

Regulatory Alert: CMS Updates surveyor guidance for oversight of compounding in Critical Access Hospitals

Background:

The Centers for Medicare & Medicaid Services (CMS) routinely updates the State Operations Manual (SOM) for surveyors who assess whether providers enrolled in Medicare are meeting all the Conditions of Participation (CoPs) of the program. Along with revisions resulting from two recent Final Rules for Critical Access Hospitals (CAHs), CMS has revised the interpretive guidelines contained in Appendix W for CAHs of the SOM.

The agency took this opportunity to:

...update the guidance for the portions of 42 CFR 485.635 addressing the following topics, in order to bring them into alignment with current accepted standards of practice: pharmacy services; infection prevention and control; dietary services; services under arrangement; nursing services; and rehabilitation services.

Unlike the CoPs, interpretive guideline revisions do not require rule making, which allows CMS to update surveyor guidance as needed to reflect changes in national standards and principles of professional practice. Most significantly for pharmacists, CMS has explicitly addressed compounding standards under their section on handling of drugs and pharmaceuticals. ASHP's Government Affairs staff has reviewed the changes to the SOM and has prepared this summary of the changes to the use of compounded drugs in CAHs. The full revised Appendix W is available [here](#). The discussion on compounding begins on page 20 of the document.

Handling of drugs and biologicals; Compounding

Through these interpretive guidelines, CMS is establishing the USP/NF chapters on compounding as the minimum threshold for quality that CAHs must meet under the Medicare program. The agency states that:

All compounding of medications used or dispensed by the CAH must be performed consistent with accepted professional principles which are equivalent to or more stringent than those described in the compounding-related chapters in the USP/NF, which are recognized as authoritative standards regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.

CMS cites USP Chapter <795> for the definition of compounding. The agency goes on to say that a pharmacy in a CAH must be able to demonstrate that their sterile and non-sterile products are being prepared, dispensed, and/or administered to the patients in a manner that ensures chemical strength and a lack of chemical or microbial contaminations.

The guidelines explicitly state that USP Chapters <795> and <797> are the minimum standards for non-sterile and sterile compounding respectively and that a CAH's standard operating procedures for all compounding performed in house, and for ensuring the quality of outsourced compounding services and products must reflect the relevant USP standards

CMS also discusses the new FDA category of registered outsourcing facilities (503B facilities) in the context of the Drug Quality and Security Act (DQSA) and references an FDA letter from January 2014 in which the Commissioner of the FDA encouraged the use of 503B facilities for outsourced compounded products. The letter stated that the 503B facilities would be inspected on a risk-based schedule, held to CGMP requirements, monitored for adverse drug events, and required to submit appropriate labeling.

CMS does not require the use of 503B facilities for compounded products that are not prepared at CAHs, but the SOM does require that CAHs obtaining compounded medications from a compounding pharmacy demonstrate that the vendor is adhering to USP Chapters <795> and <797>.

Finally, CMS mentions the ASHP Research and Education Foundation™ tool for assessing vendors that provide compounded sterile products as a useful reference for CAHs as they evaluate compounding pharmacies not registered with the FDA as 503B outsourcing facilities.

Next Steps

The new interpretive guidelines are not yet published in CMS's online manual for the CAH program and therefore the official version may contain additional minor revisions. Although the guidelines are currently limited to CAHs, we believe that that CMS will similarly revise the interpretive guidelines for hospitals as well those for as other settings where sterile and nonsterile compounding is performed.

ASHP staff will remain engaged with CMS as the agency develops training materials for surveyors evaluating compounding practices in CAHs. ASHP will actively work with CMS to support incorporating standards that ensure safe compounding.

ASHP's is revising its [Guidelines for Outsourcing Sterile Compounding Services](#) to reflect the new Drug Quality and Security Act requirements and anticipates publication by the end of March. The ASHP Research and Education Foundation™ Outsourcing Contractor Assessment Tool will be revised to align with the guidelines as soon as they are available. The new guidance will give healthcare professionals the tools to evaluate compounding pharmacies and to ensure quality and responsibility for the products that they are purchasing.

Pharmacists and other appropriate individuals in CAHs should carefully review the current standard operating procedures in regards to compounding, both in-house and contracted, to ensure they are compliant with all Medicare requirements.

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

These materials are provided only for general informational purposes and do not constitute professional or legal advice. The reader should not under any circumstances solely rely on, or act on the basis of, these materials. These materials and information are not a substitute for obtaining professional or legal advice.