Essential Copy Regulations Applicable to Utah Pharmacies

For questions or concerns regarding compounded preparations please contact the Utah Pharmacy Compounding Education Advisory Committee at pharmacy@utah.gov.

Current Utah law states the following regarding essential copies

Utah Code 58-17b-102(18)(a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:

(i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;
(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or
(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(b)"Compounding" does not include:

(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;
(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or
(iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons

Unprofessional Conduct 58-17b-502 (1) "Unprofessional conduct" includes:

(m) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner

Federal Law

Section 503A of the Federal Food, Drug and Cosmetic Act Current federal law states the following regarding essential copies**.**

- (1)(D) [Compounder] does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.
- Definition- For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

- **FDA Guidance**
  - In January 2018 the FDA published has also published guidance called Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.

References

1. Pharmacy Practice Act, UT Code § 58-17b-102 (2021).
2. Pharmacy Practice Act, UT Code § 58-17b-502 (2021).
3. Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Department of Health and Human Services. (2018).

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