Summary of Policy Changes to S. 959 from Reported-Out Bill

Title I: Human Drug Compounding

- Office Use: Created a standard to allow traditional compounders to provide drugs to practitioners for their office use, while preserving the incentive to go through the approval process. Pharmacies that compound for office use will need to limit such compounding to 10% of the products they dispense and will need to reconcile the names of patients who receive the office use product within 14 days. States may make additional restrictions on compounding for office use.

- Standards to Guide FDA: In the provisions of the bill allowing FDA to designate drugs that cannot be compounded and bulk ingredients that cannot be used in compounded products, added standards to guide the Secretary's discretion.

    - To be included on the list of drugs too difficult to compound, a drug must be "reasonably likely to lead to an adverse effect on the safety or effectiveness of that drug or category of drugs taking into account the risks and benefits to patients."
    - In creating the list of bulk drug substances that cannot be used for compounding, the Secretary must take into account historical use, reports in peer-reviewed literature, or other criteria identified by the Secretary.

- Streamlined Notice for Compounding in Drug Shortages: In the provisions requiring a compounder that wants to copy an FDA-approved drug in a drug shortage to provide notice to the Secretary, added a requirement that the notice not place an undue burden on the compounder and language clarifying that only a single notice is required (or annual notice if the drug is in shortage for more than a year).

- Repackaging Biologics: Compounding manufacturers will be permitted to repackage biologics without a prescription.

- Non-Sterile Compounding by CMs: To help preserve incentives to go through the FDA approval process, compounding manufacturers will only be able to compound non-sterile drugs included on a list developed by FDA.

- Transparency: On its website, FDA will list the names of each compounding manufacturer along with the State where it is registered, whether the entity compounds from bulk drug substances, and whether any such bulk compounding is sterile or non-sterile.

- Risk-Based Inspections: Added requirement that when compounding manufacturers register they must list products made in the past 6-months, to give FDA a more immediate ability to set its risk-based inspection schedule.

Title II: Drug Supply Chain Security

- Product Tracing: To help ensure supply chain efficiencies, four years after the date of enactment of this Act when manufacturers are required to serialize product, they will provide transaction information, transaction history, and transaction statements in an electronic format to their trading partners.