

Memorandum of Understanding Under Section 503A



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Section 503A:

“A drug product may be compounded... only if such drug product is compounded in a State...



...that has not entered into the memorandum of understanding and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the state in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.”

Section 503A:

“A drug product may be compounded... only if such drug product is compounded in a State...



...that has entered into a memorandum of understanding with the secretary which addresses the distribution of inordinate amounts of compounded drug products interstate”

“A drug product may be compounded... only if such drug product is compounded in a State...



**...that provides for
appropriate investigation by
a state agency of complaints
relating to compounded drug
products distributed outside
such state”**

Original Draft MOU:



State will investigate complaints relating to compounded drug products:

- 1) that caused physical harm**
- 2) where strength, purity or quality falls below compendium standards**
- 3) that fail to qualify for exemptions in 503A**

Original Draft MOU:



“the state in which the compounding pharmacy or physician is located or the state into which the subject product was distributed, or both, may be responsible for...investigating a complaint”

2013 Changes to Idaho Code



- **Allows Idaho to inspect non-resident drug outlets and charge expenses**
- **Non-resident drug outlets and pharmacists must follow Idaho law unless it conflicts with their home state law**
- **Idaho may take any action against non-resident as it can against a resident**
- **Idaho may take action against non-resident drug outlets for the actions of their exempt employees**
- **Allows mirroring of other's orders**

503A: Exemption from 501(a)(2)(B), 502(f)(1), and 505



“...if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order...”

21 CFR Definitions



208.3: Dispense to patients means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) by a licensed practitioner...

(2) by an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner

208.3 Distribute means the act of delivering, other than by dispensing, a drug product to any person.

1306.21(B): “an individual practitioner may administer or dispense... without a prescription”

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Issues



- **If pharmacies can not distribute compounded drug product at all, they will certainly not be able to distribute more than 5%, so why is an MOU needed at all?**
- **If distribute is somehow interpreted to mean dispense: a physician does not issue prescription (orders) when dispensing, so how can one calculate 5% of the prescription drug orders that he dispenses?**