

AGENCY FISCAL ESTIMATE OF PROPOSED REGULATION

Agency Submitting Regulation: Department of Consumer Protection

Date: 03-16-2011

Subject Matter of Regulation: Non-sterile Compounding

Regulation Section No.: 20-576-69 to 20-576-73

Statutory Authority: 4-168; 20-576(a)

Other Agencies Affected: n/a

Effective Date Used In Cost Estimate: Upon Passage (Filing with the Secretary of the State).

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SUMMARY OF COST AND REVENUE IMPACT OF PROPOSED REGULATION

Agency: Department of Consumer Protection Fund Affected: n/a

	First Year	Second Year	Full Operation
Number of Positions	n/a	n/a	n/a
Personal Services	\$0	\$0	\$0
Other Expenses	\$0	\$0	\$0
Equipment	\$0	\$0	\$0
Grants	\$0	\$0	\$0
Total State Cost or (Savings)	\$0	\$0	\$0
Estimated Revenue Gain or (Loss)	\$0	\$0	\$0
Total Net State Cost or (Savings)	\$0	\$0	\$0

Explanation of State Impact of Regulation:

No fiscal impact is anticipated. The Department of Consumer Protection's Drug Control Division currently regulates the activities of all pharmacies in Connecticut.

Explanation of Municipal Impact of Regulation:

No impact on municipalities is anticipated. The Department has jurisdiction over these regulations.

Explanation of Small Business Impact of Regulation:

Please see the Department's Small Business Impact Statement for more details.

Currently there are approximately 10 pharmacies that are devoted to compounding non-sterile products. There are no additional costs on existing pharmacies attributable to this regulation. For new entrants in this practice area, the cost is minimal, or there is no cost, depending on the products produced. Some non-sterile products require standard pharmacy equipment to produce. However, other products may require additional equipment in order to comply with the specific environmental controls applicable to the production process.

Also, some requirements for insurance reimbursement may require accreditation by the Joint Commission, which will in turn require compliance with USP 795. This would lead to some additional costs.

SMALL BUSINESS IMPACT STATEMENT

Prior to adopting a new section or amendment, Section 4-168a of the Connecticut General Statutes (C.G.S.) requires that each state agency consider the affect of such action on small businesses as defined in C.G.S. Section 4-168a. When such a regulatory action may have an adverse affect on small businesses, C.G.S. Section 4-168a directs the agency to consider regulatory requirements that will minimize the adverse impacts on small businesses if the addition of such requirements (1) will not interfere with the intended objectives of the regulatory action and (2) will allow the new section or amendment to remain consistent with public health, safety and welfare.

State Agency submitting proposed regulations: **Department of Consumer Protection**

Subject matter of Regulation: **Non-sterile Compounding**

Date of Agency analysis: **March 16, 2011**

Check the appropriate box:

- The regulatory action will not have an affect on small businesses.
- The regulatory action will have an affect on small businesses, but will not have an adverse affect on such small businesses.
- The regulatory action may have an adverse affect on small businesses, and no alternative considered would be both as effective in achieving the purpose of the action and less burdensome to potentially affected small business. Alternatives considered include the following:
- (1) The establishment of less stringent compliance or reporting requirements for small businesses;
 - (2) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
 - (3) The consolidation or simplification of compliance or reporting requirements for small businesses;
 - (4) The establishment of performance standards for small businesses to replace design or operational standards required in the new section or amendment; and
 - (5) The exemption of small businesses from all or any part of the requirements contained in the new section or amendment.
- The regulatory action will have an adverse affect on small businesses that cannot be minimized in a manner that is consistent with public health, safety and welfare.

The Department of Consumer Protection **notified** / (did not notify) the Department of Economic and Community Development of its intent to take the proposed action, and **completed** / (did not complete) the Agency Fiscal Estimate of Proposed Regulations.

Explanation of Small Business Impact of Proposed Regulation:

Currently there are approximately 10 pharmacies that are devoted to compounding non-sterile products. The cost of this regulation is minimal, or there is no cost, depending on the products produced. Some non-sterile products require standard pharmacy equipment to produce. However, other products may require additional equipment in order to comply with the specific environmental controls applicable to the production process. Some requirements for insurance reimbursement may require accreditation by the Joint Commission, which will in turn require compliance with USP 795. This would lead to additional costs.

For any pharmacies not meeting industry standards, insurers would not undertake business with the wayward companies. The potential costs associated with this proposed regulation would apply to new pharmacies who wish to engage in non-sterile compounding. Pharmacy trade associations were specifically consulted in the drafting of these new pharmacy regulation sections for non-sterile compounding.

Small business exemptions from these new provisions are not consistent with the objective of protecting the health and safety of Connecticut residents who may be administered or prescribed drugs prepared through the process of non-sterile compounding. The Department specifically considered the alternatives listed in Conn. Gen. Stat. Section 4-168a. Additional costs are expected only if new pharmacy locations decide to engage in non-sterile compounding. The costs associated with this regulation would mainly be one-time costs, while a small percentage would be ongoing, as they relate to everyday practices and record keeping functions.

1. Estimated number of pharmacy locations in Connecticut that engage in non-sterile compounding: 10

(Above estimate obtained from Departmental records, as of January, 2011)

2. Estimated number of pharmacy locations in Connecticut that already meet the additional requirements set forth in the proposed regulation, and therefore would not have to incur additional costs for compliance: 10

(Above estimate based upon Departmental records, as of January, 2011)

3. Estimated number of pharmacy locations that would have to incur costs to comply with the proposed regulation: None that are currently operating, but pharmacies entering this area of practice in the future would have an outlay of between \$50,000 to \$100,000.

(Above estimate results from subtracting the number of locations in #1 from that in #2)

4. Estimated number of firms defined as “small businesses” per statute (with fewer than 75 full-time employees) to be affected by proposed regulation: 10 firms

(Above estimate based upon Departmental records, as of January, 2011)

5. Estimated cost of proposed regulation on small businesses: \$0.00.