

Congress of the United States  
U.S. House of Representatives  
Committee on Small Business  
2501 Rayburn House Office Building  
Washington, DC 20515-0515

February 22, 2023

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Ave. S.W.  
Washington, D.C. 20201

Dear Secretary Becerra:

The Committee on Small Business is investigating the Department of Health and Human Services' (HHS) implementation of the Regulatory Flexibility Act (RFA), the Small Business Regulatory Enforcement Fairness Act (SBREFA), and Executive Order 13272 (EO13272).<sup>1</sup> Republicans on this Committee wrote to you last Congress and you failed to respond. We write today to request additional documents and information.

As mentioned in our last letter, the RFA, SBREFA, and EO13272 were designed to provide small businesses notice of proposed agency rules that affected their business and provide them the opportunity to participate in the process.<sup>2</sup> Despite this stated goal, it seems that some agencies are failing to properly implement these measures to the detriment of small businesses across the country.

As you are well aware, agencies across the federal government are provided discretion when determining a regulation's impact on the small businesses. Agencies are required to produce an Initial Regulatory Flexibility Analysis (IRFA) in proposed rules only after the agency determines the proposed rule is expected to have a "significant impact" on a "substantial number of small entities."<sup>3</sup> If not, the agency simply certifies the rule will not have a significant economic impact on a substantial number of small entities and provides a "factual basis for such certification."<sup>4</sup> That certification is published in the Federal Register and reported to the Chief Counsel for Advocacy at SBA at the time the proposed or final rule is published for public comment.<sup>5</sup>

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<sup>1</sup> 5 U.S.C. §§ 601-12; Pub. L. No. 104-121 (Mar. 29, 1996); Proper Consideration of Small Entities in Agency Rulemaking, 67 Fed. Reg. 53,461 (Aug. 16, 2002).

<sup>2</sup> 5 U.S.C. §§ 601-12.

<sup>3</sup> 5 U.S.C. § 603(a).

<sup>4</sup> 5 U.S.C. § 603(b).

<sup>5</sup> *Id.*

If the agency determines that the proposed rule will have a significant impact on a substantial number of small entities, section 212 of SBREFA requires agencies to publish one or more small entity compliance guides for each rule, or group of rules.<sup>6</sup> 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.”<sup>7</sup>

Small businesses across America deserve to know how the HHS is working to consider small businesses in their rulemaking process. We therefore request the following documents and information, as soon as possible but no later than March 10, 2023:

1. Identify any central HHS position or office, if one exists, responsible for ensuring that HHS complies with the RFA, SBREFA, and EO13272.
2. Identify any HHS positions or offices responsible for reducing the regulatory burden on small businesses.
3. Provide all small entity compliance guides produced or in use at the agency within the last calendar year.
4. Provide the agency’s definition of “significant impact” and “substantial number of small entities” from 2010 until present, including any and all changes over that time and the justifications for those changes.
5. Provide the name, docket number, and citation of all rules, proposed and final, that that the agency certified as having no significant impact on a substantial number of small entities from 2020 to present.
6. All documents and communications relating to the agency’s determination of whether there was a “significant impact” on a “substantial number of small entities” for all proposed and final rules from 2020 until present.
7. All documents and communications detailing any and all factors the agency considers when determining whether the proposed rule will have a “significant impact” on a “substantial number of small entities” and the weight of each factor given in the determination.
8. All documents and communications relating to consideration of alternate rule proposals when the agency has determined a proposed or final rule has a substantial impact on a substantial number of small entities from 2020 until present.

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<sup>6</sup> 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).

<sup>7</sup> 5 U.S.C. § 604(a)(4).

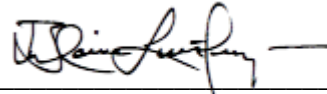
9. All documents and communications relating to instances where input from mandated SBREFA panels compelled the agency to amend a proposed rule, with supporting documents, from 2020 to present.
10. All documents and communications relating to the standards the agency uses to determine its “factual basis” to support a determination that a proposed rule would not have a significant impact on a substantial number of small businesses.

To schedule the delivery of responsive documents or ask any related follow-up questions, please contact Committee on Small Business Majority Staff at (202) 225-5821. The Committee on Small Business has broad authority to investigate “problems of all types of small business” under House Rule X. Thank you in advance for your cooperation with this inquiry.

Sincerely,



Roger Williams  
Chairman  
Committee on Small Business



Blaine Luetkemeyer  
Vice Chairman  
Committee on Small Business



Beth Van Duyne  
Chairman  
Subcommittee on Oversight,  
Investigations, and Regulations



Pete Stauber  
Member of Congress  
Committee on Small Business



Dan Meuser  
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Marc Molinaro  
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Aaron Bean  
Member of Congress  
Committee on Small Business

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A handwritten signature in blue ink that reads "Nick LaLota". The signature is written in a cursive style and is positioned above a horizontal line.

Nick LaLota

Member of Congress

Committee on Small Business

cc: The Honorable Nydia M. Velasquez, Ranking Member  
Committee on Small Business

The Honorable Dean Phillips, Vice Ranking Member  
Committee on Small Business