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# OIG STUDIES MEDICARE'S OVERSIGHT OF HOSPITAL PHARMACEUTICAL COMPOUNDING PRACTICES IN WAKE OF 2012 MENINGITIS OUTBREAK

## EXECUTIVE SUMMARY

In response to the 2012 meningitis outbreak traced to tainted injections compounded by the New England Compounding Center, OIG recently published a study entitled "Medicare's Oversight of Compounded Pharmaceuticals Used in Hospitals: OEI-1-13-0040" ("Study"). OIG made the following findings:

- State survey agencies and accreditation agencies (e.g., The Joint Commission, HFAP, DNV, Center for Improvement in Healthcare Quality) overseeing Medicare-certified hospitals ("Oversight Entities") address *most* industry recommended safety and quality practices related to compounded sterile preparations ("CSPs") at least *some* of the time;
- Only one Oversight Entity out of five always reviews hospital contracts with standalone compounding pharmacies providing customized pharmaceuticals to hospital patients even though 80% of those hospitals outsource CSP compounding to at least one standalone pharmacy;
- Oversight Entities lack the manpower to thoroughly assess a hospital's preparation and use of CSPs;
- Surveyors lack training specific to compounding, and pharmacists are not usually included on hospital survey teams; and
- No Oversight Entities plan to change how they oversee hospitals' contracts with standalone compounding pharmacies.

Pursuant to the Study findings, OIG made the following recommendations with which CMS concurs:

1. CMS should ensure that hospital surveyors receive training on standards governing safe compounding practices set forth by nationally recognized organizations (e.g., United States Pharmacopoeia, Institute for Safe Medication Practices). This will establish surveyor basic competencies necessary to evaluate compounding in hospitals as well as the ability to determine when additional survey expertise is needed. Moreover, CMS should ensure that accreditation agencies applying or reapplying for "deeming authority" also provide equivalent training for their surveyors; and
2. CMS should amend the hospital conditions of participation ("CoPs") interpretive guidelines to address hospitals' contracts with standalone compounding pharmacies[1]. For example, this guidance could reference hospitals' responsibility for overseeing their contracted services, including recall procedures and storage, under the quality assessment and performance improvement CoP and the governing body CoP. In addition, OIG suggested CMS could also require that when surveyors assess hospitals' management of contracts with compounding pharmacies, they review whether these pharmacies have registered with the FDA under the Drug Quality and Security Act of 2013.

Per CMS's comments to OIG, CMS intends to:

- Consider developing online training materials for its surveyors and collaborating with national experts to develop the training;
- Consider revising its interpretive guidelines to make surveyors aware that CSPs used in hospitals often are compounded by outside specialty pharmacies;
- Have surveyors assess the hospitals' contracts with standalone compounding pharmacies to see how the hospitals ensure that the contracted services comply with the CoPs. However, since the CoPs do not require hospitals and critical access hospitals ("CAHs") to use only FDA-registered compounding pharmacies, surveyors would not make any inquiries as to the pharmacies' FDA registration status.

The Study can be found here.

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**BACKGROUND**

According to the CDC, in 2012, a nationwide meningitis outbreak caused by contaminated injections resulted in 751 fungal infections and 64 deaths. This catastrophe raised concerns about the safety of CSPs, custom-made prescription drugs usually administered to the target patient by infusion or injection. After this sentinel event, OIG determined that almost all acute-care hospitals use CSPs and most contract with standalone compounding pharmacies to provide some CSPs. Further, CMS oversees the safety of CSPs used in Medicare participating hospitals through the hospital certification process in which either state survey agencies or accreditation agencies approved by CMS evaluate hospital compliance with the requirements for drug compounding. OIG conducted the Study to determine whether Medicare's oversight of hospitals adequately addresses recommended practices for CSPs.

**PRACTICAL TAKEAWAYS**

In light of the January 2015 OIG Study, its recommendations and CMS's agreement to those recommendations, hospitals and CAHs should expect future changes in the CoPs addressing pharmaceutical services and drugs and biologicals. They can also expect Oversight Entity surveyors to be more educated on CSP safety and more attentive to hospital CSP practices and hospitals' own quality and safety oversight of the standalone compounding pharmacies with which they contract.Given the scope and severity of the 2012 meningitis outbreak, hospitals and CAHs should review in-house CSP practices and the robustness of oversight of outside compounding pharmacies even before the surveyors come a callin'. An ounce of prevention . . .If you have any questions, would like additional information about the regulation of pharmaceutical compounding or require assistance preparing for an inspection, please contact:

- Adele Merenstein at (317) 752-4427 or amerenst@hallrender.com;
- Mark R. Dahlby at (414) 721-0902 or mdahlby@hallrender.com; or
- Your regular Hall Render attorney.

Please visit the Hall Render Blog at http://blogs.hallrender.com/ for more information on topics related to health care law.[1] Medicare's quality oversight of hospitals is based on compliance with the Medicare Conditions of Participation.

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