

work in Washington, D.C., and everything is still clear as mud!” For the sake of the book, we will draw a dotted line between the two definitions.

THE STATES—TAG, YOU’RE IT!

The states and the state boards of pharmacy have always regulated pharmacists. As we mentioned, there was a gray area between the FDA and the state boards of pharmacy on who had oversight responsibility for compounding pharmacies. After the Drug Quality and Security Act was signed into law, a number of states enacted legislation to come into compliance with the Drug Quality and Security Act and try to “fill the gaps.” Let’s review a few of the key states and their legislative responses to this new law.

Massachusetts: Their Response

To the credit of the state of Massachusetts, they became proactive in their efforts to address a gray area between the FDA and the Massachusetts State Board of Pharmacy regarding oversight of compounding pharmacies. On July 10, 2014, Governor Deval Patrick signed into law the Massachusetts Compounding Pharmacy Oversight Bill. This new law includes (among other items) new licensing and labeling requirements, steps up fines for violations of state rules, and requires the board’s inspectors to be trained in sterile and nonsterile compounding practices. “I think this puts us ahead of other states,” Patrick said after a statehouse bill-signing ceremony. “The gray area that I and so many other people talked about is an area of considerable ambiguity about where state authority leaves off and federal authority begins.”¹³

Personally, I think he is correct on multiple counts. The FDA now regulates compound manufacturers. The state boards of pharmacy regulate traditional compounding. Who regulates the compounding pharmacies that compound medicines for office use? In addition, as we will see in Chapter 2, there is a big difference between sterile and nonsterile compounding of medicines.

This bill also created four new specialty licenses: a retail sterile compounding specialty license, a retail complex nonsterile compounding specialty license, an institutional pharmacy specialty license, which applies to hospitals, and an out-of-state pharmacy license for out-of-state pharmacies doing business in Massachusetts. The latter license is extremely important