

DEPARTMENT OF CONSUMER PROTECTION

Notice of Intent to Amend Regulations

In accordance with the authority granted in Sections 4-168 and 20-576 of the Connecticut General Statutes, it is the intention of the State of Connecticut, Department of Consumer Protection to amend the Regulations of Connecticut State Agencies by adding Sections 20-576-69 through to 20-576-73, concerning non-sterile compounding.

All interested persons who wish to express their views orally may do so at a public hearing to be held at the Department of Consumer Protection, Room 119, State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106 at 10:00 a.m. on May 30, 2012.

All interested parties who wish to submit data, views or arguments may do so in writing within thirty (30) days following the publication of this notice. Such written materials should be directed to William M. Rubenstein, Commissioner, Department of Consumer Protection, Room 103, State Office Building, 165 Capitol Avenue, Hartford, Connecticut, 06106.

A copy of the proposed regulation, the Fiscal Note, and the Small Business Impact Statement applicable to the proposed regulation (as required by Public Act 09-19) are available for inspection at the address cited above, by requesting a copy of the same by telephoning the Department at 860-713-6086, or by viewing the same by clicking on the "Laws and Regulations" link on the Internet homepage of the Department: www.CT.gov/DCP.

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.