

## **Federation of State Medical Boards**

### **White Paper on 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. While the Federation of State Medical Boards (FSMB) does not have purview over defining the term for physicians or pharmacies, it recognizes that many office and clinic-based medical specialties compound to some extent under current broad definitions of compounding which include dilution, mixture, and reconstitution. 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 exist in any instance of compounding, whether this occurs in an outsourcing facility, pharmacy, or physician's office. Additional concerns were raised related to compounding after a series of serious incidents involving harm to patients from contaminated injectable compounded preparations. Congress responded to these incidents by enacting the Drug Quality and Security Act (DQSA) which exceeded the remedial need to license outsourcing facilities and included physician office-based compounding. The first title of the DQSA is the Compounding Quality Act, which clarifies and enhances health protections related to compounded drugs. The DQSA also clarifies and expands the responsibilities and powers of the Food and Drug Administration (FDA), which has since issued new guidelines about compounding and now performs risk-based inspections of outsourcing facilities.

It is critical that compounding occur in accordance with conditions and practices designed to prevent contamination, including careful and sterile manipulation of medications, and according to protocols related to storage, "Beyond Use Date" (BUD), and adding ingredients 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. When preparing a compound to be administered by a patient's primary care provider, physicians should not compound medications for patients of other providers who are not also their own patients. Clear guidelines, standards, 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 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, including a justification of medical necessity, 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 or lower 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. Outsourcing facilities are required to compound according to "current good manufacturing practices" (CGMPs) and are subject to risk-based inspections by the FDA. Traditional compounding facilities are subject to additional USP 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, aside from those considered exempt under USP Chapter <797> (described below).

If sterile medications are compounded by physicians, there is a responsibility for the physician and the staff to know, understand and employ aseptic techniques. If physicians choose to compound medications themselves, they must comply with Federal and state laws regarding compounding and dispensing drugs. Physicians are encouraged, to limit compounding activity to non-sterile preparations, unless the particular compounding activity forms a regular part of the practice of the physician's specialty and all accepted safety protocols are employed. In such instances, physicians must ensure that they have all equipment and materials necessary to comply with applicable standards, as well as adequate physical space.

In addition to following state laws addressing compounding, 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 standards 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. In instances where staff assist in the compounding manipulations, the treating physician is ultimately responsible for proper sterile preparation of the medication.

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 inspection 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. State medical boards should continue their process of investigating and adjudicating complaints made concerning in-office compounding and final disciplinary action related to a complaint for inappropriate or unsafe compounding should remain in the purview of the state medical board.