Interstate Compounding Plan Jars Hospitals
The Definitions of “Distribution” and “Inordinate” Stir Concern

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Proposed Food and Drug Administration (FDA) restrictions on pharmacy compounding would have a particularly negative effect on health systems in which hospital central pharmacies distribute compounded medications to outlying affiliated community pharmacies—especially pharmacies across a state border. The latest FDA regulatory effort stemming from the 2013 Drug Quality and Security Act (DQSA) concerns the FDA’s concept of a memorandum of understanding (MOU) that a state would have to sign with the FDA if the state wanted to allow its retail and hospital pharmacies to “distribute” an “inordinate” amount of compounded drugs over state lines.1

The FDA wants to define “inordinate” as up to 30% in the instance where a state signs an MOU with the FDA. The terms of that MOU as envisioned by a draft the FDA has released have created significant controversy. If the state did not sign an MOU, pharmacies could only distribute 5% beyond the state’s borders. The MOU with the FDA would commit the state to address “the distribution of inordinate amounts of compounded drug products interstate and provide for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside such state.”

The draft MOU the FDA published in February has come under fire from numerous sources, including hospitals. The American Hospital Association (AHA) “believes that a pharmacy within a health care system should not be considered to have ‘distributed’ compounded drugs interstate if the pharmacy is merely moving drugs between facilities that are part of the same health care system, even if the movement occurs between facilities located across state lines,” says Linda E. Fishman, AHA Senior Vice President for Public Policy Analysis and Development. Even a 30% cap could seriously inhibit the transfer of drugs within some hospital systems in areas located amid multiple state boundaries. Fishman says the movement of compounded drugs among the facilities of such a health care system is analogous to moving them from the pharmacy on one floor to a patient care area on another floor in the same building or to a clinic on the same campus.

Meeting one of the two options in the proposed MOU—less than 5% versus less than 30%—qualifies that hospital pharmacy for an exemption from three requirements that would otherwise affect pharmacies regulated by a state: current good manufacturing practice (CGMP) requirements, labeling of drugs with adequate directions for use, and getting approval for preparing compounded drugs as if they are new drugs. The same two caps would also apply to freestanding retail pharmacies, even if the pharmacy is shipping a compounded medicine across state lines to a physician who has presented a patient-specific prescription and plans to administer the drug in his or her office.

In part, the FDA has reasoned that limits on pharmacy compounding will be mitigated because the new 503B “outsourcing facilities” can amply serve both physicians and hospital pharmacies. These 503B facilities will be regulated and policed by the FDA, not the states, and must meet higher quality standards, allowing them to ship compounded drugs in unlimited quantities across state lines. Of course, a health system’s central pharmacy could register under 503B, thereby getting around any “inordinate” caps. But that is unlikely given the program’s requirements.

Part of the outcry from the pharmacy industry has to do with the FDA’s definition of “distribution,” which includes the term “dispensing”—a word that does not appear in the DQSA and that implies a broader restriction on compounding than Congress intended. “Using ‘distribute’ to mean both ‘dispense and distribute’ may serve the purposes of the MOU; however, it is insufficiently precise and moreover contradicts the definition commonly understood by the pharmacy profession,” says Christopher J. Topoleski, Director of Federal Regulatory Affairs for the American Society of Health-System Pharmacists.

Some of the MOU responsibilities that states would have to assume go way beyond those in a previous MOU the FDA published in 1999. States would have to notify the FDA within 72 hours of any complaints relating to a compounded human drug product distributed outside the state involving a potential public health risk or immediate safety concern, such as a report of a serious adverse drug experience or serious product quality issue, the state’s initial assessment of the validity of the complaint, and any actions the state has taken or plans to take to address such complaints.

Compared to the 1999 MOU, the new draft clarifies the types of complaints about compounded human drug products that should be investigated. Those include allegations of any adverse drug experience (not just serious adverse drug experiences, which were given as an example of the types of complaints to be investigated in the 1999 draft) and product quality issues that if left uncorrected could lead to potential public health risks or safety concerns. Retail specialty pharmacies and compounding pharmacies that won’t enter 503B have their own problems with the draft MOU. As a result, it seems likely that the FDA will make some changes, and perhaps publish another draft, before finalizing the MOU. But perhaps not. The FDA, as always in these instances, is being tight-lipped about its intentions.

REFERENCE