“This legislation establishes a clear boundary between traditional compounders and compounding manufacturers. It clarifies a national, uniform set of rules for compounding manufacturers while preserving the states’ primary role in traditional pharmacy regulation.” Timko and Crooker (2014).

Reference:


A regulatory perspective of pharmaceutical compounding http://ctt.ec/9Opvs+ @ivteam #ivteam

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Abstract:

At one time, nearly all prescriptions were compounded preparations. There is an ongoing demand for compounded prescription medications because manufacturers cannot fulfill the needs of all individual patients. Compounding pharmacies are a long standing yet less frequently discussed element in the complex matrix of prescription drug manufacturing, distribution, and patient use. The drug shortage situation for many necessary and life-saving drug products is a complicating factor that has led to the numerous quality issues that
Currently plague large-scale compounding pharmacies. The states are the primary regulator of pharmacies, including community drug stores, large chains, and specialty pharmacies. Pharmacies making and distributing drugs in a way that is outside the bounds of traditional pharmacy compounding are of great concern to the U.S. Food and Drug Administration. The U.S. Congress has recently passed the Drug Quality and Security Act. This legislation establishes a clear boundary between traditional compounders and compounding manufacturers. It clarifies a national, uniform set of rules for compounding manufacturers while preserving the states’ primary role in traditional pharmacy regulation. It clarifies the U.S. Food and Drug Administration’s authority over the compounding of human drugs while requiring the Agency to engage and coordinate with states to ensure the safety of compounded drugs.

Other intravenous and vascular access resources that may be of interest (External links – IVTEAM has no responsibility for content).