

Issue Summary:

Office of Inspector General Report on Medicare's Oversight of Compounded Pharmaceuticals Used in Hospitals

Background:

As expected, on January 22, 2015, the Office of Inspector General of the Department of Health and Human Services released the findings of a survey of how the Centers for Medicare and Medicaid Services (CMS) and its accreditors gauge how well hospitals are incorporating recommended practices into their compounding practices.

ASHP's Government Affairs staff has been engaged with the OIG on compounding studies and surveys since the fungal meningitis outbreak in 2012 and has prepared this summary of the report and recommendations to CMS. CMS agrees with the OIG's findings. The full report can be found [here](#).

Methodology:

The OIG reviewed the practices of the five entities that oversee hospitals that participate in Medicare—namely, CMS and the four hospital accreditors approved by CMS. The OIG identified 55 recommended practices for compounding sterile preparations (CSP) oversight in acute-care hospitals and surveyed the five overseeing entities to see how their surveys incorporated these recommended practices.

Findings:

- The six areas that oversight entities examine some of the time include physical plant and environmental quality, policies and procedures for compounding CSPs, pharmacy personnel training and evaluation, patient monitoring and adverse event reporting, CSP storage, and compounding equipment use and maintenance
- Only one oversight entity always reviews hospitals' contracts with standalone compounding pharmacies
- Pharmacists are not routinely included on most hospital survey teams, but surveyors can draw on pharmacists' expertise when needed

- Only two oversight entities employ pharmacists as hospital surveyors
- Neither includes a pharmacist on every survey team
- Surveyors receive limited training specific to compounding
 - Two oversight entities do not provide any compounding-specific training to their surveyors.
 - The other three oversight entities vary in the compounding-specific training they provide, ranging from observation of compounding during training surveys to an online training module dedicated to USP 797.
- Three oversight entities are considering changes to their oversight of hospitals' preparation and use of CSPs
- Despite outsourcers being the source of the fungal meningitis outbreak, none of the oversight entities plan to change how their oversight addresses hospital contracts with outsourcing facilities or compounding pharmacies.

OIG recommendations to CMS and the CMS Response

OIG Recommendation: Ensure that hospital surveyors receive training on standards from nationally recognized organizations related to safe compounding practices

CMS Response: While it is not reasonable to expect that all hospital surveyors will be experts on all aspects of pharmacy compounding, the agency agrees that there should be greater training of surveyors to ensure assessment of basic competencies in hospital pharmacy compounding. The OIG does not recommend how that training should occur, and CMS only mentions that it will explore on-line training as one possible way to train Medicare hospital accreditation surveyors. It is possible that CMS could address this recommendation as part of their routine review of applications for the five accreditation programs.

OIG Recommendation: Amend the interpretive guidelines to address hospitals' contracts with standalone compounding pharmacies

CMS Response: CMS also agrees with this recommendation and states that they will explore revising interpretive guidelines for Medicare's Conditions of Participation (CoP) for hospitals. Importantly, CMS is not signaling at this time that they will require hospitals to purchase compounded products only through outsourcing facilities registered with the FDA under Section 503B or the Food Drug and Cosmetic Act. The agency states that:

However, since Medicare regulations do not require hospitals and CAHs [Critical Access Hospitals] to use only those compounding pharmacies that have voluntarily registered with the FDA, surveyors would limit their assessment of the contracts with standalone

compounding pharmacies to how the facility assures that its contracted services comply with the regulations.

Next Steps

ASHP staff will remain engaged with CMS, the OIG, and other stakeholders as they develop training materials for surveyors. It will be important for the agency to have ASHP's input to appropriately incorporate compounding standards to ensure that compounding is being performed safely.

ASHP's comprehensive guidelines for selecting a compounding outsourcer are currently being revised to reflect the new Drug Quality and Security Act requirements, and are expected to be released by the end of March. The new guidance will give health care professionals the tools to evaluate compounding pharmacies and to ensure quality and responsibility for the products that they are purchasing.

For additional inquiries about this report, please contact Christopher Topoleski, Director of Federal Regulatory Affairs at 301-664-8692 or via e-mail at ctopoleski@ashp.org

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