Chapter 3

Immediate-Use Compounding

Jeannell M. Mansur

Introduction

In the United States, until approximately 2005, sterile compounding was widely performed at the bedside by personnel other than pharmacy staff. Although the extent of compounding was widespread throughout the hospital setting, it was especially prevalent in intensive care units, where the presumption was that in this fast-changing, highly intense environment, it was difficult to anticipate the needs of a critically ill patient. Currently, compounding on nursing units by nurses has dramatically declined. Several reasons account for this change. The Joint Commission (TJC) released Medication Management Standard MM.05.01.07 stating "a pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations (CSPs) except in urgent situations in which a delay could harm the patient or when the product's stability is short."[1]

Thereafter, routine bedside preparation of sterile admixtures did not meet TJC expectations. At the same time, the availability of premixed medication admixtures from pharmaceutical manufacturers resulted in a supply of precompounded preparations for stocking on the nursing unit that would meet the expectation of MM.05.01.07. The Centers for Medicare & Medicaid Services (CMS) address medication compounding in both Pharmaceutical Services (§482.25) and Nursing Services (§482.23) depending on where preparation occurs.[2,3] CMS expects that medication preparation will be performed in accordance with state and federal laws and regulations and also according to accepted standards of practice.

Defining Immediate Use

In 2015, CMS issued updated interpretive guidelines specifying that USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations. would be used as the best practice resource for compounding.[4] As part of this reinterpretation, CMS required hospitals to meet all currently accepted standards for safe preparation and administration of CSPs (1) whether they are compounded as low-, medium- or high-risk preparations, as defined by USP Chapter <797>, within the pharmacy, or (2) whether they are compounded by

nursing or other healthcare personnel outside of the pharmacy and intended for "immediate use."[5] These interpretive guidelines state that immediate-use CSPs are prepared for "immediate or emergency use for a particular patient and are not to be stored for anticipated needs."[6]

CMS references within these interpretive guidelines the following requirements, many of which are derived from USP Chapter <797>:

- Preparation of an immediate-use CSP must only involve "simple transfer of not more than three commercially manufactured…sterile nonhazardous products from the manufacturer's original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device." Note: USP Chapter <797> does not allow immediate-use compounding of hazardous drugs.[4]
- Administration begins no later than 1 hour following the start of the preparation of the CSP (if not, the CSP must be appropriately discarded).
- Meticulous aseptic technique must be followed during all phases of preparation. If the CSP is not administered to the patient as soon as it is ready, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces…contamination and/or confusion with other CSPs.
- Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer,… the CSP must be labeled with at least the following:
  - Patient identification information
  - The names and amounts of all ingredients
  - The name or initials of the person who prepared it
  - The exact 1-hour "beyond-use date"[5]

CMS defines the *beyond-use date* as the date after which medications may not be used, stored, or transported. The revised interpretive guidelines clarify that the immediate-use product compounded outside of the pharmacy must be initiated within 1 hour of preparation. This applies to injections as well as infusions and is applicable to immediate-use products that are compounded in the operating room, procedural areas, and other clinical settings including nursing units.

Immediate-use CSPs are singly prepared and are exempt from the requirements of USP Chapter <797> low-risk CSPs (e.g., full garbing, admixture in an International Organization for Standardization [ISO 5 environment within an ISO 7 buffer area] as part of a controlled environment cleanroom, etc.).[4] At the time of printing of this chapter, TJC has not yet chosen, in its accreditation standards, to adopt the term *immediate use* for compounding. However, as part of the standard, MM.05.01.07, TJC defines when compounding outside the pharmacy is acceptable ("in urgent situations in which a delay could harm the patient or when the product's stability") and when the use of a laminar airflow hood or other ISO 5 environment is required (when "...preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours."). TJC defines an *intravenous (IV) admixture* as "a pharmaceutical product whose preparation requires the addition of a measured amount of medication to a 50 mL or greater bag or bottle of IV fluid. It does not include the drawing up of medications into a syringe, the addition of a medication to a Buretrol (inline burette) or the assembly or activation of IV system that does not involve the measurement of an additive."[1]

The American Pharmacists Association defines *sterile compounding* as the mixing of ingredients, including dilution, admixture, repackaging, reconstitution, and other manipulations of a sterile product to make it ready for patient use.[7]

Effective January 2017, TJC launched a new Medication Compounding Certification program for hospital and home care agency compounding pharmacies. The certification program includes assessment of compliance of USP Chapters <797> and <795>. Also, at this time, TJC is in the process of reviewing its standards relating to compounding as part of its general accreditation process. It is expected that future versions of the Comprehensive Accreditation Manual for Hospitals will have standards more closely aligned with both CMS and USP Chapter <797> requirements.