June 17, 2014

United States Pharmacopeia Convention
CompoundingSL@usp.org

To whom it may concern,

The College of Psychiatric and Neurologic Pharmacists (CPNP) has reviewed the draft USP General Chapter 800 Hazardous Drugs – Handling in Healthcare Settings. CPNP is the professional society of pharmacists who specialize in mental healthcare. Our members serve in a variety of roles including as clinical pharmacists (public and private), managers and directors of pharmacy, academia, state mental healthcare and in industry. The mission of CPNP is to advance the reach and practice of neuropsychiatric pharmacists. CPNP recognizes the importance of protecting healthcare workers from hazardous medications and supports the intent of the chapter. However, CPNP opposes use of the NIOSH Hazardous Drugs List for classification of a medication as hazardous. USP should reconsider the use of the NIOSH list and the appropriateness and necessity of including non-cytotoxic/non-antineoplastic agents such as psychiatric medications under the same handling regulations as cytotoxic chemotherapy.

CPNP has previously expressed concerns to the National Institute for Occupational Safety and Health regarding inclusion of certain psychotropics on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012. It is the position of CPNP that risk to healthcare workers from routine exposure to these non-cytotoxic medications is minimal, even when individual doses are divided or crushed. In fact, hundreds of thousands of family members, assisted living staff, and health professionals have been exposed to some of the maintenance medications for chronic conditions (such as many psychiatric medications) on the NIOSH list for decades without the detection of significant toxicity of the type that prompted USP to develop Chapter 800. This lack of evidence further justifies their exclusion from Chapter 800.

CPNP supports the classification of medications that present acute or chronic occupational hazards as hazardous drugs. This would include drugs for which manufacturer’s labeling recommend precautions and that are designated as known or probable carcinogens (by International Agency for Research on Cancer and National Toxicology Program). Unnecessary and substantial burdens would be placed upon healthcare facilities if medications are classified as hazardous only through extensive extrapolation.
In addition, the classification of several psychiatric medications as hazardous presents unique problems in psychiatric facilities. In these facilities, the majority of exposure arises from administering solid dosage forms of psychiatric medications. Since many commonly used psychiatric medications have recently been classified as hazardous by NIOSH, incorporating policies and procedures appropriate for cancer chemotherapy would negatively impact the care given to psychiatric patients and unnecessarily consume resources allocated to care for a vulnerable population.

Patient care and safety may also be adversely affected if Chapter 800 retains the use of the NIOSH list. Some patients with psychiatric illnesses experience symptoms that include paranoid delusions. Implementation of policies that demand common psychiatric medications be treated as hazardous could reinforce the attitudes of these patients that health care workers are attempting to harm them with medication. Requiring that nursing staff gown and glove when administering oral medications such as risperidone or that staff use a respirator to clean up a spill of valproic acid liquid is also unjustified and harmful to patient care. A common and unpredictable occurrence in psychiatric facilities is the expectoration of medication by a patient. The details of Chapter 800 would require that staff wear face shields when administering common psychiatric medication such as oral clonazepam and ziprasidone in the event a patient may expectorate the tablet. Furthermore, our most vulnerable patients include children and adolescents with serious psychiatric disorders. The need to summon a hazardous spill team for expectorated or spilled medication would negatively impact medication adherence and the patient milieu.

Another problem with the NIOSH list is what appears to be a lack of consistency in determining what is added to the list. For example, risperidone (a generic agent) is on the list. The brand name agent paliperidone, an active metabolite of risperidone which differs from the parent compound only by the presence of an additional hydroxyl group is not. There is no data supplied by NIOSH that explains why these drugs with very similar pharmacologic activity should be classified differently.

The NIOSH list also calls for reassessment of the list and workplace specific generated hazardous drug lists. USP should similarly recommend these measures based on workplace generated lists and not the NIOSH list. Even though NIOSH calls for reassessment of the list, the currently posted NIOSH list (2012) is based on updates from 2010 and before. The lack of timely reassessment and failure to consider data from actual exposure in the real world means that mandating use of the NIOSH list could require a facility to undertake expensive renovations even if data exists that suggests lack of toxicity. This is obviously unacceptable and not USP’s intent.

Finally, the requirement to install negative airflow facilities for institutions that do not stock or administer antineoplastics or cytotoxic agents on site would cost the health care system and governments millions of dollars. Such an expenditure is difficult to justify in this era of increasing health costs and limited resources.

Attached is a document that outlines by line number, CPNP comments on Chapter 800. We ask that the USP weigh the demonstrated risk of oral psychiatric medications to staff working in psychiatric facilities against the financial burden of the procedures outlined in Chapter 800 and the potential deleterious impact on patient care and safety. In its current form, Chapter 800 makes it virtually impossible to provide appropriate patient care to patients with psychiatric disorders.
It is the request of CPNP that USP eliminate references to the NIOSH list and that the application of this chapter be restricted to medications that are carcinogenic or which have a significant likelihood of resulting in organ toxicity, reproductive toxicity or genotoxicity at doses achievable by accidental topical or inhalation exposure (e.g., cytotoxic chemotherapy). The unintended consequences of referring to an unnecessarily expansive list such as that generated by NIOSH will not only be expensive, they could adversely impact patient care.

The USP is an internationally respected standards setting organization that is renowned for its scientific approach and its transparency in developing standards. CPNP urges USP to carefully examine the science behind the NIOSH List and the degree to which practicing health professionals have input into its development and maintenance. Any list that USP incorporates into its standards should meet the same level of rigorous science, transparency and opportunity for widespread health professional input as a USP standard.

Thank you for your review and thoughtful consideration of these comments.

Sincerely,

Steven M. Burghart, DPh, MBA, BCPP
President-Elect, College of Psychiatric and Neurologic Pharmacists
Comments by Line Number

Line 114-117 – “The entity shall include all items on the current NIOSH list.” The NIOSH list contains cytotoxic as well as non-cytotoxic medications. NIOSH itself states the list is intended for guidance. The NIOSH list is without regard to dose, type of exposure, and whether there is human data to justify the hazard classification. Data does not support the benefit of treating non-cytotoxic medications in the same manner as cytotoxic medications. In addition, it would be very costly to healthcare systems to comply with this chapter for non-cytotoxic medications. The cost that would be incurred to implement procedures stated in this chapter would divert money from patient care and adversely impact health care facilities and governments.

Line 241 – “Unless in unit dose, HDs must be stored separately and in a manner to prevent contamination and exposure to personnel which includes a negative pressure room with 12 air changes per hour”. This would require even health facilities that do not stock or receive cytotoxic agents to renovate the pharmacy department to install negative airflow in the event that HDs are not available in unit dose. Although, this may be appropriate for cytotoxic drugs, it is not justifiable for medications such as oral divalproex capsules or oxcarbazepine tablets.

Line 242 – “Refrigerated HDs must be stored in a dedicated refrigerator...” This would require healthcare facilities to purchase separate refrigerators for risperidone Consta®, a long-acting antipsychotic injectable. This would result in an unnecessary expenditure.

Line 264-266 – “HDs that require alteration shall be manipulated (mixed, diluted, compounded, and others) in a C-PEC in an area that is physically separated from other preparation areas, that is under negative pressure, externally ventilated , and has at least 12 ACPH.” This would require nurses to prepare risperidone Consta® long-acting antipsychotic injection in a negative pressure room. There is no data to support this practice. Furthermore, this would potentially result in lack of use of long-acting antipsychotic injections in non-adherent or partially adherent patients with schizophrenia. This could result in increased rates of re-hospitalization with significant costs to society and harm to patients.

Line 445-448 – Personnel protective equipment (PPE) may be appropriate for cytotoxic drugs in receiving and stocking in pharmacy, transporting, and administering. Specifically line 552 – 554 – “Personnel unpacking HDs that are not contained in plastic should wear an elastomeric half-mask with a multi-gas cartridge and P100-filter.” This would require that receiving clerks in pharmacy departments wear a gas cartridge face mask when unpacking medications such as oral clonazepam. Again, data does not support handling non-cytotoxic medications in this manner and would result in purchase of unnecessary equipment.