Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE'S OVERSIGHT OF COMPOUNDED PHARMACEUTICALS USED IN HOSPITALS

Daniel R. Levinson
Inspector General

January 2015
OEI-01-13-00400

EXECUTIVE SUMMARY: MEDICARE'S OVERSIGHT OF COMPOUNDED PHARMACEUTICALS USED IN HOSPITALS
OEI-01-13-00400

WHY WE DID THIS STUDY

A 2012 nationwide meningitis outbreak caused by contaminated injections, which were produced by a standalone compounding pharmacy, raised concerns about compounded sterile preparations (CSPs). Subsequent Office of Inspector General (OIG) work found that almost all acute-care hospitals use CSPs and most contract with standalone compounding pharmacies to provide at least some of these products. The Centers for Medicare & Medicaid Services (CMS) oversees the safety of CSPs prepared and used in Medicare-participating hospitals through the hospital certification process, in which State survey agencies or CMS-approved accreditors assess hospital compliance with requirements for drug compounding. This study provides information about the extent to which Medicare's oversight of hospitals addresses recommended practices for CSPs. In 2013, Congress passed the Drug Quality and Security Act, which clarifies the Food and Drug Administration's authority over standalone compounding pharmacies.

HOW WE DID THIS STUDY

We reviewed the practices of the five entities that oversee hospitals that participate in Medicare—namely, CMS and the four hospital accreditors approved by CMS. Through consultation with experts in CSP oversight, OIG identified 55 recommended practices for CSP oversight in acute-care hospitals. Representatives from each oversight entity participated in a structured interview and completed a questionnaire about how their respective surveys of hospitals incorporate these recommended practices. We analyzed the data from the interviews and the questionnaire to determine the extent to which Medicare's oversight addresses recommended practices for CSP oversight.

WHAT WE FOUND

Oversight entities address most of the recommended CSP-related practices at least some of the time. However, only one oversight entity always reviews hospital contracts with standalone compounding pharmacies. Oversight entities may also lack the human capital required to thoroughly review hospitals' preparation and use of CSPs. Surveyors receive limited training specific to compounding, and most oversight entities do not routinely include pharmacists on hospital surveys. Finally, although most oversight entities are considering changes to how they oversee hospitals' preparation and use of CSPs, none of them are considering changes to how they oversee hospitals' contracts with standalone compounding pharmacies.

WHAT WE RECOMMEND

CMS should (1) ensure that hospital surveyors receive training on standards from nationally recognized organizations related to safe compounding practices and (2) amend its interpretive guidelines to address hospitals' contracts with standalone compounding pharmacies. CMS concurred with both recommendations.

TABLE OF CONTENTS

OBJECTIVE

To determine the extent to which Medicare's oversight of hospitals addresses recommended practices for compounded sterile preparations.

BACKGROUND

A 2012 nationwide meningitis outbreak caused by contaminated injections that were compounded by the New England Compounding Center raised major concerns about compounded pharmaceutical products. The Centers for Disease Control and Prevention (CDC) reports that 751 cases of fungal infections and 64 deaths are linked to this outbreak.[1]

Pharmaceutical compounding is the creation of a prescription drug tailored to meet the needs of an individual patient. For example, a compounding pharmacist may produce a version of a drug without an ingredient to which a patient may be allergic, or the pharmacist might create a liquid form of a drug for a patient who is unable to swallow a pill. Traditionally, pharmacies compounded a drug upon receipt of a prescription for an individual patient. However, recent trends in drug compounding have included the large-scale production of certain drugs by standalone compounding pharmacies to meet the needs of some hospitals.[2] Hospitals may contract with multiple standalone pharmacies and may also compound drugs within their own pharmacies.

Compounded Drugs

There are two broad categories of compounded drugs: nonsterile preparations and sterile preparations, also known as compounded sterile preparations (CSPs). Nonsterile preparations—such as ointments applied to the skin or capsules or pills that a patient takes orally—are lower risk products. Standards for producing nonsterile preparations are less stringent than those for CSPs.

CSPs are higher risk products that are generally administered to patients via injection or infusion. Preparation of CSPs requires more expertise and more extensive safety measures. CSPs may be prepared in a variety of settings, including a patient's bedside for immediate use, a hospital pharmacy, or a contracted standalone pharmacy. Risks associated with CSP preparation include the use of the wrong medium or the wrong concentration for mixture, contamination with pathogens, and human

[1] CDC, *Multistate Outbreak of Fungal Meningitis and Other Infections*. Accessed at http://www.cdc.gov/hai/outbreaks/meningitis.html on November 26, 2014.

[2] S. Tavernise, "FDA Chief Seeks Expanded Authority to Improve Safety of Drug Compounders," *The New York Times*, November 14, 2012.

error. Among hospitals that participate in Medicare, 92 percent use CSPs.[3] Of these hospitals, almost 80 percent contract with at least one standalone compounding pharmacy to provide CSPs.

United States Pharmacopoeia

The United States Pharmacopoeia (USP) is an official compendium of drug standards in the United States.[4] Chapter 797 of the USP *Pharmaceutical Compounding—Sterile Preparations*, commonly referred to as USP 797, provides product safety and quality standards for preparing CSPs.[5] USP 797 includes standards for all risk levels of CSPs, including those prepared at a patient's bedside for immediate use. Pharmacies engaged in compounding have widely adopted USP 797 standards, which 28 States enforce to varying degrees.[6, 7] The Centers for Medicare & Medicaid Services (CMS) requires the hospital pharmacy to be administered in accordance with accepted professional principles. The standards in USP 797 qualify as accepted professional principles.

Other Guidelines Related to Sterile Compounding

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization that aims to educate the health care community and consumers about safe medication practices. In 2013, ISMP published guidelines for the safe preparation of CSPs. Experts developed these guidelines to provide procedures and safe practices for reducing errors in CSP preparation.[8] Among other things, the guidelines address drug storage, compounding, product labeling, and staff management.

---

[3] OIG, *Memorandum Report: High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them*, OEI-01-13-00150, April 2013.

[4] The Federal Food, Drug, and Cosmetic Act §§ 201(j) and (g)(1)(A) (21 U.S.C. §§ 321(j) and (g)(1)(A)) (defining the terms "official compendium" and "drug").

[5] The United States Pharmacopeial Convention. "USP-NF General Chapter 797 Pharmaceutical Compounding—Sterile Preparations." *The United States Pharmacopoeia and the National Formulary*, ch. 797 (2011).

[6] American Society of Health Systems Pharmacists (ASHP), *The ASHP Discussion Guide on USP Chapter <797> for Compounding Sterile Preparations*. Accessed at https://www.ashp.org/s_ashp/docs/files/DiscGuide797-2008.pdf on November 26, 2014.

[7] National Conference of State Legislatures, *State Regulation of Compounding Pharmacies*. Accessed at http://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx on November 26, 2014.

[8] ISMP, *Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds*. Accessed at http://www.ismp.org/tools/guidelines/IVSummit/IVCGuidelines.pdf on November 26, 2014.

In 2010, ASHP published guidelines on contracting for sterile compounding services.[9] These guidelines provide factors for hospitals to consider when deciding whether to contract with a standalone compounding pharmacy, as well as suggested contract provisions. They also provide guidance on how to evaluate a standalone compounding pharmacy's performance and how to address quality or performance issues with a standalone compounding pharmacy.

Medicare's Oversight of Hospitals

Medicare's quality oversight of hospitals is based on the Medicare Conditions of Participation (hereinafter referred to as the CoPs).[10] The CoPs are baseline health and safety requirements that hospitals must meet to be eligible for participation in Medicare.[11] They cover practices ranging from the credentialing and privileging of physicians to hospital management. Each CoP details specific standards that hospitals must meet.

Hospital pharmaceutical compounding is addressed directly by the CoP for pharmaceutical services and indirectly in the CoPs for governing body and infection control.[12] The pharmaceutical services CoP requires that all compounding be performed either by pharmacy personnel or under the supervision of pharmacy personnel.[13] The governing body CoP applies to hospitals that contract with standalone pharmacies insofar as this CoP requires hospital executives to monitor contracted relationships.[14] Finally, the infection control CoP mandates that hospitals maintain a sanitary environment that discourages the spread of infection through the facility.[15]

Hospitals may choose to demonstrate that they meet the CoPs through an onsite inspection, typically called a survey, that is conducted by either an accreditor or a State survey agency (hereinafter State agency).[16] Both accreditors and State agencies rely on surveys to determine whether hospitals newly enrolling in Medicare meet the CoPs, to reevaluate those

---

[9] ASHP, *ASHP Guidelines on Outsourcing Sterile Compounding Services*. Accessed at http://www.ashp.org/doclibrary/bestpractices/mgmtgdloutsourcingsterilecomp.aspx on November 26, 2014.

[10] 42 CFR pt. 482.

[11] Social Security Act, § 1861(e), 42 U.S.C. § 1395x(e); 42 CFR § 488.3(a)(2).

[12] 42 CFR § 482.25 (Pharmaceutical Services); 42 CFR § 482.12(e) (Governing Body); 42 CFR § 482.42 (Infection Control).

[13] CMS, *State Operations Manual*, Appendix A, A-0501. Accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf on June 24, 2014.

[14] Ibid., A-0083.

[15] Ibid., A-0747 and A-0749.

[16] Social Security Act, § 1865, 42 U.S.C. § 1395bb; 42 CFR § 488.5(a).

already in the Medicare program, and to respond to complaints and adverse events. Accreditors conduct surveys using their own survey protocols, whereas State agencies conduct surveys following the guidance outlined in the interpretive guidelines maintained by CMS.[17] CMS reviews the results of these surveys to determine whether the hospital is eligible to participate in Medicare.[18]

Pursuant to the Social Security Act, hospitals accredited by certain national accreditors may be deemed to meet the CoPs.[19] Hospitals pay accreditors to go through their accreditation processes. Four organizations accredit hospitals for participation in Medicare: the Joint Commission, the American Osteopathic Association, Det Norske Veritas Healthcare, and the Center for Improvement in Healthcare Quality. The Joint Commission accredits the majority of accredited hospitals.

Standalone Compounding Pharmacy Registration

In November 2013, Congress passed the Drug Quality and Security Act, clarifying the Food and Drug Adminstration's (FDA) oversight authority over standalone compounding pharmacies.[20] This new law allows standalone compounding pharmacies to voluntarily register with FDA as CSP-outsourcing facilities. FDA inspects registered pharmacies according to a risk-based schedule, and these pharmacies must comply with FDA's current good manufacturing practices, among other requirements.[21] As of January 1, 2015, 26 standalone compounding facilities had registered with FDA.[22]

---

[17] CMS, *State Operations Manual*, Appendix A. Accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf on June 24, 2014.

[18] 42 CFR § 488.12

[19] Social Security Act, § 1865, 42 U.S.C. § 1395bb; 42 CFR § 488.12.

[20] P.L. No. 113-54, § 102.

[21] FDA, *Compounding Quality Act*. Accessed at http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ on June 4, 2014.

[22] FDA, *Registered Outsourcing Facilities*. Accessed at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm on August 4, 2014.

Related Office of Inspector General Work

In 2013, OIG released a memorandum report on the extent to which Medicare-participating acute-care hospitals used CSPs and purchased them from standalone pharmacies.[23] This study found that 92 percent of hospitals used CSPs and about 80 percent of these hospitals contracted with at least one standalone pharmacy to provide CSPs.

In April 2014, OIG released a study that found that CMS does not track the number of claims for compounded drugs under Medicare Part B or the corresponding amounts paid.[24] That study also found that Part B claims do not contain adequate information to identify compounded drugs and do not identify the compounding pharmacies that produced the drugs.

METHODOLOGY

We used three data sources in our review. First, we interviewed experts in the field of compounding oversight and reviewed guidance and recommendations from USP, ISMP, and ASHP. We then conducted structured interviews with CMS—as it provides the guidelines for State and accreditor surveys—and with the four CMS-approved hospital accreditors. (Hereinafter, we refer to CMS and the accreditors as "oversight entities.") We also asked them to complete a questionnaire detailing the compounding-specific elements of their surveys. To the extent possible, we corroborated their responses by reviewing their survey policy and procedure manuals.

Scope

This study is national in scope. It examined the oversight activities of the five oversight entities. We examined CMS policies and procedures for State survey and certification agencies, but we did not examine the oversight activities of each individual State agency. This study focused on Medicare's oversight of hospital use of CSPs because of the greater risk these may present to patients relative to those of nonsterile preparations, such as ointments and capsules.

[23] OIG, *Memorandum Report: High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them*, OEI-01-13-00150, April 2013.
[24] OIG, *Compounded Drugs Under Medicare Part B: Payment and Oversight*, OEI-03-13-00270, April 2014.

Data Collection

Identifying Recommended Practices for Oversight of CSP Preparation and Use in Acute-Care Hospitals. Through consulting with experts in the oversight of CSPs, OIG identified 55 recommended practices for the oversight of CSP preparation and use in acute-care hospitals. These recommended practices include measures identified by USP, ISMP, ASHP, and other experts. For this analysis, we grouped the recommended practices into seven areas:

(1) physical plant and environmental quality,
(2) policies and procedures for compounding CSPs,
(3) pharmacy personnel training and evaluation,
(4) patient monitoring and adverse event reporting,
(5) CSP storage,
(6) compounding equipment use and maintenance, and
(7) contracts with standalone compounding pharmacies.

Structured interviews of oversight entities. We interviewed representatives from oversight entities to learn more about how Medicare oversight incorporates the recommended practices related to CSPs. During these interviews we asked oversight entities to describe:

(1) the documents that surveyors review prior to hospital surveys,
(2) the way in which surveyors learn about compounding in hospitals,
(3) compounding-specific training that surveyors receive,
(4) the way in which oversight entities cite hospitals for deficiencies related to compounding, and
(5) any future plans that oversight entities have for changing the way that surveys address compounding in hospitals.

We conducted four of these interviews over the phone and one in person.

Questionnaire sent to oversight entities. We sent oversight entities a questionnaire about how their hospital survey processes incorporate recommended practices for oversight of sterile drug compounding. The questionnaire asked whether each recommended practice is "always," "some of the time," or "never" addressed during surveys of hospitals that use CSPs. We asked oversight entities to corroborate their responses by providing us with the relevant sections of their manuals on policies and procedures for surveys. See Appendix A for a complete inventory of questionnaire responses.

Data Analysis

We analyzed the data from the questionnaire and the structured interviews to determine the extent to which Medicare's oversight addresses the 55 recommended practices we identified across 7 areas. We totaled the responses for each area to determine the extent to which Medicare's oversight of hospitals addresses recommended practices for CSPs. To corroborate covered entities' responses to the questionnaire, we reviewed the survey policy and procedure manuals that they provided to us. For added context, we aggregated the structured interview data and identified how oversight entities approach oversight of CSPs in hospitals.

Limitations

Medicare does not require that the recommended practices we identified be incorporated into hospital surveys. We did not evaluate the validity of hospital surveys conducted by the five oversight entities. Our review relied on self-reported data from the oversight entities. It was not feasible to independently verify these data.

Standards

This study was conducted in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Oversight entities address most of the expert-recommended practices related to CSPs at least some of the time

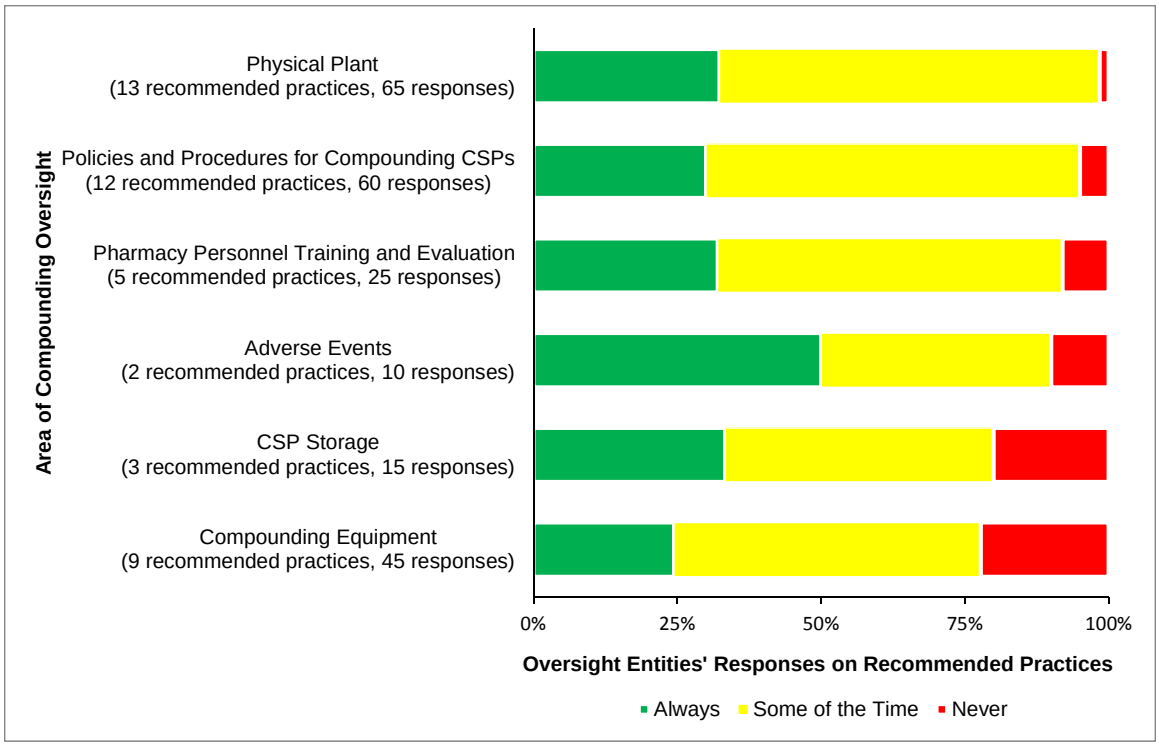
Because they have limited time to assess hospitals' entire operations, oversight entities may address some of the recommended practices for oversight of CSPs on a case-by-case basis. Oversight entities are more likely to address CSPs when a problem with CSPs is apparent during the current survey or was apparent during a prior survey. Although oversight entities reported not always asking hospitals directly about CSP preparation and use during hospital surveys, they generally reported that they assume hospitals prepare and use CSPs.[25]

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 (see Figure 1 on the next page).

Physical plant. Oversight of the physical area where compounding occurs includes assessing its cleanliness and appropriateness for the types of CSPs prepared, including hazardous CSPs (such as chemotherapy drugs). Most oversight entities reported that they always assess the environmental quality and control in hospital compounding areas and the appropriateness of the areas where hazardous CSPs are prepared. However, with regard to hospitals' written policies and procedures related to maintaining the hospital compounding area, most oversight entities review these documents on some, but not all, surveys. Some oversight entities told us that surveyors prioritize observing hospitals' maintenance practices in compounding areas and review written procedures only when necessary to confirm that hospital procedures comply with the oversight entity's standards.

[25] Two oversight entities reported that they ask hospitals whether they prepare CSPs onsite. The three other oversight entities reported that they most often learn about CSP preparation while touring the pharmacy. With regard to use of CSPs, only one oversight entity reported asking each hospital directly about CSP use. Two of the oversight entities reported that they assume that all hospitals use CSPs, and two more reported that they observe CSP use during their tours of hospitals.

Figure 1: Extent to Which the Five Oversight Entities Incorporate Recommended Practices for Each Area of Compounding Oversight Into Surveys



Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Note: Responses represent the number of recommended practices multiplied by the five oversight entities.

Policies and procedures for compounding CSPs. Recommended oversight of policies and procedures for preparing CSPs includes ensuring that hospitals' policies and procedures address (1) the safety of staff when they are preparing hazardous CSPs and (2) the quality and sterility of CSPs. Most oversight entities reported that they always assess hospitals' procedures for keeping staff safe when compounding hazardous CSPs. Additionally, on some, but not all, surveys, oversight entities generally review written policies and procedures for CSPs compounded onsite and for outsourcing CSPs. Most oversight entities told us that they would request these policies and procedures only if a surveyor discovered a noncompliant practice related to compounding CSPs.

Pharmacy personnel training and evaluation. Oversight of pharmacy personnel training and evaluation includes assessing whether the hospital provides continuing education and competency evaluation to ensure that staff prepare CSPs in accordance with accepted standards. Most oversight entities always review the training and competency records of pharmacy personnel. However, most oversight entities delve into a hospital's requirements for compounding-specific training and competency evaluation only on some surveys. Generally, they look more deeply into

personnel training and evaluation for a sample of personnel or in instances when they identify a problem with personnel during the survey.

Adverse events. We identified two recommended practices related to adverse events: (1) assessing hospitals' feedback mechanisms for patients and caregivers to report CSP-related concerns and (2) determining whether hospitals track outsourced CSPs to the patient level. Most oversight entities reported that they always assess hospitals' feedback mechanisms for patients and caregivers to report concerns about CSPs. Oversight entities vary as to how often they determine whether hospitals track outsourced CSPs to the patient level: four always or sometimes do this, while one does not do this at all.

CSP storage. Oversight of CSP storage includes assessing whether hospitals store CSPs under the conditions necessary to maintain their sterility and stability. On some, but not all, surveys, most oversight entities assess whether hospitals store CSPs under proper conditions. Two oversight entities told us that surveyors always review medication storage. The other three oversight entities review this some of the time.

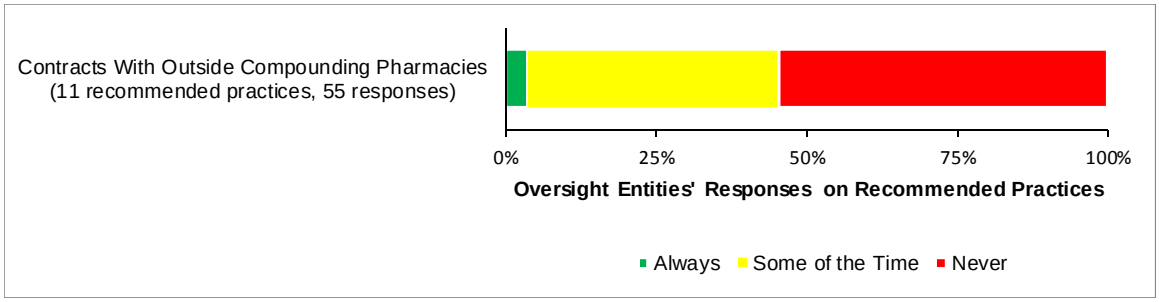
Compounding Equipment. Recommended practices related to compounding equipment focus on reviewing hospitals' procedures for equipment use and maintenance to ensure that CSPs are prepared safely and accurately. Two oversight entities consistently review hospitals' preventative maintenance documentation for all equipment used to prepare CSPs. In general, oversight entities give surveyors the discretion to decide which equipment policies and procedures to assess. For instance, a surveyor might review policies and procedures related to equipment use only if related concerns arise through observation or interviews during the survey.

Only one oversight entity always reviews hospitals' contracts with standalone compounding pharmacies

Four of the five hospital oversight entities either do not or only sometimes review hospital contracts with standalone compounding pharmacies during surveys. This review could include whether the terms of the contracts address CSP recall procedures, proper storage of CSPs while in transit, and quality assurance related to CSP sterility and potency, among others. All oversight entities request lists of hospitals' contracted services during surveys. One oversight entity always reviews hospitals' contracts with standalone pharmacies and assesses whether hospitals evaluate pharmacies' compliance with the contracts. (See Figure 2 on the next page.) Most hospitals that use CSPs contract with one or more standalone pharmacies to produce some of their CSPs. In particular, hospitals tend to

outsource the highest risk CSPs, such as the compounded injections responsible for the 2012 fungal meningitis outbreak.

Figure 2: Extent to Which the Five Oversight Entities Incorporate Recommended Practices for Oversight of Contracts With Outside Contracting Pharmacies Into Surveys



Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Note: Responses represent the number of recommended practices multiplied by the five oversight entities.

Finally, three oversight entities do not determine whether the standalone pharmacies that hospitals use have voluntarily registered with FDA as CSP-outsourcing facilities. The remaining two oversight entities sometimes take standalone pharmacies' FDA registration status into account when they examine hospital contracts. Standalone compounding pharmacies that register with FDA are subject to FDA inspection. Because most hospitals do not inspect the standalone pharmacies with which they contract, a satisfactory FDA inspection might be the only indicator of the conditions at a standalone pharmacy.

Oversight entities may lack the human capital required to thoroughly review hospitals' preparation and use of CSPs

We acknowledge that many of the recommended practices included in our review are highly technical and specific to compounding—one of many activities that hospital oversight entities must assess. In fact, experts we spoke with said that only a trained pharmacist would be able to perform a comprehensive review of these recommended practices.

Pharmacists are not routinely involved in most hospital surveys, but surveyors can draw on pharmacists' expertise when needed

Only two oversight entities employ pharmacists as hospital surveyors; however, neither includes a pharmacist on every survey team. One of these oversight entities regularly sends pharmacists on hospital surveys and tries to include a pharmacist on surveys of larger hospitals with more complicated pharmacy operations. The other oversight entity with pharmacist surveyors does not regularly include them on surveys, but may include a pharmacist on complaint surveys related to alleged pharmacy

problems. Surveyors at two other oversight entities have access to a pharmacist-consultant on an as-needed basis if a pharmacy-related problem arises during a survey. Finally, surveyors at one oversight entity do not have access to pharmacists during the survey process.

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.

Most oversight entities are considering changes to their oversight of hospitals' preparation and use of CSPs

Three oversight entities are considering changing the way they address preparation of CSPs in hospitals, but they have not committed to doing so. For instance, one oversight entity is revising how it oversees drug compounding in home infusion pharmacies and may apply the changes it makes for this setting to hospitals. Potential changes include revising training for surveyors, so that they have the tools to consistently evaluate compounding practices and the compounding environment during surveys. Another oversight entity has created optional standards for hospitals related to CSPs and is considering applying these standards to all surveys. The remaining oversight entity is considering incorporating additional elements of USP 797 into its surveys. The other two oversight entities do not plan to change their oversight of CSP preparation in hospitals.

Finally, despite outsourced compounded injections' being responsible for the 2012 fungal meningitis outbreak, none of the oversight entities plan to change how their oversight addresses hospital contracts with standalone compounding pharmacies.

CONCLUSION AND RECOMMENDATIONS

CSPs are a complex and highly technical aspect of hospital operations. We identified 55 recommended practices for overseeing CSPs in hospitals by consulting with experts and reviewing standards from nationally recognized organizations. However, CSPs are only one of many areas of hospital operations that Medicare oversight entities must assess during onsite surveys.

Accordingly, oversight entities must—and do—exercise their discretion when determining how they assess CSP-related hospital operations. Indeed, in this evaluation, we found that oversight entities follow most recommended practices at least some of the time and that their surveyors exercise discretion as to the scope and depth of their reviews on the basis of what they encounter at each hospital.

To exercise their discretion most effectively in the oversight of CSPs, surveyors need the appropriate knowledge of this highly technical aspect of hospital operations. However, we found that oversight entities provide limited training specific to compounding to their surveyors.

In addition, contracting with standalone pharmacies for CSPs gets limited attention from the oversight entities. Only one of the five oversight entities always reviews hospitals' contracts with standalone pharmacies. Such a review could include whether contracts adequately address CSP recall procedures, proper storage of CSPs while in transit, and quality assurance related to CSP sterility and potency, among others. Finally, none of the entities plan to change how they assess these contracts in light of FDA's new initiative to register and inspect standalone compounding pharmacies.

Therefore we recommend that CMS:

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

CMS's interpretive guidelines for hospital surveys state that pharmaceutical services must be administered in accordance with standards or recommendations promoted by nationally recognized professional organizations. We recognize that it is not reasonable to expect surveyors to be experts on the highly technical aspects of pharmaceutical compounding. However, CMS should work with experts and professional organizations, such as USP, ISMP, and ASHP, to develop surveyor training on standards for compounding from nationally recognized organizations. This training could help ensure that CMS and

State agency surveyors have the basic competencies necessary to assess compounding in hospitals and to determine when they need to call on additional expertise beyond that of the survey team. When accreditation organizations apply or reapply for "deeming" authority, CMS should ensure that they have equivalent training in place for their surveyors.

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

Medicare's pharmaceutical services CoP covers the compounding of medications, but it does not speak to hospitals' contracts with standalone compounding pharmacies. Hospitals often contract with such pharmacies for high-risk CSPs, such as those that caused the 2012 meningitis outbreak.

To improve oversight of hospitals' contracts with standalone compounding pharmacies, CMS should amend the interpretive guidelines for hospital surveys. Specifically, within guidance on the pharmaceutical services CoP, CMS could instruct surveyors to assess hospitals' management of contracts with standalone compounding pharmacies. This guidance could reference hospitals' responsibility for overseeing their contracted services under the quality assessment and performance improvement (QAPI) CoP and the governing body CoP. The QAPI CoP requires hospitals to have an ongoing, data-driven performance improvement program that covers all hospital services, including those furnished under contract. The governing body CoP holds hospitals' governing bodies accountable for all contracted services and requires governing bodies to use the QAPI program to assess services provided under contract. Referencing these requirements within the pharmaceutical services CoP could help to ensure that surveyors always review hospitals' contracts with standalone compounding pharmacies.

Additionally, within the interpretive guidelines, CMS could require that when surveyors assess hospitals' management of contracts with standalone compounding pharmacies, they review whether these pharmacies have registered with FDA. We understand that CMS may need to seek additional authority to make this change.

Finally, CMS should ensure that any changes it makes to the interpretive guidelines are reflected in accreditors' survey procedures when they apply or reapply for "deeming" authority.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with both of our recommendations.

In response to our first recommendation, CMS stated that surveyors could benefit from more training in assessing compounding practices in hospitals. It will explore developing online training materials for surveyors with State survey agencies and will explore ways to collaborate with national experts to develop this training. CMS also noted that approved hospital accreditors must have survey procedures comparable to those established for State survey agencies and that they use qualified surveyors.

In response to our second recommendation, CMS stated that it will explore revising its interpretive guidelines to make surveyors aware that the CSPs used in hospitals are frequently handled by contracted compounding pharmacies. It further stated that because Medicare regulations do not require hospitals to contract with compounding pharmacies that have registered with FDA, surveyors would limit their assessments to how hospitals ensure that their contracted pharmacy services comply with regulations.

OIG supports CMS's efforts to improve Medicare's oversight of pharmaceutical compounding in hospitals. We will monitor these efforts through our recommendations-tracking process.

For the full text of CMS's comments, see Appendix B.

APPENDIX A

Oversight Entity Responses to the Office of Inspector General Questionnaire on Recommended Practices for Hospital Compounding Oversight

Table A1: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to the Hospital Physical Plant and Environmental Quality

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request a copy of the hospital's pharmacy cleaning logs?	1	4	0
Do surveyors request a copy of the hospital's pharmacy environmental sampling logs?	0	5	0
If the hospital prepares CSPs onsite, do surveyors assess whether the area of preparation is appropriate for all CSP risk levels compounded at the hospital?	2	3	0
If the hospital prepares hazardous CSPs onsite, do surveyors assess the appropriateness of the physical area where hazardous CSPs are compounded?	3	2	0
If the hospital prepares CSPs onsite, do surveyors assess the environmental quality and control in the area of preparation?	3	2	0
If always or some of the time, do surveyors assess the adequacy of the environmental quality and control for each risk level of CSP prepared at the hospital?	2	3	0
If the hospital prepares CSPs onsite, do surveyors review the hospital's written procedures outlining the following:			
Cleaning and disinfecting of the compounding areas?	1	4	0
Personnel hand hygiene and garbing in compounding areas?	3	2	0
Employee aseptic technique in compounding areas?	2	3	0
Environmental sampling in compounding areas?	0	5	0
Facility and engineering control testing and certification in compounding areas?	0	4	1
If the hospital prepares CSPs onsite, do surveyors assess the adequacy of personnel protective equipment for compounding CSPs, including applicable policies and procedures for personnel protective equipment?	2	3	0
For hospitals that prepare hazardous CSPs onsite, do surveyors assess the adequacy of personnel protective equipment for compounding hazardous CSPs, including applicable policies and procedures?	2	3	0

Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A2: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to Policies and Procedures for Compounding CSPs

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request copies of all the hospital's policies and procedures related to any pharmacy-compounded sterile preparations (CSPs)?	0	5	0
Do surveyors request copies of all the hospital's policies and procedures for outsourcing CSPs?	0	4	1
Do surveyors request a copy of the hospital's most recent USP 797 Gap Analysis?	0	3	2
Do surveyors determine whether the hospital has a quality assurance plan in place to verify the accuracy and sterility of compounded CSPs?	3	2	0
Do surveyors perform an assessment of the hospital's pharmacy procedures for finished preparation checks?	2	3	0
Do surveyors assess the hospital's policies and procedures for maintaining CSP quality and purity until time of dispensing or beyond-use date?	1	4	0
Do surveyors assess the extent to which the hospital's policies and procedures for immediate use CSPs correspond with USP 797 in all areas of the hospital?	0	5	0
Do surveyors review the hospital's policies and procedures for establishing beyond-use dating?	1	4	0
Do surveyors assess the appropriateness of beyond-use dates on opened or needle-punctured single-dose and multiple-dose containers in all areas of the hospital?	2	3	0
Do surveyors determine whether all orders entered into a computerized prescriber order-entry system at the hospital are verified by a pharmacist?	3	2	0
Do surveyors review the hospital's policies and procedures for compounding hazardous CSPs, such as chemotherapy drugs?	2	3	0
If a hospital prepares radiopharmaceutical CSPs, do surveyors assess the hospital's procedures to limit staff radioactivity exposure?	4	1	0

Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A3: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to Pharmacy Personnel Training and Evaluation

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request a copy of the hospital's pharmacy personnel training and competency records?	3	2	0
For hospitals that prepare CSPs onsite, do surveyors determine whether the hospital requires that personnel receive continuing education (e.g., annually) on compounding CSPs?	1	4	0
For hospitals that prepare CSPs onsite, do surveyors determine whether the hospital requires (e.g., annually) that personnel demonstrate competencies on compounding CSPs?	1	4	0
Do surveyors review past performance evaluations for pharmacy personnel?	0	4	1
If surveyors always or sometimes review past performance evaluations for pharmacy personnel, do surveyors review how the hospital addresses pharmacy personnel performance issues?	3	1	1

Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A4: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to Patient Monitoring and Adverse Event Reporting

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors assess the hospital's feedback mechanism for patients and caregivers to report concerns regarding CSPs or CSP-administration devices?	3	2	0
Do surveyors determine if the hospital has a policy for tracking outsourced compounded medications to the patient level?	2	2	1

Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A5: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to CSP Storage

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors assess whether the hospital stores CSPs under proper conditions for the specified beyond-use date on the label?	2	3	0
If the hospital uses hazardous CSPs (i.e., chemotherapy), is there a separate assessment of the storage conditions for hazardous CSPs?	3	2	0
Do surveyors review whether the hospital has documented justification if CSPs are stored longer than deemed appropriate for the beyond-use date and storage conditions per USP 797?	0	2	3

Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A6: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to Compounding Equipment Use and Maintenance

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors review whether routine preventive maintenance is documented for all equipment used during the compounding of CSPs?	2	3	0
Do surveyors review whether routine calibration is documented for all equipment used during the compounding of CSPs?	2	1	2
Do surveyors review whether certification of equipment and areas used during the compounding of CSPs is current and without lapse for one year?	1	3	1
For hospitals that prepare CSPs onsite, do surveyors review hospitals' written procedures outlining the following with respect to compounding equipment:			
Required equipment calibration?	1	3	1
Routine (scheduled) equipment maintenance?	2	2	1
Monitoring for proper equipment function?	1	3	1
Procedures for equipment use?	1	3	1
Equipment cleaning?	1	3	1
Verifying the accuracy and precision of automated compounding devices for parenteral nutrition compounding?	0	3	2

Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A7: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to Hospital Contracts With Standalone Compounding Pharmacies

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors determine whether the outside pharmacies that the hospital contracts with to provide CSPs are registered with FDA?	0	2	3
Do surveyors review the hospital's contracts with outside compounding pharmacies?	1	2	2
If surveyors always or sometimes review contracts between the hospital and outside compounding pharmacies, do surveyors review whether the terms of the contracts address the following			
The hospital's right to inspect the contracted compounding pharmacy?	0	1	4
CSP recall procedures?	0	1	4
Requirements for the contracted compounding pharmacy to submit quality reports to the hospital?	0	3	2
Proper storage of CSPs while in transit?	0	2	3
Quality assurance related to CSP sterility?	0	2	3
Quality assurance related to CSP potency?	0	2	3
Quality assurance related to CSP stability and expiration dating?	0	2	3
If surveyors always or sometimes review contracts between the hospital and outside compounding pharmacies, do surveyors review whether the hospital documents each contracted pharmacy's compliance with the terms of the contract?	0	3	2
If surveyors always or sometimes review contracts between the hospital and outside compounding pharmacies, do surveyors review whether the hospital evaluates each contracted pharmacy's compliance with the terms of the contract?	1	3	1

Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

APPENDIX B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

NOV 2 1 2014

To: Daniel R. Levinson
Inspector General
Office of the Inspector General

From: Marilyn Tavenner /S/
Administrator
Centers for Medicare & Medicaid Services

Subject: Medicare Exercises Discretion in Oversight of Pharmaceutical Compounding in Hospitals (OEI-01-13-00400)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of the Inspector General's (OIG) draft report. CMS is committed to ensuring hospital compliance with requirements for drug compounding, including prevention of the spread of infections through proper compounding, particularly of compounded sterile preparations (CSPs) for intravenous use. CMS oversees hospitals through the certification process, which includes assessing hospital compliance with requirements for drug compounding, either via State Survey Agencies acting on CMS's behalf or via accreditation under a CMS-approved Medicare accreditation program. CMS relies on the Food and Drug Administration (FDA) oversight of manufacturers to ensure safety of commercially available prescription drugs.

CMS concurs with the OIG's findings that hospital oversight entities address most recommended practices related to CSPs, and that recommended oversight practices included in the review are highly technical and specific to compounding.

OIG Recommendation
The OIG recommends that CMS ensure that hospital surveyors receive training on national standards related to safe compounding practices.

CMS Response
CMS concurs with this recommendation. While it is not reasonable to expect hospital surveyors to be experts on the highly technical aspects of compounding, surveyors could benefit from more training to ensure their basic competencies in assessing compounding practices in hospitals. CMS will explore developing on-line training materials for surveyors with State Survey Agencies and ways to collaborate with national expert organizations in developing such training.

With respect to CMS-approved Medicare hospital accreditation programs, the applicable regulations at 42 CFR 488.8(a)(2)(ii) require that they have survey procedures comparable to those established for State Survey Agencies, and that they use qualified surveyors. All renewal applications for these accreditation programs are routinely reviewed for their comparability to the survey process current as of the time of the renewal application.

OIG Recommendation

The OIG recommends that CMS amend the interpretive guidelines to address contracts with standalone compounding pharmacies.

CMS Response

CMS concurs with this recommendation. We will explore revising the interpretive guidelines for the hospital pharmacy Condition of Participation (CoP) for pharmaceutical services at 42 CFR 482.25 and the critical access hospital (CAH) CoP requirement for storing and handling drugs and biologicals at 42 CFR 483.635(a)(3)(iv) to make surveyors aware that compounding of CSPs used in hospitals frequently is handled by a contracted compounding pharmacy. However, since Medicare regulations do not require hospitals and CAHs 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.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office; Kenneth Price, Deputy Regional Inspector General; and Russell Hereford, Deputy Regional Inspector General.

Jessica Fargnoli served as the team leader for this study, and Jesse Valente served as the lead analyst. Central office staff who provided support include Christine Moritz and Talisha Searcy.

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.