



STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

TO: Legislative Regulation Review Committee
Capitol Building, Hartford, Connecticut

FROM: William M. Rubenstein, Commissioner of Consumer Protection
165 Capitol Avenue, Hartford, Connecticut

DATE: August 27, 2012

SUBJECT: Proposed Regulations Concerning Non-Sterile Compounding

Enclosed please find the original proposed regulations concerning Non-Sterile Compounding. If you should have any questions, please call Attorney Jerry Padula of my legal staff at 713-6087.

SUMMARY OF REGULATION

Connecticut General Statutes, Section 20-576(a)(2), permits the Commissioner of Consumer Protection, with the advice and assistance of the Commission of Pharmacy, to adopt regulations specifying classes of pharmacies and setting requirements for specific classes of pharmacies. These regulations establish requirements for pharmacies classified as non-sterile compounding pharmacies.

These regulations set standards for pharmacies classified by the Commission of Pharmacy as non-sterile compounding pharmacies. In addition to the laws applicable to all pharmacies, non-sterile compounding pharmacies must comply with the standards for non-sterile compounding pharmacies set by the United States Pharmacopeia, a non-profit organization that establishes national standards for drug products. In addition, these regulations require non-sterile compounding pharmacies to have a policy and procedure manual.

These regulations set additional standards that non-sterile compounding pharmacies must follow. If these regulations are violated, the pharmacy may face administrative action against its pharmacy license. The administrative remedies include revocation or suspension of the license, probation, civil penalties or a letter of reprimand.

Enclosures

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