

February 16, 2018

The Honorable Orrin Hatch  
Chairman  
Committee on Finance  
Washington, DC 20510

The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments in response to your February 2, 2018, request for input on potential policy recommendations to address the opioid crisis. We applaud the Committee's emphasis on a holistic approach to preventing substance use disorders, improving the treatment of pain, and breaking the cycle of addiction. PhRMA represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA and its companies are leading the way in the search for new cures, with members investing an estimated \$65.5 billion in 2016 in the discovery and development of new medicines.

We share the Committee's commitment to supporting appropriate prescribing that reflects evidence-based clinical considerations. PhRMA and its members look forward to working with the you and other stakeholders to seek a balanced approach to opioid use that acknowledges and supports the legitimate medical need for opioids in some patients, and the need to reduce the risk of diversion, misuse, abuse, and addiction.

We support a range of public policies to address the opioid crisis that is impacting individuals and their families, first responders, and communities across the country, including policies to:

- Foster the development of medical advances to address the crisis, including new treatment options for pain, such as non-opioid analgesics, medication-assisted treatments (MAT) for addiction, and medications to reverse opioid overdoses.
- Provide physicians and other prescribers with the appropriate training and tools to ensure they can meet their patients' legitimate medical needs while reducing the potential for abuse.
- Address coverage and access barriers to abuse-deterrent formulations (ADFs) that have potential to meaningfully deter abuse, non-opioid pain medications, and medications to treat opioid use disorders and overdose.

The Honorable Orrin Hatch  
The Honorable Ron Wyden  
February 16, 2018  
Page 2 of 4

- Ensure sufficient tools and capacity across federal agencies to combat diversion, fraud, and abuse.

PhRMA offers the following recommendations regarding how the Center for Medicare & Medicaid Services (CMS) can address the opioid crisis.

- To promote evidence-based care, the U.S. Department of Health and Human Services (HHS) agencies, notably CMS and Centers for Disease Control and Prevention (CDC) should engage with state medical societies, and state licensing boards, and various medical subspecialties to support the identification of and implementation of core competencies in preventing and managing prescription drug abuse in the curricula for medical professionals. The development of core competencies will help ensure that medical students will, by the time they graduate, have learned to evaluate pain, risk of addiction, and pharmacologic and non-pharmacologic options for pain management; recognize prescription drug misuse; develop patient-centered addiction treatment plans; identify a case of opioid overdose; and correctly use opioid overdose reversal agents.<sup>i</sup> CMS in collaboration with other federal agencies, including the Drug Enforcement Administration (DEA), should consider developing and implementing minimum medical education and training requirements as a condition of state or DEA licensure. HHS should undertake a systematic review of current continuing medical education requirements in the more than 20 states which have such requirements to inform the development of best practices and core competencies to be incorporated into effective prescriber education programs.
- The Committee should consider whether there is sufficient coordination between CMS, DEA, and state agencies to ensure timely action by CMS to deny or revoke enrollment for physicians and other eligible health care professionals who prescribe in Medicare if his or her DEA certificate of registration is suspended or revoked, or if the applicable licensing or administrative body for any state in which the physician or other eligible health care professional's practices suspends or revokes the ability to prescribe drugs.
- CMS should engage with the DEA to assess whether as a condition of DEA certification, prescribers should be required to use Prescription Drug Monitoring Programs, which have been demonstrated to be effective in identifying potential doctor shopping and informing individualized pain management plans. Similarly, CMS should engage with prescribers regarding what type of data on their own prescribing practice patterns and broader prescribing patterns would be most useful to promote appropriate prescribing.
- Given CMS plays a key role in developing and disseminating educational materials and guidance for beneficiaries, we urge that CMS consider how prescription information inserts and explanations of benefits can be expanded to better address appropriate use, misuse, and abuse, secure storage, and appropriate disposal of unused medicines.

The Honorable Orrin Hatch  
The Honorable Ron Wyden  
February 16, 2018  
Page 3 of 4

- PhRMA supports CMS' recent proposal to ensure that no more than 7 days of an opioid are prescribed for the treatment of acute pain, with appropriate exceptions. However, CMS also seeks to implement expansive limits on opioids for the treatment of chronic pain without sufficient efforts in place to ensure that appropriate coverage and access is provided to non-opioid analgesics or non-pharmacological alternative treatment options. Increased emphasis should be placed on exploring additional incentives to ensure the development and implementation of comprehensive plans for the treatment of chronic pain and appropriate monitoring and adjustments as needed.
- Additional coordination and emphasis across federal agencies is urgently needed to further develop the evidence base needed to determine effective treatment options for different populations and different types of pain. Increased coordination with other HHS agencies is necessary to ensure not just coordination of effort but also to prevent duplication of effort in expanding the evidence base to inform coverage determinants of alternative therapies.
- Given MATs for substance use disorders including addiction in combination with counseling and behavioral therapies have been found to be effective in reducing opioid use disorder, CMS should prioritize addressing coverage and access barriers to these treatments. PhRMA is pleased to see CMS is taking steps to limit the use of prior authorization requirements for buprenorphine products in Part D. Additionally, CMS should expand engagement with the states to support innovative approaches to providing the full continuum of care by introducing service, payment, and delivery reforms to improve access to and quality of care for those with substance use disorders and addiction. CMS should assess whether additional regulatory changes are needed in Medicaid to further encourage the number of qualified prescribers of buprenorphine and increase access to all forms of MATs as well as to opioid overdose reversal agents. CMS should assess whether formulary changes are needed across Medicare and Medicaid to expand coverage and access to naloxone, a life-saving opioid overdose reversal agent; all forms of MATs; and non-opioid analgesics. CMS should continue to engage with state Medicaid programs to promote naloxone access, including tools to support co-prescribing of naloxone for patients whose opioid use reaches certain thresholds of dose, frequency, and/or duration.
- PhRMA has ongoing concerns that the Center for Medicare and Medicaid Innovation (CMMI) has overstepped its mission and authority by proposing to make near nationwide, mandatory changes to Medicare and jeopardizing quality and access to care for beneficiaries, and therefore appropriate guardrails are needed. We also believe CMMI's substantial resources could be leveraged to explore new payment and delivery interventions to address opioid use disorder and other substance abuse disorders in the Medicare and Medicaid populations. With appropriate guardrails in place, CMMI could explore coordinated care models to help improve care among the 8.2 million adults in the U.S. with both a substance use disorder and a mental illness.<sup>ii</sup> Unfortunately, just 9.1% of adults with co-occurring substance use and mental disorders received care for both

The Honorable Orrin Hatch  
The Honorable Ron Wyden  
February 16, 2018  
Page 4 of 4

disorders in the past year, highlighting a significant unmet need and opportunity to improve care among these patients.<sup>iii</sup> We would urge that CMMI resources be used to (1) explore the use of technology and telemedicine services to expand access to addiction treatment and recovery support to underserved areas and (2) explore the use of coordinated care models for chronic pain patients in rural and medically underserved areas, including use of technology and telemedicine approaches to expand the reach of available services. We also continue to support the Administration's efforts to create a set of principles for CMMI that establish a more transparent process for developing and testing new models, and ensure that models are first tested on a small-scale, voluntary basis, and that permanent policy changes are left to Congress.

- Existing efforts that have the potential to further promote evidence-based care that the Committee should consider include:
  - HHS' task force efforts to develop and disseminate best practices in pain management;
  - CDC's efforts to help states identify, implement, and assess evidence-based strategies to address the opioid crisis in the states; and
  - The National Governors' Association's efforts to develop a roadmap to addressing the crisis in the states.

PhRMA recognizes the seriousness of the current opioid crisis and applauds the Committee's focus to identify meaningful steps that can be taken to address the substantial public health concerns at issue. PhRMA appreciates the Committee's leadership and focus on solutions to addressing this public health crisis. We look forward to a continued dialogue with the Committee and other stakeholders on policies to support appropriate prescribing and to prevent misuse, abuse, and addiction.

Sincerely,



Stephen J. Uhl  
President and CEO

---

<sup>i</sup> **Massachusetts Department of Public Health Governor's Medical Education Working Group on Prescription Drug Misuse.** Medical education core competencies for the prevention and management of prescription drug misuse. November 2015. Available at: <http://www.mass.gov/eohhs/docs/dph/stop-addiction/governors-medical-education-working-group-core-competencies.pdf>

<sup>ii</sup> Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Health Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration

<sup>iii</sup> B Han, WM Compton, C Blanco, and LJ Colpe, Prevalence, Treatment, and Unmet Treatment Needs of US Adults with Mental Health and Substance Use Disorders, *Health Affairs* 36, No. 10 (2017): 1739-1747.