



October 3, 2017

VIA ELECTRONIC CORRESPONDENCE

Don J. Wright, M.D.
Acting Secretary U.S. Department of Health
And Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

As a result of President Trump's executive orders, 13771 and 13777, the Office of Advocacy (Advocacy) has begun an effort to hear first-hand from small businesses across the country about specific federal regulatory burdens facing their businesses. As you know, under the Regulatory Flexibility Act (RFA), agencies are required to consider the impact of their regulations on small entities when promulgating federal regulations.¹ We believe the RFA and consideration of small business economic impacts is a good place to start when an agency is selecting rules that are being reviewed for reform or elimination.

We recently hosted regional roundtables in a number of states, including, but not limited to, Louisiana, Washington, Iowa, Missouri and Kansas. Also, Advocacy invited small businesses who could not attend the regional roundtables to submit their comments on Advocacy's website. I would like to inform you of the specific concerns and regulations that we heard about from

¹ Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives. 5 U.S.C. § 601 et seq.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy. The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so. Small Business Jobs Act of 2010 (PL 111-240) § 1601.

small businesses in those regions and online regarding agencies within HHS. Those comments are included herein for your review.

I. General Small Business Areas of Regulatory Concern

The Affordable Care Act (ACA)

Small businesses uniformly told Advocacy that they wished to provide their employees with healthcare coverage. However, small entities worry that there is great uncertainty about how to acquire insurance coverage and it is prohibitively expensive to obtain and maintain. Those small businesses that have coverage complained about:

- The exponentially rising cost of health insurance.
- The difficulty some small businesses (especially in rural areas) have in joining other small businesses in an effort to reduce the cost of coverage. Also, many would like to purchase coverage across state lines.
- Small entities suggest that the paperwork burdens associated with compliance with the ACA is too burdensome and many have had to hire additional employees to comply with filing forms and to avoid penalties.
- The uncertainty of policy changes on a year-to-year basis.
- Difficulty determining full-time versus part time employment for coverage under the ACA.
- The tax implications associated with the ACA.
- The costs associated with complying with the employer mandate for small businesses with more than 50 employees.
- Employees are not adequately informed of their responsibilities under the ACA as far as the individual mandate is concerned.
- Insurance brokers are concerned about the fact that insurance companies are not paying their commissions as is required under the ACA.
- The lack of insurance companies that offer qualifying plans under the ACA leads to higher costs, lack of competition and choice.

The Food Safety Modernization Act (FSMA)

- In general, small businesses complained that FSMA rules are too onerous and expensive.
- Small food manufacturers complain about the difficulties they are having ensuring vendor qualifications under FSMA and about the expense of using third party auditors for their certifications. This is especially true for businesses that source hundreds of ingredients.

Food Labeling Rules

- Small businesses complain that despite the delay of the FDA's food labeling rule, many have already expended significant sums on relabeling.
- They would be supportive of a regulatory alternative that would allow greater use of online labeling and content/caloric information.

- Genetically modified (GMO) labeling laws/regulations are not aligned and there is little consistency between GMO labelling and other types of food labeling.

FDA Tobacco Deeming Rule

- Small business manufacturers and retailers expressed concern over uncertain requirements and costs associated with the tobacco deeming rule.

Approval Rate for Innovative Devices and Pharmaceuticals

- Small businesses complain that innovation happens quickly but FDA approval is too costly and slow.
- There is great inconsistency in the product review process and FDA staff rollover can further complicate the review process.
- Need ability to have greater access to the reviewer as there is too much guess work about where the product is in the review process.
- One medical device manufacturer asked that suppliers be subject to the same quality regulations that they are.

II. Specific Small Business Request for Regulatory Reform or Elimination

Centers for Medicare and Medicaid Services (CMS)

- Suspend the Five Star Rating System from the Hospital Compare Website. Small businesses suggest that the rating system is generally inaccurate and misleading to consumers.
- Cancel Stage 3 of the Meaningful Use Program. Hospitals complain that the reporting burdens of “meaningful use” requirements are overly burdensome and expensive with no clear benefit to patient care. They argue that the situation will get worse when Stage 3 begins in 2018.
- Rule on Pharmacy direct and indirect remuneration fees is directly impacting small and independent pharmacies and it should be reformed or eliminated.
- Suspend electronic clinical quality measure reporting requirements. CMS acknowledged that previously submitted electronic clinical quality measurement data from hospitals did not adequately measure the quality of care provided, CMS plans to increase the rules that require such reporting with no apparent benefit to patient care.
- Remove duplicative and conflicting hospital quality measures, especially inpatient and outpatient quality reporting added after August 1, 2016.
- Eliminate the long-term care hospital (LTCH) 25% rule and consider a site-neutral payment policy.
- End the home health agency’s pre-claim review as it is causing patient care and payment delays in the first of five states under the Medicare test demonstration program.
- Restore ICD-9-CM compliant codes for inpatient rehabilitation facility (IRF) 60% Rule.

- Hold Medicare Recovery Audit Contractors (RACs) more accountable for their decisions by implementing a poor performance rating system and imposing financial penalties.
- Withdraw proposed Mandatory Part B drug demonstration as it is too onerous on hospitals.
- Undertake rulemaking on disproportionate hospital share hospital payments because the current interpretive rule will significantly impact hospitals' access to Medicaid funds thereby impacting Medicaid beneficiaries.
- Prohibit enforcement of direct "supervision requirements" of outpatient therapeutic services that negatively impact small and rural hospitals, as well as beneficiary care in rural and underserved communities.
- Do not enforce the 96-Hour rule which would force critical access hospitals to eliminate certain services provided to beneficiaries beyond the 96-hour cutoff.

Food and Drug Administration (FDA)

- Maintain timely patient access to laboratory developed tests by eliminating FDA's draft framework for regulatory oversight of laboratory developed tests. This will ensure that patients have access accurate high-quality tests for which no commercial tests exist.
- Allow patient access to hospital compounded drugs by eliminating provision requiring the "one-mile limitation" with an alternative approach.
- Evaluate whether Multiple Device Reporting (21 CFR Part 803), Recall Reporting (21 CFR Part 806), and the Quality System Regulation (21 CFR Part 820) add significant value in terms of safety/effectiveness versus burden imposed.
- FDA's anticipated "meaningful use" modification should be subjected to rulemaking, not clarification.
- FDA's guidance on "new dietary ingredients" should not be pursued as the guidance makes requirements more onerous, not less.
- FDA should revoke or revise the new definition of "dietary fiber" and reinstate the previously used, "chemical definition."
- FDA's guidance for clinical investigators titled, Sponsors, and Institutional Review Boards on Investigational New Drug Applications; Determining whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application, should be withdrawn.

The Office of Advocacy looks forward to working with your agency to reduce the burden of federal regulations on behalf of the small businesses that have asked us to be their voice in this regulatory reform process. We hope that you will include these specific rules when you compile your list of rules to review. Advocacy would be happy to meet with you or your representative so that we may detail the concerns and help suggest less burdensome alternatives for small business as rules are being considered for revision. I have provided the contact information for Assistant Chief Counsel, Linwood L. Rayford, III, below.

As we continue to hear from small businesses across the country at our regional regulatory reform roundtables or through our outreach from our regulatory reform website, we will update you with additional summaries from those locations.

Thank you for considering small business impacts as a vital part of your regulatory reform efforts and for including the Office of Advocacy as an important part of the process.

Sincerely,

/s/ Major L. Clark, III

Major L. Clark, III
Acting Chief Counsel for Advocacy

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Cc: Ann Agnew, Executive Secretary and Regulatory Reform Officer, Department of Health and Human Services