Compounding Pharmacy Reform Moves Forward

Senate Bill’s Exemption of Hospital Pharmacies Stirs Debate

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Both the House and Senate are making progress on bills that would ostensibly clamp down on the big compounding pharmacies that are key vendors to hospitals. However, the Senate bill gives the FDA more authority to regulate these compounders, such as the New England Compounding Center (NECC), whereas the House bill appears to strengthen state inspection programs of all pharmacies without giving the FDA any new tools. It is too soon to know which approach will end up on President Obama’s desk for his signature. Betting odds should probably favor the Senate bill, because it originated in the Committee on Health, Education, Labor, and Pensions (HELP) with substantial bipartisan support, which is less likely to be true of the House bill.

Whichever bill is passed will have a large impact on hospital pharmacies, because they purchase large quantities of compounded drugs and often perform a lot of compounding themselves. The Senate bill is called the Pharmaceutical Compounding Quality and Accountability Act (S. 959). One of its key provisions exempts hospital pharmacies from a newly established category, called “compounding manufacturers.” This term is meant to encompass the “NECCs” of the world, which for the first time would be subject to FDA authority—another respect, it might be considered more regulatory. The House bill would require pharmacies, including those in hospitals, to adhere to the U.S. Pharmacopeial Convention (USP) guidelines on compounding. Three chapters are pertinent: 71 covers sterility tests; 795, nonsterile preparations; and 797, sterile preparations.

Some states currently require pharmacies to adhere to those chapters, but almost none of them inspect pharmacies to ensure that the pharmacies are complying with regulations. Consequently, many hospital pharmacists are unaware of these three USP chapters.

David G. Miller, RPh, Chief Executive Officer of the International Academy of Compounding Pharmacies (IACP), strongly objects to hospital pharmacies being exempt from the compounding manufacturer category established by the Senate bill. He doesn’t have a problem with hospitals that compound medications for patients within their own premises. Those drugs are not dispensed unless there is a prescription for a particular patient. Those pharmacies should continue to be regulated by state boards of pharmacy. However, when a hospital pharmacy pushes sterile injectable products beyond its four walls to other health care facilities owned by the health care system, that, David Miller says, is an entirely different scenario.

He commented (by e-mail):

Under the exemption provision of S.959, a large multistate health system could have a single compounding facility that distributes non–patient-specific compounded medicines across state lines to its affiliated hospitals, outpatient clinics, ambulatory surgery centers, long-term care facilities, home-infusion subsidiaries, etc., without any federal oversight, while a non–health system facility would have to be registered and fall under the jurisdiction of the FDA—two drastically different levels of protection.

The American Society of Health-System Pharmacists (ASHP) supports the Senate bill. During a HELP committee meeting in May, Kasey K. Thompson, Vice President of Office of Policy, Planning, and Communications at ASHP, testified:

...We believe the committee got it right with this proposed legislation. It is critical to make the distinction between health systems—which are fully accountable for the comprehensive care of the patient—and a ‘compounding manufacturer’ that prepares and sells its products across state lines without a prescription or knowledge of the patient to a third party for administration.

Although the ASHP doesn’t think its members need new federal regulation, it supports regulation of large outside vendors by the FDA. In addition to giving the FDA clear inspection and regulatory authority over the NECCs of the world, the Senate bill requires compounding manufacturers to adhere to good manufacturing practices (GMPs). The FDA has long established GMPs for manufacturers of brand-name and generic drugs, but there are none for compounders. The FDA would have to develop them.

During the Senate committee markup (i.e., the process of debating, amending, rewriting, and voting on the proposed legislation), Senator Al Franken (D-Minn.) made clear that these GMPs for compounders will address their special circumstances and will differ from those rules that traditional drug manufacturers must comply with. The Senate bill also says that commercially available products should not be compounded except when they must meet specific medical needs or drug shortages.

The fact that President Obama will probably back the Senate bill makes it more likely that most of its provisions will survive in any final bill—that is, if there is one.