S. 3794, SAFE Drugs Act

Section 1. Short Title.
This Act may be cited as the "Safeguarding Americans from Fraudulent and Experimental Drugs Act of 2026" or the "SAFE Drugs Act of 2026".

Section 2. Definitions Relating to Compounding of Drug Products.
This section amends the Federal Food, Drug, and Cosmetic Act to clarify, within the criteria under which 503A compounding pharmacies are permitted to compound drug products, that such compounding pharmacies may not compound any drug product that is essentially a copy of a commercially available drug product more than 20 times in a single month. This replaces the existing restriction that such compounding pharmacies cannot compound such copies "regularly or in inordinate amounts (as defined by the Secretary)."

This section also amends the definition of the term "essentially a copy of a commercially available drug product" within the Act to mean any drug product that contains any active ingredient found in a commercially available drug product in which there is no change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner.

This section also adds an explicit definition of the term "commercially available drug product" meaning including any drug product that is sold in the U.S. commercial market and manufactured in one of more facilities required to comply with section 501(a)(2)(B), pertaining to protections against adulterated drugs, and which is not included in the FDA's discontinued drug list in section 505(j)(7)(A).

Section 3. Reporting Requirement.
This section amends the Federal Food, Drug, and Cosmetic Act pertaining to 503A compounding pharmacies to require any pharmacy, facility, or facility that compounds any drug product that contains any active ingredient found in a commercially available drug product more than 20 times in a single month, for patients residing in a different state(s), to report annually to the Secretary—each type of drug product compounded and the total times each month each type of drug product is compounded. The report is due to the Secretary before the end of each calendar year. The Secretary may prescribe the form and manner of reporting. Pharmacies located on the premises of a hospital compounding for patients of the hospital are excluded from reporting.

Section 4. Large-Scale Outsourcing Facilities
This section amends the Federal Food, Drug, and Cosmetic Act pertaining to 503B compounding pharmacies (outsourcing facilities) to require the risk-based inspections already required under the Act to occur prior to such facility compounding any drug product for the first time and in the case of reinspections to occur not less than biennially. This section defines the 503B compounding pharmacies subject to this enhanced inspection requirement as "large-scale outsourcing facilities" meaning those that compound any drug product more than 100 times in a single year.

This section also amends the exception to registration and reporting requirements in section 510(g)(1), pertaining to compounding pharmacies that regularly dispense prescription drugs based on prescriptions from health care providers and intended for patients under the care of those providers and which do not sell such drugs for other purposes, not to pertain to 503B outsourcing facilities.

Section 5. Base Establishment Fee.
This section amends the Federal Food, Drug, and Cosmetic Act to increase establishment fees pertaining to 503B outsourcing facilities from $15,000 multiplied by an inflation adjustment factor to "a base amount deemed appropriate by the Secretary to fund activities to ensure the safety of compounded drug products."