

that compound sterile, injectable drug products and others for dispensing in the state of California. It also provides a path for physical inspections of nonresident pharmacies that compound sterile, injectable drug products and others and ship these products into California for dispensing. The pharmacies that produce the sterile compound medicines are also required to prepare a written master formula record for each product.<sup>17</sup>

## **Florida**

The state of Florida has come a long way in the past 10–15 years in terms of pharmaceutical drug regulations. When the Drug Quality and Security Act was signed into law, the Florida Board of Pharmacy rules allowed pharmacies to engage in office use compounding. Specifically, these rules allowed physicians to use compounded medicines to treat patients in their offices. They did not allow physicians to dispense compounded medicines to their patients. The Florida Board of Pharmacy made the decision after the Drug Quality and Security Act on May 1, 2014, to rule that all sterile pharmaceutical drugs produced by licensed compounding pharmacies must be for specific patients. All other compounded medicines, including for office use, must be done by a registered outsourcing facility. When I inquired by phone with the Florida Board of Pharmacy, I was told they made this strict definition to ensure that Florida pharmacies holding a sterile compounding permit did not make any mistakes and unknowingly violate the new federal law.<sup>18</sup>

Needless to say, I am impressed. Florida drew a hard line where the line was blurred and subject to interpretation. Florida pharmacies can now only compound sterile pharmaceutical drug products for human use directly for patients with prescriptions. All office use compound sterile pharmaceutical drug products must be produced by licensed outsourcing facilities. The Florida Board of Pharmacy now mandates that hospitals and medical practices can only procure their sterile compounded medicines from licensed outsourcing facilities.

Personally, I still believe that the smaller compounding pharmacies that produce sterile pharmaceutical drug products for physicians *on a daily basis* are producing for specific patients. However, Florida took a practical approach to implement the new law and minimize the gray area. I hope the smaller compounding pharmacies do not elect to go out of business, rather than choose to be licensed outsourcing facilities. The additional regulations are ominous, and if the smaller compounding pharmacies