Chapter 16

Documentation of Compounded Sterile Preparations

Ryan A. Forrey

Introduction

Documentation is a record of activities. In the case of compounding sterile preparations, documents tell how a preparation was processed and what quality attributes it possesses. This documentation helps to ensure that a system is in place to compound preparations properly and also serves as a checklist for compounding procedures. Documentation must be performed precisely, consistently, quickly, and in sufficient detail to permit another individual to investigate or duplicate the compounding process exactly.

Uses of Documentation

Outside Organizations

Many organizations including state boards of pharmacy, third-party payers, the Joint Commission and other accrediting agencies, the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) may inspect the sterile compounding records. These organizations use documentation records when determining payments, granting licensure, and, possibly, justifying continued accreditation of certain programs. Standards of practice including USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations and USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings provide requirements for documentation of environmental and equipment quality, personnel training and technique, compliance with compounding procedures, and safe handling of hazardous drugs.[1,2] The Federal Food, Drug and Cosmetic Act, sections 503A and 503B also outline the documentation required for traditional compounders and outsourcing facilities, respectively.[3]

Note: The author acknowledges E. Clyde Buchanan who wrote this chapter in the previous edition.

Legal Situations

If a patient pursues litigation related to a compounded sterile preparation (CSP), an attorney may subpoena the pharmacy's quality assurance records and other relevant documents. These records would also be reviewed by the organization's legal counsel as well as its malpractice insurance carrier. In this situation, the quality of documentation may prevent a costly lawsuit or judgment.

Workload Justification

Besides serving as a record of past actions, documentation of goods and services provided by the pharmacy can be used to develop workload statistics and productivity ratios. This information can subsequently support a formal request for adding staff, equipment, or workspace or for reallocating these same resources elsewhere. Because several very high-profile outsourcing compounder contamination tragedies have occurred, these data may also help in showing a return on investment and justification for insourcing all CSPs. (See Chapter 32.)

Quality Improvement

If problems are discovered with CSPs, all documentation should be double-checked as soon as possible. Whenever the quality of a CSP is questioned, the appropriate documents should be stored in a secure place. Results of the investigation then should be used in a continuous quality improvement process to do the following (Chapter 31):

- Identify problems
- Take action to improve problem areas
- Evaluate the effectiveness of the action taken

Documented Information

Documentation can be brief or extensive as long as important facts are not omitted. Forms, worksheets, and computer software can prompt the user to document all essential information. Computerized labels, noncarbon forms, or addressographs may save time by avoiding duplicate data entries (e.g., patient names and locations). If used, many of the integrated electronic medical records or pharmacy information systems provide for documentation of required compounding information (e.g., lot numbers, expiration dates, beyond-use dates [BUDs], and formulation records) within the system. Documentation should occur *when* and *where* the work is completed or while it is in progress.

Documentation errors must be handled carefully to avoid the appearance of a cover-up. As with any legal document or medical record, correction fluid should never be used on pharmacy records; a single line should be drawn through the mistake, and the word *error* with the person's initials should be written by it.

Medication-Related Records

Maintenance of all medication-related records (including prescription documents and medication orders for hospital and home care patients) must follow the mandates established by federal and state laws. Prescription records must be readily retrievable for the number of years required by the state board of pharmacy; however, records may need to be retained longer for other purposes (e.g., 5 years for Medicare). Often, noncarbon copies or faxed copies of physicians' orders are sent to institutional pharmacies. These copies may not have to be kept long term, as long as the original medication order is in the patient's medical record and all other documents (e.g., patient medication profile and batch record) are filed by pharmacy personnel. The storage location of all records (electronic or paper) must provide security from theft, alteration, or unintended destruction.

Special Drug Categories

Records for controlled substances and investigational drugs require special handling. Inventories and prescriptions for controlled substances may be kept separately or have the letter "C" stamped in the lower right corner for easy retrieval. Controlled drug order forms must be stored for at least 2 years, but note that state laws vary. A perpetual inventory is usually maintained for both controlled substances and investigational drugs. A biennial controlled substance inventory is also required. Records for handling radiopharmaceuticals must meet Nuclear Regulatory Commission regulations,