SBA Office of Advocacy
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Fact Sheet

Advocacy: the voice of small business in government

Advocacy Suggests Improvements to the FDA's Electronic Distribution of Prescribing Information for Human Prescription Drugs

On May 13, 2015, the Office of Advocacy's Acting Chief Counsel, Claudia Rodgers, sent a letter to the U.S. Food and Drug Administration (FDA) suggesting improvements in the agency's Regulatory Flexibility Act analyses contained in the Electronic Distribution of Prescribing Information for Human Prescription Drug proposed rule. A copy of Advocacy's comment letter may be accessed at www.sba.gov/advocacy.

On December 18, 2014, the FDA published a rule in the *Federal Register* (79 Fed. Reg. 75506) that proposed to require that prescribing information be distributed electronically and to require that paper inserts containing prescribing information no longer be distributed with the prescription drug. The FDA complied with the Regulatory Flexibility Act by concluding that the proposed rule would have a significant impact on a substantial number of small businesses, and the agency published an Initial Regulatory Flexibility Analysis (IRFA).

A number of small businesses and their representatives approached Advocacy concerned that the proposed regulation would have a negative impact on their businesses. Those small businesses that contacted Advocacy were primarily comprised of small independent pharmacies and small paper and print companies that currently print the prescription drug inserts attached to pharmaceutical drugs prescribed to patients. Advocacy wrote the comment letter to provide the FDA with the aforementioned industries' concerns and to suggest ways that the agency could improve its economic analysis of the small entity impacts associated with the rule.

- FDA acknowledged areas where its economic assumptions associated with the rule's costs and benefits were difficult to analyze.
- Given the considerable uncertainty surrounding FDA's assumptions and estimates on the costs necessary for the affected pharmacy industry to transition to an electronic prescription information system only, Advocacy encouraged the FDA to give increased weight to the comments voiced by affected entities in the final rule. As part of its review of comments submitted by interested parties to this regulation, Advocacy suggested that the FDA should analyze how the anticipated impacts of this rule will affect costs in the final rule.
- Advocacy also maintained that he FDA should entertain reasonable alternatives designed to reduce impacts on affected small entities, including analyzing the costs and benefits of using the dual-system alternative suggested by the small entities that will be impacted by the regulation's requirements.

For more information, visit Advocacy's web page here or contact Linwood Rayford at (202) 205-6533.