VIA ELECTRONIC SUBMISSION

July 7, 2020

NIOSH Docket Office
Robert A. Taft Laboratories, MS–C34
1090 Tusculum Avenue
Cincinnati, OH 45226–1998

Re: Docket No. CDC–2020–0046; NIOSH–233–C; Comments on *NIOSH Managing Hazardous Drug Exposures: Information for Healthcare Settings*

Dear Sir/Madam:

The United States Pharmacopeia (USP)[1] appreciates the opportunity to comment on the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) draft document, *Managing Hazardous Drug Exposures: Information for Healthcare Settings*.[2]

USP supports NIOSH's goal to help healthcare facilities manage hazardous drugs in their formularies by developing a suite of tools designed to assist with the identification of hazardous drugs and their handling precautions, as reflected in its draft document, *Managing Hazardous Drug Exposures: Information for Healthcare Settings*. USP's Compounding Expert Committee developed a public health standard: General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*, a practice and quality standard for handling hazardous drugs to promote patient safety, worker safety, and environmental protection, which complements such efforts.[3] USP strongly recommends reference to Chapter <800> in the draft document, *Managing Hazardous Drug Exposures: Information for Healthcare Settings* for reasons discussed below.

USP and NIOSH have worked together for years to ensure our shared goal of managing hazardous drugs is achieved. For example, USP Chapter <800> refers to the NIOSH list[4] of antineoplastic and other hazardous drugs to help stakeholders identify whether a drug is hazardous and to determine specific handling requirements. When NIOSH announced the publication of the updated draft of the

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[1] USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines, foods, and dietary supplements.

[2] Docket No. CDC-2020-0046; NIOSH-233-C: "Hazardous Drugs: Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020; Procedures; and Risk Management Information," at https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-09332.pdf.

[3] For more information, *see* "USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings," at https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

[4] *See* NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (2016), at https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.

NIOSH list, among other documents, on May 1, 2020, USP announced its intent to publish a Revision Bulletin to clarify that for the purposes of Chapter <800>, the term "antineoplastic" refers to those included in Table 1 of the most current NIOSH list.[5] This Revision Bulletin, issued on June 26, 2020, helps to clarify how healthcare workers can use the NIOSH list, whether it is the current 2016 list or the 2020 list (when finalized), to identify antineoplastic hazardous drugs that require all of the containment requirements described in Chapter <800>.[6]

The NIOSH list document last published in 2016 refers to USP, and specifically Chapter <800>, in Table 5, "Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings" which provides information on recommended exposure controls for hazardous drugs based on formulations.[7] NIOSH proposes to remove Table 5 from the NIOSH list document and in its place, developed a new document on risk management strategies, *Managing Hazardous Drug Exposures: Information for Healthcare Settings*.

USP supports NIOSH's decision to expand upon Table 5 in this draft document; however, we note that it does not include reference to USP or Chapter <800>. We encourage including a reference to Chapter <800> in the draft document, *Managing Hazardous Drug Exposures: Information for Healthcare Settings*, as it would help advance our shared goals around hazardous drugs. We believe this approach would be particularly helpful for practitioners and other public health entities who rely on both documents.

Other public health resources continue to reference USP Chapter <800>. The American Society of Health-System Pharmacists (ASHP) *Guidelines on Handling Hazardous Drugs* references Chapter <800> and supports several hazardous drug handling recommendations from the chapter, for example, receipt of hazardous drugs.[8] The Oncology Nursing Society (ONS) *Toolkit for Safe Handling of Hazardous Drugs for Nurses in Oncology* contains a section explaining how Chapter <800> impacts nursing practices.[9] The American Society of Clinical Oncology (ASCO) Safe Handling of Hazardous Drugs standards state that its Expert Panel endorses the best practices for safe handling of hazardous drugs as issued by Chapter <800> in medical surveillance, closed system transfer devices, external ventilation of containment secondary engineering controls or containment segregated compounding areas, and alternative duties.[10] Therefore, USP strongly recommends

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[5] *See* Notice of Intent to Revise, <800> Hazardous Drugs—Handling In Healthcare Settings, at https://www.uspnf.com/notices/800-nitr-20200501 (May 1, 2020).

[6] *See* Revision Bulletin, at, https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-800-rb-notice-20200626.pdf (June 26, 2020).

[7] *See supra* note 4.

[8] *See* ASHP "Guidelines on Handling Hazardous Drugs," at https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx (2018).

[9] *See* ONS "Toolkit for Safe Handling of Hazardous Drugs for Nurses in Oncology," at https://www.ons.org/sites/default/files/2018-06/ONS_Safe_Handling_Toolkit_0.pdf

[10] *See* "Safe Handling of Hazardous Drugs: ASCO Standards," at https://ascopubs.org/doi/full/10.1200/JCO.18.01616 (2019).

referring to Chapter <800> in the draft document, *Managing Hazardous Drug Exposures: Information for Healthcare Settings*.

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Thank you again for the opportunity to provide these comments for your consideration. We welcome the opportunity to discuss how USP and NIOSH can continue to work together to help ensure safe handling on hazardous drugs and clarity for our stakeholders.

For more information, please contact Marissa Chaet Brykman, Director, U.S. Regulatory Engagement, at marissa.brykman@usp.org; (301) 692-3660.

Sincerely yours,

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