

Statement Regarding USP Chapter <800>

The Minnesota Board of Pharmacy was recently made aware that USP Chapters <795>, <797> and <825> are being appealed. These chapters were set to become effective December 1, 2019. USP Chapter <800> was not a subject of the appeals and is still scheduled to go into effect on December 1, 2019. However, USP has noted that Chapter <800> is “informational and not compendially applicable”.

During the appeal process, the Minnesota Board of Pharmacy wants to remind pharmacies that there are already federal and state OSHA requirements regarding employee safety. The Employee Right-to-Know Act was enacted by the Minnesota Legislature in 1983. The Act was intended to ensure that employees are aware of the dangers associated with hazardous substances. Employers are required to evaluate, or survey, their workplaces for the presence of hazardous substances, harmful physical agents, and infectious agents - and to provide training. It’s important to note that the OSHA requirements apply to all employers, including pharmacies.

The OSHA requirements are very similar to the requirements of USP <800>. While USP <800> will not become enforceable on December 1, 2019, the Board of Pharmacy will most likely adopt USP <800> by reference into Rule. Therefore, pending the resolution of the appeal, the Board of Pharmacy will continue to encourage the adoption of both the USP <800> and OSHA standards for employee safety. It’s important to note that Minnesota Rules and Statutes contain language that already requires pharmacies to comply with all federal and state regulations. It would be unprofessional conduct to violate any Board, state or federal statute or rule that applies to a licensee.

The Minnesota office of OSHA is called MNOSHA. It is part of the Minnesota Department of Labor and Industry. They provide enforcement activity, facility inspections, evaluations and consultations. Pharmacies are encouraged to contact them with questions about OSHA requirements or to have them come to do an evaluation or consultation.

Compliance requirements include:

1. Displaying the 5 different state mandated posters where they can be seen.
 - a. Age discrimination
 - b. Minimum wage
 - c. Safety and health protection on the job
 - d. Unemployed
 - e. Workers compensation
2. Keeping an accurate OSHA log of recordable work-related injuries
 - a. Department of Labor and Industry offers free seminars about OSHA record keeping requirements.
3. Compliance with Hazard Communication Standards, which includes drugs

- a. The Hazard Communication Standards require a written hazard communication program, listing of all hazardous substances, SDS sheets and employee training.
4. Annual employee training as required by Minnesota Employee Right to Know Act.
5. Performing a workplace evaluation for necessary personal protective equipment (PPE)

The Minnesota Board of Pharmacy will continue to encourage pharmacies to meet USP Chapter <800> requirements. The Minnesota Board of Pharmacy also reminds pharmacies that they must comply with the requirements of OSHA. Employees have the right to know about exposure to hazardous substances, harmful physical agents and infectious agents.

To find out more about the USP <800> and OSHA requirements see attached resources and FAQ.

Resources:

USP <795> - <https://www.usp.org/news/new-revised-compounding-standards>

USP <797> - <https://www.usp.org/news/new-revised-compounding-standards>

USP <800> - <https://www.usp.org/news/new-revised-compounding-standards>

USP <825> - <https://www.usp.org/news/new-revised-compounding-standards>

NIOSH 2016 - <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>

MN Rule 6800.2250 - [Unprofessional Conduct](#)

MN Rule 6800.3300 - [Compounding Standards](#)

MN Rules 5205.0100 to 5205.1200 - ["Employee Right to Know Standards"](#)

MN Rules 5206.0700 - ["Employee Right to Know training requirements.](#)

MN Rule Chapter 5206 - [Hazardous Substances; Employee Right to Know Standards](#)

MN Statute 151.071 Subd. 2. (7) - [Grounds for Disciplinary Action](#)

MN Statute 182.653 - [Rights and Duties of Employers](#)

29 CFR 1910.1200 - [OSHA Laws and Regulations - Hazard communication standard](#)

MN OSHA Standards and Regulations: <https://www.dli.mn.gov/business/workplace-safety-and-health/mnosha-compliance-standards-and-regulations>

Workplace posters: www.dli.mn.gov/about-department/workplace-posters

OSHA record keeping requirements: www.dli.mn.gov/business/workplace-safety-and-health/mnosha-compliance-recordkeeping-standard

OSHA.gov eTool for common safety and health hazards:

www.OSHA.gov/SLTC/etools/hospital/pharmacy/pharmacy.html