August 29, 2014

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer
United States Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, Maryland 20852-1790
Sent electronically to CompoundingSL@usp.org

RE: Chapter <800> Hazardous Drugs – Handling in Health care Settings

Dear Dr. Piervincenzi:

The Oncology Nursing Society (ONS) is pleased to submit comments on proposed General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. ONS, a professional association of more than 35,000 nurses, is committed to promoting excellence in oncology nursing and the transformation of cancer care. For 40 years, ONS has provided a professional community for oncology nurses, developed evidence-based education programs including treatment information, and advocated for patient care, all in an effort to improve quality of life and outcomes for patients with cancer and their families. It is ONS’s hope that USP revises the current proposed USP <800> to ensure sound evidence-based recommendations coupled with an acknowledgement of current capital restraints. Otherwise, we fear that the required implementation of these guidelines will result in hampered patient access to key oncology products, due to the ultimate closure of key facilities, including community oncology clinics, due to over-stringent, unsupported restrictions.

As part of ONS advocacy, we strive to improve patient care while ensuring that nursing professionals delivering care are afforded appropriate protections. For this reason, ONS supports specialized education of the registered nurse (RN) who administers chemotherapy and biotherapy. This specialized education ensures a safe level of care for individuals receiving these agents and a level of protection for the nurses handling these hazardous drugs. ONS offers the ONS/ONCC Chemotherapy Biotherapy Certificate Course providing up-to-date resources pertaining to treatments. Guidelines and recommendations for administering and handling chemotherapy and biotherapy are described in *Chemotherapy and Biotherapy Guidelines and Recommendations for Practice* (Polovich, Olsen, & LeFevbre 2014) and the consensus-based American Society of Clinical Oncology/ONS Chemotherapy Administration Safety Standards (Neuss et al., 2013).

These and other publications describe basic clinical content necessary for safe and competent administration and handling of chemotherapeutic and biologic drugs (Gullatte, 2014; Wilkes & Barton-
Burke, 2014). Didactic learning is followed by successful completion of a clinical practicum under the auspices of an RN’s institution or supporting agency.

As part of that learning process, ONS supports the following core competencies which relate specifically to USP 800: Principles of safe preparation, storage, labeling, transportation, and disposal of chemotherapeutic and biologic agents, as well as appropriate use and disposal of personal protective equipment. As part of the interdisciplinary health care team, nurses and pharmacists are the two groups of health care workers that are at a higher risk from occupational exposures to hazardous drugs such as chemotherapy and biotherapy. We concur with our pharmacist colleagues in their statement that these regulations should be strictly enforced and ONS, as an organization, supports these proposed regulations with a few considerations expressed below, as this will provide greater safety in handling hazardous drugs.

The guidelines, in attempting to eliminate all personnel exposures to hazardous drugs (HDs), do not take into account the current status of compounding and administration of HDs. For instance, facility design and engineering controls (beginning on line 196) do not take into account the limited space currently available for such activities. To appropriately comply with such requirements, there may need to be substantial capital improvement in current facilities. Especially relating to requirements to unpack and store HDs and non-HDS in distinctly different areas, as well as requirements that non-sterile drug compounding be performed separately from sterile hazardous drug compounding in an ISO environment. It is unclear whether such re-designs would provide significant safety over current facilities. Thus it would be helpful if, rather than focusing only on eliminating all personnel exposures, the guideline emphasized a more cost-effective approach to exposures, focusing on those interventions which have a strong evidence-base for achieving stated goals.

There are many best practices included in the proposed chapter. Opportunity to perform appropriate analyses, including cost and impact on service delivery to patients while integrating best practices has not been accomplished at this time. There has been no assessment of financial impacts or potential disruption to medication access to patients. In addition, we recommend an evaluation of implementation of the standards after a period of time.

In addition, please find below additional comments and concerns, referencing specific line numbers, as requested. The reference to feedback from nurses stems from direct feedback and negative learning outcomes from our customer base.

Lines 42-44: ONS supports these statements, however ONS is very aware that HDs are being prepared in many non-oncology settings as well. Historically, these nurses have not been provided education on compounding or administering these drugs. Implementation of Chapter <800> may result in larger knowledge and competency gap with staff in non-oncology settings.

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ONS supports these statements. ONS acknowledges that the use of CSTDs for all HD administration will be a difficult transition for many sites. Nurses have noted the cost of the equipment and the limited options currently available. Several nurses shared that they were taught by others in their facility that PPE is not needed when using CSTDs.

ONS supports these statements. Several nurses have shared concerns over the cost of PPE, and subsequent lack of availability. One nurse reported that when she insisted the recommended PPE be made available to herself and colleagues, she was told to seek other employment as the products were too expensive.

Consider the terminology of “hand washing” rather than “hand hygiene.” The use of alcohol-based gels has not been shown to remove chemotherapy residue. The NIOSH Alert states to, “Wash hands with soap and water before donning protective gloves and immediately after removal.”(p.13) Feedback from our customers indicate that many continue to utilize alcohol-based gels and therefore may still be at risk for HD exposure.

ONS supports these statements. Many nurses share that they reuse disposable gowns, removing and hanging them up between patients, or using the same disposable gown for the full shift or week. Consider using the same terminology as the NIOSH Alert, “Dispose of protective gowns after each use.”(p.13)

ONS supports these statements. Please note that nurses are often hired into a practice or clinic without experience and may not be familiar with USP requirements. Because most nurses do not compound hazardous drugs, comprehensive education regarding this topic is not included in nursing education, and nurses will need access to the training required.

We appreciate that the USP <800> acknowledges that ONS’ Safe Handling of Hazardous Drugs publication contains additional details that may be incorporated into Standard Operating Practices or SOPs.

Again, we appreciate that your document acknowledges the work of ONS by highlighting that guidelines like ours recommend medical surveillance as the recognized standard of occupational health practice for personnel who handle HD. However, to aid in the implementation, it may be best if the USP provided additional clarity regarding the specific surveillance processes and what would be considered adequate, which may involve the use of case studies.

We appreciate your time and attention to this matter and hope that you continue to view ONS as a partner in developing appropriate standards for ensuring the safety of personnel working with HDs. ONS and the cancer care community seek to reduce risks, incidence, and burden of cancer by encouraging healthy lifestyles, promoting early detection, and improving management of cancer symptoms and side effects throughout the disease trajectory.
Should you have any questions regarding our comments, please contact Alec Stone, MA, MPA, ONS Director of Health Policy, at astone@ons.org. The Oncology Nursing Society appreciates USP’s consideration of its feedback and looks forward to working with the organization to help ensure the safety of both nursing professionals who administer chemotherapy and biotherapy and the patients receiving these agents.

Sincerely,

Margaret Barton-Burke

President
Oncology Nursing Society