

February 15, 2018

Chairman Orrin Hatch  
Senate Committee on Finance  
219 Senate Dirksen Office Building  
Washington, DC 20510

Ranking Member Ron Wyden  
Senate Committee on Finance  
219 Senate Dirksen Office Building  
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

Thank you for the opportunity to respond to your inquiry related to the opioid epidemic. We appreciate your leadership on this public health crisis and your willingness to seek input from a wide-range of stakeholders.

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors, the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The medications that HDA members deliver are prescribed by physicians, dentists, veterinarians, and other authorized practitioners; administered in hospitals, clinics, and long-term care facilities; and dispensed by pharmacies. Federal and state requirements impact every step of this process.

Distributors do not manufacture, prescribe, dispense, or drive demand for medicines. Instead, our industry's primary mission is to operate the safest and most secure and efficient supply chain in the world. In this effort, pharmaceutical distributors work closely with supply chain partners and numerous regulatory agencies, most notably the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), as well as regulatory authorities in every state. Primary pharmaceutical distributors have invested heavily in information technology systems to help better flag suspicious ordering patterns, and have enhanced overall "know your customer" due diligence efforts to further prevent the abuse, misuse and potential diversion of controlled substances.

HDA and its members recognize our role and responsibility to advance meaningful initiatives to address the serious, complex issues raised by the opioid abuse crisis. HDA is participating in federal regulatory initiatives to identify and implement solutions on an ongoing basis, including conversations led by both the Centers for Medicare and Medicaid Services (CMS) and FDA. We agree with the recent recommendations made by the President's Commission on Combating Drug Addiction and the Opioid Crisis<sup>1</sup>, as well as the National Academies of Science,

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<sup>1</sup> [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-15-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf)  
(accessed 2/8/18).

Engineering, and Medicine<sup>2</sup> that the challenges presented by prescription drug abuse and diversion call for a collaborative effort by insurers, healthcare providers, pharmacists, distributors, manufacturers and state and federal authorities. HDA also applauds Congress's commitment to finding and implementing solutions to the opioid abuse epidemic. Further, HDA members endorse a comprehensive set of policies<sup>3</sup> to prevent opioid abuse and misuse, promote clinically appropriate guidelines and recommendations, and establish a path forward at the state and federal level for advancing these changes.

Your letter raises important questions for consideration. Because HDA members are not reimbursed by Medicare or Medicaid and do not interact with patients who are covered under those programs, other entities may have more specific expertise on some of the issues you raise. Nonetheless, HDA can provide perspectives on several of your questions:

**Question #4 – Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUGs while promoting the efficient access to appropriate prescriptions?**

HDA believes that it is important to facilitate greater use of securely designed electronic prescribing protocols for controlled substances (EPCS). Usage of EPCS can help limit counterfeit prescriptions and can enhance prescription drug monitoring (PDMP) data. Currently, nearly 90 percent of retail pharmacies are equipped to receive electronic prescriptions, but only 20 percent of prescribers can issue electronic prescriptions for controlled substances, meaning that the overwhelming majority of controlled substance prescriptions are still issued using paper prescriptions.<sup>4</sup> HDA previously has encouraged the Drug Enforcement Administration to streamline the EPCS process and address physician work-flow concerns about its use, to encourage adoption. EPCS can be an important tool in stemming opioid misuse and abuse by helping to reduce prescription fraud and protecting against “doctor shopping.”

**Question #5 – How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?**

HDA supports the FDA's proposal to work with prescriber groups that would develop expert guidelines on proper prescribing by indication. We note that this approach has been supported by numerous practitioner organizations, including the American College of Emergency Physicians<sup>5</sup> and the American Society of Regional Anesthesia and Pain Medicine.<sup>6</sup> We understand that some related efforts are underway.

In developing expert guidelines, prescriber groups can account for specifics of the practice, and can work in collaboration with state medical boards and other entities that govern the practice of medicine. While the Centers for Disease Control (CDC) have developed a necessary and useful *Guideline for Prescribing Opioids for Chronic Pain*, that guideline is intended for the primary

<sup>2</sup> [http://nationalacademies.org/hmd/reports/2017/pain-management-and-the-opioid-epidemic.aspx?\\_ga=2.20254911.681758302.1511290384-1216471816.1511290384](http://nationalacademies.org/hmd/reports/2017/pain-management-and-the-opioid-epidemic.aspx?_ga=2.20254911.681758302.1511290384-1216471816.1511290384) (accessed 2/8/18).

<sup>3</sup> <https://hda.org/~media/pdfs/government-affairs/hda-practical-solutions-final.ashx> (accessed 11/21/17).

<sup>4</sup> <http://surescripts.com/news-center/national-progress-report-2016/#/EPCS-readiness-by-state> (accessed 2/9/18).

<sup>5</sup> [https://www.acep.org/uploadedFiles/ACEP/Advocacy/federal\\_issues/Emergency %20Medicine%20Opioid%20Principles.pdf](https://www.acep.org/uploadedFiles/ACEP/Advocacy/federal_issues/Emergency%20Medicine%20Opioid%20Principles.pdf) (accessed 2/8/18).

<sup>6</sup> <https://www.regulations.gov/document?D=FDA-2017-N-5608-0348> (accessed 2/8/18).

care setting. Where that guideline uses vague language like “major surgery”—necessary because of its broad applicability—prescriber groups can delve deeper into details and can address both pharmacologic and nonpharmacologic treatments appropriate to specific situations.

Ideally, prescriber groups and their partners will develop plans to disseminate their newly developed guidelines and any additional educational materials. CMS’s assistance in dissemination may be useful. As the National Academies described, “Prescribing guidelines may be able to improve provider prescribing behavior but may be most effective when accompanied by provider education and other measures designed to facilitate implementation.”<sup>7</sup> The sharing and uptake of such information still presents challenges. Despite the attention to the opioid prescribing guideline issued by the CDC last year, not all prescribers are aware of it, according to the *Final Report* issued by the President’s Commission on Combating Drug Addiction and the Opioid Crisis.

Another critical component of education is that of patient education. As the President’s Commission described in its *Final Report*, “Patients are often ill-informed about the risks of taking opioid analgesics and, therefore, are not able to balance the potential benefits of opioid analgesics with the associated risks.”<sup>8</sup> HDA supports the Commission’s recommendation for a national prevention strategy focused on sharing “prevention messages specific to opioids, to include patient and family education on what opioids are, the hazards of opioids, safeguarding of prescription medications, and disposing of unused pills.”<sup>9</sup>

Additionally, as the President’s Commission recommended, HDA agrees that there is an opportunity to increase disposal efforts and to educate providers and patients about proper disposal. According to the *Final Report*, “The National Prescription Drug Take Back Day, organized by the DEA with state and local partners, provides communities a safe and convenient way to dispose of their unneeded prescription drugs, while educating the public about the dangers for the public of abuse and misuse. Providers wrote nearly a quarter of a billion opioid prescriptions in 2013. This is enough for every American adult to have a bottle of prescription opioids. Many misusers of prescription drugs have indicated they received prescriptions from their family and friends’ medicine cabinets.”<sup>10</sup> HDA supports national take back days and other methods of appropriate disposal.

HDA also supports greater education of patients about their ability to request a “partial fill” of their opioid prescription. Partial fill provisions allow pharmacists to dispense part of the prescription on one day and, if the patient or prescriber requests, the remaining prescription at a later time. Partial fill provisions mitigate the likelihood that a patient would have more medication than he or she needs, but still can receive the entire amount if necessary. This also provides the pharmacist and patients with additional opportunities to interact, allowing the patient to ask any new questions and the pharmacist to provide advice and to detect signs of misuse.

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<sup>7</sup> National Academies, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* 12 (2017).

<sup>8</sup> President’s Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report* 49 (2017).

<sup>9</sup> *Id.* at 46.

<sup>10</sup> [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-15-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf) (Accessed 2/8/18).

Recently, HDA initiated efforts to help fill this patient education gap. HDA is pleased to participate and provide the initial funding to support the formation of Allied Against Opioid Abuse (AAOA). AAOA is a collaborative effort that brings together key stakeholders, including HDA, the Caregiver Action Network, Mental Health America, National Alliance of State Pharmacy Associations, National Council on Patient Information and Education and the PA Foundation, to engage providers, pharmacists and the public in education about the rights, risks and responsibilities associated with prescription opioids.

**Question #6 – What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?**

As you may be aware, all 50 states and the District of Columbia have authorized the operation of a PDMP. A 2015 report from the Johns Hopkins Bloomberg School of Public Health found that prescribers checked PDMP data only 14 percent of the time before prescribing opioids.<sup>11</sup> We are hopeful that the usage rate has increased over the past two years. The most effective PDMPs are those that have been incorporated into the regular prescribing and dispensing practices of doctors and pharmacists. HDA believes that more widespread adoption should be encouraged. To the extent that prescribers would benefit from continuing education in accessing, interpreting and applying PDMP data, HDA supports such training. Improvements in PDMPs that allow for easier interpretation of patient data, better alignment with electronic health records and streamlining of data updates also could increase usage and utility.

Distributors also support improving the connectivity of PDMP databases across state lines and between prescribing and dispensing locations. Increasingly connected and easily accessible information will assist prescribers and pharmacists in identifying patients involved in drug abuse and misuse, even if they travel to different states to fill prescriptions. Access to this information can prevent those patients from attaining dangerous drugs and help move them into appropriate treatment programs. In addition, HDA supports efforts to provide pharmacists with tools to identify potential instances of fraud or opioid misuse to protect patient safety.

Distributors are committed to helping to develop solutions to ensure patients have access to safe, effective treatments while also working toward ending their abuse and diversion. Thank you for the opportunity to respond to your questions and we look forward to working with you on this critical issue.

Sincerely,



John M. Gray  
President and Chief Executive Officer

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<sup>11</sup> <https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/archive/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf> (accessed 2/8/18).