Drug Compounding Bill Signed into Law

The Drug Quality and Security Act, which allows drug compounding facilities to register with the U.S. Food and Drug Administration (FDA) as outsourcing facilities, was signed by President Obama on November 27 after approval by Congress earlier in the month. The bipartisan act fosters more FDA oversight of safety regulations for registered facilities and, for unregistered facilities, institutes new drug and labeling requirements. The act also authorizes creation and implementation of a new drug tracking system in the national pharmaceutical supply chain.

The FDA recommends that health care providers use only registered compounding pharmacies for their supply of compounded drugs. Under the new law, more information will be available regarding the source and production of drugs.

"These facilities will also be subject to inspection by FDA on a risk-based schedule," said Margaret A. Hamburg, MD, FDA Commissioner. "If compounders register with FDA as outsourcers, hospitals and other health care providers will be able to provide their patients with drugs that were compounded in facilities that are subject to FDA oversight and federal requirements for current good manufacturing practice, among others. To that end, we will be encouraging health care providers and health networks to consider purchasing compounded products from facilities that are registered with FDA and subject to risk-based inspections."

The bill is the result of actions taken in the wake of a 2012 outbreak of fungal meningitis resulting from contaminated steroid injections compounded at the New England Compounding Center (Framingham, MA). The public health crisis caused 64 fatalities and illness in an additional 751 individuals. In addition to meningitis, the contaminated drugs also caused localized epidural abscess, vertebral osteomyelitis, phlegmon, arachnoiditis, and discitis. The outbreak spread to 20 states and 76 outpatient surgery centers supplied by the compounding center, resulting in public outcry and a voluntary recall of 3 lots of the compound in September 2012. The U.S. Centers for Disease Control and Prevention considers this an ongoing investigation, and a criminal investigation has been opened by the U.S. Federal Bureau of Investigation.

This and similar incidents led to introduction of the Verifying Authority and Legality in Drug (VALID) Compounding Act of 2013 (HR 2186) in May 2013, which was later replaced by the introduction of the Drug Quality and Security Act (HR 3204) in September 2013 by Rep. Fred Upton (R-MI). The act was passed by the House of Representatives on September 28 and by the Senate on November 18. It officially amends the Federal Food, Drug, and Cosmetic Act regarding regulation of compounded drugs.

The associated Drug Supply Chain Security Act, which proposes a new tracking system as a part of the Drug Quality and Security Act, will require all levels of the supply distribution chain—from original manufacturers and compounding pharmacies, wholesale distributors, logistics services, and endpoint pharmacies—to use an electronic bar coding system and scan drugs at every step until delivery at final destinations for clinical use. FDA-registered outsourcing facilities will not be required to track their products. The system is meant to authenticate drugs that are not under FDA oversight and make it easier to enforce safety guidelines and recall contaminated drugs in the event of noncompliance. Such a tracking system may take as long as a decade to implement.

Registration will require that outsourcing facilities report biannually to the U.S. Secretary of Health and Human Services and provide detailed information about drugs that were compounded at the facility as well as adverse event reports. The secretary will be responsible for publishing data on drugs that compromise drug safety or effectiveness. Some compounds will now require an FDA New Drug Application, and a "do not compound list" may be created, which could prohibit copying of some drugs. Failure to register will not result in penalties, but FDA registration is encouraged, and an administrative framework for registration is expected to be ready in 2014.