Position of the Federation of State Medical Boards

Compounding of Medications by Physicians

Compounding is a non-specific term that may encompass a variety of actions ranging from the simple dilution of a prescribed medication for a specific patient in a physician's office to the production of a drug from bulk drug substance(s) and other ingredients by a licensed pharmaceutical manufacturer. The definition of compounding in these many settings may vary depending on the source of the definition. Before writing any regulations on compounding, state medical boards are encouraged to ensure they use the definition of compounding that aligns with the situation they intend to regulate.

Safety concerns have been raised around compounding after a series of serious incidents involving harm to patients using medications compounded in "outsourcing" facilities. Congress, the Food and Drug Administration and U.S. Pharmacopeia responded to these incidents by proposing new guidelines and standards that exceeded the remedial need to license outsourcing facilities and included physician office-based compounding. The USP and the FDA continue to try and reconcile their definitions and the revised USP standards are still being considered and are not final. The need for careful and sterile manipulation of medications is not debatable. Further, there are documented incidents where either the ingredients or the final product have been kept beyond their designated "By Use Date" (BUD), thus again risking contamination and potential injury to patients. Correct storage of medications is also important. It is therefore critical that compounding occur in accordance with conditions and practices designed to prevent contamination and according to protocols to ensure that ingredients are added in the appropriate proportions.

In any setting, the decision to compound or prescribe a compounded medication should be in the best interests of the patient. The prescription of a compound and the act of compounding should be triggered by a specific medical need in an individual patient. In the office setting, physicians should only compound medications for their own patients and not for patients of other physicians or healthcare practitioners. Clear guidelines and training should be available for any staff who assist with manipulating the medications. Medications should not be compounded in large quantities in anticipation of patients who exhibit a particular set of symptoms or for retail sale. This could fall under the definition of conventional medication manufacturing, a practice that presents greater safety risks to patients and is therefore restricted to entities that are registered with the U.S. Food and Drug Administration (FDA) and abide by a more stringent set of safeguards for the preparation of medications. However, section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides for "anticipatory compounding" by a licensed pharmacist or a licensed physician in limited quantities before receiving a prescription for an identified individual patient. To remain in compliance with federal legislation regarding drug compounding, physicians should not engage in anticipatory compounding beyond such limited quantities.

Physicians must ensure that active ingredients included in a compound are necessary for treating a medical condition in an individual patient. The medical condition and rationale for prescribing a compounded medication should be reflected in the patient's medical record. Physicians should not add or request the addition of unnecessary substances in order to ensure a higher rate of reimbursement, as this would unnecessarily put patients at risk. Physicians should also refrain

from exploiting patients by charging unreasonable or excessive fees for compounded medications.

In instances where patients require medications in forms that are different from those commercially available, physicians are encouraged to establish relationships with pharmacies or other entities that have registered as outsourcing facilities with the FDA. These facilities are required to compound according to "good manufacturing practices" and are subject to risk-based inspections by the FDA and additional standards that reduce the risk that contamination or other product quality problems might occur during the compounding process. As a rule, the physician should not compound any medication for which there is an FDA approved drug that could be obtained from a licensed and inspected facility.

If physicians choose to compound medications themselves, they are encouraged, where possible, to limit compounding activity to non-sterile preparations[1] and they must comply with Federal and state laws regarding compounding and dispensing drugs. If sterile medications are compounded by physicians, there is a responsibility for the physician and the staff to know, understand and employ aseptic techniques. While state laws on compounding vary across the U.S., physicians should comply with the standards set out in the United States Pharmacopeia-National Formulary (USP-NF), particularly Chapters 795, 797, and 800. Chapters 795 and 797 provide guidance on the preparation of non-sterile and sterile compounds and describe conditions and practices that can prevent patient harm. Chapter 800 addresses the compounding and handling of hazardous drugs in healthcare settings. These Chapters of the USP-NF also describe the responsibilities of supervisors of compounding practices, which may be relevant for physicians who oversee compounding activities of employed staff.[2]

Legislation and practices regarding the oversight of in-office compounding vary by state. Some state boards of pharmacy grant compounding licenses to individual providers and may perform inspections of facilities where medications are compounded. Inspections are also performed by state Departments of Health and through facilities accreditation processes for those clinics affiliated with a hospital or health system. While in-office compounding may occur in some states in the absence of regulatory oversight, it is unlikely that state medical boards have the resources or established protocols to provide this function. It is therefore recommended that clear lines of communication be established between state medical boards and state boards of pharmacy to ensure that any existing regulatory gaps are closed.

[1] Exceptions exist in some medical professions such as Allergy and Immunology where accepted practice regularly includes the preparation of sterile compounds by or under the supervision of a specially trained physician for their individual patients. In such instances physicians should follow aseptic technique, as well as the protocols developed by their specialty and set forth in applicable published practice parameters.

[2] Please note that at the time of drafting this position statement, the USP-NF is undergoing significant revision. Confusion exists regarding the current USP-NF Chapter 797 definition of "immediate use" which is intended only to apply in emergency code circumstances. It is recommended that until the revised USP-NF 797 is completed, physicians and state medical boards interpret "immediate use" to apply to rare circumstances when a compounded medication is needed urgently (e.g., cardiopulmonary resuscitation) for a single patient, and preparation of the compounded medication under the conditions currently specified in USP-NF 797 would subject the patient to additional risk due to delays in therapy.

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