

SECTION 4: SMALL BUSINESS IMPACT STATEMENT

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: CID

Subject matter of Regulation: Clinical Trials

In accordance with C.G.S. Section 4-168a, staff analyzed the affect on small businesses of the proposed regulations and determined the following:

True False (Check all appropriate boxes):

- | | | |
|-------------------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | The regulatory action will not have an affect on small businesses. |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The regulatory action will have an affect on small businesses, but will not have an adverse affect on such small businesses. |
| <input type="checkbox"/> | <input type="checkbox"/> | 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:
<ol style="list-style-type: none">(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. |
| <input type="checkbox"/> | <input type="checkbox"/> | 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 State agency listed above notified the Department of Economic and Community Development of its intent to take the proposed action and completed the Agency Fiscal Estimate of Proposed Regulations.

Estimating Small Business Economic Impact of a Proposed Regulation

Clinical Trials -- relates to preauthorization form for participating in trials

Industry Code	Industry Code Description	Employees	Total Firms	Avg Employees
621111	Physician Offices	28,232	2612	11
62149	Outpatient centers	5006	184	27
621498	All other outpatient centers	2773	105	26
622110	General medical and surgical hospitals	62401	34	1835
622310	Specialty hospitals	2293	7	327
Total		100,705	2942	34

Step 3. Determine the cost of complying with the proposed regulation.

- a. Specify the actions required of the affected businesses by the proposed regulation and their costs.

This regulation will expand the number of health care providers required to submit the preauthorization request for clinical trial participants; prior regulation laws limited to cancer hospitals and outpatient centers

- b. Multiply the approximate cost by the average number of employees. The added cost to each firm will be approximately $\$20 \times 34 = \680 per year.

Step 4. Complete small business economic impact estimate.

- a. Estimated number of small businesses to be affected:

2942

- b. The projected costs, including reporting, recordkeeping and administration, and other costs required for compliance with the proposed regulation:

Estimate an average of 100 patients/yr/25% of all provider (735)/trial = cost of preparing form=
\$147,000