



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

APhA

February 11, 2016

The Honorable Paul D. Tonko
2463 Rayburn House Office Building
Washington, DC 20515

RE: The Recovery Enhancement for Addiction Treatment Act (H.R.2536) and the Opioid Addiction Treatment Modernization Act (H.R.2872)

Dear Congressman Tonko:

On behalf of the American Pharmacists Association (APhA) we appreciate the opportunity to provide input on H.R. 2536, the Recovery Enhancement for Addiction Treatment Act (TREAT Act) and H.R. 2872, the Opioid Addiction Treatment Modernization Act. 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, physician office practices, managed care organizations, hospice settings, and the uniformed services.

APhA supports medication-assisted treatment as an important component of a multipronged approach to addressing abuse of opioid medications. APhA recognizes that because opioid medications are widely prescribed, the risk of misuse, abuse, addiction, overdose and mortality may be greater, and a transition to medication-assisted treatment could contribute to the safe use of opioid containing products.

Pharmacists are the medication experts and health care professional many patients see the most and with nearly 95 percent of Americans living within five miles of a pharmacy, APhA believes pharmacists are often an underutilized health care resource. While APhA supports legislative, regulatory, and private sector efforts that include pharmacists in identifying solutions to opioid abuse, misuse and treatment, we also believe it is important to balance those efforts with the legitimate needs of the millions of patients living with pain. Below, APhA raises issues and proposes recommendations to consider when evaluating legislation intending to provide access to medication addicted therapy (H.R. 2536) and modernize the treatment of opioid addiction (H.R. 2872):

A. The Recovery Enhancement for Addiction Treatment Act (TREAT Act) (H.R.2536)

While APhA supports the intent of the TREAT Act -- to provide access to medication-assisted therapy for opioid addiction, we have some recommendations to strengthen it.

Pharmacists should be included as a "qualifying practitioner." The TREAT Act intends to increase the access to medication-assisted therapy that qualifies under the Drug Addiction Treatment Act of 2000 (DATA Act) requirements. The legislation increases the types of

providers and the number of patients allowed under the DATA waiver. APhA recommends expanding the definition of “qualifying practitioner” in Sec. 4 to include pharmacists in addition to nurse practitioners and physician assistants.

Currently 48 states and the District of Columbia allow pharmacists to enter into collaborative practice agreements with physicians and other prescribers to provide advanced care to patients. There are states that currently allow pharmacists to prescribe Schedule III, IV and V; therefore, the TREAT Act represents a valuable opportunity for Congress to build from work already accomplished at the state level to expand access to medication assisted treatment through pharmacists who have a license to prescribe schedule III, IV, and V medications for pain per their state scope of practice.

Considering the TREAT Act’s goal to expand access, it is of utmost importance to remember that pharmacists are the most accessible health care professionals whose expertise is in pharmaceuticals and patient care. As the Food & Drug Administration noted¹ specifically in relation to suboxone and subutex, “pharmacists will play a role in the delivery of opiate addiction treatment” which may include dispensing medication, patient counseling, and confirming that a prescription is legitimately prescribed. Additionally, SAMSHA’s 2015 [Federal Guidelines for Opioid Treatment Programs](#) considers pharmacists in a similar light to nurse practitioners and physician assistants, by stating “Some aspects of medication-assisted treatment services may be provided by an authorized health care professional other than a physician such as an advanced practice nurse, physician assistant, or advanced-practice pharmacist.” Given the opportunity to further advance the goals of the TREAT Act and the potential increased access to treatment, APhA strongly urges the legislation to include pharmacists as qualified professionals in addition to nurse practitioners and physician assistants.

Prescribing Cap. APhA supports increasing the prescribing cap as described in the TREAT Act. Recent research shows that 48 states and the District of Columbia have opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates.² Although only 27.5 percent of physicians have increased their patient limit capacity to 100, the finding that 82 percent of opioid treatment programs are operating at capacity clearly indicates the need for additional treatment options.³ APhA believes that by increasing the prescribing cap, physicians and healthcare professionals treating patients with buprenorphine will be able reach more patients.

Information Exchange. APhA supports expanding access to medication assisted therapy by increasing the limit on the number of patients a practitioner can treat under the DATA waiver. However, an undesirable side-effect of increasing the patient limits may be an increased risk of diversion, abuse, and misuse, in addition to communication errors. APhA would like to highlight the pharmacists’ role in providing quality care and preventing diversion. For pharmacists to assess appropriateness of prescribed medications and to assist in the prevention of diversion, it is essential that pharmacists have access to the patient’s health information. Consequently, it is

¹ 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).

² Jones, Christopher M., Campopiano, M., Baldwin, G. & McCance-Katz, Elinore. (2015). National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment, *American Journal of Public Health*, 105(8), e55-e63.

³ Jones, Christopher M., Campopiano, M., Baldwin, G. & McCance-Katz, Elinore. (2015). National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment, *American Journal of Public Health*, 105(8), e55-e63, e59.

critical for pharmacists to be able to exchange pertinent clinical information using health information technologies. APhA suggests that any implementation of the legislation address information exchange between healthcare practitioners, including pharmacists involved in the patient's care.

Prescription Drug Monitoring Programs. APhA applauds the TREAT Act's requirement that qualifying practitioners fully participate in their State's Prescription Drug Monitoring Program (PDMP), but is concerned that practitioners in Missouri, which doesn't have a PDMP will be unable to satisfy the requirements under the legislation, thus being unintentionally excluded from its benefits. As the legislation is currently drafted, it is unclear whether qualifying practitioners in states without PDMPs would be able to satisfy the requirement that they fully participate, "pursuant to applicable state guidelines." Although beyond the scope of this legislation, APhA supports nationwide integration of PDMPs that incorporate federal, state, and territory databases for the purpose of providing health care professionals with accurate and real-time information to assist in clinical decision making when providing patient care services related to controlled substances.

B. Opioid Addiction Treatment Modernization Act (H.R.2872)

The goal of the Opioid Addiction Treatment Modernization Act (H.R.2872) is to increase awareness and access to all treatment options for opioid addiction, overdose reversal, and relapse prevention. APhA supports appropriate initial and ongoing training on opioid addiction treatment modalities, and the need for a variety of options for health care practitioners to meet training requirements. APhA also supports improving access to treatment providers to address this important public health epidemic. To that end, we request that additional healthcare practitioners with appropriate training be considered to improve access to these treatments.

Signed Written Agreements. Patient involvement in and understanding of their opioid addiction treatment program, both benefits and risks, is critical. APhA believes there should be more clarity regarding how individualized treatment plans will be communicated to other members of the care team including pharmacists in order to facilitate coordinated care.

Guidelines. APhA supports guidelines that are developed transparently, with meaningful input from a variety of stakeholders, including pharmacists. Under this legislation, the Secretary must update the treatment improvement protocol in consultation with government officials and "other substance abuse disorder professionals". APhA believes it is important that pharmacists, the medication experts on the patient's health care team, be included in these medication-related discussions and guidelines. In addition, such an update should be part of a formal rulemaking to provide for transparency and stakeholder input.

Thank you for the opportunity to provide comments on the TREAT Act and the Opioid Addiction Treatment Modernization Act. As you move forward, please do not hesitate to use APhA as resource. If you have any questions or require additional information, please contact Michael Spira, Senior Lobbyist, Government Affairs at mspira@aphanet.org or by phone at (202) 429-7507.

Sincerely,



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

cc: Stacie Maass, BSPHarm, JD, Senior Vice President, Pharmacy Practice and Government
Affairs
Jenna Ventresca, JD, Associate Director of Health Policy