Preserving Patient Access to Compounded Medications
Federal Legislation
Congressional One Pager

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 current 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.

2. Clarifies Definition of Dispensing:
   Ensures the MOU restrictions on distribution across state lines does not apply to a compounded prescriptions leaving the facility in which it was compounded for delivery to a patient, patient's agent, or health care facility (including a hospital, physician's office, or other health care setting) pursuant to a prescription for an identified patient.

3. Anticipatory Compounding - no changes to current 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.

4. Office-use Compounding - adds office-use compounding in accordance to state law to current 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.

5. 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 – adds dietary supplements to current 503A and adds requirement of formal rulemaking process for the creation of the bulk drug substance list
   a. The legislation adds "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. Legislation requires
      i. All bulk drug substances or dietary supplements used for compounding must
         1. Comply with the monograph standards in any section of the United States Pharmacopeia (USP) or National Formulary if a monograph exists; OR
         2. If a monograph does not exist, the bulk drug substance~~s~~ must be component~~s~~ of drug~~s~~ approved by the Secretary; OR
         3. If such monograph does not exist and the drug substance or dietary supplement is not a component of a drug approved by the Secretary, then the bulk drug substance or dietary supplement must appear on a list developed by the Secretary through regulations.
            a. The list must be developed with PCAC and through formal rulemaking procedures pursuant to the Administrative Procedures Act.

ii. All bulk drug substances must be manufactured by an establishment that is registered under section 510.
iii. All bulk drug substances must be accompanied by valid certificates of analysis for each bulk drug substance.

2. Other Substances that are NOT Bulk Drug Substances – no changes from current 503A:
    a. Must comply with the standards of an applicable United States Pharmacopeia or National Formulary Monograph.

3. Interstate Office-use Compounding is Limited by 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 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 for office-use that exceed more than 5% as stated within the MOU.

4. Do Not Compound Lists – no changes to the current 503A lists excepts adds the requirement of formal rulemaking procedures
    a. Prohibits compounding a drug product that appears on a list published by the Secretary of drug products withdrawn or removed from the market.
    b. Prohibits compounding a drug product that is recognized by the Secretary as a drug product that presents demonstrable difficulties for compounding.
    c. These lists shall be developed through formal rulemaking procedures pursuant to the Administrative Procedures Act.

5. Commercially Available Drugs – no changes to current 503A
    a. Does not compound commercially available drugs regularly or in inordinate amounts.