Regulatory Flexibility Analysis and Impact Statement Form

For Proposed New and Amended Regulations Affecting Small Businesses or Individuals

Introduction

Beginning January 1, 2016, agencies submitting proposed new or amended regulations that affect small businesses or individuals are required, under the new Regulatory Transparency and Accountability Acts of 2015 (see 80 Del. Laws, c. 112 and 113), to submit a Regulatory Flexibility Analysis (RFA) and a Regulatory Impact Statement (RIS) with the proposed regulation to the Registrar of Regulations (see **29 Del.C. Ch. 104**).

This RFA and RIS form is intended to benefit the small businesses and individuals impacted by proposed regulations by ensuring a reasonable level of consistency in the formatting of RFAs and RISs across different agencies and regulations.

State agencies proposing new or amended regulations that are substantially likely to impose additional costs or burdens on small businesses[1] or individuals[2] must submit a Regulatory Flexibility Analysis (RFA) **and** a Regulatory Impact Statement (RIS) to the Registrar of Regulations, with the proposed regulation. For agencies proposing amendments to existing regulations, the promulgating agency shall only be required to complete the RFA and RIS for the proposed amended portion of the existing regulation, and not for the entire existing regulation.

What is a Regulatory Flexibility Analysis (RFA)?

In each RFA, an agency must consider, where applicable, lawful, feasible and desirable, specific methods of reducing the burdens of the regulation on individuals and/or small businesses, including: (1) establishing less stringent requirements and deadlines; (2) establishing performance standards to replace design standards; (3) exempting individuals and small businesses from all or part of the regulation; and (4) examining other ways to accomplish the regulation's purpose, while minimizing the impact upon individuals and/or small businesses.

What is a Regulatory Impact Statement (RIS)?

Among other things, each RIS must (1) describe the purpose of the regulation; (2) identify the individuals and/or small businesses subject to it; (3) provide an estimate of the potential costs of compliance; and (4) describe any less intrusive or less costly alternative methods of achieving the purpose of the regulation. In addition, the Act further enhances transparency by requiring the Registrar of Regulations to transmit regulatory impact statements to the appropriate standing committee of the General Assembly.

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[1] "Small business" means any not-for-profit enterprise, sheltered workshop or business enterprise which is engaged in any phase of manufacturing, agricultural production or personal service, regardless of the form of its organization, when such enterprise or workshop employs fewer than 50 persons, has gross receipts of less than $10,000,000 and is not owned, operated or controlled by another business enterprise.

[2] "Individual" means any natural person, including any sole proprietorship. The term "individual" does not include any natural person affected by a regulation in his/her capacity as an officer, director, or employee of an organization that is not a "small business"; *e.g.* the CEO of a large business.

Agencies, Boards, and Commissions: please fill out this form when proposing new or amended regulations for the purpose of informing the public and business community. All proposed regulations, even if an exemption applies, must have this form attached when submitting to the Registrar of Regulations.

Date 09.15.2016 Agency Dept of Education Division/Office Secretary's Office

Contact Name Tina Shockley

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Regulation # 817 Title Medications and Treatments

Exemptions

(●) *Exemption A*: This proposed regulation is **not subject to Chapter 104, Title 29 of the Delaware Code**, because it will not apply to small businesses or individuals at all.

( ) *Exemption B*: The agency, board, or commission is exempt from completing the RFA and Impact Statement due to the nature of the proposed regulation.

Choose the reason for exemption:

( ) *B1*. This proposed regulation is not substantially likely to impose additional costs or burdens upon individuals and/or small businesses. Explain this conclusion:

( ) *B2.* This is an emergency regulation pursuant to **29 Del.C. §10119**.

( ) *B3.* This proposed regulation is exempt from the procedural requirements of the Administrative Procedures Act, **29 Del.C. §10113(b)**. Choose which reason:

( ) *B3a*. Descriptions of agency organization, operations and procedures for obtaining information

( ) *B3b*. Rules of practice and procedure used by the agency

( ) *B3c*. Delegations of authority to subordinates

( ) *B3d*. Nonsubstantive changes in existing regulations to alter style or form or to correct technical errors

( ) *B3e*. Amendments to existing regulations to make them consistent with changes in basic law but which do not otherwise alter the substance of the regulations

( ) *B3f*. Codifications of existing agency or judicial principles of decision derived from previous decisions and rulings

☐ *B4*. This proposed regulation defines standard of conduct or qualifications of individuals applying for licensure or as licensed professionals. Identify which professional license or professional qualification this would apply to:

☐ *B5*. Regulations that are required by federal law and/or have already complied with the federal Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. (*If this is checked, the agency, board, or commission shall cite the federal law, regulation, directive, or guidance strictly mandating such state regulation and shall attach any applicable Federal RFA related to the regulation, if available. Attach the Federal RFA statement to this form, or provide the URL)*:

End of Exemption Section

Regulatory Flexibility Analysis

State agencies, boards, and commissions proposing to adopt or amend a regulation that is substantially likely to impose additional costs or burdens upon individuals and/or small businesses shall consider, where **applicable, lawful, feasible and desirable**, the following methods of reducing the additional costs and burdens of proposed regulations **on individuals and small businesses**:

1. The establishment of less stringent compliance or reporting requirements;
2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements;
3. The consolidation or simplification of compliance or reporting requirements;
4. The establishment of performance standards to replace design or operational standards required in the proposed regulation;
5. The exemption of certain individuals or small businesses from all or part of the requirements contained in the proposed regulation; and
6. Such other alternative regulatory methods that will accomplish the objectives of the proposed regulation while minimizing the adverse impact upon individuals and small businesses.

Explain whether each of the above methods would be applicable, lawful, feasible, and desirable to reduce the costs or burdens of the proposed regulation:

1.

2.

3.

4.

5.

6.

If the above RFA section does not address each of the six methods and there is not an exemption that applies, explain why the agency, board, or commission decided it was not applicable, lawful, feasible, and desirable to complete the RFA section above:

End of Regulatory Flexibility Analysis Section

Regulatory Impact Statement

Any agency, board, or commission that proposes to adopt or amend a regulation that is substantially likely to impose additional costs or burdens upon individuals and/or small businesses must submit the below Regulatory Impact Statement (RIS).

- Reference the statutory provision that allows for the adoption or amendment of the regulation and the statutory provisions that address the subject matter of the regulation. In addition, provide the URL to the specific section of the Delaware Code to allow the public easy access to view the provision.
    - Statutory Citation: _____
    - URL: _____
    - Subject Matter Statutory Citation: _____
    - URL: _____
- Describe the purpose of the proposed regulation (what is the need for the proposed regulation?):

- What are the anticipated benefits of the proposed regulation? (Describe the benefits that are expected to accrue as a result of the implemented regulation). Please quantify such benefits, as feasible:

- Identify the types of individuals and/or small businesses that would be subject to compliance under the regulation:

- Provide a **good-faith estimate** of the potential cost of compliance for individuals and/or small businesses, which at minimum shall include the projected reporting, recordkeeping, and other administrative costs required to comply with the proposed regulation. Use the below space for a free-text response (*Cost Estimate Option 1*) or, use the questionnaire below to guide the response (*Cost Estimate Option 2*):

Cost Estimate Option 1:

	Cost Estimate Option 2	**Yes**	**No**	**Unknown**
1	Is this regulation being proposed to implement a state or federal program that provides funds to Delaware?	○	○	○
2	If this regulation is not implemented, will individuals, businesses, or programs lose federal funding?	○	○	○
3	Does this regulation implement a plan that has already been approved by the federal government, after an opportunity for public comment?	○	○	○
4	Does this regulation follow industry standards and best practices?	○	○	○
5	Are there potential costs in not establishing these standards?	○	○	○
6	Does the regulation require capital costs (building costs, material costs, upgrades to property or structures, retrofitting of systems, *etc*.)?	○	○	○
7	Does the regulation require additional recurring costs on small businesses or individuals?	○	○	○
8	Does the regulation impose additional administrative burden for a small business or individual?	○	○	○
8a	If answering yes to #8, is it ongoing reporting or one time? (Choose answer) ○ Ongoing ○ One Time ○ Unknown			
8b	If answering yes to #8, generally, how much administrative effort will be required to comply with the regulation? ○ Large Amount ○ Small Amount ○ Unknown			
9	Does the regulation require new or changed record keeping that will create new processes or change processes already in place for small businesses or individuals?	○	○	○

	Cost Estimate Option 2 (continued)	**Yes**	**No**	**Unknown**
10	Would a small businesses or individual be required to hire an outside professional to comply with the proposed regulation (such as an attorney, accountant, tax advisor, environmental consultant, engineering firm, etc.)?	○	○	○
10a	If answering yes to #10, estimate how many hours an outside professional may be needed to assist			
10b	If answering yes to #10, will a small business or individual be required to retain the services of the outside professional on an ongoing basis?	○	○	○
11	Does the regulation require small businesses to purchase goods or services that are unusual or not commercially reasonable?	○	○	○
12	Does the regulation require that small businesses exceed commercially reasonable data storage and transmission standards?	○	○	○
13	Will small businesses have to hire additional employees in order to comply with the proposed regulation?	○	○	○
14	Does the regulation require small businesses to cooperate with audits, inspections, or other regulatory enforcement activities?	○	○	○
15	Does the regulation have the effect of creating additional licenses, taxes and/or fees for small businesses?	○	○	○
16	Does the regulation require small businesses to obtain additional education to keep up to date with regulatory requirements?	○	○	○
17	Please further explain any additional costs or burdens, which at a minimum shall include the projected reporting, recordkeeping, and other administrative costs required to comply with the proposed regulation.			

- Provide a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation, and why these methods were not preferred to a regulation:

- *(Optional)* Estimate the amount of agency, board, or commission staff hours it took to prepare this RFA and RIS statement:

- *(Optional)* Agencies are encouraged to list trade or industry groups, small businesses, or other stakeholders such as currently regulated parties that were consulted by the agency, board, or commission in preparing this RFA and RIS. The agency, board, or commission is further encouraged to send them a copy of the RFA and RIS upon completion:

End of Regulatory Impact Statement Section