

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515-6515

The Honorable Xavier Becerra
United States Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Becerra:

As members of the U.S. House of Representative's Committee on Small Business, we are ever vigilant of the regulatory burden imposed upon small businesses. As such, we are writing you to request information about the Department of Health and Human Services' (HHS) implementation of the Regulatory Flexibility Act ("RFA"),¹ Small Business Regulatory Enforcement Fairness Act ("SBREFA"),² and Executive Order 13272³ as part of the Committee's ongoing work to conduct oversight of small business concerns.

As you are aware, these measures were designed to bring small businesses that traditionally operate on thin margins to the regulatory decision-making table. Specifically, these measures require agencies to give small businesses explicit notice of proposed rules, provide small businesses with exceptional opportunities to raise concerns, and compel agencies to consider such concerns.⁴ Despite the desired intent, there is ongoing concern that implementation of these measures have left small businesses wanting in the regulatory arena.

Built into the rulemaking process, Agencies across the federal government are provided discretion when determining a regulations impact on the nation's small businesses. If an Agency's economic analysis concludes that a proposed rule is expected to have a "significant economic impact" on a "substantial number of small entities," then the Agency must produce an Initial Regulatory Flexibility Analysis (IRFA) in the proposed rule.⁵ Alternatively, if an economic analysis concludes that there is no significant impact on a "substantial number of small entities", then the Agency does not need to produce an IRFA.⁶ Instead, the agency simply certifies the rule's undue hardship on small entities and provides a "factual basis for such certification."⁷ To justify the certification, the agency must publish the factual basis in the Federal Register and report the factual basis to the Chief Counsel for Advocacy of the Small Business Administration at the time the proposed or final rule is published for public comment.⁸

¹ 5 U.S.C. §§ 601-12.

² Pub. L. 104-121 (Mar. 29, 1996).

³ Proper Consideration of Small Entities in Agency Rulemaking, 67 Fed. Reg. 53,461 (Aug. 16, 2002).

⁴ *Supra* note, 1.

⁵ 5 U.S.C. § 603(a).

⁶ 5 U.S.C. § 605(b).

⁷ *Id.*

⁸ *Id.*

The bulk of the RFA's protections for small businesses apply when an agency affirmatively determines that a proposed rule will have a "significant impact" on a "substantial number of small entities."⁹ In that instance, section 212 of SBREFA also requires agencies to publish one or more small entity compliance guides for each rule, or group of rules, the agency determines has a significant impact on a substantial number of small entities.¹⁰ Additionally, in the final rule, the agency needs to publish a Final Regulatory Flexibility Analysis (FRFA) that includes but is not limited to "a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available."¹¹

As part of our ongoing oversight investigation into the effectiveness of these critical small business focused measures, we seek the following information from your agency no later than November 7, 2022:

1. Identify any central HHS position or office, if one exists, responsible for ensuring that HHS complies with the RFA, SBREFA, and Executive Order 13272.
2. Identify any HHS positions or offices responsible for reducing the regulatory burden on small businesses.
3. Provide the agency's current definition of "significant impact" and "substantial number of small entities."
 - a. How often, if ever, has the agency changed this definition since 2010 and what were the methods for publicizing each change?
4. Are indirect impacts considered in the agency's determination that a proposed rule will have a "significant impact?"
 - a. If indirect impacts are considered, please describe how this is considered and what weight it has on the determination.
 - b. If indirect impacts are not currently considered, please identify whether the agency is planning to consider indirect impacts in making future determinations; and if so, what steps the agency is taking to incorporate indirect impacts in its "significant impact" analysis.
5. Are both adverse and beneficial impacts weighed in the agency's determination on whether a proposed rule will have a "significant impact?"
 - a. If both adverse and beneficial impacts are considered, please describe what impact those considerations have on the determination and provide examples of when adverse and beneficial impacts were considered with supporting documents.

⁹ *Supra* note, 6.

¹⁰ Small Business Regulatory Enforcement Fairness Act, Pub. L. 104-121, § 212 (as amended by the Small Business and Work Opportunity Act of 2007, Pub. L. 110-28 § 8302).

¹¹ 5 U.S.C. § 604(a)(4).

6. To what extent does the agency consider alternative rules that have less of a regulatory impact on small businesses? Describe the process the agency uses to decide to implement or reject a less burdensome alternative.
7. Provide recent examples of instances where input from mandated SBREFA panels compelled the agency to amend a proposed rule along with supporting documents.
8. What was the total number of rules the agency promulgated last fiscal year, regardless of RFA applicability?
9. Of the total number of rules the agency promulgated last fiscal year, how many did the agency certify as having no significant impact on a substantial number of small entities?
10. What standards does the agency use to determine its “factual basis” to support the determination that a proposed rule would not have a significant impact on a substantial number of small businesses?
11. Identify any recent or upcoming plans to address small business regulatory issues within the agency.
12. Provide all small entity compliance guides produced or in use at the agency within the last calendar year.

The Committee on Small Business has jurisdiction over “assistance to and protection of small business, including financial aid, regulatory flexibility, and paperwork reduction” under House Rule X. Should you have any questions regarding this request, please contact the Committee’s Republican Staff Director, David Planning, at (202) 225-5821. Thank you for your attention to this matter.

Sincerely,



Blaine Luetkemeyer
Ranking Member
House Committee on Small Business



Beth Van Duyne
Ranking Member
House Committee on Small Business
Subcommittee on Oversight, Investigations,
and Regulations