Preserving Patient Access to Compounded Medications
Federal Legislation

If a 503A facility complies with this legislation, the 503A facility is exempt from current Good Manufacturing Practices (cGMP), labeling requirements, and the new drug approval process.

What the Federal Legislation Allows:

1. Dispensing to Individual, Identified Patients - no changes to 503A:
   Allows dispensing based on a prescription or order for an individually-identified patient by a licensed physician, pharmacist, or other licensed practitioner authorized by state law to prescribe drugs.

   Result of the Legislation: ALL dispensing intrastate and interstate of both sterile and nonsterile is allowed and NOT capped under the MOU. As such, as long as there is an individual patient prescription, then dispensing is allowed for both sterile **and** nonsterile intrastate **and** interstate.

2. Anticipatory Compounding - no changes to 503A:
   Allows compounding prior to the receipt of a valid prescription or order, in limited amounts where the compounded medications are kept within the facility where compounded, as long as compounded by a licensed pharmacist or physician and based on a history of the pharmacist or physician receiving valid prescriptions and an established relationship between the physician, pharmacist, and patient.

   Result of the Legislation: ALL anticipatory compounding is allowed under criteria above.

3. Office-use Compounding - Adds office-use compounding in accordance to state law to 503A:
   Allows compounding by a licensed pharmacist or licensed physician pursuant to a valid prescription or drug order and the compounded drug is distributed or dispensed to a licensed prescriber in accordance with state law and subject to the limitations of the MOU for **interstate office-use** for administration to a patient in an office or clinical setting.

   Result of the Legislation:

   1. Currently, FDA prohibits **ALL** office-use both intrastate and interstate nonsterile and sterile. **ALL** office-use is prohibited **EVEN WHERE** States allow the practice of office-use. As such, patient and prescriber access has decreased to compounded medications.
   2. Legislation addresses this concern and **permits ALL** office-use where states allow office-use and separates between intrastate office-use (both sterile and nonsterile) and interstate office-use (both sterile and nonsterile).
      a. **Intrastate office-use** of nonsterile AND sterile is allowed if permitted by state law.

      b. **Interstate office-use** is limited by the MOU or default 5% cap of all dispensing and distribution. Thus, the denominator that the 5% cap is determined on, includes both dispensing and distribution.

i. Minimum MOU is 5% as are most current State laws BUT maximum shipment is left to FDA define (the draft MOU states 30% but is not final).

4. Records Exemption - clarifies that the Records Exemption found within 21 U.S. Code §374(a)(2)(A) applies to all 503A facilities that maintain establishments in conformance with state law.

Limitations:

1. Bulk Drug Substances Positive List – adds dietary supplements to current 503A and adds requirement of formal rulemaking process for the creation of the bulk drug substance list

    a. Legislation adds USP "dietary supplement monographs" to the wording of 503A in order to address statements made by FDA during a PCAC meeting and later codified by FDA in guidance documents that FDA interprets "applicable monograph" within the statute not to include the dietary supplements monographs.

    b. This does NOT require uniform USP as a quality standard. This section only allows the Pharmacy Compounding Advisory Committee to consider both the USP drug monographs and USP dietary supplement monographs when adding APIs to the positive bulk drug list.

    c. Legislation adds that all FDA decisions on the API positive list must go through formal rulemaking to allow stakeholder comments and input.

2. **Interstate** Office-use Compounding is Under the Memorandum of Understanding (MOU):
    a. If the drug product is **interstate**, and compounded for office-use, then the following limitations apply –

        i. If the State has entered into a MOU with the Secretary, then the MOU determines the interstate distribution cap for interstate drugs compounded ONLY for office-use.

        ii. If the state has **not** entered into a MOU with the Secretary, then the compounding pharmacy or physician may not distribute interstate, compounded drug products that exceed more than 5%.

3. Do Not Compound Lists – no changes to 503A lists except legislation adds the requirement of formal rulemaking procedures

    a. Current 503A prohibits compounding a drug product that appears on a list published by the Secretary of drug products withdrawn or removed from the market.

    b. Current 503A prohibits compounding a drug product that is recognized by the Secretary as a drug product that presents demonstrable difficulties for compounding.

    c. Legislation adds these lists shall be developed through formal rulemaking procedures pursuant to the Administrative Procedures Act.