Essential Copy Guidance

As a compounding pharmacy, Empower is monitored by various state and federal regulatory agencies, including all 50 State Boards of Pharmacy, the DEA, and the FDA. The FDA enforces the Drug Quality and Security Act which states that compounding pharmacies may not make “Essential Copies” of commercially available drug products unless the Prescriber has requested a change to the formulation that will make a “Clinical Difference” for that individual patient. Under this provision, certain prescriptions of compounded medicines must have a “Clinical Difference Statement” notated on the prescription.

This is required for any compounded medication that meets the following:

1. The compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product.
2. The API(s) have the same, similar, or easily substitutable dosage strength.
3. The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug.

Clinical Difference Statements must indicate why the Prescriber chose a compounded product versus a commercially available product.

- We are requesting that you comply by providing a full statement on each prescription that applies to any of the affected medications.
- To continue serving your patients, we must be compliant and therefore the Clinical Difference Statement is mandatory.
- Any prescriptions identified will be held until we can seek clarification from the prescriber, which might cause unnecessary delays.

For a full list of affected medications requiring Clinical Difference Statements, see our 503A Patient-Specific Prescription Products Requiring Clinical Difference Statements , and our 503B Office-Use Products Requiring Clinical Difference Statements.

Revised 01.09.2023