transfer, Journal of Substance Abuse Treatment, 2004, 26(3); 203-8.
[18] The *Expanded Access to Opioid Abuse Treatment Act of 2017 (H.R. 3991)* makes pharmacists eligible to obtain a Drug Addiction and Treatment Act of 2000 (DATA) waiver. Practitioners with a DATA waiver may prescribe schedule III medications, such as buprenorphine, for substance use disorder treatment in settings other than an opioid treatment program.

which can be viewed as an important step in preventing the overutilization, misuse or abuse of opioids, force pharmacists to spend time on the phone with payers and providers to obtain an appropriate medication for a patient, as opposed to time with the patient. Therefore, APhA reiterates the need to advance evidence-based policies, evaluate implemented policies' effectiveness in achieving intended goals, and monitor for unintended consequences.

Thank you for the opportunity to provide comments on House Ways & Means Committee. We support the Committee's ongoing efforts to continue to fight the opioid epidemic. If you have any questions or require additional information, please contact Alicia Kerry Mica, at amica@aphanet.org by phone at (202) 429-7507.

Sincerely,

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