OUTSOURCING FACILITIES: The Compounding Quality Act of 2013 improved patient safety and accountability for oversight of compounding by creating a category of compounders, outsourcing facilities, which produce sterile drugs under good manufacturing practices. Congress intended to ensure that there was a clear line between traditional compounding, in which drugs are compounded pursuant to a prescription, and this new category of compounding, in which drugs are produced in bulk and distributed without a prescription. FDA has made important progress implementing this law by issuing and proposing guidance documents that help define and distinguish the roles of the traditional compounder, outsourcing facility, and pharmaceutical manufacturer. This clarity is important for compounders as well as for the states, who remain the primary regulators of traditional pharmacy compounding. States have made significant progress strengthening their compounding oversight by recognizing the outsourcing facility category and by ensuring compliance with quality standards appropriate to the risk of the compounding activities. Continued clarity from FDA on the line between traditional compounding and outsourced compounding will support state regulators, outsourcing facilities, and traditional compounders in their efforts to ensure that patients have access to safe compounded drugs while reducing the risks associated with sterile drugs produced in bulk.