Compounding Oversight—New Regulations for Medical Spas and Compounding Pharmacies - Part 2

June 2, 2026

By: Grant M. Achenbach and Madison Hartman Harada

This is the second article in a two-part series regarding Senate Enrolled Act ("SEA") 282 (2026). Part 1 of the series can be found here: Compounding Oversight—New Regulations for Medical Spas and Compounding Pharmacies.

The second major substantive component in SEA 282 consists of new restrictions and state agency oversight for entities and individuals performing compounding of prescription drugs. As the use of compounding has expanded to keep up with patient demand, particularly for GLP-1s, states and various other stakeholders have sought to regulate compounding via law or informal agency policy. Prior to SEA 282, the Indiana Board of Pharmacy had limited authority to regulate compounding. However, following the effective date of SEA 282, the Board of Pharmacy and other state agencies will have the authority to oversee and investigate compounding practices to ensure compliance with federal law.

First, SEA 282 defines "compounding" as the "combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance." Compounding may be performed by a licensed pharmacist, licensed physician, or an individual working under the supervision of a pharmacist or physician. With respect to compounding by pharmacies, SEA 282 aligns with the federal standards, as specified in the Food Drug & Cosmetic Act (FD&C) and Food & Drug Administration (FDA) guidance. Specifically, 503A and 503B pharmacies should ensure that their compounding practices align with the corresponding sections of the FD&C Act and United States Pharmacopeia (USP) standards.

For compounding with bulk drug substances, SEA 282 imposes additional standards, some of which exceed federal requirements. First, a "bulk drug substance" is defined as a substance that is intended for incorporation into a finished drug product to furnish pharmacological activity or other direct effect in the diagnosis, cure, treatment, etc., or any function of the body. It does not include an amino acid, vitamin, mineral, herb, essential oil, other non-pharmacological ingredient. Second, compounders must ensure that any bulk drug substance utilized is: (1) manufactured by a facility registered with the FDA as a human drug establishment, and (2) is accompanied by a valid certificate of analysis (COA) containing the following information: a) the identity and content of the bulk drug substance, and b) the country where bulk drug substance was originally manufactured. In addition, the bulk drug substance must have gone through quality control testing. Third and finally, any individual engaged in the sale, transfer, or distribution of compounded drugs is required to maintain all records related to the acquisition, examination, and testing of bulk drug substances for a period of at least two (2) years from the date of the last lot of compounded drugs containing the bulk drug substance.

Finally, the Indiana Board of Pharmacy may investigate the compounding, sourcing, handling, and storage of a prescription drug, including any alleged violation of the compounding provisions of SEA 282. Non-resident pharmacies are also required to comply with SEA 282 and must be able to provide documentation to the Indiana Board of Pharmacy evidencing such compliance.

All of the above requirements take effect ***July 1, 2026.***

If you have questions about how your pharmacy or practice will be impacted by the compounding provisions within SEA 282, please contact Grant M. Achenbach or Madison Hartman Harada.
