

Minnesota Board of Pharmacy

Outsourcing Compounded Sterile Products

The Board strongly suggests that, on an ongoing basis, you review your policies and procedures regarding outsourced compounded sterile preparations and revise them as necessary.

The Board suggests that you use the following as resources for this review:

- -American Society of Health-System Pharmacists (ASHP) “Guidelines on Outsourcing Sterile Compounding Services” found at:
<http://www.ashp.org/DocLibrary/Bestpractices/MgmtGdlOutsourcingSterileComp.aspx>
- ASHP “Outsourcing Sterile Products Preparation: Contractor Assessment Tool” found at:
<http://www.ashpfoundation.org/SterileProductsTool>
- USP <1163> Quality Assurance in Pharmaceutical Compounding - outsourcing section

The Board suggests you include the following in your policy (if applicable):

- Proper regulatory compliance including licensure verification
- Validation of quality processes of the outsourced pharmacy focusing on the beyond-use date and USP <797> compliance.
- Pharmacist-in-Charge oversight, to include documented approval of outsourced products and vendors and assuming complete responsibility for patient outcomes from all medication-related activities.
- P&T (or equivalent) and risk management committee review and approval of outsourced product policy and allowed outsourced products.
- Collaboration with clinic prescribers to determine which products are **truly** needed or if a commercially available manufactured product is available.
- Establish an ongoing communication process with prescribers to inform them of drug shortages and discuss how to handle the shortages
- Do not allow prescribers to use their own supplies of compounded products while they are providing services at your facility.

The Board reminds pharmacists to review the compounding memo found on the Boards website at: <http://www.phcybrd.state.mn.us/cmpdmemo.pdf>. It is not legal to purchase drugs at wholesale from any entity that is not licensed by the Board as a drug wholesaler. It is also not legal to purchase any “compounded” products at wholesale from any company that is not also licensed as a manufacturer. Any prescription dispensed for a specific patient would need documentation of a prescription which per **M.S. 151.01 subd.16** must contain: the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber. As the PIC it would be wise to verify that all staff clearly understands these regulations.

Please do not hesitate to contact the Surveyors at the Board office at (651) 201-2839 if you have any additional questions.