

December 21, 2017

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Attn: Docket No. FDA-2017-N-5608 for “Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments”
Electronically filed.

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP)¹ welcomes the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) concerning approaches around the national opioid crisis. We believe that public quality standards can play a role, in tandem with other approaches, in helping to mitigate this complex problem that grips so many communities today. Currently, federal and state agencies, along with organizations across multiple sectors and disciplines, are seeking new and effective approaches to help prevent further suffering and deaths from opioids abuse and misuse. An intensive and coordinated response across public and private sectors is clearly needed. Public quality standards—including those related to medication labeling, storage, and disposal as well as consumer education and counseling—can have a positive impact by supporting and advancing the initiatives of FDA and others.

I. Public standards play a critical role in advancing public health

For nearly 200 years, USP has been building foundations essential for a healthier world through public quality standards. Our work helps improve medication quality across the supply chain and the healthcare continuum, including safe medication delivery, dispensing, and disposal, and also provides clear specifications to guide manufacturers, practitioners, and regulators. As a standard-setting body, USP has a well-established history of developing and updating standards, including drug monographs for individual products and across product classes, as well as general chapters. These standards have been successfully leveraged to address public health issues and crises.² USP is similarly committed to working with stakeholders to develop standards in combatting the opioid crisis.

¹ USP is an independent, nonprofit, scientific organization governed by a Convention comprising over 450 leading organizations and institutions in health and science from the public sector; academia; industry; healthcare practitioners; and consumer and patient communities. USP sets public standards for the identity, strength, quality, purity, packaging, compounding, and labeling of medicines. These public standards provide consistent benchmarks that help define the target for quality medicines for industry, also contributing to regulator, practitioner, and patient confidence in the integrity of these products. USP develops public standards through a collaborative and transparent process that brings together patients, practitioners, regulators, academia, and industry. USP also contributes its expertise through other activities, such as the National Quality Forum National Quality Partners Stewardship Action Team, which is working to develop responses to the opioid crisis.

² In numerous instances, USP has quickly developed or revised standards to address an urgent public health need, working closely with FDA and other stakeholders. Examples include changes in requirements for packaging and labeling, such as Vincristine Sulfate for Injection, Potassium Chloride for Injection Concentrate, and the therapeutic class of neuromuscular blocking agents. USP standards have also been useful for enhancing prescription container labeling, an initiative that was spearheaded by the National Academy of Medicine (formerly the Institute of Medicine) to improve health literacy, leading to development of a USP General Chapter in this area.

II. USP initiative on standards to combat the opioid crisis

USP has been considering and evaluating ways that public quality standards can make a difference in efforts to address the national problem of prescription opioid abuse and misuse. We have gained insights into stakeholders' ideas, efforts, and perspectives by convening a Discussion Forum and a Roundtable (held in August and October 2017), where participants considered concepts within the scope of USP's public standards-setting mission that could help further the nationwide response. Contributors included experts from healthcare provider groups, research organizations, patient advocacy groups, government agencies, industry representatives, and others.

USP is grateful for the engagement and valuable expertise received as we consider concepts relating to public quality standards, with the goal of reducing prescription opioid misuse and abuse and preventing patient deaths. These conversations inform USP's Healthcare Quality and Safety Expert Committee, which is charged with developing, strengthening, and revising key healthcare quality standards to improve patient safety and public health. The Expert Committee includes members from academia, research, clinical practice, and consumer interest, as well as government liaisons participating from FDA, Centers for Medicare and Medicaid Services, and the Agency for Healthcare Research and Quality. We believe that the concepts evaluated at the Discussion Forum and Roundtable, further described below, can contribute to the national dialog around fostering solutions and reducing risk, thereby supporting and advancing the work of FDA and others.

Approaches being considered include the following:

- 1. Safe storage and disposal of opioids: develop recommendations for effectively and safely storing and disposing of prescription opioids; this includes strategies for communicating the information.** USP is considering a standard to help ensure that patients receive consistent and appropriate storage and disposal recommendations. Novel concepts in using packaging to facilitate safe home storage and disposal may be part of the solution³—as well as a component of patient education initiatives.⁴ Many patients are unaware of appropriate methods to safely store prescription opioids and dispose of unused or unwanted product. We hope to consider recommendations that are practical and feasible, including bringing attention to existing information and recommendations where there may be gaps in awareness, and taking into account studies where they may exist (e.g. human factor studies).
- 2. Patient-centered labeling of prescription opioid containers: develop prescription label information for opioids.** USP has been exploring ways to enhance public standards for prescription container labeling, including innovative uses of containers to convey information. USP's current standard for prescription container labeling is intended to structure the label consistently and help patients understand medication instructions. While the container label 'real estate' is limited, this could be an opportunity to advance clear, useful, and consistent information to patients about safe opioid use, storage, and disposal, together with other relevant information.

³ Packaging and associated information can play an important role in patient care, including helping patients and their families prevent and respond to unintentional overdosing, and reinforcing messages communicated between patient and caregiver.


⁴ Home storage and disposal of prescription opioids is an important facet of the problem. According to a 2015 Substance Abuse and Mental Health Services Administration study, prescription opioid abuse began with diversion in the home for a significant number of the nearly 2 million Americans who abused prescription opioids for the first time in 2015.

3. **Consumer-directed labeling for naloxone: develop easy-to-follow instructions for administering naloxone.** Health care practitioners and others, including family, friends, and caretakers, need to quickly understand when and how to administer naloxone, a life-saving antidote. With expanded access to naloxone in almost all states, there may be an enhanced role for consistent, easy-to-follow instructions for effective naloxone administration and follow-up. This will help ensure that those who may administer naloxone have the clearest possible information—an important consideration because the medication may be administered months after it is dispensed, and possibly by a family member, friend, or others who did not receive instructions. Facilitating such approaches for naloxone instructions will require close collaboration and alignment between regulators, industry, USP, and other stakeholders.
4. **A framework for counseling patients about prescription opioids.** USP is considering developing resources that could be used as a framework for healthcare practitioner counseling of patients, as part of the prescribing, dispensing, and administration of opioids. These resources could provide a universal structure for discussions between patients and their healthcare providers so that critical information is covered in a consistent manner at each interaction. Counseling resources tailored specifically to opioids might also help prioritize key messages around safe storage and disposal, use of naloxone, interactions between opioids and other medications, and how to identify signs of overdose.

III. Conclusion

Thank you for FDA's leadership and for considering our comments. USP recognizes the need to work closely with FDA and others in developing resources that may help address this complex and challenging public health crisis. We welcome the opportunity to work collaboratively and facilitate efforts in confronting addressing this very critical issue. USP strives to be adaptive and incorporate new information as the situation and strategies evolve. For additional information, please do not hesitate to contact Elizabeth Miller, Pharm.D., Vice President, U.S. Public Policy and Regulatory Affairs, at ehm@usp.org; (240) 221-2064.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jaap Venema', is written over a horizontal line.

Jaap Venema, Ph.D.

Executive Vice President and Chief Science Officer

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