



Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 16-18-Hospitals & CAHs

DATE: March 18, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Pharmaceutical Compounding in Hospitals and Critical Access Hospitals (CAH)
Online Surveyor Training

Memorandum Summary

- **Purpose of Pharmaceutical Compounding Training:** The Centers for Medicare & Medicaid Services (CMS) is providing training to Hospital and CAH surveyors on assessing compliance with the nursing and pharmaceutical services requirements related to compounding and safety practices.
- **Three-Part Online Training:** CMS has partnered with the American Society of Health System Pharmacists (ASHP) to develop a three-part online training course related to pharmaceutical compounding and United States Pharmacopeia (USP) Chapter <797> standards. Surveyors will take an online course consisting of two technical trainings from ASHP and one regulatory compliance module from CMS.
- **ASHP Course Cost: This course is mandatory for all State Agency (SA) and Regional Office (RO) Hospital and CAH surveyors and reviewers with completion by May 2017.** The cost of the online course access on ASHP's website is \$12/per user/year. States should claim this cost as part of their training costs incurred.

Background

CMS is committed to patient safety and ensuring compliance with requirements for pharmaceutical compounding, including prevention of the spread of infections through proper compounding. Due to contaminated injections produced by a compounding pharmacy in 2012, a nationwide outbreak of meningitis occurred. This outbreak prompted an investigation by the Office of Inspector General (OIG) regarding pharmaceutical compounding, specifically CMS's oversight of this process in hospitals.

The final report issued January 2015 (<http://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf>), identified 55 recommended practices for compounded sterile preparation (CSP) oversight in acute-care hospitals. The recommended practices include focusing on environmental quality, policies and procedures for compounding CSPs, training of compounding personnel, patient

monitoring and adverse event reporting, CSP storage, compounding equipment use and maintenance, and contracts with compounding pharmacies.

Recommendations from the OIG are:

- To ensure that hospital surveyors receive training on standards from nationally recognized organizations related to safe compounding practices; and,
- To amend its interpretive guidelines to address hospital contracts with standalone compounding pharmacies.

CMS released updated CAH interpretive guidance in January 2015, and the hospital guidance was released in October 2015. The updated guidance reflects important issues related to safe compounding and how CMS ensures compounding safety through various Conditions of Participation requirements.

In collaboration with ASHP, CMS has developed an online training program for SA and RO Hospital and CAH surveyors and reviewers. CMS does not expect surveyors to be experts on the highly technical aspects of compounding; however, additional training is beneficial for surveyors for assessing compounding practices in Hospitals and CAHs.

Target Audience

This course is mandatory for all SA and RO Hospital and CAH surveyors and reviewers. The course must be completed by the end of May 2017.

Course Components

The online course consists of three-parts: two online learning modules from the ASHP and one online learning module regarding CMS regulations. These modules are:

- Module 1: Compounding Sterile Preparations: ASHP's Guide to Chapter <797> *The Basics of USP Chapter <797>*
- Module 2: Compounding Sterile Preparations: ASHP's Guide to Chapter <797> *Handling CSPs*
- Module 3: Assessing Compounding Safety in Hospitals and CAHs

Prior to starting the course modules, the surveyor will receive an enrollment code from their State Training Coordinator (STC)/State Agency Training Designee for registering for the ASHP courses. The enrollment code will be valid for one year following the purchase of the code from the SA.

The *Fact Sheet for ASHP Three Part Online Training Course* provides an overview on how to register and begin the course modules. Additionally, the *STC Fact Sheet for Obtaining Enrollment and Administrative Codes* outlines the process for obtaining the enrollment and administrative codes for their State.

Estimated Course Completion Time

This three-part course has an estimated overall seat time of four to six hours.

Contact: For enrollment or registration questions, please contact the Training Coordinator, Ruth Rivera at Ruth.Rivera@cms.hhs.gov. For questions regarding course content, please contact the CMS SCG Hospital Program mailbox at hospitalscg@cms.hhs.gov.

Effective: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment(s): Fact Sheet for ASHP Three Part Online Training Course
STC Fact Sheet for Obtaining Enrollment and Administrative Codes

cc: Survey and Certification Regional Office Management
State Agency Directors
Regional Training Administrators
State Training Coordinators