The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCCMERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication use system.
We recognize that outsourcing facilities such as Nephron, Premier Pharmacy Labs, and others are trying to expedite products to alleviate pharmaceutical shortages. However, this can cause unintended consequences such as unsafe labeling and packaging and variability in the way critical information is expressed on labels, which can lead to serious errors. Thus, ISMP has asked FDA to convene an FDA Pharmacy Compounding Advisory Committee meeting to discuss medication errors related to the labeling and packaging of products from outsourcing facilities and to inform the next steps. These next steps might include an FDA guidance on labeling and packaging for outsourcing facilities, requiring outsourcing facilities to follow current USP or FDA labeling and packaging standards, or some other strategy that prevents outsourcing facilities from following different container labeling standards than commercial manufacturers.

Until then, healthcare providers should consider the following recommendations:

■ Whenever possible, only use commercial FDA-approved products or, when necessary, products from outsourcing facilities that follow USP <7> labeling standards.

■ Anticipate unexpected differences in the labeling and packaging of products from outsourcing facilities given the lack of guidance on these topics from FDA.

■ Assess the labeling and packaging of all products from outsourcing facilities for safety. If the product is a high-alert medication, consider conducting a streamlined failure mode and effects analysis (FMEA).

■ Take steps to reduce the risk of errors if critical vulnerabilities with labeling and packaging have been identified with an outsourcing facility’s product during assessment. For example, circle “potassium” or “calcium” to draw attention to the drug name on look-alike vials, or add an auxiliary label that clearly provides necessary information.

■ Embed safety strategies for potassium chloride for injection concentrate and other concentrated electrolytes such as magnesium sulfate injection, calcium chloride injection, and sodium chloride injection greater than 0.9%. Potassium chloride for injection concentrate must never leave the pharmacy undiluted. Consider appropriate restrictions for other concentrated electrolytes as well.

■ Communicate with staff about drug shortages. If switching from a commercial product to an outsourcing facility product, notify all practitioners potentially impacted by the switch and alert them to any differences between the products, labeling and packaging issues, and steps the organization is taking to reduce the risk of errors. Include product photographs whenever possible.

■ Employ barcode scanning technology to verify that the correct medication has been selected prior to dispensing and/or administration, including during pharmacy compounding. Otherwise pharmacists will need to rely on manual independent double checks.

■ Report all errors and safety concerns associated with the labeling and packaging practices of outsourcing facilities to ISMP (www.ismp.org/merp) and FDA (www.fda.gov/Safety/MedWatch/).

This alert is based on information from the National Medication Errors Reporting Program (MERP) operated by the Institute for Safe Medication Practices (ISMP).