Insourcing Sterile I.V. Compounding Services Initiative

Background

Compounding of sterile parenteral preparations is a critical component of health-system pharmacy practice. Over the last decade, many hospital/health-system pharmacy departments in the United States contracted with external compounding pharmacies (503A organizations) and outsourcing facilities (503B organizations) for the preparation of parenteral medications. Data from hospitals that participated in the 2020 ASHP National Survey of Pharmacy Practice in Hospital Settings[1] indicate 79% of hospitals outsource preparation to external organizations. 40% of hospitals outsource patient-specific CSPs (such as TPNs) to 503A pharmacies. The most frequent medications outsourced to 503B facilities include anesthesia syringes (63%), patient-control analgesia (71%), epidurals (55%), and critical care infusions (32%).[2] Numerous organizational and operational factors weighed into the decision to outsource these services, including quality and safety considerations, staffing capabilities, technology infrastructure, regulatory requirements, and financial implications. Subsequent to the nationwide fungal meningitis outbreak in 2012 associated with medications that were prepared by a compounding pharmacy, some hospitals decided to resume pharmacy department preparation of these medications.

Several important safety and quality implications must be considered when hospitals/health-systems decide to internalize or insource preparation of sterile parenteral products for use in the institution. These implications impact numerous stakeholders beyond the department of pharmacy, including physicians, nurses, and, most important, patients. Factors that must be considered when deciding whether to insource include the following:

- Patient safety;
- Quality management specifically as it relates to facility cleaning and validation, staff training, and competency assessments;
- Staffing needs/capabilities;
- Information systems and other infrastructure;
- Facilities/physical plant;
- Education and training of pharmacy staff;
- Organizational and pharmacy department policies and procedures for specific compounding practices;
- Risk assessment;
- Regulatory requirements and accreditation standards;
- Inventory and supply chain issues;
- Emergency preparedness implications; and
- Financial implications.

These factors apply to all medications that have been outsourced by departments of pharmacy. However, additional focus should be directed to those medications that the evidence indicates are most frequently outsourced, including patient-controlled analgesia and epidural solutions, oxytocin, intravenous admixtures/small volume solutions, anesthesia syringes, total parenteral nutrition, and cardioplegia solution.

ASHP has developed an online tool kit containing resources to assist institutions in evaluating, developing, and implementing best practices as they insource the compounding of sterile parenteral medications, which were previously provided by a compounding or outsourcing pharmacy. The examples provided in the tool kit highlight and explain issues to consider during the decision-making and implementation phases of insourcing any sterile i.v. preparations.

References

1. Pedersen CA et al, ASHP national survey of pharmacy practice in hospital settings: dispensing and administration – 2020, Am J Health-Sys Pharm, 78(12):1074-1092, 2021 (June 15)
2. Office of the Inspector General, US Department of Health and Human Services, Most hospital obtain compounded drugs from outsourcing facilities, which must meet FDA quality standards, OEI-01-17-00090, June 2019, available at https://oig.hhs.gov/oei/reports/oei-01-17-00090.pdf.