

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2561 Rayburn House Office Building
Washington, DC 20515-6515

September 7, 2018

The Honorable Alex M. Azar II
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Small Business is conducting oversight over the Department of Health and Human Services' compliance with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. No. 104-121, enacted March 29, 1996) (SBREFA), as amended by the Fair Minimum Wage Act of 2007 (Pub. L. No. 110-28, enacted May 25, 2007) (FMWA).¹

On May 1, 2018, the Committee sent a letter to you regarding the Department of Health and Human Services' non-compliance with section 212 of SBREFA, which requires the publication of small entity compliance guides to assist small entities with complying with agency rules. The statute also requires an agency to annually submit a report to the Committee on Small Business of the House of Representatives, the Committee on Small Business and Entrepreneurship of the Senate, and any other committee of relevant jurisdiction.² The report must describe the status of the agency's compliance with section 212(a)(1) through (5) of SBREFA, and must be received no later than one year after the date of the enactment of the FMWA, and annually thereafter.³ The FMWA was enacted on May 25, 2007.

To date, the Committee has received only the following small entity compliance guide reports from the following sub-agencies since the statute's enactment in 2007:

1. Centers for Medicare & Medicaid Services: reports for years 2017, 2016, 2014, and 2013; and
2. Food and Drug Administration: reports for years 2018, 2017, 2014, 2012, and 2011.

The Committee has not received any response to our letter for the remaining sub-agencies at the Department of Health and Human Services, in spite of the fact that the letter imposed a deadline of May 25, 2018. Small businesses deserve transparency from the federal government and for their voices to be heard in the federal rulemaking process. It is imperative that all federal agencies comply with the law by producing

¹ The Small Business and Work Opportunity Act of 2007 amended SBREFA to include specific requirements for small entity compliance guides. *See* U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Pub. L. No. 110-28, § 8302, 121 Stat. 112, 204-05 (codified as amended at 5 U.S.C. § 631 note). This letter will cite to the statutory sections of SBREFA, as amended.

² Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, § 212(a)(6), 110 Stat. 847 (codified at 5 U.S.C. § 631 note).

³ *Id.*

these documents and presenting them to the Committee so we can understand the unique effects of regulations on small businesses.

The Committee requests the following information and documents as soon as possible, but no later than September 21, 2018:

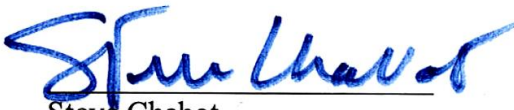
1. Any annual small entity compliance guide reports that have been transmitted to the Committee since the reporting requirement began in 2007. If no reports have been transmitted, an explanation as to why the Committee has not received any reports;
2. The annual small entity compliance guide report on your agency's compliance with section 212 of SBREFA for the year 2017;
3. The location of the small entity compliance guides on your agency's website; and
4. A list of the affected entities that your agency distributed, or will distribute, the guides to.

The Committee also requests that the Department of Health and Human Services provide a briefing to discuss its non-compliance with section 212 of SBREFA.

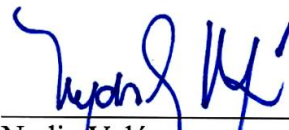
When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2361 of the Rayburn House Office Building and the Minority Staff in Room 2069 of the Rayburn House Office Building. The Committee prefers, if possible, to receive all documents in electronic format.

If you have any questions about this request and to schedule a briefing, please contact Stephanie Fekete of the Majority Staff at (202) 225-5821 or Melissa Jung of the Minority Staff at (202) 225-4038. Thank you for your attention to this matter.

Sincerely,



Steve Chabot
Chairman
Committee on Small Business



Nydia Velázquez
Ranking Member
Committee on Small Business

cc: Steven Wagner, Acting Assistant Secretary, Administration for Children and Families
cc: Lance Robertson, Administrator and Assistant Secretary for Aging, Administration for Community Living
cc: Gopal Khanna, Director, Agency for Healthcare Research and Quality
cc: Patrick Breyse, Director, Agency for Toxic Substances and Disease Registry
cc: Robert R. Redfield, Director, Center for Disease Control and Prevention
cc: Seema Verma, Administrator, Centers for Medicare and Medicaid Services
cc: Scott Gottlieb, Commissioner of Food and Drugs, Food and Drug Administration
cc: George Sigounas, Administrator, Health Resources and Services Administration
cc: Rear Admiral Michael D. Weahkee, Acting Director, Indian Health Service
cc: Dr. Francis Collins, Director, National Institutes of Health
cc: Elinore F. McCance-Katz, Assistant Secretary for Mental Health and Substance Abuse, Substance Abuse and Mental Health Services Administration