



Report to the Chairman,  
Committee on Small Business,  
House of Representatives

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April 2025

# REGULATORY FLEXIBILITY ACT

Improved Policies for  
Analysis and Training  
Could Enhance  
Compliance

# GAO Highlights

Highlights of [GAO-25-106950](#), a report to the Chairman of the Committee on Small Business, House of Representatives

## Why GAO Did This Study

RFA was enacted in 1980 in response to concerns about the effect of federal regulations on small entities. SBA's Office of Advocacy provides RFA compliance training to federal agencies.

GAO was asked to review agencies' implementation of RFA. This report examines CMS's, Energy's, EPA's, and SBA's RFA analyses for 2022–2023 rules and the extent to which Advocacy has provided RFA training, among other objectives.

GAO selected these agencies because they published the greatest numbers of significant final rules and RFA analyses in fiscal years 2022 and 2023. Collectively, they published 30 percent of significant final rules and 36 percent of analyses. GAO reviewed all 55 proposed rules these agencies certified and all 20 rules that contained initial and final regulatory flexibility analyses. GAO compared these rules and agency policies for conducting RFA analyses against RFA requirements and key practices recommended by Advocacy, OMB, and GAO. GAO also reviewed Advocacy's training activities.

## What GAO Recommends

GAO is making six recommendations, including that CMS's, Energy's, and EPA's policies and procedures be revised to more fully incorporate recommended elements; SBA develop RFA compliance procedures; and Advocacy establish procedures for RFA compliance training. Advocacy and HHS agreed, SBA partially agreed, and Energy and EPA neither agreed nor disagreed. GAO maintains that its recommendations should be addressed.

View [GAO-25-106950](#). For more information, contact Jill Naamane at [naamanej@gao.gov](mailto:naamanej@gao.gov).

April 2025

## REGULATORY FLEXIBILITY ACT

### Improved Policies for Analysis and Training Could Enhance Compliance

## What GAO Found

To comply with the Regulatory Flexibility Act (RFA), agencies generally must conduct regulatory flexibility analysis when promulgating a new rule. This analysis assesses the rule's potential impact on small entities and explores alternatives for minimizing the rule's economic impact. Alternatively, agencies may certify that a rule would not have a significant economic impact on a substantial number of small entities, and that such analysis is therefore not needed. GAO found that in fiscal years 2022 and 2023, federal agencies published 195 significant final rules (e.g., those with a large annual effect on the economy) that were subject to RFA requirements. Agencies certified in 142 instances (73 percent) that the proposed rule would not have a significant impact on a substantial number of small entities.

GAO also found that analyses conducted by the Centers for Medicare & Medicaid Services (CMS), the Department of Energy, the Environmental Protection Agency (EPA), and the Small Business Administration (SBA) generally met statutory requirements. However, the analyses were sometimes inconsistent with recommendations from SBA's Office of Advocacy and key practices from the Office of Management and Budget (OMB) and GAO for conducting regulatory and economic analysis. For example:

- **Certifications.** The certifications GAO reviewed generally met statutory requirements, such as providing a statement of factual basis to support the certification. However, GAO found that several of the analyses supporting the certifications did not include information recommended by Advocacy, such as the rule's potential benefits for small entities or the thresholds used for determining "significant impact" or "substantial number."
- **Regulatory flexibility analyses.** The initial and final regulatory flexibility analyses that GAO reviewed generally met statutory requirements, such as describing and estimating the number of affected small entities. However, the analyses were sometimes inconsistent with recommended practices from Advocacy, OMB, and GAO. For example, some did not disclose their data sources, and none considered the indirect costs of the rule.

Fully incorporating Advocacy guidance and other recommended elements into RFA policies and procedures could help CMS (within the Department of Health and Human Services (HHS)), Energy, and EPA enhance their ability to analyze a rule's economic impact on small entities. Additionally, SBA does not have policies and procedures specific to RFA requirements. Developing such procedures could improve the agency's ability to ensure consistent compliance.

Advocacy is charged with providing training to agencies on RFA compliance, but it has not trained 87 of 181 rulemaking agencies since its training program began in 2003. Further, in fiscal years 2019–2023, 26 of the 41 agencies that Advocacy identified as having deficiencies in their RFA analyses did not receive training. Advocacy does not have formal policies and procedures for its RFA training program, such as methods for identifying all rulemaking agencies or targeting those in need of training. By establishing training policies and procedures, Advocacy could better equip agencies to comply with RFA requirements.

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## Abbreviations

CMS	Centers for Medicare & Medicaid Services
CFPB	Consumer Financial Protection Bureau
EPA	Environmental Protection Agency
HHS	Department of Health and Human Services
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
RFA	Regulatory Flexibility Act
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act

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April 10, 2025

The Honorable Roger Williams  
Chairman  
Committee on Small Business  
House of Representatives

Dear Mr. Chairman:

Federal agencies publish thousands of regulations each year, with 3,088 final rules published in fiscal year 2023, according to the *Federal Register*. The Regulatory Flexibility Act (RFA) was enacted more than 4 decades ago in response to concerns about the effect federal regulations can have on small entities, such as small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. For example, regulations can disproportionately affect small entities because they have fewer resources and personnel to comply with new requirements.

RFA requires rulemaking agencies to conduct a regulatory flexibility analysis, which assesses a rule's potential impact on small entities and considers significant alternatives that may reduce that burden.<sup>1</sup> Alternatively, agencies may certify that a rule would not have a significant economic impact on a substantial number of small entities, and that a regulatory flexibility analysis is therefore not required.

We have previously found that uncertainties about and varying agency interpretations of RFA requirements limit the act's application and effectiveness.<sup>2</sup> Members of Congress and small businesses have raised questions about how agencies are evaluating the impact of their rulemaking on small entities.

You asked us to review agencies' implementation of RFA. This report examines the extent to which

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<sup>1</sup>Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified as amended at 5 U.S.C. §§ 601-612).

<sup>2</sup>GAO, *Regulatory Flexibility Act: Congress Should Revisit and Clarify Elements of the Act to Improve Its Effectiveness*, [GAO-06-998T](#) (Washington, D.C.: July 20, 2006).

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1. significant rules published in fiscal years 2022 and 2023 included required RFA analysis or were certified as not having a significant economic impact on a substantial number of small entities,
  2. selected agencies followed RFA requirements and related guidance in certifying their rules,
  3. selected agencies followed RFA requirements and related guidance in performing required RFA analysis,
  4. selected agencies' policies and procedures are consistent with RFA and related guidance, and
  5. the Small Business Administration's (SBA) Office of Advocacy has provided agencies with required compliance training.

For our first objective, we analyzed all 283 final rules that were deemed significant under Executive Order 12866 and published in the *Federal Register* in fiscal years 2022 and 2023.<sup>3</sup> For the 195 rules with a proposed rulemaking, we analyzed the proposed and final rule notices to quantify how many rules included a regulatory flexibility analysis or a certification that analysis was not required.<sup>4</sup>

For the second, third, and fourth objectives, we selected for review four agencies that were among those with the greatest number of significant final rules and regulatory flexibility analyses, among other criteria. We selected the Centers for Medicare & Medicaid Services (CMS), the Department of Energy, the Environmental Protection Agency (EPA), and SBA. Collectively, these four agencies published 30 percent of the significant final rules and conducted 36 percent of the regulatory flexibility analyses.

For the second objective, we selected all 55 final rules certified by these agencies in fiscal years 2022 and 2023. We reviewed the *Federal Register* notices and rule dockets for their corresponding proposed rules.<sup>5</sup>

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<sup>3</sup>Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51735 (Oct. 4, 1993). The 283 rules include 35 interim final rules that were determined to be significant and were evaluated under RFA.

<sup>4</sup>Although we reviewed final rules published during fiscal years 2022 and 2023, some of their corresponding proposed rules may have been published prior to this time frame.

<sup>5</sup>We reviewed certifications in both the proposed and final rules. We focused primarily on proposed rules because omitting a regulatory flexibility analysis at the proposed rulemaking stage may limit an agency's understanding of a rule's impacts and hinder small entities' ability to offer informed comments.

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We examined the extent to which the rule notices were consistent with RFA requirements, the Office of Advocacy's guide on complying with RFA, and other key practices for rulemaking.<sup>6</sup>

For the third objective, we reviewed *Federal Register* notices and related documents from the rule dockets for all 20 significant rules for which the selected agencies performed an initial and final regulatory flexibility analysis. We compared agencies' analyses against RFA requirements, the Office of Advocacy's guide on complying with RFA, and other key practices for rulemaking.

For the fourth objective, we reviewed internal agency policies and procedures for conducting initial and final regulatory flexibility analyses or certifying that such analyses were not required. We also interviewed agency officials regarding their policies and procedures for RFA compliance. We assessed these policies and procedures against RFA requirements, Executive Order 13272 requirements, the Office of Advocacy's guide on complying with RFA, and other key practices for rulemaking.<sup>7</sup>

For the fifth objective, we analyzed SBA's Office of Advocacy annual reports for fiscal years 2019 to 2023 (the five most recent reports available) to determine how frequently RFA training was provided and to which agencies. We also interviewed Advocacy officials about their training and compared their training efforts against Executive Order 13272 requirements and federal internal control standards.<sup>8</sup> We also compared Advocacy's training performance measure against key

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<sup>6</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (Washington, D.C.: Aug. 31, 2017); Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Washington, D.C.: Sept. 17, 2003); and GAO, *Assessment Methodology for Economic Analysis*, [GAO-18-151SP](#) (Washington, D.C.: Apr. 10, 2018). The Office of Advocacy's guide is intended to be used by agency officials as a step-by-step manual for complying with RFA. While it is not binding on agencies, it represents key practices for regulatory flexibility analyses, and we assessed agencies' analyses against these practices. The Office of Management and Budget's Circular A-4 provides information on analyzing the benefits and costs of regulations. This circular was updated on Nov. 9, 2023, after the rules in our sample (fiscal years 2022 and 2023) were published. GAO's *Assessment Methodology for Economic Analysis* compiles the key methodological elements of a sound economic analysis.

<sup>7</sup>Exec. Order No. 13272, *Proper Consideration of Small Entities in Agency Rulemaking*, 67 Fed. Reg. 53461 (Aug. 16, 2002).

<sup>8</sup>Exec. Order No. 13272 and GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

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practices to help effectively implement federal evidence-building and performance-management activities.<sup>9</sup> For more information on our scope and methodology, see appendix I.

We conducted this performance audit from July 2023 to April 2025 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

### Regulatory Flexibility Act

The uniform application of regulations can disproportionately affect smaller entities, as they often have smaller staffs and fewer resources to comply with new rules and absorb increased compliance costs. RFA was enacted in 1980 in part to address this disparity. The act requires that federal agencies analyze the impact of proposed and final regulations on small entities.<sup>10</sup> When the agency does not certify that a proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, it must prepare a regulatory flexibility analysis that describes the impact of the rule on small entities and any significant alternatives that would minimize this impact while achieving the rule's objectives.

RFA does not seek preferential treatment for small entities, nor does it require agencies to adopt regulations that impose the least burden on small entities. Rather, it requires agencies to use an analytical process that identifies barriers to small business competitiveness.

RFA's requirements only apply to rules that are subject to notice-and-comment rulemaking under section 553 of the Administrative Procedure Act or another law.<sup>11</sup> Not all rulemaking includes a notice of proposed

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<sup>9</sup>GAO, *Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts*, [GAO-23-105460](#) (Washington, D.C.: July 12, 2023).

<sup>10</sup>5 U.S.C. §§ 603 and 604. RFA defines "small entity" to include small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. 5 U.S.C. § 601(6).

<sup>11</sup>5 U.S.C. § 601(2). Section 553 contains exemptions from its notice and comment requirements, including rules the agency exempts for good cause. *Also see* Small Business Administration, Office of Advocacy, *A Guide for Government Agencies*.

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rulemaking. Agencies often publish final rules without such a notice, citing “good cause” (e.g., the rule pertains to a technical correction) and other statutory exceptions, according to our prior work.<sup>12</sup>

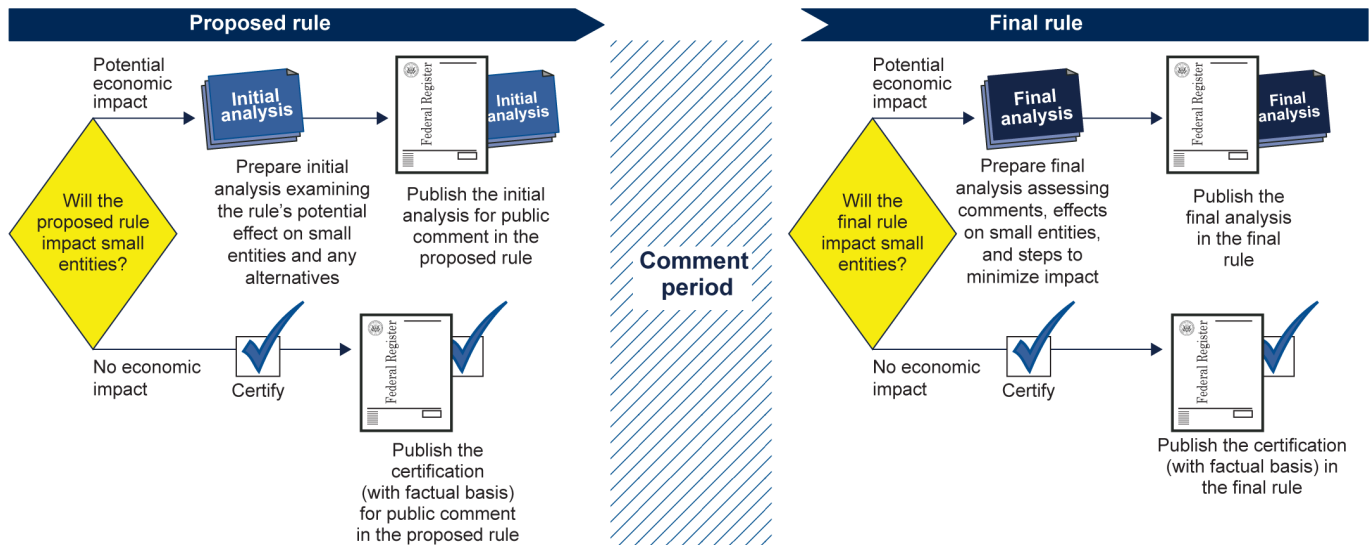
For every proposed rule, RFA requires agencies to prepare an initial regulatory flexibility analysis, unless the agency head certifies that the proposed regulation would not have a “significant” economic impact on a “substantial” number of small entities (see fig. 1). The act does not define either of these terms, however, and we have previously found that compliance with RFA varies because agencies interpret them differently.<sup>13</sup> These initial regulatory flexibility analyses must describe the rule’s potential impact on small entities. The analyses must also describe any significant alternatives to the rule that would minimize the impact on small entities while achieving its goals. RFA requires that agencies publish their initial regulatory flexibility analysis, or a summary, in the *Federal Register* with the proposed rule.

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<sup>12</sup>Under the Administrative Procedure Act, before promulgating a rule, agencies are generally required to publish a notice of proposed rulemaking in the *Federal Register* and take public comments concerning the proposed rule. 5 U.S.C. § 553. In a December 2012 report, we found that agencies did not publish a notice of proposed rulemaking for about 35 percent of major rules and about 44 percent of nonmajor rules published from 2003 through 2010. (Major rules are those that, among other things, have resulted in or are likely to result in an annual effect on the economy of \$100 million or more. While significant regulatory actions are generally subject to the same \$100 million economic effect threshold, the definition of major rule is broader than that of significant regulatory actions.) The Act allows agencies to issue final rules without the use of a notice of proposed rulemaking in certain cases, including when the agency determines for “good cause” that notice and comment procedures are “impracticable, unnecessary, or contrary to the public interest.” In practice, agencies may find a notice of proposed rulemaking “impracticable” when the rule must be published by a statutory deadline, “unnecessary” when the rule pertains to technical corrections, and “contrary to the public interest” in an emergency situation. GAO, *Federal Rulemaking: Agencies Could Take Additional Steps to Respond to Public Comments*, [GAO-13-21](#) (Washington, D.C.: Dec. 20, 2012).

<sup>13</sup>[GAO-06-998T](#).

**Figure 1: The Regulatory Flexibility Act Decision Process**



Economic impact: significant economic impact on a substantial number of small entities  
 Initial analysis: initial regulatory flexibility analysis  
 Final analysis: final regulatory flexibility analysis

Source: GAO analysis of Regulatory Flexibility Act requirements. | GAO-25-106950

Following a period for public comment on the proposed rule, RFA requires agencies to conduct a similar analysis when they promulgate the final rule—the final regulatory flexibility analysis. This analysis must address significant issues raised in comments received on the initial regulatory flexibility analysis. It also must include a description of the steps the agency took to minimize the rule’s significant economic impact on small entities. Agencies then must publish the final analysis, or a summary, with the final rule.

If the head of the agency certifies in the *Federal Register* that the proposed or final rule would not have a significant economic impact on a substantial number of small entities, the agency does not have to conduct

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the initial or final analysis. This certification can be made in lieu of the analysis at either the proposed or final rule stage, or at both stages.<sup>14</sup>

The Small Business Regulatory Enforcement Fairness Act of 1996 amended RFA in response to concerns by the small business community that federal regulations were too numerous, complex, and expensive to implement.<sup>15</sup> The act requires agencies to include a statement providing a factual basis for certifying that regulatory flexibility analysis is not required, among other changes.<sup>16</sup>

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## Executive Orders on Regulatory Review

Executive Order 12866, *Regulatory Planning and Review*, requires agencies to submit draft or proposed significant regulatory actions for review to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs before they are published in the *Federal Register*.<sup>17</sup> Under the order, the Office of Information and Regulatory Affairs has up to 90 days (which can be extended) to review a rule. This review, known as the interagency review process, helps to promote interagency review of draft proposed and final regulatory actions to avoid inconsistent, incompatible, or duplicative policies.

For significant rules, Executive Order 12866 requires agencies to complete a regulatory impact analysis. The order deems rules to be

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<sup>14</sup>According to Office of Advocacy officials, Advocacy's training stresses that if an agency certifies the proposed rule and later determines that the rule would have a significant economic impact on a substantial number of small entities, the agency cannot simply include a final regulatory flexibility analysis in the final rule. Instead, the agency should revisit the process by conducting an initial regulatory flexibility analysis, obtaining comments on it, and then completing a final regulatory flexibility analysis.

<sup>15</sup>Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, tit. II, 110 Stat. 847, 857 – 874 (codified at 5 U.S.C. §§ 601-612 and scattered sections of title 15).

<sup>16</sup>The Small Business Regulatory Enforcement Fairness Act of 1996 also amended RFA to require EPA and the Occupational Safety and Health Administration to convene a panel of small entities (small business advocacy review panel) for each proposed rule that the agency does not certify prior to publication of the initial regulatory flexibility analysis. 5 U.S.C. § 609(b)(1) – (3) and (d). The panel reviews the rule and documents its findings in a report that the agency includes in the rulemaking record, along with any changes the agency makes to the rule or analysis as a result. 5 U.S.C. § 609(b)(4) – (6). None of the rules in our review required the agency to convene a small business advocacy review panel. The Dodd-Frank Wall Street Reform and Consumer Protection Act added the Consumer Financial Protection Bureau to the list of agencies that must comply with the review panel requirements of 5 U.S.C. § 609. Pub. L. No. 111-203, §1100G, 124 Stat. 1376, 2112 (2010).

<sup>17</sup>Exec. Order No. 12866 (Oct. 4, 1993).



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significant based on specific criteria, such as having a large annual effect on the economy as defined by the order.<sup>18</sup> This regulatory impact analysis evaluates the costs and benefits anticipated from the regulatory action. OMB's Circular A-4 provides guidance on developing this analysis.<sup>19</sup> To reduce duplication and overlap, agencies may use other required regulatory analyses, such as the regulatory impact analysis, to satisfy RFA requirements, provided the analyses address impacts on small entities.<sup>20</sup>

Executive Order 13272, *Proper Consideration of Small Entities in Agency Rulemaking*, requires agencies to develop and publish policies and procedures for complying with RFA.<sup>21</sup> It also requires agencies to engage with SBA's Office of Advocacy during the interagency review process. If a draft regulation might have a significant impact on a substantial number of small entities, the agency must notify Advocacy.<sup>22</sup>

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## SBA's Office of Advocacy

Advocacy is generally recognized as an independent office within SBA whose role is to serve as the independent voice for small businesses

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<sup>18</sup>Exec. Order No. 12866 (Oct. 4, 1993). Significant regulatory actions are defined by Executive Order 12866 as any regulatory action likely to result in a rule that may (1) have an annual effect on the economy of \$100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this executive order. In a now-rescinded Executive Order, President Biden increased the monetary threshold to \$200 million, among other changes. See Exec. Order No. 14148 rescinding Exec. Order No. 14094, 90 Fed. Reg. 8237 (Jan. 28, 2025). The economically significant rules we reviewed were determined to be significant under the \$100 million threshold set by Executive Order 12866.

<sup>19</sup>Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Washington, D.C.: Sept. 17, 2003). This circular was updated on Nov. 9, 2023, after the rules in our sample (fiscal years 2022 and 2023) were published. Agencies may have their own policies and procedures for conducting this analysis.

<sup>20</sup>5 U.S.C. § 605(a).

<sup>21</sup>Exec. Order No. 13272 (Aug. 16, 2002).

<sup>22</sup>The agency must notify Advocacy when it submits the draft rule to the Office of Information and Regulatory Affairs under Executive Order 12866, if required, or at a reasonable time prior to publication, if submission is not required.

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within the federal government.<sup>23</sup> RFA designates certain responsibilities to SBA's Chief Counsel for Advocacy, including monitoring and reporting on agency compliance with RFA and providing information to agencies on such compliance.<sup>24</sup> To fulfill these responsibilities, Advocacy publishes annual reports evaluating agency compliance with RFA and Executive Order 13272. Advocacy also publishes a step-by-step guide for agency officials on complying with RFA.<sup>25</sup> In addition, Executive Order 13272 requires the Office of Advocacy to provide training to agencies on RFA compliance.<sup>26</sup> Advocacy also reviews federal rules for their impact on small businesses. Advocacy can submit formal comment letters to agencies regarding RFA compliance during a rule's notice and comment period.

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## The Majority of Significant Rules Were Certified, and the Rest Included Analyses as Required

### Federal Agencies Certified That Most Rules Would Not Have a Significant Impact on a Substantial Number of Small Entities

Most of the significant rules published by federal agencies in fiscal years 2022 and 2023 were subject to RFA requirements, according to our

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<sup>23</sup>The Office of Advocacy has its own statutory charter. 15 U.S.C. §§ 634a-634g. In 2010, Congress expanded Advocacy's independence from SBA, requiring budget requests submitted by the President to include a separate statement of the amount of appropriations requested for Advocacy and designating a Department of the Treasury account that is separate from SBA's. See Small Business Jobs Act of 2010, Pub. L. No. 111-240, § 1602(b), 124 Stat. 2504, 2551 (codified at 15 U.S.C. § 634g).

<sup>24</sup>5 U.S.C. § 612(a).

<sup>25</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies*. Advocacy originally issued this guide in 2003 and updated it in 2012 and 2017.

<sup>26</sup>Exec. Order No. 13272 (Aug. 16, 2002).

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review.<sup>27</sup> According to our analysis, for 195 of 283 significant final rules (69 percent), agencies published a notice of proposed rulemaking and were required to comply with RFA's requirements.<sup>28</sup> This result is consistent with our prior analysis of rulemaking government-wide, which found that about 65 percent of major rules published from 2003 through 2010 had a proposed rule.<sup>29</sup>

Of the 195 rules subject to RFA requirements, agencies certified in 142 instances (73 percent) that the proposed rule would not have a significant economic impact on a substantial number of small entities (see fig. 2). In nearly all cases where agencies certified the proposed rule, they also certified the final rule.<sup>30</sup>

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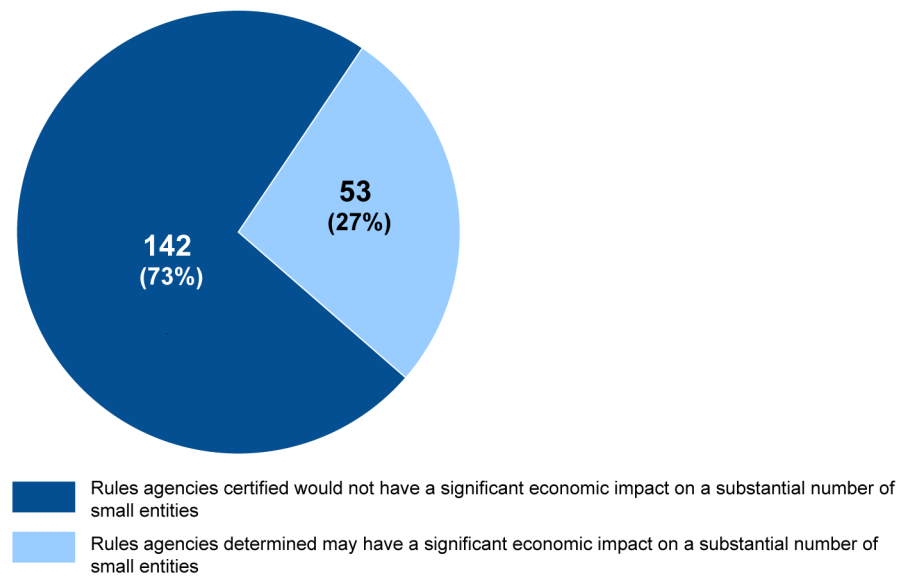
<sup>27</sup>As previously discussed, in general, rules that are not subject to notice and comment requirements of the Administrative Procedure Act or other laws are not subject to RFA's analytical requirements, such as conducting an initial regulatory flexibility analysis or certifying that the rule would not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. §§ 603(a) and 605(b). RFA defines "rule" to mean any rule for which the agency publishes a notice of proposed rulemaking pursuant to section 553(b) of the Administrative Procedure Act. 5 U.S.C. § 601(2). For the rules we reviewed, we did not determine if the rulemaking was subject to notice and comment. Rather, we relied on the existence of a proposed rule to determine if RFA applied.

<sup>28</sup>One of the 195 rules was an interim final rule that adopted a proposed rule published in 2013. See 87 Fed. Reg. 29606 (May 13, 2022) and 78 Fed. Reg. 5998 (Jan. 28, 2013). The 88 significant final rules without a proposed rulemaking include five interim final rules that became final rules in the same time frame. Agencies also published 13 joint final significant rules in fiscal years 2022 and 2023. Of the 13 joint rules, six did not have a proposed rule and therefore were not subject to RFA requirements. Of the seven joint rules that did have a proposed rule, agencies certified that six of the proposed rules would not have a significant economic impact on a substantial number of small entities. In one rule, the agency conducted an initial regulatory flexibility analysis before certifying the final rule. See app. II for the number of significant rules published by agency.

<sup>29</sup>[GAO-13-21](#).

<sup>30</sup>In two of the 142 rules, the agencies certified the proposed rule but then conducted a final regulatory flexibility analysis rather than certifying the final rule. In one case, the agency certified the proposed rule but solicited comments from small entities on the rule's compliance costs. 75 Fed. Reg. 62008 (Oct. 7, 2010). In the final rule, the agency concluded there would be a significant impact on a substantial number of small entities and completed a final regulatory flexibility analysis. 88 Fed. Reg. 11642 (Feb. 23, 2023). In the second case, the agency certified that the proposed rule would not meet the agency's threshold for a significant economic impact. 87 Fed. Reg. 19442 (Apr. 4, 2022). In the final rule, the agency determined that the rule would exceed the threshold and completed a final regulatory flexibility analysis. 87 Fed. Reg. 45669 (July 29, 2022).

**Figure 2: Percentage of Significant Proposed Rules in Which the Agency Certified No Significant Economic Impact, Fiscal Years 2022–2023**



Source: GAO analysis of published rules. | GAO-25-106950

Note: We reviewed final significant rules published during fiscal years 2022 and 2023 that had a proposed rule (i.e., were subject to Regulatory Flexibility Act requirements). Some of the corresponding proposed rules may have been certified prior to this time frame.

Although agencies are not required to conduct further analysis if they certify the proposed rule, agencies chose to do so for 11 rules. For example:

- The Department of Commerce’s Bureau of Industry and Security certified that a proposed rule amending the export control list would not have a significant impact on small entities.<sup>31</sup> The agency nevertheless conducted an analysis to consider alternatives that could accomplish the rule’s objectives while minimizing its impact on small entities.
- The Federal Aviation Administration certified a proposed rule that expanded implementation of an airport safety management system, but it requested comments on potential compliance costs specific to small entities.<sup>32</sup> After receiving feedback from many commenters about additional burdens on small airports, the agency conducted a

<sup>31</sup>87 Fed. Reg. 31195 (May 23, 2022).

<sup>32</sup>75 Fed. Reg. 62008 (Oct. 7, 2010).

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final regulatory flexibility analysis. As a result, it changed the final rule to reduce the number of small airports affected.

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### Agencies Conducted Regulatory Flexibility Analyses When Required

Federal agencies completed regulatory flexibility analyses when required. Specifically, agencies determined that 53 proposed rules may have a significant economic impact on a substantial number of small entities, and they conducted an initial regulatory flexibility analysis as required for all of them.

For 49 of the 53 rules where agencies conducted an initial regulatory flexibility analysis, they also conducted a final regulatory flexibility analysis. For the other four rules, the agency certified that the final rule would not have a significant economic impact on a substantial number of small entities instead of conducting a final regulatory flexibility analysis.

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### Certifications by Selected Agencies Generally Met Statutory Requirements but Sometimes Did Not Align with Relevant Guidance

Our review of the 55 proposed rules that CMS, Energy, EPA, and SBA certified found that the certifications generally met RFA statutory requirements.<sup>33</sup> However, the analysis for many of these certifications did not include key elements recommended by Advocacy, OMB, and GAO.<sup>34</sup> In addition, in some cases, the basis for the certification, certification language, or some of the key certification elements were unclear.

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<sup>33</sup>These are the corresponding proposed rules for all 55 significant final rules that CMS, Energy, EPA, and SBA published and certified in fiscal years 2022 and 2023. Some proposed rules may have been published prior to this time frame.

<sup>34</sup>Advocacy's guide on complying with RFA is a step-by-step manual for agency officials. While it is not binding on agencies, it compiles key practices for regulatory flexibility analyses. OMB's Circular A-4 provides information on analyzing the benefits and costs of regulations. GAO's *Assessment Methodology for Economic Analysis* describes the key methodological elements of a sound economic analysis. While guidance from OMB and GAO is not specific to RFA, its principles can be applied to the regulatory flexibility analysis.

## Over Half of Certifications Concluded That the Proposed Rule Would Impact Some Small Entities but Not Significantly

In 32 of the 55 certifications we reviewed, the agencies determined that the proposed rule would affect *some* small entities or have *some* economic impact on small entities, but not a *significant* economic impact on a *substantial* number of small entities (see table 1). For example, EPA found that a proposed rule on asbestos reporting requirements would affect 14 small businesses that process asbestos, with 12 of them experiencing a cost impact of less than 1 percent of annual revenue.<sup>35</sup>

**Table 1: Basis for Regulatory Flexibility Act Certifications in Selected Agencies' Proposed Rules, Fiscal Years 2022–2023**

Agency	Rule impacts small entities but not a substantial number, or has some economic impact but not significant <sup>a</sup>	Rule does not impact small entities <sup>b</sup>	Rule does not have economic impact <sup>c</sup>	Rule has beneficial impact <sup>d</sup>	Total certifications
Centers for Medicare & Medicaid Services	13	5	2	1	21
Department of Energy	0	2	4	0	6
Environmental Protection Agency	12	3	2	4	21
Small Business Administration	7	0	0	0	7
<b>Total</b>	<b>32</b>	<b>10</b>	<b>8</b>	<b>5</b>	<b>55</b>

Source: GAO analysis of published rules. | GAO-25-106950

Note: We reviewed final significant rules published during fiscal years 2022 and 2023. Some of the corresponding proposed rules may have been certified prior to this time frame.

<sup>a</sup>Agency determined that the proposed rule would affect some small entities or have some economic impact on small entities, but the impact would not be significant or substantial.

<sup>b</sup>Agency determined that the proposed rule would not impact small entities. This category includes rules that would impact entities that exceeded Small Business Administration size standards.

<sup>c</sup>Agency determined that the proposed rule does not have any economic impact. This category includes rules that do not impose requirements on regulated entities.

<sup>d</sup>Agency determined that the proposed rule has beneficial impact on small entities. This category includes rules that increase revenue to small entities.

In 10 of 55 proposed rule notices, the agency concluded that the rule would not impact small entities. This was typically because the rule regulated entities that exceeded SBA size standards or fell outside RFA's definition of small entities. For example, CMS concluded that a proposed rule revising Medicare enrollment and eligibility would impose costs on the federal government and states rather than small entities.<sup>36</sup> In a few

<sup>35</sup>87 Fed. Reg. 27060 (May 6, 2022).

<sup>36</sup>87 Fed. Reg. 25090 (Apr. 27, 2022).

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instances, the agency conducted some analysis to determine whether small entities would be affected. For example, EPA determined that one proposed rule amending recommendations for site remediation would affect 46 firms, none of which were small according to SBA size standards.<sup>37</sup>

In eight of 55 proposed rule notices, the agency concluded the rule would have no economic impact. These rules generally did not impose standards or requirements on regulated entities or pertained to the internal processes of the agency. For example, Energy found that a proposed rule revising a waiver process would not impose any new requirements on manufacturers, including small entities.<sup>38</sup>

Agencies can include supporting analysis in a certification, which can help small entities understand why the agency made the certification and enable them to comment effectively. The degree to which agencies included additional analysis to support a certification of no economic impact varied by agency and by rule. For example, for a proposed rule that reinstated prior standards for dishwashers and washing machines, Energy collected data from its compliance certification database to determine the number of small entities affected.<sup>39</sup> In contrast, for a different rule that would change definitions of general service lamps, Energy also certified its findings but did not include additional analysis in the proposed rule, such as quantifying the number of small entities.<sup>40</sup>

The agencies found that the remaining five of the 55 rules would have a beneficial impact on small entities because they reduced regulatory burden or had a positive net impact on revenue. For example, CMS found

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<sup>37</sup>81 Fed. Reg. 29821 (May 13, 2016).

<sup>38</sup>86 Fed. Reg. 46793 (Aug. 20, 2021).

<sup>39</sup>86 Fed. Reg. 43970 (Aug. 11, 2021).

<sup>40</sup>86 Fed. Reg. 46611 (Aug. 19, 2021). Energy officials said that there was no analysis to conduct because (1) the rule did not have any economic impacts and (2) they had already performed RFA analysis in prior rulemakings. We found that in the final rule, Energy determined that eight small manufacturers could be impacted by the rule. 87 Fed. Reg. 27461 (May 9, 2022). Regarding the second point, the proposed rule does state that three other rulemakings from 2016 address impacts on small entities, but it does not link to these rules. Advocacy's guide stresses that small entities should be able to easily identify relevant information in order to offer informed comment.

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for one proposed rule that updating payment rates for inpatient psychiatric facilities would increase facility Medicare revenues by about 1.5 percent.<sup>41</sup>

The extent to which EPA included additional analysis to support a certification of beneficial impact varied by rule. For example, in a proposed rule on heavy-duty test procedures, EPA stated that the rule would have a beneficial impact by reducing testing burdens and adjusting other compliance provisions.<sup>42</sup> The agency did not include any analysis of the number of small entities affected or the cost impacts of these adjustments to small entities. In contrast, in a different proposed rule, EPA found that establishing an exemption for pesticides created through biotechnology would relieve regulatory burden, and it estimated the percentage of affected entities that were small and the potential cost savings per product to support that finding.<sup>43</sup>

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## Certifications Generally Met Statutory Requirements

Certifications we reviewed from the four selected agencies generally met RFA statutory requirements. As shown in table 2, nearly all certifications were published by the agency head or a designated official.<sup>44</sup> Agencies generally used the appropriate language to certify that the proposed rule would not have a significant economic impact on a substantial number of small entities. Additionally, all of the proposed rules included a statement providing the factual basis or reasoning for the certification. Compliance with these statutory requirements helps make clear to affected small entities that the agency is certifying the proposed rule.

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<sup>41</sup>87 Fed. Reg. 19415 (Apr. 4, 2022).

<sup>42</sup>85 Fed. Reg. 28140 (May 12, 2020).

<sup>43</sup>85 Fed. Reg. 64308 (Oct. 9, 2020).

<sup>44</sup>We considered certifications to come from the agency head if the rule notice was signed by the agency head or a delegated official. Two EPA rule notices were signed by officials other than the agency head. 87 Fed. Reg. 27060 (May 6, 2022); 85 Fed. Reg. 3492 (Jan. 21, 2020). EPA told us that it has a standing delegation of authority for signature authority on proposed or final rule certifications from the Administrator to the Assistant Administrator, Associate Administrator, or Regional Administrator. However, the two notices did not include information regarding this delegation of signing authority, which would have made the certifier's authority clear to the public.



**Table 2: Extent to Which RFA Requirements Were Met Among 55 Certifications from Selected Agencies, Fiscal Years 2022–2023**

	Rules with required element (out of 55)
Certification statement came from head of agency <sup>a</sup>	53
Certification stated that the rule “will not have a significant impact on a substantial number of small entities”	52
Certification included a statement providing the factual basis for certifying the rule	55

Source: GAO analysis of published rules and Regulatory Flexibility Act (RFA) requirements. | GAO-25-106950

Note: The selected agencies were the Centers for Medicare & Medicaid Services, Department of Energy, Environmental Protection Agency (EPA), and Small Business Administration. We reviewed final rules published during fiscal years 2022 and 2023. Some of the corresponding proposed rules may have been certified prior to this time frame.

<sup>a</sup>Two EPA notices were signed by officials other than the head of agency. EPA told us that it has a standing delegation of authority for signature authority on proposed or final rule certifications. However, the two notices did not include information regarding this delegation of signing authority.

In six rules, CMS and SBA used unclear certification language that made it difficult to determine whether they were certifying the rule. For example, CMS took two different approaches in two similar situations. In one rule notice, the Secretary of Health and Human Services found that the proposed rule would have a “positive revenue impact” on a substantial number of small entities, and the agency conducted a certification analysis and certified the proposed rule as not having a significant economic impact.<sup>45</sup> In another rule notice, the Secretary found a “significant positive revenue impact,” and the agency conducted an initial regulatory flexibility analysis in lieu of certifying the proposed rule.<sup>46</sup> We had to consult with CMS officials to determine whether the agency intended to certify the rule.

In one SBA rule, the SBA Administrator stated that the agency did “not believe the impact would be significant.”<sup>47</sup> The rule did not mention the extent to which the rule may affect small entities or whether SBA was certifying the rule. We had to consult with SBA officials to determine that SBA had intended the language to signal that it was certifying the rule.

<sup>45</sup>87 Fed. Reg. 19415 (Apr. 4, 2022). Because CMS is an agency within the Department of Health and Human Services (HHS), the Secretary makes the certification.

<sup>46</sup>87 Fed. Reg. 38464 (June 28, 2022).

<sup>47</sup>87 Fed. Reg. 64724 (Oct. 26, 2022).

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This lack of clarity could pose a challenge for small entities, which may struggle to understand the agency's intention.

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## Certifications Were Sometimes Inconsistent with the Office of Advocacy's Guide and Other Key Practices

Agency certifications we reviewed sometimes were inconsistent with Advocacy's guide and GAO and OMB key practices for rulemaking, according to our review of 37 certifications by CMS, EPA, and SBA.<sup>48</sup> Our analysis excluded the 10 certifications where agencies determined the proposed rule would not impact small entities and the eight certifications where agencies determined the proposed rule would have no economic impact.

### Analyzing Impacts

The certifications we reviewed were sometimes inconsistent with Advocacy's guide and other key practices for analyzing economic impacts and ensuring transparency.<sup>49</sup> Advocacy's guide describes key elements that agencies should include in their analysis when certifying proposed rules. Including these elements helps agencies to obtain meaningful public comment regarding the rule's impact on small entities. The elements include

- a description and estimate of the number of small entities affected by the rule;
- a description and estimate of the economic impacts on small entities, including costs, benefits, and indirect impacts; and

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<sup>48</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies*; Office of Management and Budget, *Circular A-4* (Washington, D.C.: Sept. 17, 2003); and [GAO-18-151SP](#). The Office of Advocacy's guide is intended to be used by agency officials as a step-by-step manual for complying with RFA. While it is not binding on agencies, it represents key practices for regulatory flexibility analyses, and we assessed agencies' analyses against these practices. OMB's Circular A-4 provides information on analyzing the benefits and costs of regulations. GAO's *Assessment Methodology for Economic Analysis* compiles the key methodological elements of a sound economic analysis. Energy certified six proposed rules during our time frame, determining that four of them would have no economic impact and two of them would not impact small entities. Therefore, none of Energy's certifications are included in our subsequent analysis of agency certifications.

<sup>49</sup>For these certified rules, we analyzed the proposed rule notices and other documentation in the rule dockets, as appropriate. This finding is consistent with Advocacy's annual reports on RFA compliance, which identify inadequate analysis of impacts as the most common deficiency in rule notices. According to Advocacy officials, inadequate analysis occurs when agencies have not quantified the rule's impact or provided numerical estimates. See app. III for the full list of deficiencies Advocacy identified in fiscal years 2019–2023.

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- criteria for determining “significant economic impact” and “substantial number,” such as percentage of revenue or percentage of small businesses affected.

However, the agencies’ certification analyses sometimes did not include these elements, as discussed below.

**Description and estimate of small entities affected.** Of the 37 certifications we reviewed, 35 described the small entities affected by the rule, while two EPA certifications did not.<sup>50</sup> Advocacy’s guide says that, at a minimum, agencies should describe the small entities affected by the rule. In addition, 31 of the 37 certifications provided a quantitative estimate of the number of small entities affected by the rule. One CMS proposed rule said that 75 percent of affected entities were small but did not mention how many entities in total were affected.<sup>51</sup> Three EPA certifications did not provide such estimates. According to EPA officials, these rules were intended to relieve regulatory burden, and the agency generally does not conduct further analysis on rules with beneficial impact. However, Advocacy’s guide states that agencies should examine all rules that may have a significant economic impact on small entities, regardless of whether that impact is positive or negative.

In the two other certifications, the agencies could not estimate the number of small entities that would be affected by the proposed rule because data were not available. For example, in one rule, SBA quantified the total number of lenders affected but could not determine the size of the lenders, as it did not collect financial statements from the parent companies.<sup>52</sup> In the second rule, EPA faced several data limitations, including the absence of a nationwide dataset of Clean Water Act certification reviews.<sup>53</sup> Instead, EPA conducted an in-depth qualitative analysis to assess the rule’s impact on small entities. Advocacy’s guide suggests options when quantitative data are unavailable, including

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<sup>50</sup>Both of the EPA proposed rules described the affected industries, but they did not include estimates of the number of small entities within each industry. 86 Fed. Reg. 59684 (Oct. 28, 2021); 85 Fed. Reg. 28140 (May 12, 2020). According to Advocacy’s guide, because nearly every industry has more small entities than large, determining the impact on small entities plays a key role in compliance with RFA.

<sup>51</sup>87 Fed. Reg. 1842 (Jan. 12, 2022).

<sup>52</sup>87 Fed. Reg. 66963 (Nov. 7, 2022).

<sup>53</sup>87 Fed. Reg. 35318 (June 9, 2022).

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conducting qualitative analysis or explaining the data limitations and requesting public comments.

**Description and estimate of the impacts on small entities.** Each of the three agencies conducted at least one certification analysis that did not describe or estimate impacts on small entities. Specifically, two of 37 certifications did not describe the cost impacts on small entities, and five of 37 did not include a quantitative estimate of the cost impact on small entities. For example, one EPA rule notice did not describe or quantify the economic impact because the rule relieved regulatory burden.<sup>54</sup>

CMS rules we reviewed often used the broader regulatory impact analysis to estimate economic impacts on small entities because the agency stated that most hospitals and other providers were small. RFA allows agencies to use these broader analyses to satisfy RFA requirements, provided they specifically address impacts on small entities.<sup>55</sup> However, we found that the extent to which CMS's regulatory impact analyses focused on small entities varied across the rules we reviewed. For example:

- In one proposed rule, CMS estimated that 515 independent dialysis facilities and 378 hospital-based dialysis facilities were small. CMS estimated the economic impacts on these facilities in both the regulatory impact analysis and RFA sections.<sup>56</sup>
- In another proposed rule, CMS estimated that 77 of 479 health insurance issuers were small, but the regulatory impact analysis did not differentiate between impacts on small versus large insurers.<sup>57</sup>
- In a different proposed rule, CMS stated that most ambulatory surgical centers and community mental health centers were small entities. The regulatory impact analysis provided the total number of ambulatory surgical centers and community mental health centers, but did not

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<sup>54</sup>86 Fed. Reg. 59684 (Oct. 28, 2021). EPA officials stated that the agency generally does not conduct further analysis for rules with beneficial impact. However, Advocacy's guide states that agencies should examine all rules that may have a significant economic impact on small entities, regardless of whether that impact is positive or negative.

<sup>55</sup>An agency subject to RFA may perform the initial or final regulatory flexibility analysis in conjunction with or as part of any other analysis required by any other law if such other analysis satisfies the analytical requirements set out in RFA. See 5 U.S.C. § 605(a).

<sup>56</sup>86 Fed. Reg. 36322 (July 9, 2021).

<sup>57</sup>87 Fed. Reg. 584 (Jan. 5, 2022).

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specify how many of these entities were small. The analysis discussed the economic impacts of the rule but did not clarify whether these impacts would be felt by all affected entities, regardless of size.<sup>58</sup>

One of the objectives of the certification analysis is to encourage agencies to consider how a rule might affect small entities differently, such as whether the rule would place small entities at a competitive disadvantage.

**Consideration of beneficial impacts.** Of the 37 certifications, 11 from CMS and EPA did not examine the beneficial impacts on small entities.<sup>59</sup> This is contrary to Advocacy’s guide, which emphasizes consideration of both beneficial and adverse impacts in an analysis.<sup>60</sup> The guide states that the term “significant” is neutral with respect to whether the rule’s impact is beneficial or harmful to small entities, meaning agencies should consider beneficial impacts in their RFA analysis. The guide also states that analyzing beneficial impacts lends credibility to the agency’s choice of alternatives.

**Consideration of indirect impacts.** We found that 30 of 37 certifications by CMS, EPA, and SBA did not examine the proposed rule’s indirect impact on small entities.<sup>61</sup> Although RFA does not require it, Advocacy’s guide recommends that agencies consider indirect impacts on small

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<sup>58</sup>86 Fed. Reg. 42018 (Aug. 4, 2021).

<sup>59</sup>For one of these rules, EPA described cost savings for small entities in the final rule. Proposed rule notice at 87 Fed. Reg. 27060 (May 6, 2022); final rule notice at 88 Fed. Reg. 47782 (July 25, 2023). EPA officials questioned how they could analyze beneficial impacts if a rule did not have any. However, in our review, we were looking for evidence that agencies had considered potential benefits and costs to small entities, even if they ultimately determined there were none.

<sup>60</sup>In its guide, Advocacy acknowledges that agencies have taken issue with this interpretation but maintains that it is possible to analyze beneficial impacts with minimal effort and without necessarily triggering the need for a full regulatory flexibility analysis.

<sup>61</sup>According to EPA officials, EPA analyzes indirect impacts within the larger economic analysis. However, Advocacy’s guide recommends that agencies consider indirect impacts on small entities as part of the RFA analysis. In addition, CMS officials told us that for three rules, data were not available to quantify indirect impacts. However, agencies can consider and describe potential indirect impacts in the absence of quantitative data.

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entities.<sup>62</sup> For example, the guide states that an agency should examine potential effects on small entities that conduct business with entities directly regulated by the rule. In one proposed rule that did consider indirect impacts, EPA noted in supporting documents that proposed changes to the Clean Water Act's water quality certification review process could delay federal licensing or permitting for small businesses' infrastructure projects.<sup>63</sup>

**Criteria for determining “significant economic impact” and “substantial number.”** Each of the three agencies conducted at least one certification analysis that did not include the thresholds used to determine whether the rule impacted a substantial number of small entities or had a significant economic impact. Specifically, 27 of 37 certifications did not describe thresholds for determining a “substantial number” of small entities. Thirteen of 37 did not describe thresholds for “significant economic impact.”<sup>64</sup>

While RFA does not provide set criteria, Advocacy's guide states that agencies should discuss the criteria used for determining that a rule does not significantly impact a substantial number of small entities. The guide suggests criteria to consider when determining “significant impact” or “substantial number.” For example, the rule's impact could be significant if the cost of the proposed regulation eliminates more than 10 percent of the businesses' profits or exceeds 1 percent of the entities' gross revenue in a particular sector. The rule could affect a substantial number of small entities if it will have a significant economic impact on 25 percent of small entities in the sector.

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<sup>62</sup>Advocacy's guide notes that courts have held that RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities. However, the guide states that Advocacy believes that it is good public policy for the agency to perform a regulatory flexibility analysis even when the impacts of its regulation are indirect. The guide says that an agency should examine the reasonably foreseeable effects on small entities that purchase products or services from, sell products or services to, or otherwise conduct business with entities directly regulated by the rule.

<sup>63</sup>87 Fed. Reg. 35318 (June 9, 2022). Economic analysis available at [Regulations.gov](https://www.regulations.gov) using docket number EPA-HQ-OW-2022-0128-0016.

<sup>64</sup>Four of the 27 proposed rules that did not describe thresholds for determining “substantial number” and three of the 13 proposed rules that did not describe thresholds for “significant economic impact” were EPA rules that relieved regulatory burden. As stated previously, EPA officials told us that because they do not conduct analysis for rules that reduce regulatory burden, they would not describe these thresholds.

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## Documenting Analysis

The certifications we reviewed were sometimes inconsistent with Advocacy's guide or key practices from OMB and GAO for documenting an analysis. Advocacy's guide recommends that certification analysis disclose assumptions and describe the data sources used in the economic analysis.<sup>65</sup> Similarly, OMB and GAO guidance emphasizes that agencies should ensure transparency by describing and justifying the analytical choices, assumptions, and data used.<sup>66</sup>

Certifications we reviewed generally included a justification for the certification. However, some did not disclose assumptions or describe data sources:

- **Disclosing assumptions.** Of the 37 certifications, four by CMS and EPA did not disclose the assumptions used in the analysis.<sup>67</sup>
- **Describing data sources.** Each of the three agencies conducted at least one certification analysis that did not disclose the data sources used for determining the number of small entities affected or the economic impacts. Specifically, seven of 37 rules did not identify the data sources used to determine the number of small entities affected by the rule.<sup>68</sup> Nine of 37 rules did not identify the data sources used to analyze economic impact.<sup>69</sup>

## Ensuring Transparency

Guidance from Advocacy, OMB, and GAO emphasizes the importance of transparency in rulemaking to ensure that small entities and the public can comment effectively on the impacts of proposed rules. Advocacy's guide stresses that analyses should enable small entities to easily identify

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<sup>65</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies*.

<sup>66</sup>Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Washington, D.C.: Sept. 17, 2003), and [GAO-18-151SP](#).

<sup>67</sup>EPA stated that its two proposed rules (one extending a compliance date and the other proposing changes to testing and certification procedures) would have only modest positive impacts. Thus, no analysis was needed and there would be no assumptions to explain. 86 Fed. Reg. 59684 (Oct. 28, 2021); 85 Fed. Reg. 28140 (May 12, 2020). Advocacy's guide states that the agency's reasoning and assumptions underlying its certification should be explicit in order to elicit public comment.

<sup>68</sup>In one proposed rule, SBA disclosed the source it used to estimate costs, but it did not disclose its source for determining the number of affected small entities. 87 Fed. Reg. 64724 (Oct. 26, 2022).

<sup>69</sup>In one proposed rule, SBA disclosed the source it used to determine the number of affected small entities, but not the source used to calculate compliance costs. 87 Fed. Reg. 63436 (Oct. 19, 2022).

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relevant information.<sup>70</sup> As noted previously, guidance from both OMB and GAO similarly stresses that transparency requires agencies to include key elements in their analysis to help the public assess agency choices and understand the economic effects of the rule.<sup>71</sup>

However, we found that for the 37 certifications we reviewed, it was sometimes difficult to locate RFA information. For example:

- EPA provided a quantitative cost estimate for 13 rules, but for six of these, the estimates were found in supporting documents, not in the rule notice itself.<sup>72</sup> Readers were directed to the rule docket, which can contain hundreds of documents and be difficult to search. In addition, once readers located the correct document, they would still need to search for information specific to RFA.
- A CMS proposed rule stated that hospitals, ambulatory surgical centers, and community mental health centers would be considered small entities, but the economic impacts for each type of provider were located across different sections.<sup>73</sup> Therefore, to identify all the relevant information on small entities, readers would have to review the entire 342-page rule notice.

RFA requires certifications and the accompanying statements of factual basis to be published in the *Federal Register* concurrent with the notice of proposed rulemaking or final rule, but it does not prohibit agencies from including any supporting analysis in the rule docket.<sup>74</sup> However, Advocacy officials told us the certification analysis should be prominently placed in the RFA section of the rule notice for easy access by small entities. They also discourage agencies from referring readers to other documents for details and stress that the analysis should be clear enough for small entities to easily identify whether a rule applies to them.

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<sup>70</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies*. Advocacy also stresses transparency in its RFA training, stating that agencies should use simple, clear language.

<sup>71</sup>Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Washington, D.C.: Sept. 17, 2003), and [GAO-18-151SP](#).

<sup>72</sup>Further, EPA provided data sources for 11 of the 13 cost estimates, 10 of which were located in supporting documents, not the rule notice itself.

<sup>73</sup>87 Fed. Reg. 44502 (July 26, 2022).

<sup>74</sup>5 U.S.C. § 605.



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Not including recommended elements—such as criteria for determining “significant” and “substantial” and data sources—could limit agencies’ ability to understand a rule’s impact on small entities and limit small entities’ ability to offer informed comments in response. In reviewing the selected agencies’ policies and procedures for RFA compliance, we found that they were missing some elements recommended by Advocacy, OMB, and GAO. We discuss the agencies’ policies and procedures in detail later in this report.

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## Selected Agencies Generally Met Requirements for RFA Analyses but Often Did Not Consider Indirect and Beneficial Impacts

The RFA-required analyses we reviewed for CMS, Energy, and SBA generally met statutory requirements.<sup>75</sup> However, they often did not include indirect and beneficial impacts on small entities, as recommended by Advocacy.<sup>76</sup> It was also difficult to find the required information for some rules.

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## RFA Analyses Generally Met Statutory Requirements

### Initial Regulatory Flexibility Analysis

The 20 initial regulatory flexibility analyses we reviewed largely met RFA statutory requirements. For example, all 20 proposed rule notices described the need for the rule, the rule’s objectives and legal basis, and the type and number of affected small entities (see table 3). There were two requirements that several rules did not address: (1) describing the

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<sup>75</sup>EPA published 21 significant final rules subject to RFA requirements in fiscal years 2022 and 2023, the time frame for our sample. It certified all of them and therefore was not required to conduct any initial or final regulatory flexibility analyses. As a result, we analyzed 20 initial and final regulatory flexibility analyses conducted by CMS, Energy, and SBA.

<sup>76</sup>As previously stated, Advocacy acknowledges in its guide that some agencies have taken issue with Advocacy’s interpretation that “significant impact” under RFA includes adverse and beneficial impacts. The guide also acknowledges that courts have held that RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities. However, the guide states that Advocacy believes that it is good public policy for the agency to perform a regulatory flexibility analysis even when the impacts of its regulation are indirect.

professional skills needed to comply with the rule and (2) identifying federal rules that duplicate, overlap, or conflict with the rule.

**Table 3: RFA Requirements Included in 20 Initial Regulatory Flexibility Analyses from Selected Agencies, Fiscal Years 2022–2023**

	Rules with required element (out of 20)
Description of need for the rule	20
Statement of proposed rule’s objectives	20
Statement of proposed rule’s legal basis	20
Description of affected small entities	20
Estimate of number of affected small entities	20
Description of reporting, recordkeeping, and other compliance requirements	19 <sup>a</sup>
Description of necessary professional skills	15 <sup>b</sup>
Identification, to the extent practicable, of federal rules that may duplicate, overlap, or conflict with the proposed rule	11
Description of alternatives to the proposed rule	16 <sup>c</sup>

Source: GAO analysis of published rules and Regulatory Flexibility Act (RFA) requirements. | GAO-25-106950

Note: The selected agencies were the Centers for Medicare & Medicaid Services, Department of Energy, and Small Business Administration. We reviewed final rules published during fiscal years 2022 and 2023. Some of the corresponding proposed rules may have been published prior to this time frame.

<sup>a</sup>For the remaining rule, Energy officials said they updated their analysis in a supplemental notice of proposed rulemaking to include compliance requirements. See 81 Fed. Reg. 39756 (June 17, 2016); 86 Fed. Reg. 47744 (Aug. 26, 2021).

<sup>b</sup>In one rule notice, the agency said the rule did not have any compliance requirements.

<sup>c</sup>In two rule notices, the agency said there were no alternatives considered. For one rule, Energy officials said they updated their analysis in a supplemental notice of proposed rulemaking to include alternatives to the proposed rule. 81 Fed. Reg. 39756 (June 17, 2016); 86 Fed. Reg. 47744 (Aug. 26, 2021).

Final Regulatory Flexibility Analysis

Most of the 20 final regulatory flexibility analyses we reviewed met RFA statutory requirements. For example, all or nearly all of the analyses described the need for the rule, the rule’s objectives, and the affected small entities, and included the reasons for selecting the alternative adopted in the final rule (see table 4). Seven rule notices did not describe steps to minimize impact on small entities, including two in which the agency determined that the rule would have a positive economic impact on small entities and therefore did not seek to minimize the impact. In the other five notices, agencies generally considered alternatives and explained why they selected the alternative they chose. Five notices did not describe the professional skills needed to comply with the rule,

including one that explained that because there were no compliance requirements, a description of professional skills was unnecessary.

**Table 4: RFA Requirements Included in 20 Final Regulatory Flexibility Analyses from Selected Agencies, Fiscal Years 2022–2023**

	Rules with required element (out of 20)
Description of need for the rule	20
Description of rule's objectives	20
Description of issues raised in public comments on the initial regulatory flexibility analysis	13 <sup>a</sup>
Response to any comments filed by the Small Business Administration's Office of Advocacy	n/a <sup>b</sup>
Description of affected small entities	20
Estimate of number of affected small entities	19
Description of reporting, recordkeeping, and other compliance requirements	20
Description of necessary professional skills	15 <sup>c</sup>
Description of steps to minimize impact on small entities	13 <sup>d</sup>
Description of reasons for selecting alternative adopted in final rule	19 <sup>e</sup>

n/a = not applicable

Source: GAO analysis of published rules and Regulatory Flexibility Act (RFA) requirements. | GAO-25-106950

Note: The selected agencies were the Centers for Medicare & Medicaid Services, Department of Energy, and Small Business Administration.

<sup>a</sup>In three rule notices, the agency said it did not receive public comments on the initial regulatory flexibility analysis.

<sup>b</sup>Our analysis of Advocacy's compliance reports found that Advocacy did not file comments on any of the rules in our review. Therefore, we consider all of the analyses to be compliant with this requirement.

<sup>c</sup>In one rule notice, the agency said the rule had no compliance requirements.

<sup>d</sup>In five rule notices, the agency generally considered alternatives and explained why it selected the alternative it chose. In two rule notices, the agency determined that the economic impacts were beneficial to small entities, so the agency would not seek to minimize the impact. Because the rule notices from the Centers for Medicare & Medicaid Services that met this requirement stated that most affected entities were small, the regulatory impact analysis considered alternatives that would minimize impact on all affected entities, not small entities specifically.

<sup>e</sup>In one rule notice, the agency said there were no alternatives.

## RFA Analyses Were Sometimes Inconsistent with Guidance and Key Practices

The 20 initial and final regulatory flexibility analyses we reviewed for CMS, Energy, and SBA sometimes did not contain elements

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recommended by Advocacy's guide and key practices from OMB and GAO for conducting regulatory and economic analysis.<sup>77</sup>

**Beneficial impacts.** Three of the initial regulatory flexibility analyses by Energy and CMS did not describe beneficial impacts on small entities. As previously stated, Advocacy's guide asserts that the term "significant" is neutral with respect to whether the rule's impact is beneficial or harmful to small entities and therefore agencies should consider beneficial impacts in RFA analysis.

**Indirect impacts.** None of the 20 regulatory flexibility analyses we reviewed described indirect impacts on small entities. As previously stated, although RFA does not require agencies to describe indirect impacts, Advocacy's guide encourages agencies to consider them.

**Documentation.** A few rules did not include data sources for estimating the number of affected entities or the compliance costs of the rule. For example, of the 19 final regulatory flexibility analyses that estimated the number of small entities subject to the rule, three CMS analyses did not include a data source. Similarly, two of the 13 final regulatory flexibility analyses estimating compliance costs did not include a data source. As previously noted, OMB and GAO guidance states that an economic analysis should clearly cite all data sources used.

**Transparency.** The clarity of information on economic impacts and affected small entities varied by agency. For example, CMS's initial and final regulatory flexibility analysis often did not have clear information on small entity impacts. This was partly due to the variety of entities regulated in the Medicare payment system and the use of analyses from other sections of the rule notice to satisfy RFA requirements. In contrast, SBA and Energy's analyses included all information on small entity impacts in the RFA section of the rule notice.

As stated previously, Advocacy officials recommend that agencies include the information relevant to small entities in the RFA section. Further, Advocacy's guide states that the initial and final analyses should allow small entities to compare the impacts of regulatory alternatives on different sizes and types of entities affected by the rule to help them

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<sup>77</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies*; Office of Management and Budget, *Circular A-4* (Washington, D.C.: Sept. 17, 2003); and [GAO-18-151SP](#).

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determine how alternatives will affect them. Additionally, OMB guidance states that results should be transparent and reproducible.

Not including recommended elements—such as analysis of indirect and beneficial impacts—could limit agencies’ and small entities’ ability to fully understand a rule’s impact. In reviewing the selected agencies’ policies and procedures for RFA compliance, we found that they were missing some elements recommended by Advocacy, OMB, and GAO. We discuss the agencies’ policies and procedures in the next section of this report.

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## Selected Agencies’ Policies and Procedures Do Not Include Recommended Elements from Advocacy and Other Key Practices

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### CMS, Energy, and EPA Have Developed Policies and Procedures for Complying with RFA Requirements, and SBA Has Not

Of the four agencies we selected for review, CMS, Energy, and EPA have policies and procedures specifically for complying with RFA posted publicly on their websites; SBA has not developed such policies and procedures.<sup>78</sup> Under Executive Order 13272, agencies are required to establish policies and procedures to promote compliance with RFA. This includes issuing written policies and procedures to ensure that agencies properly consider the potential impacts of rules during rulemaking. The order also states that agencies’ policies and procedures should be made publicly available, such as on the agency’s website.

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<sup>78</sup>CMS is an agency of HHS and uses its guidance on regulatory flexibility analysis. The Assistant Secretary for Planning and Evaluation within HHS developed this guidance, and it was reviewed by SBA’s Office of Advocacy prior to publication. See Department of Health and Human Services, *Guidance on Proper Consideration of Small Entities in Rulemakings* (Washington, D.C.: May 2003); Department of Energy, *Executive Order 13272; Consideration of Small Entities in Agency Rulemaking* (Washington, D.C.: Feb. 19, 2003); and Environmental Protection Agency, *Final Guidance for EPA Rulewriters: Regulatory Flexibility Act* (Washington, D.C.: November 2006).

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CMS's, Energy's, and EPA's policies and procedures for their rule writers restate RFA requirements when explaining how to complete the certification and regulatory flexibility analyses. Energy generally refers rule writers to Advocacy's guide for these analyses instead of providing agency-specific guidance. CMS and EPA provide some additional detail on elements of RFA analyses that may require further interpretation. For example:

- **CMS.** CMS uses the Department of Health and Human Services' (HHS) policies and procedures, which highlight the need to consider compliance costs beyond just record-keeping and reporting in the initial regulatory flexibility analysis.<sup>79</sup> These may include expenses such as hiring additional personnel or revenue reductions. HHS also clearly defines criteria for determining "significant economic impact" and "substantial number of small entities" to support the certification analysis.<sup>80</sup>
- **EPA.** EPA's policies and procedures for conducting regulatory flexibility analyses include guidance on describing and estimating the number of small entities impacted.<sup>81</sup> For example, the guidance emphasizes distinguishing among the small entities that are more and less susceptible to the proposed regulation's economic impacts. In addition, EPA provides rule writers with factors to consider when setting thresholds for "significant" and "substantial" and provides examples of thresholds used in past analyses.<sup>82</sup>

In contrast, SBA has policies and procedures for conducting regulatory economic analysis but does not have separate policies and procedures

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<sup>79</sup>Department of Health and Human Services, *Guidance on Proper Consideration*.

<sup>80</sup>HHS defines "significant economic impact" to be an average annual impact of 3–5 percent or more on small entities. It defines a "substantial number" as 5 percent or more of affected small entities within the industry that the rule affects. As previously mentioned, RFA and Advocacy do not define "significant" or "substantial."

<sup>81</sup>Environmental Protection Agency, *Final Guidance*.

<sup>82</sup>Factors include the (1) magnitude of economic impact that small entities may experience, (2) total number of regulated small entities that may experience the impact, and (3) percentage of regulated small entities that may experience the impact. The policies and procedures note that, on the basis of prior rules, EPA has often defined the threshold for "significant economic impact" to be compliance costs of 1–3 percent of sales and the threshold for "substantial number" as 20 percent of affected small entities. However, the policies and procedures conclude that the final certification decision depends on the three factors.

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specific to complying with RFA.<sup>83</sup> SBA officials told us they consider their regulatory economic analysis guidance to serve as their policies and procedures for RFA compliance. These more general policies and procedures include suggested thresholds for determining when to certify a rule, and they explain when regulatory flexibility analyses are required.<sup>84</sup>

However, these SBA policies and procedures do not describe the required and recommended elements of certification and regulatory flexibility analyses. They also do not explain how rule writers are expected to conduct such analyses. Without specific RFA policies and procedures for its rule writers, SBA is not adhering to Executive Order 13272 and cannot ensure consistent and complete compliance with RFA requirements in its rulemakings.

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### CMS, Energy, and EPA Policies and Procedures Do Not Include Certain Key Practices

Our review found that Energy's policies and procedures for RFA compliance did not explain how rule writers should address certain statutory requirements and key elements recommended in Advocacy, OMB, and GAO guidance for conducting regulatory analyses (see table 5). We also found that CMS's and EPA's RFA policies did not incorporate some recommended elements.<sup>85</sup> This lack of specific policies and procedures to help rule writers implement requirements and recommended elements may have contributed to the weaknesses in analyses we identified earlier in this report. As previously stated, Advocacy's guide helps agencies interpret and implement RFA requirements, OMB's Circular A-4 provides information on benefit-cost

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<sup>83</sup>Small Business Administration, *Framework and Guidelines for Regulatory Economic Analysis* (Washington, D.C.: June 30, 2020). As of January 2025, this document was not publicly available on SBA's website.

<sup>84</sup>SBA's policies and procedures state that the threshold for significant impact is typically set when costs or savings exceed 1 percent of revenue for a small entity. The threshold for a substantial number is typically when 20 percent of the small entities in affected industries will experience a significant impact.

<sup>85</sup>Agencies may have additional guidance on conducting broader regulatory or economic analysis, but our review focused on policies and procedures specifically related to analyzing impacts on small entities. For example, CMS noted that HHS's regulatory impact analysis guidance supplements the department's RFA guidance. However, this guidance offers only a high-level overview of RFA requirements and directs users to HHS's RFA policies and procedures for detailed compliance information. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Guidelines for Regulatory Impact Analysis* (Washington, D.C.: 2016).

analysis, and GAO's guidance compiles the key methodological elements of a sound economic analysis.<sup>86</sup>

**Table 5: Extent to Which Selected Agencies' Policies and Procedures for Regulatory Flexibility Analysis Describe How to Address Statutory and Recommended Elements**

	Centers for Medicare & Medicaid Services <sup>a</sup>	Department of Energy	Environmental Protection Agency
<b>Certification analysis element<sup>b</sup></b>			
Estimate the number of affected small entities	✓	X	✓
Determine the size of the economic impacts	✓	X	✓
Describe why the number of entities or size of impacts justifies the certification	✓	X	✓
<b>Initial regulatory flexibility analysis element<sup>c</sup></b>			
Estimate the number of affected small entities	✓	✓	✓
Describe alternatives to the rule that minimize impacts on small entities	✓	X	✓
Describe reporting, recordkeeping, and other compliance requirements	✓	✓	✓
<b>Final regulatory flexibility analysis element<sup>c</sup></b>			
Estimate the number of affected small entities	✓	X	✓
Describe steps taken to minimize the rule's impact on small entities	✓	X	✓
Describe reporting, recordkeeping, and other compliance requirements	✓	X	✓
<b>Recommended elements<sup>d</sup></b>			
Analyze indirect impacts	X	X	X
Analyze beneficial impacts	X	X	X
Document data sources	✓	X	✓
Ensure transparency	X	X	X

Legend: ✓ = yes; X = no

Source: GAO analysis of agency policies and procedures. | GAO-25-106950

<sup>a</sup>The Centers for Medicare & Medicaid Services uses the Department of Health and Human Services' policies and procedures.

<sup>b</sup>These are elements that the Small Business Administration's Office of Advocacy recommends including in the statement of factual basis that supports the certification.

<sup>c</sup>These are statutory requirements.

<sup>d</sup>These are recommended elements and key practices from Advocacy, Office of Management and Budget, and GAO guidance.

<sup>86</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies*; Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Washington, D.C.: Sept. 17, 2003); and [GAO-18-151SP](#).



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Examples of recommended practices for regulatory analysis that are not incorporated in agency RFA policies and procedures include the following:

- **Certification analysis.** Energy’s RFA policies and procedures do not explain how their rule writers should address key elements that Advocacy recommends including in the statement of factual basis supporting certification, such as how to estimate the number of affected entities. Energy’s policies and procedures do not provide thresholds to guide rule writers in defining “substantial” number and “significant” economic impact, although they do provide some factors from Advocacy’s guide to consider when making this assessment.
- **Initial and final regulatory flexibility analysis.** Energy does not have RFA policies and procedures for how its rule writers should address required elements of the final regulatory flexibility analysis, such as the steps taken by the agency to minimize the significant economic impact on small entities.
- **Analyzing indirect and beneficial impacts.** None of the three agencies—CMS, Energy, or EPA—has RFA policies and procedures that address analyzing indirect and beneficial impacts on small entities.<sup>87</sup>
- **Documenting data sources.** Energy does not have RFA policies and procedures for disclosing data sources used in analyses.<sup>88</sup>
- **Ensuring transparency.** None of the three agencies has policies and procedures for ensuring that RFA analyses clearly explain which small entities will be affected and what the rule’s impacts on them will be.<sup>89</sup> Moreover, CMS and Energy do not specify where this information should be located in the rule so that small entities can easily identify it. EPA has policies and procedures for where RFA-related information

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<sup>87</sup>HHS has procedures for estimating beneficial impacts in its guidance for conducting regulatory impact analysis, but these procedures are not specific to small entities. Its RFA guidance states that rules with a significant positive impact do not necessarily require an analysis. Similarly, EPA’s guidance has procedures for estimating indirect and beneficial impacts in its guidance for conducting regulatory impact analysis, but the procedures are not specific to small entities.

<sup>88</sup>In contrast, HHS’s and EPA’s RFA policies and procedures state that the data sources used should be cited in the analysis, along with any limitations or assumptions.

<sup>89</sup>EPA’s website links to plain language guidance from the Plain Language Action and Information Network, a federal interagency working group. However, EPA’s RFA compliance guidance does not explicitly require clear language easily understood by small entities.

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should be located in the rule notice, but it allows reference to additional details in the docket.

Furthermore, CMS's, EPA's, and Energy's policies were published in 2003, 2006, and 2003, respectively—well before Advocacy updated its guide in 2012 and 2017.<sup>90</sup> According to Advocacy officials, a proper interpretation of Executive Order 13272 would lead agencies to update their policies to reflect changes in RFA that affect compliance, as well as advancements in technology, innovation, and the evolving concerns of small businesses. However, officials at the three agencies stated that they have no plans to update their policies and procedures.

Fully incorporating Advocacy, OMB, and GAO guidance into their policies and procedures would enhance the ability of CMS, Energy, and EPA to thoroughly analyze a rule's economic impact on small entities and help these entities better understand how they will be affected.

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<sup>90</sup>Advocacy officials said they updated their guide in 2017 to incorporate relevant executive orders but noted no major changes to RFA interpretation since 2003. Advocacy is currently considering updates to the 2017 guide.

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## Advocacy Has Not Provided RFA Training to Agencies Throughout Government, and Its Performance Goal Does Not Align with This Objective

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### Many Agencies Have Not Received RFA Training, and Advocacy Does Not Have Policies and Procedures for Its Training Program

Advocacy is mandated under Executive Order 13272 to provide RFA compliance training to agencies.<sup>91</sup> Advocacy offers agencies training that covers the various steps of applying RFA requirements, such as completing the regulatory flexibility analyses, and that can be tailored to an agency's specific needs. Advocacy officials said that during the COVID-19 pandemic, they shifted from in-person to virtual training. They stated that Advocacy currently offers hybrid training that can be attended in-person or virtually. According to officials, Advocacy is updating its training program based on feedback it has received to include more examples.<sup>92</sup> To monitor their training activities, Advocacy staff stated that they track the date and location of each training session, which agencies are present, and how many staff attend.

Advocacy's most recent annual report states that it has offered RFA compliance training to all rulemaking agencies since it began its training

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<sup>91</sup>Beyond training, Advocacy officials highlighted additional resources they provide to agencies on RFA compliance. These resources include RFA guidance and data resources on their website. Advocacy staff also regularly consult with agency staff, review draft documents, and answer RFA compliance questions prior to and during the interagency review process. Finally, Advocacy also discusses RFA in roundtables attended by small entities and agency officials. Advocacy officials stated that while these sessions are not counted in Advocacy's formal training count, many agency staff attend.

<sup>92</sup>Advocacy staff also collect feedback on training effectiveness. Before the COVID-19 pandemic, Advocacy held in-person training sessions and asked participants to complete evaluation forms, according to officials. The forms asked whether the slides were clear and informative, the presenters were easy to understand, and the training was effective and useful. When Advocacy shifted to virtual training, it began soliciting feedback more informally via email. Advocacy officials stated that they are creating a new evaluation form to reflect the updated content and hybrid format. Additionally, they are exploring using polls during training as another means of obtaining feedback on training effectiveness.

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program in 2003.<sup>93</sup> However, officials said they do not maintain a comprehensive list of all rulemaking agencies, making it difficult to compare against their list of agencies trained. We used the list of rulemaking agencies compiled by the Administrative Conference of the United States and compared it with Advocacy's list of trained agencies.<sup>94</sup>

Our analysis indicates significant gaps in Advocacy's training efforts:

- **Many agencies have not been trained since 2003.** We found that as of fiscal year 2023, Advocacy had not provided training to 87 of the 181 rulemaking agencies.<sup>95</sup> Advocacy officials noted that the majority of agencies that had not received training do not issue regulations with which small entities must comply. However, Advocacy does not maintain a comprehensive list of rulemaking agencies and therefore cannot accurately determine which agencies issue regulations that affect small entities and which may need training.
- **Agencies may go an extended period without training.** Even if agencies have received training, many have not been trained in recent years, including some that have published many significant rules. Our analysis found that from fiscal years 2019 through 2023, 150 of the 181 rulemaking agencies did not receive training. Among the 10 agencies that published the greatest numbers of significant rules in fiscal years 2022 and 2023, four did not receive training from fiscal years 2019 through 2023: EPA, the Bureau of Industry and Security, the Fish and Wildlife Service, and the Office of Personnel Management (see fig. 3). Advocacy officials noted that Executive Order 13272 does not require agencies to be trained at a certain frequency.
























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<sup>93</sup>Advocacy officials said that agencies are typically receptive to training when it is offered but are not required to participate in training under Executive Order 13272.

<sup>94</sup>Every fiscal year, Advocacy publishes a report on agencies' RFA compliance that includes information on the agencies Advocacy trained that year. The Administrative Conference of the United States, an independent federal agency tasked with studying federal administrative procedures and developing recommendations for improvement, identified 181 federal agencies with rulemaking authority, on the basis of its review of relevant statutes. See Administrative Conference of the United States, *Sourcebook of United States Executive Agencies* (Washington, D.C.: October 2018).

<sup>95</sup>Advocacy did train two agencies that were not on the Administrative Conference of the United States' list of rulemaking agencies: the United States Access Board and the Trade and Development Agency. Advocacy also trained 31 programs or offices within agencies that were on the list, such as the Office of Policy within HHS.

**Figure 3: Office of Advocacy Comment Letters and Training Received by 10 Agencies That Published the Greatest Numbers of Significant Rules in Fiscal Years 2022 and 2023**

Agency	FY 2019		FY 2020		FY 2021		FY 2022		FY 2023	
	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter
Bureau of Industry and Security (Department of Commerce)	—	—	—	—	—	—	—	—	—	—
Centers for Medicare & Medicaid Services (Department of Health and Human Services)	—	—		—		—	—		—	—
Department of Energy	—		—	—			—		—	
Department of State	—	—	—	—	—	—	—	—		—
Department of Veterans Affairs		—		—	—	—	—	—	—	—
Environmental Protection Agency	—		—		—		—		—	
Federal Aviation Administration (Department of Transportation)	—	—	—	—		—		—	—	—
Office of Personnel Management	—	—	—	—	—	—	—	—	—	—
Small Business Administration	—		—	—	—	—		—	—	—
U. S. Fish and Wildlife Service (Department of the Interior)	—	—	—		—	—	—		—	

— = Did not receive

Source: GAO analysis of Office of Advocacy compliance reports and published rules. | GAO-25-106950

- **Training efforts may not target agencies that need training most.** Advocacy sends comment letters to agencies with identified RFA compliance issues, but there does not appear to be a relationship between these agencies and those receiving training.<sup>96</sup> From fiscal years 2019 through 2023, Advocacy identified 41 agencies with deficiencies in their RFA analyses, but 26 of these agencies did not

<sup>96</sup>Advocacy can submit formal comment letters to agencies regarding RFA compliance during a rule's notice and comment period. Advocacy's annual compliance reports on RFA list the comment letters it sent to agencies about RFA compliance and the most frequently cited issues.

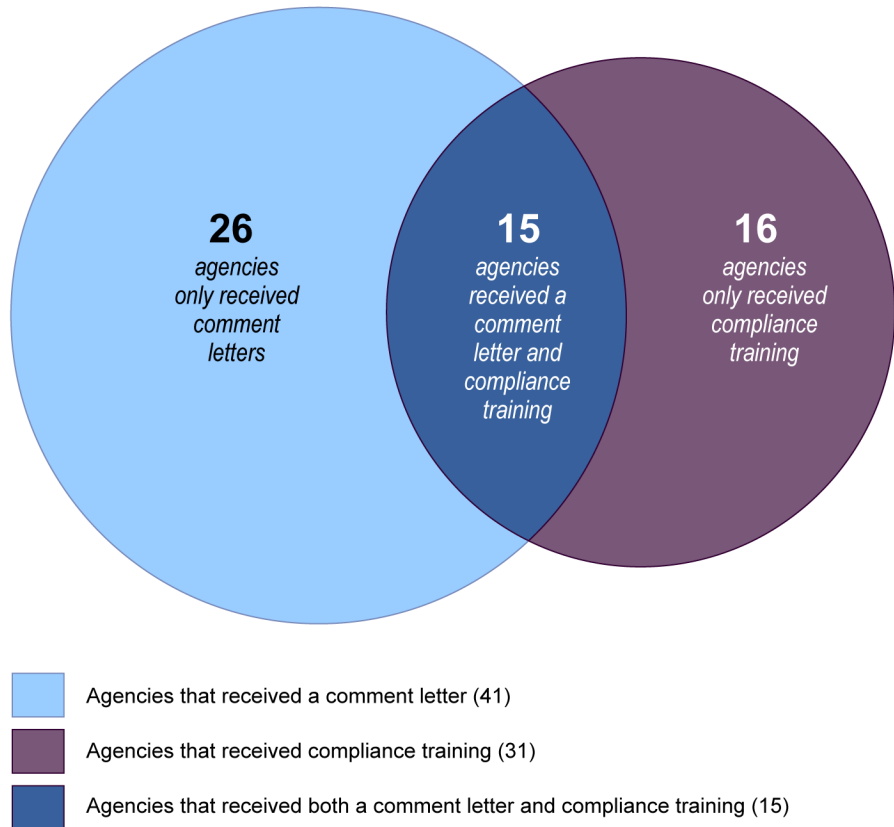
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receive any training during this period (see fig. 4). Some agencies have received multiple letters across several years without receiving training. Notably, EPA received 35 comment letters from the Office of Advocacy on RFA compliance during this period.<sup>97</sup> (See app. IV for further information on agencies that received training or comment letters from Advocacy.)

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<sup>97</sup>According to an Advocacy official, EPA received RFA compliance training in February 2025. Advocacy and EPA officials also stated that the comment letters were not all related to RFA compliance. For example, Advocacy officials noted that many of the letters issued during this time frame reflected stakeholders' concerns about policy choices EPA made when weighing its statutory goals, which would not have necessarily been remedied by training. However, we looked at the 15 comment letters Advocacy sent EPA in fiscal year 2023 and found that 10 pointed out issues with EPA's certification or expressed concerns about the analysis of small entity impacts. See app. III for the types of issues Advocacy addresses in its comment letters.

**Figure 4: Agencies That Received Comment Letters or Compliance Training from the Office of Advocacy Related to the Regulatory Flexibility Act, Fiscal Years 2019–2023**



Source: GAO analysis of Office of Advocacy compliance reports. | GAO-25-106950

Advocacy officials said they rely on informal methods to identify agencies that need training. They said their attorneys monitor staff turnover and gauge agencies' understanding of RFA during the interagency review process.<sup>98</sup> If attorneys believe training is necessary, they will extend an offer. However, Advocacy does not have formal procedures to track staff turnover or document agencies that may need additional training.

<sup>98</sup>As previously stated, agencies are required to engage with SBA's Office of Advocacy during the interagency review process.

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Federal internal control standards state that management should implement control activities through policies.<sup>99</sup> Policies may be further defined through procedures, which may include, for example, the timing of a control activity or any follow-up corrective actions when deficiencies are identified.

Advocacy does not have formal policies and procedures for implementing its mandate to provide RFA training to agencies. For example, Advocacy does not have procedures for identifying all agencies involved in rulemaking. In addition, it has no established policies on how regularly agencies should receive training. Further, Advocacy does not have formal procedures for prioritizing agencies that may need training due to identified issues.

This informal approach to agency training may lead to gaps in RFA compliance. According to Advocacy's 2023 annual compliance report, a lack of training can result in inadequate analysis of impacts on small entities and increased litigation risk.<sup>100</sup> Developing formal policies and procedures for providing RFA compliance training would enable Advocacy to systematically track training to rulemaking agencies and help ensure these agencies receive regular and refresher training as needed. This would help Advocacy provide training throughout government and better position agencies to comply with RFA.

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### Advocacy's Performance Goal Does Not Promote Training Throughout Government

To address its mandate under Executive Order 13272, Advocacy has a strategic objective of providing RFA compliance training to rulemaking officials throughout government. To achieve this objective, Advocacy set a performance goal to train at least 100 officials each fiscal year.<sup>101</sup> Advocacy officials stated that they have met this goal every year since the training program began in 2003. Our review of Advocacy's RFA compliance reports for fiscal years 2019 through 2023 confirmed this, showing that Advocacy trained over 100 officials each year through about eight to 10 trainings per fiscal year.

However, meeting this goal does not necessarily indicate comprehensive coverage across multiple agencies, as a single agency may send a large

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<sup>99</sup>[GAO-14-704G](#).

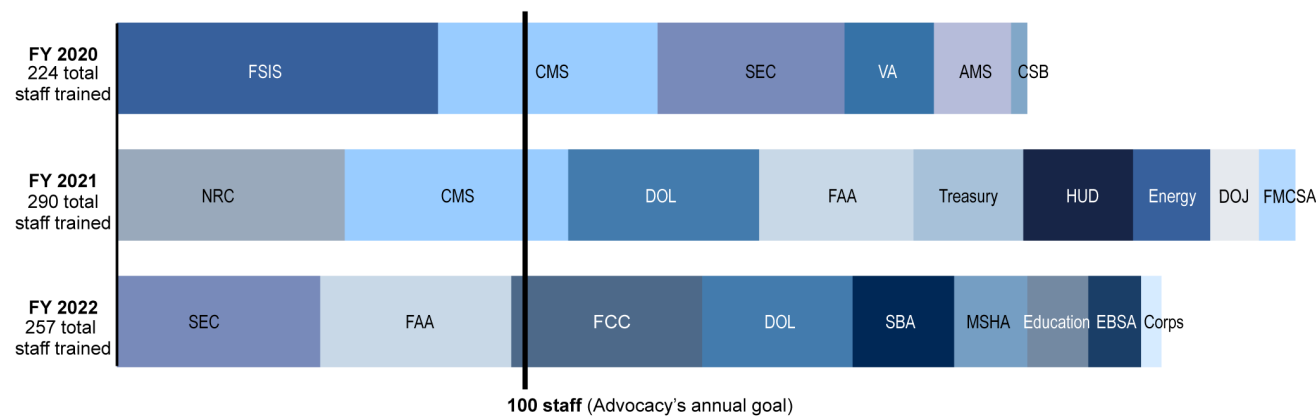
<sup>100</sup>Small Business Administration, Office of Advocacy, *Report on the Regulatory Flexibility Act FY2023* (Washington, D.C.: June 2024).

<sup>101</sup>According to Advocacy officials, they set this metric in conjunction with OMB during the budget justification process.



number of staff to a training session. For example, during each of the fiscal years 2020–2022, certain individual agencies brought at least 50 staff members to a single training, accounting for half of Advocacy’s annual goal.<sup>102</sup> As shown in figure 5, Advocacy could have met its goal by training as few as two agencies in some years.

**Figure 5: Number of Staff Attending Office of Advocacy Compliance Trainings, by Agency, Fiscal Years 2020–2022**



- Abbreviations:**

  - AMS = Department of Agriculture, Agricultural Marketing Service
  - CMS = Centers for Medicare & Medicaid Services
  - Corps = Army Corps of Engineers
  - CSB = Chemical Safety and Hazard Investigation Board
  - DOJ = Department of Justice, Civil Rights Division
  - DOL = Department of Labor, Wage and Hour Division
  - EBSA = Employee Benefits Security Administration
  - Education = Department of Education
  - Energy = Department of Energy
  - FAA = Federal Aviation Administration
- Abbreviations continued:**

  - FCC = Federal Communications Commission
  - FMCSA = Department of Transportation, Federal Motor Carrier Safety Administration
  - FSIS = Department of Agriculture, Food Safety and Inspection Service
  - HUD = Department of Housing and Urban Development
  - MSHA = Mine Safety and Health Administration
  - NRC = Nuclear Regulatory Commission
  - SBA = Small Business Administration
  - SEC = Securities and Exchange Commission
  - Treasury = Department of the Treasury
  - VA = Department of Veterans Affairs

Source: GAO analysis of Office of Advocacy compliance reports. | GAO-25-106950

Because Advocacy’s performance goal focuses on the total number of staff trained, it does not measure the extent to which training is comprehensive across government agencies. As previously discussed, no staff from 150 rulemaking agencies received training in the last 5 years. At the same time, eight of the 31 agencies that did receive training were trained multiple times, with some receiving training 2 years in a row across the 5-year period (see app. IV for more information).

<sup>102</sup>In fiscal years 2019 and 2023, no agency brought more than 24 staff to a single training session. Advocacy trained 113 staff in 2019 and 139 in 2023.

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In our previous work, we identified key practices for agency performance management activities.<sup>103</sup> One such practice is developing performance goals that link to the agency's strategic goals and objectives and that address important dimensions of program performance. Advocacy's performance goal of training 100 officials a year is not clearly aligned with its strategic objective of training rulemaking officials throughout government because those officials could be concentrated at a few agencies. By developing a performance goal that better links to its strategic objective, Advocacy could better ensure that it is providing RFA training across rulemaking agencies and complying with Executive Order 13272.

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## Conclusions

The Regulatory Flexibility Act plays an important role in ensuring that federal agencies consider and seek to minimize the impact of their regulations on small businesses. However, we identified opportunities for selected agencies to enhance implementation in the following areas:

- **Establishing policies.** SBA largely complied with RFA statutory requirements, but it has not established specific policies and procedures for implementing RFA. As a result, it is not adhering to Executive Order 13272 and cannot ensure consistent and thorough adherence to RFA requirements in its rulemakings.
- **Aligning policies with key practices.** CMS, Energy, and EPA generally complied with RFA statutory requirements, but we identified instances where their analyses did not align with Advocacy's guide and other key practices for rulemaking. By more fully incorporating Advocacy, OMB, and GAO guidance—and instructions for addressing statutory requirements, in the case of Energy—into their policies and procedures, the agencies could more consistently and effectively meet RFA objectives.
- **Ensuring comprehensive training throughout government.** SBA's Office of Advocacy does not have formal policies or procedures for providing RFA compliance training. As a result, it cannot effectively identify agencies that are most in need of training or have not received it for an extended period. Establishing formal policies and procedures for such training would better ensure that all agencies receive regular and refresher training as needed. Advocacy could further ensure comprehensive training by developing a performance

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<sup>103</sup>[GAO-23-105460](#). GAO identified key practices to help effectively implement federal evidence-building and performance-management activities.

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goal more directly tied to its strategic objective of training officials throughout the government.

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## Recommendations for Executive Action

We are making a total of six recommendations, including one to SBA, one to HHS, one to Energy, one to EPA, and two to SBA's Office of Advocacy:

The Administrator of SBA should develop and implement policies and procedures for complying with the Regulatory Flexibility Act. (Recommendation 1)

The Secretary of Health and Human Services should revise HHS's Regulatory Flexibility Act policies and procedures to more fully incorporate elements recommended by the Office of Advocacy, OMB, and GAO for conducting certification and regulatory flexibility analyses, such as considering beneficial and indirect impacts on small entities. (Recommendation 2)

The Secretary of Energy should revise Energy's Regulatory Flexibility Act policies and procedures to incorporate statutory requirements and elements recommended by the Office of Advocacy, OMB, and GAO for conducting certification and regulatory flexibility analyses, such as considering beneficial and indirect impacts on small entities. (Recommendation 3)

The Administrator of EPA should revise EPA's Regulatory Flexibility Act policies and procedures to more fully incorporate elements recommended by the Office of Advocacy, OMB, and GAO for conducting certification and regulatory flexibility analyses, such as considering beneficial and indirect impacts on small entities. (Recommendation 4)

The Chief Counsel of the Office of Advocacy should develop and implement policies and procedures for providing training to agencies on Regulatory Flexibility Act compliance, including mechanisms to identify agencies most in need of training and agencies that have not received it for an extended period. (Recommendation 5)

The Chief Counsel of the Office of Advocacy should develop one or more performance goals that more clearly link with its strategic objective of training rulemaking officials throughout the government. (Recommendation 6)

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## Agency Comments and Our Evaluation

We provided a draft of this report to Energy, EPA, HHS, SBA, and SBA's Office of Advocacy for review and comment. Each agency provided written comments, which are reprinted in appendixes V–X. Energy and EPA provided additional comments via email, as well as technical comments that we incorporated as appropriate.

**Energy.** Energy neither agreed nor disagreed with our recommendation that it update its policies and procedures, stating it would review the requirements and recommendations identified in our report and assess whether additional guidance would be beneficial.

In its letter and in an email from an Audit Resolution Specialist, Energy provided additional comments on our findings:

- Energy stated in its letter that our report did not correctly characterize the department's guidance relating to the consideration of small entities. In its emailed comments, which provided more clarification, Energy stated that its policies and procedures explicitly address RFA statutory requirements and provide guidance for analyzing the elements of an initial regulatory flexibility analysis, including using SBA's size standards to determine the small entities affected by the proposed rule. Further, Energy stated that its policies and procedures address all the other statutory and recommended elements we identified. As we stated in the report, Energy's policies and procedures restate RFA requirements for the certification and regulatory flexibility analyses. We added language to the report to clarify that policies and procedures should assist rule writers in implementing requirements, not just restate them.

We reevaluated Energy's policies and procedures for conducting initial regulatory flexibility analyses and determined they provide some information that can help rule writers estimate the number of affected small entities and describe compliance requirements. We did not, however, find additional evidence of policies and procedures that help rule writers implement the other statutory requirements and recommended elements we identify in the report, such as conducting final regulatory flexibility analyses or analyzing indirect impacts. We maintain that incorporating Advocacy, OMB, and GAO guidance into its policies and procedures would enhance Energy's ability to thoroughly analyze a rule's economic impact on small entities.

- Energy stated in its letter and emailed comments that our report inaccurately characterized the RFA analysis for specific rules and the department's process for identifying benefits to small entities. While

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we do not believe our characterization was inaccurate, we added additional context about analysis that Energy cited and conducted. In addition, Energy stated in its emailed comments that while the initial and final regulatory flexibility analyses of certain rules did not call out beneficial impacts specific to small entities, they did discuss beneficial impacts in general. However, the focus of RFA is beneficial impacts to small entities specifically. We reviewed the evidence Energy cited and revised the report accordingly where we determined that there was some consideration of benefits for small entities.

**EPA.** EPA neither agreed nor disagreed with our recommendation that it update its policies and procedures, stating that it plans to update its RFA guidance when resources allow. As part of that update, EPA said it would consider guidance from other agencies and expects to focus on RFA-related analyses addressing statutory requirements.

In its letter and via an email from an Office of Policy GAO Liaison, EPA provided additional comments on our findings:

- EPA stated that analytical elements we identified as absent from the agency's RFA analyses were included elsewhere in the broader regulatory analyses. However, as noted in our methodology, we reviewed the entire rule notice and supporting documentation for information relevant to small entities. We described an element as absent if the element was not mentioned in the rule's RFA section, the broader regulatory analysis, or the supporting documentation.
- EPA said it interprets "significant economic impact" to refer to *adverse* economic impacts, not beneficial impacts, and "substantial number of small entities" to refer only to small entities directly regulated by the proposed rule. It said Advocacy's guide notes court decisions that support this interpretation.<sup>104</sup> Thus, EPA stated that RFA does not require a certification analysis for rules with significant beneficial or indirect impacts on small entities.

We acknowledge differing agency interpretations in the report, but Advocacy's guide maintains that agencies can analyze beneficial impacts with minimal effort. While RFA does not require indirect impact analysis, Advocacy considers it good public policy to do so. As

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<sup>104</sup>Advocacy's guide does not state that courts have upheld the position that RFA requires analysis of only adverse and not beneficial impacts. In contrast, Advocacy's guide does state that the courts have held that RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities, so we added that to the report.

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our recommendation states, we believe EPA should revise its policies and procedures to be consistent with elements in Advocacy's guide.

- EPA questioned our use of OMB and GAO guidance when assessing RFA analysis. As noted in our report, while not specific to RFA, both reinforce principles in Advocacy's guide, such as the importance of documentation and transparency. We believe using the OMB and GAO guidance in conjunction with Advocacy's guide is appropriate for evaluating how agencies consider impacts on small entities in rulemaking.
- In emailed comments, EPA made two additional points regarding its certifications. First, it said that rules with "negligible" or "modest" impacts do not need analysis to support a certification. As noted in our report, Advocacy's guide states that certifications must, at a minimum, describe the affected entities and impacts to justify a certification. The guide further emphasizes making agency reasoning and assumptions explicit to support meaningful public comment and potential reevaluation. Therefore, we maintain it was appropriate for us to evaluate rules with modest impacts, including the rationale behind such determinations. Second, EPA stated that two rules signed and certified by an official with delegated authority, but without explicit reference to that delegation in the rule notice, should be considered compliant with RFA. We maintain that the delegation should be cited in the rule notice to demonstrate the certifier's authority to the public.

**HHS.** HHS agreed with the recommendation addressed to it and stated it would continue its efforts to update and provide transparency on the department's RFA policies and procedures.

**SBA.** SBA partially agreed with our recommendation to develop RFA policies and procedures and suggested that we revise the recommendation. We recommended that SBA develop and implement policies and procedures for complying with RFA; SBA proposed that we instead recommend that SBA publish its current policies and procedures on its public website.

In its letter, SBA stated that it had documented RFA policies and procedures but had not made them publicly available in accordance with Executive Order 13272. It cited its *Framework and Guidelines for Regulatory Economic Analysis*, along with regular trainings and technical assistance for all rulemaking staff. However, as noted in the report, the cited document contains few details on RFA compliance, lacking

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descriptions of required certification and regulatory flexibility analysis elements or explanations for conducting such analyses.

Although training and technical assistance support RFA compliance, Executive Order 13272 requires written policies and procedures to ensure agencies properly consider the potential impacts of rules. Therefore, we maintain that SBA should develop and implement policies and procedures for complying with RFA. We agree with SBA that having its policies and procedures publicly available on its website would be in accordance with the Executive Order.

**SBA's Office of Advocacy.** Advocacy agreed with the two recommendations addressed to it and submitted two comment letters. In its first letter, submitted on January 17, 2025, Advocacy committed to developing policies and procedures for RFA training as we recommended. It also stated that it was fully committed to working with OMB to explore new and appropriate metrics for RFA training performance goals that better reflect Executive Order compliance and agency needs. Additionally, Advocacy commented on the importance of agencies exploring alternative regulatory approaches to minimize burdens on small entities. Advocacy also noted that it provides RFA compliance assistance beyond formal training. We added some detail on Advocacy's other efforts to provide compliance assistance to our report.

In its second comment letter, submitted on February 28, 2025, Advocacy reiterated its agreement with the two recommendations we made and provided additional comments. First, it stressed that while Executive Order 13272 requires Advocacy to provide RFA compliance training, agencies are not obligated to participate. We note this in the report, as well as noting that Advocacy officials told us agencies are typically receptive to training when it is offered.

Second, Advocacy cautioned that developing formal procedures for RFA compliance training would not resolve all RFA issues. It pointed out that addressing issues earlier at the drafting stage or through the interagency review process can be more successful. Our report discusses several mechanisms that can help ensure consistent and complete RFA analyses, including communication during the interagency review process, agency-specific RFA policies and procedures, and RFA compliance training.

Advocacy provided further comments about our findings related to agency compliance with RFA:

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- Advocacy indicated that our report did not thoroughly address agencies' RFA compliance because we did not treat its guide, *How to Comply with the Regulatory Flexibility Act*, as requirements. Advocacy stated that the guide outlines the minimum requirements agencies must meet to be considered fully compliant with RFA and that these requirements should not be viewed as optional. This is not accurate. Advocacy's guide is not binding on agencies; agencies are not required to follow it by RFA or any other statute. However, we believe it is a valuable resource for instructing agencies on how to implement RFA. We used it as criteria for our evaluation of selected agencies' RFA analyses, in addition to guidance from OMB and GAO, and recommended that these agencies incorporate elements of the guide into their RFA policies and procedures.
  - Similarly, Advocacy stated that our report incorrectly classified several rules as generally RFA compliant that fall short of what Advocacy considers an "adequate" factual basis for certification. In particular, Advocacy stated that because EPA did not adequately describe small entities affected by a rule in a certification, we should not have concluded that EPA's certifications were RFA compliant.

RFA section 605 states that the agency head must certify that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities and publish this certification along with "a statement providing the factual basis" for such certification. It does not list requirements for what must be in the statement of factual basis, nor does it define what an "adequate" statement of factual basis would be.

Given these minimal statutory requirements, we evaluated agencies' statements of factual basis using criteria from Advocacy, OMB, and GAO guidance, including the same three criteria that Advocacy listed in its letter. As discussed in our report, we found that agencies, including EPA, did not include certain key elements, such as sufficiently analyzing impacts, documenting their analysis, and ensuring transparency in their certifications as recommended by Advocacy, OMB, and GAO. However, not including all recommended elements from these nonbinding sources does not mean that a rule is not in compliance with RFA.

- Advocacy took issue with our statement that the initial and final regulatory flexibility analyses conducted by the agencies we reviewed "generally met requirements." This is a summary statement; the report



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discusses compliance with the specific statutory requirements in more detail, including where an agency fell short.

- Advocacy said that we did not assess the quality of the alternatives considered in initial regulatory flexibility analyses. We evaluated whether agencies considered alternatives in their regulatory flexibility analyses and whether they included the reason for selecting the alternative that they adopted in the final rule, as required by statute. In addition, we evaluated the extent to which agencies assessed a rule's economic impact on small entities, including indirect and beneficial impact, which informs the quality of alternatives considered.
- Advocacy incorrectly stated that we examined 195 significant final rules from four executive branch agencies, 142 of which were certified, and that our sample was thus too small.<sup>105</sup> The 195 significant final rules were the total rules subject to RFA across *all* government, not just the four agencies we reviewed. As shown in appendix II, the 195 rules were promulgated by 25 different department-level agencies. By selecting the four agencies that we did, we were able to evaluate 55 of the 142 certifications made government-wide, or 39 percent, as stated in the report.
- Advocacy stated that the four agencies we selected are not agencies that regulate small businesses and that it would have been preferable to select agencies that "imposed greater regulatory burden on small businesses." Advocacy said that we should have considered agencies that conduct Small Business Regulatory Enforcement Fairness Act (SBREFA) panels, namely the Consumer Financial Protection Bureau (CFPB) and the Occupational Safety and Health Administration (OSHA).<sup>106</sup>

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<sup>105</sup>Advocacy's letter also stated there were 310 significant rules issued in fiscal years 2022 and 2023. We found 283. However, because the source Advocacy cited uses presidential years (February 1–January 31) not fiscal years, the numbers are not comparable. Also, Advocacy's source relied on the *Federal Register*. As we discuss in app. I, the *Federal Register* is a good but imperfect resource, and we took several methodological steps to ensure our results were accurate, including cleaning the data and comparing our results with results from an additional database.

<sup>106</sup>As previously mentioned, CFPB, EPA, and OSHA are required to convene a panel of small entities (also called SBREFA panel) for each proposed rule that the agency does not certify prior to publication of the initial regulatory flexibility analysis. Advocacy also cited National Small Business Association survey findings to suggest that other agencies might have been more appropriate for our sample. However, the survey cited in Advocacy's letter is not generalizable, and we cannot comment on the extent to which its design mitigated potential bias toward the businesses that chose to respond. Further, it was not conducted within the same time period as our report's focus (it was done in 2017), and was, therefore, outside the scope of our report.

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As stated in our report, one of the criteria we used to select agencies was the number of initial and final regulatory flexibility analyses conducted.<sup>107</sup> We maintain that this is a good indicator of which agencies promulgate rules that impose a burden on small businesses.

Regarding Advocacy's assertion that we should have chosen CFPB or OSHA for analysis because they conduct SBREFA panels, CFPB is an independent regulatory agency and at the time of our review it was not subject to the same requirements under Executive Order 12866, so we excluded it from our study.<sup>108</sup> In 2016, we completed a report examining CFPB's compliance with the SBREFA panel process.<sup>109</sup> That report found that CFPB completed the required steps for conducting the panels and that the small entity representatives who participated in the panels generally believed the process was useful but could be improved. With regard to OSHA, it promulgated one rule in fiscal years 2022–2023 that was significant under Executive Order 12866, and it did not conduct a SBREFA panel for it. We do not agree that examining the one rule OSHA promulgated would have “represented the regulatory activity that impacts small businesses the most.”

- In addition, Advocacy indicated that we should have considered its comment letters in selecting agencies. As stated in our report, we used several objective criteria—including the number of significant rules published and whether agencies received at least one Advocacy comment letter—to select an unbiased sample of agencies. CMS, Energy, EPA, and SBA have all received at least one comment letter from Advocacy in the past 5 fiscal years; in particular, EPA received 35.

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<sup>107</sup>EPA did not conduct any initial or final regulatory flexibility analyses during our time frame. In its letter, Advocacy stated that we could not conclude that EPA was complying fully with RFA without examining an initial regulatory flexibility analysis and SBREFA panel. However, RFA section 605 allows agencies to certify in lieu of conducting an initial regulatory flexibility analysis. As discussed in the report, we found that EPA's certification analyses were sometimes inconsistent with key practices from Advocacy, OMB, and GAO.

<sup>108</sup>A February 2025 Executive Order requires all agencies, including independent regulatory agencies, to submit for review all proposed and final significant regulatory actions to OMB's Office of Information and Regulatory Affairs before publication in the *Federal Register*. The Executive Order also broadened the definition of agencies subject to 12866 to include independent agencies. See Exec. Order No. 14215, *Insuring Accountability for All Agencies*, 90 Fed. Reg. 10447 (Feb. 24, 2025).

<sup>109</sup>GAO, *Consumer Financial Protection Bureau: Observations from Small Business Review Panels*, [GAO-16-647](#) (Washington, D.C.: Aug. 10, 2016).

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- Finally, Advocacy stated that our report contradicts other reports, including the report we issued in January 2018.<sup>110</sup> First, it is important to reiterate that we conducted this performance audit in accordance with generally accepted government auditing standards, which included maintaining independence in developing our findings and conclusions for this report. Second, we disagree with Advocacy's characterization of our prior work. The conclusions in our current report align with those in our January 2018 report, even though the two reports examine different agencies several years apart. Both reports found that agencies' certifications and regulatory flexibility analyses were not always consistent with Advocacy and OMB guidance. Both reports identify similar issues, such as missing data sources, missing criteria for "substantial number" and "significant economic impact," and limited evaluation of impacts. Both reports conclude that the weaknesses identified in certifications and regulatory flexibility analyses can be attributed to agency policies and procedures, and both reports recommend that agencies develop or improve their policies and procedures to align better with Advocacy and OMB guidance.
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We are sending copies of this report to the appropriate congressional committees, the Secretaries of Health and Human Services and Energy, the Administrators of EPA and SBA, and the Office of Advocacy's Deputy Chief Counsel. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at [naamanej@gao.gov](mailto:naamanej@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix XI.

Sincerely,

//SIGNED//

Jill Naamane  
Director, Financial Markets and Community Investment

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<sup>110</sup>GAO, *Financial Services Regulations: Procedures for Reviews under Regulatory Flexibility Act Need to Be Enhanced*, [GAO-18-256](#) (Washington, D.C.: Jan. 30, 2018).

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# Appendix I: Objectives, Scope, and Methodology

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This report examines the extent to which (1) significant rules published in fiscal years 2022 and 2023 included required Regulatory Flexibility Act (RFA) analysis or were certified as not having a significant economic impact on a substantial number of small entities, (2) selected agencies followed RFA requirements and related guidance in certifying their rules, (3) selected agencies followed RFA requirements and related guidance in performing required RFA analysis, (4) selected agencies' policies and procedures are consistent with RFA and related guidance, and (5) the Small Business Administration's (SBA) Office of Advocacy has provided agencies with required compliance training.

To address the first objective, we analyzed all final rules deemed significant under Executive Order 12866 and published in the *Federal Register* during fiscal years 2022 and 2023, the two most recent fiscal years at the time of our review.<sup>1</sup> Using the document search on the official *Federal Register* website, we downloaded all such rules, for a total of 570 rules. We created a spreadsheet-based data collection instrument to track and review these rules.

To identify any additional significant rules in our review period that had not been identified through our *Federal Register* search, we used data from the Unified Regulatory Agenda.<sup>2</sup> We identified seven such rules and

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<sup>1</sup>Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51735 (Oct. 4, 1993). Significant regulatory actions are defined by Executive Order 12866 as any regulatory action likely to result in a rule that may (1) have an annual effect on the economy of \$100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this executive order. In a now-rescinded Executive Order, President Biden increased the monetary threshold to \$200 million, among other changes. See Exec. Order No. 14148 rescinding Exec. Order No. 14094, 90 Fed. Reg. 8237 (Jan. 28, 2025). Our review included 35 significant interim final rules that were evaluated under RFA. The rules we reviewed included economically significant rules subject to the \$100 million threshold set by Executive Order 12866.

<sup>2</sup>The Office of Information and Regulatory Affairs within the Office of Management and Budget compiles regulatory agendas from all federal entities that currently have regulations under development or review into the Unified Regulatory Agenda. Per Executive Order 12866, agencies are required to prepare an agenda of all regulations under development or review and include information such as the Regulation Identifier Number, the legal authority for the rule, and a brief summary of the rule.

added them to our review, for a total of 577 rules.<sup>3</sup> Through this data reliability check, we determined that the *Federal Register* data were sufficiently reliable for determining the number of significant rules published in fiscal years 2022–2023.

We removed 279 rules that we determined were not relevant to our analysis. These were rules exempt from Executive Order 12866, such as those by independent regulatory agencies and technical corrections (149 rules); rules deemed not significant by agencies (105 rules); acquisition regulations (24 rules); and one rule that extended the effective date of a previous rule, with no substantive changes.<sup>4</sup> Of the remaining 298 rules, 15 were joint rules (published by more than one agency) that we analyzed separately, leaving 283 significant rules in our primary analysis.

We then analyzed each rule notice to quantify how many rules did not have a proposed rule.<sup>5</sup> For the 195 rules with proposed rules, we reviewed the proposed and final rules to determine the number that included (1) an initial regulatory flexibility analysis in the proposed rule, (2) a final regulatory flexibility analysis in the final rule, or (3) an agency certification that RFA analyses were not required. We used the Regulation Identifier Numbers or citations from the final rules to locate and analyze the proposed rules.

To address the second, third, and fourth objectives, we used the results of our analysis of significant final rules published in fiscal years 2022–2023 to select four agencies that were among the top five agencies that had (1) published the greatest numbers of significant rules, (2) published

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<sup>3</sup>Specifically, of the 269 rules in the Unified Agenda data set, 180 rules had been identified in our initial *Federal Register* search and 63 rules were published outside of our time frame (243 in total). We reviewed the remaining 26 rules and found that 19 were outside our scope for other reasons, such as not being significant under Executive Order 12866 or being published by independent regulatory agencies whose rulemakings were at the time not subject to most of the requirements of Executive Order 12866.

<sup>4</sup>A February 2025 Executive Order changed the requirements for independent regulatory agencies, but this was not in effect during the time of our review. See Exec. Order No. 14215, *Insuring Accountability for All Agencies*, 90 Fed. Reg. 10447 (Feb. 24, 2025).

<sup>5</sup>Rules that are not subject to the notice and comment requirements of Section 553 of the Administrative Procedure Act or other laws are not subject to RFA's analytical requirements, such as conducting an initial regulatory flexibility analysis or certifying that the rule would not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. §§ 601(2), 603(a) and 605(b). For the rules we reviewed, we did not determine if the rulemaking was subject to notice and comment. Rather, we relied on the existence of a proposed rule to determine if RFA applied.

the greatest numbers of significant rules with a proposed rulemaking, (3) certified the most proposed rules, (4) conducted the most initial and final regulatory flexibility analyses, and (5) received at least one comment letter from SBA's Office of Advocacy.<sup>6</sup> On the basis of these results, we selected the Centers for Medicare & Medicaid Services (CMS), Department of Energy, Environmental Protection Agency (EPA), and SBA. These four agencies collectively published 30 percent of all significant final rules in fiscal years 2022–2023, 39 percent of certified proposed rules, and 36 percent of regulatory flexibility analyses.

To address the second objective, we used the data we collected on rules to identify all rules published by CMS, Energy, EPA, and SBA in which the agency certified that the proposed rule would not have a significant economic impact on a substantial number of small entities. We identified a total of 55 rules: 21 from EPA, 21 from CMS, six from Energy, and seven from SBA.

For these rules, we analyzed the proposed rule notices and other documentation in the rules' dockets, obtained from the Regulations.gov website.<sup>7</sup> We examined the extent to which agencies followed RFA requirements, Advocacy's guide for complying with RFA, regulatory analysis guidance from the Office of Management and Budget (OMB), and key practices for economic analysis from GAO.<sup>8</sup> Our analysis concentrated on the RFA and regulatory impact analysis sections of each notice, with additional review of documents in the public docket when

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<sup>6</sup>The Office of Advocacy, generally recognized as an independent agency within SBA, can submit formal comment letters to agencies regarding RFA compliance during a rule's notice and comment period.

<sup>7</sup>We reviewed certifications in both the proposed and final rules. We focused primarily on proposed rules because omitting a regulatory flexibility analysis at the proposed rulemaking stage may limit an agency's understanding of a rule's impacts and hinder small entities' ability to offer informed comments.

<sup>8</sup>Small Business Administration, Office of Advocacy, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (Washington, D.C.: Aug. 31, 2017); Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Washington, D.C.: Sept. 17, 2003); and GAO, *Assessment Methodology for Economic Analysis*, [GAO-18-151SP](#) (Washington, D.C.: Apr. 10, 2018). The Office of Advocacy's guide is intended to be used by agency officials as a step-by-step manual for complying with RFA. While it is not binding on agencies, it represents key practices for regulatory flexibility analyses, and we used it as criteria for this report. OMB's Circular A-4 provides information on analyzing the benefits and costs of regulations. This circular was updated on Nov. 9, 2023, after the rules in our sample (fiscal years 2022 and 2023) were published. GAO's *Assessment Methodology for Economic Analysis* compiles the key methodological elements of a sound economic analysis.

referenced in the rule notice. We did not assess compliance with other aspects of agency rulemaking, such as regulatory analyses for purposes unrelated to RFA, like the Paperwork Reduction Act.

To address the third objective, we used the data we collected on rules to identify all rules published by CMS, Energy, EPA, and SBA in which the agency conducted both an initial and final regulatory flexibility analysis (20 rules in total). We reviewed all 20 initial regulatory flexibility analyses (in proposed rules) and 20 final regulatory flexibility analyses (in final rules). CMS completed 10 of each type of analysis, Energy three of each, and SBA seven of each. EPA did not conduct any initial or final regulatory flexibility analyses for significant rules in fiscal years 2022 and 2023. It certified all of the significant rules it published during that time frame and therefore was not required to conduct any initial or final regulatory flexibility analyses.

For each rule, we examined the extent to which the agency followed RFA requirements and guidance from Advocacy, OMB, and GAO for regulatory flexibility analysis. We assessed the analyses contained in the RFA and regulatory impact analysis sections of the rule notices. If we could not find relevant information in those sections, we reviewed other sections of the rule notice. We also reviewed supporting documentation in the rule docket if the rule notice specifically referred to it or if we found a relevant document in the docket.

To address the fourth objective, we reviewed agency policies and procedures from CMS, Energy, and EPA for conducting regulatory flexibility analyses or certifying that such analyses were not required. We assessed these policies and procedures against RFA requirements, Executive Order 13272 requirements, Advocacy's guide on complying with RFA, and key practices from OMB and GAO for conducting regulatory and economic analysis.<sup>9</sup> SBA did not have policies and procedures specifically for complying with RFA. We also interviewed agency officials regarding their policies and procedures for RFA compliance. For CMS, EPA, and SBA, we also reviewed their guidance

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<sup>9</sup>Exec. Order No. 13272, *Proper Consideration of Small Entities in Agency Rulemaking*, 67 Fed. Reg. 53461 (Aug. 16, 2002).

on completing a regulatory impact analysis to determine the extent to which they included specifics on complying with RFA.<sup>10</sup>

To address the fifth objective, we analyzed Advocacy’s annual compliance reports from fiscal years 2019 through 2023 (the five most recent reports available). We identified how frequently RFA training was provided and to which agencies. We also interviewed Advocacy officials about their policies, procedures, and performance goals related to training. We compared their training efforts against Executive Order 13272 requirements.<sup>11</sup>

We also determined that the control activities component of internal control was significant to this objective, along with the underlying principle that management should implement control activities through policies and procedures.<sup>12</sup> We assessed the extent to which Advocacy has training policies and procedures and the extent to which its training activities support its objectives. We also compared Advocacy’s training performance goal against key practices for federal evidence-building and performance-management activities.<sup>13</sup>

To help determine whether Advocacy had trained all rulemaking agencies, we reviewed a 2018 report from the Administrative Conference of the United States that identified which agencies have rulemaking authority, derived through a review of relevant statute. We assessed the reliability of this list by reviewing documentation on its data collection processes. We determined that the data collection approach was sufficiently reliable for the purpose of capturing all federal rulemaking agencies. We compared this list with appendix C in Advocacy’s fiscal year 2023 compliance report, which lists all the agencies trained from 2003 through 2023.

We conducted this performance audit from July 2023 to April 2025 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

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<sup>10</sup>These three agencies referred us to their regulatory impact analysis guidance in addition to their RFA policies, while Energy did not.

<sup>11</sup>Exec. Order No. 13272 (Aug. 16, 2002).

<sup>12</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

<sup>13</sup>GAO, *Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts*, [GAO-23-105460](#) (Washington, D.C.: July 12, 2023).



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sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

# Appendix II: Number of Significant Final Rules Published in Fiscal Years 2022–2023, by Agency

We analyzed all final rules that were deemed significant under Executive Order 12866 and published in the *Federal Register* in fiscal years 2022 and 2023 (283 rules).<sup>1</sup> Table 6 shows the number of these rules by agency.

Table 6: Significant Final Rules Published in Fiscal Years 2022–2023, by Agency	
Agency	Significant rules published
Department of Health and Human Services	52
Department of Transportation	26
Environmental Protection Agency	23
Department of Commerce	22
Department of Agriculture	16
Small Business Administration	16
Department of Homeland Security	15
Department of Energy	14
Department of Labor	14
Department of State	12
Department of Veterans Affairs	11
Department of Justice	10
Department of the Interior	10
Office of Personnel Management	9
Department of Housing and Urban Development	7
Department of the Treasury	6
Department of Defense	5
Department of Education	4

<sup>1</sup>Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51735 (Oct. 4, 1993). Significant regulatory actions are defined by Executive Order 12866 as any regulatory action likely to result in a rule that may (1) have an annual effect on the economy of \$100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this executive order. In a now-rescinded Executive Order, President Biden increased the monetary threshold to \$200 million, among other changes. See Exec. Order No. 14148 rescinding Exec. Order No. 14094, 90 Fed. Reg. 8237 (Jan. 28, 2025). The 283 rules include 35 significant interim final rules that were evaluated under the Regulatory Flexibility Act. The rules we reviewed included economically significant rules subject to the \$100 million threshold set by Executive Order 12866.

**Appendix II: Number of Significant Final Rules  
Published in Fiscal Years 2022–2023, by  
Agency**

<b>Agency</b>	<b>Significant rules published</b>
General Services Administration	3
Pension Benefit Guaranty Corporation	2
Architectural and Transportation Barriers Compliance Board	1
Committee for Purchase from People Who Are Blind or Severely Disabled	1
Council on Environmental Quality	1
Government Ethics Office	1
National Science Foundation	1
Social Security Administration	1
<b>Total</b>	<b>283</b>

Source: GAO analysis of published rules. | GAO-25-106950

Of these 283 significant rules, we determined that 195 rules were subject to Regulatory Flexibility Act requirements because the agency issued a notice of proposed rulemaking. Table 7 shows the number of these rules by agency.

**Table 7: Significant Final Rules Subject to RFA Requirements in Fiscal Years 2022–2023, by Agency**

<b>Agency</b>	<b>Significant rules subject to the Regulatory Flexibility Act (RFA)</b>
Department of Health and Human Services	43
Environmental Protection Agency	21
Department of Transportation	16
Small Business Administration	14
Department of Labor	13
Department of Commerce	12
Department of Agriculture	10
Department of Energy	10
Department of Justice	10
Office of Personnel Management	9
Department of Homeland Security	6
Department of Housing and Urban Development	6
Department of the Interior	5
Department of the Treasury	4
Department of Education	3
Department of Defense	2

Appendix II: Number of Significant Final Rules  
Published in Fiscal Years 2022–2023, by  
Agency

Agency	Significant rules subject to the Regulatory Flexibility Act (RFA)
Department of State	2
Department of Veterans Affairs	2
Architectural and Transportation Barriers Compliance Board	1
Committee for Purchase from People Who Are Blind or Severely Disabled	1
Council on Environmental Quality	1
General Services Administration	1
Government Ethics Office	1
National Sciences Foundation	1
Social Security Administration	1
<b>Total</b>	<b>195</b>

Source: GAO analysis of published rules. | GAO-25-106950

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# Appendix III: Most Frequently Cited RFA Compliance Issues in Office of Advocacy Annual Reports, Fiscal Years 2019–2023

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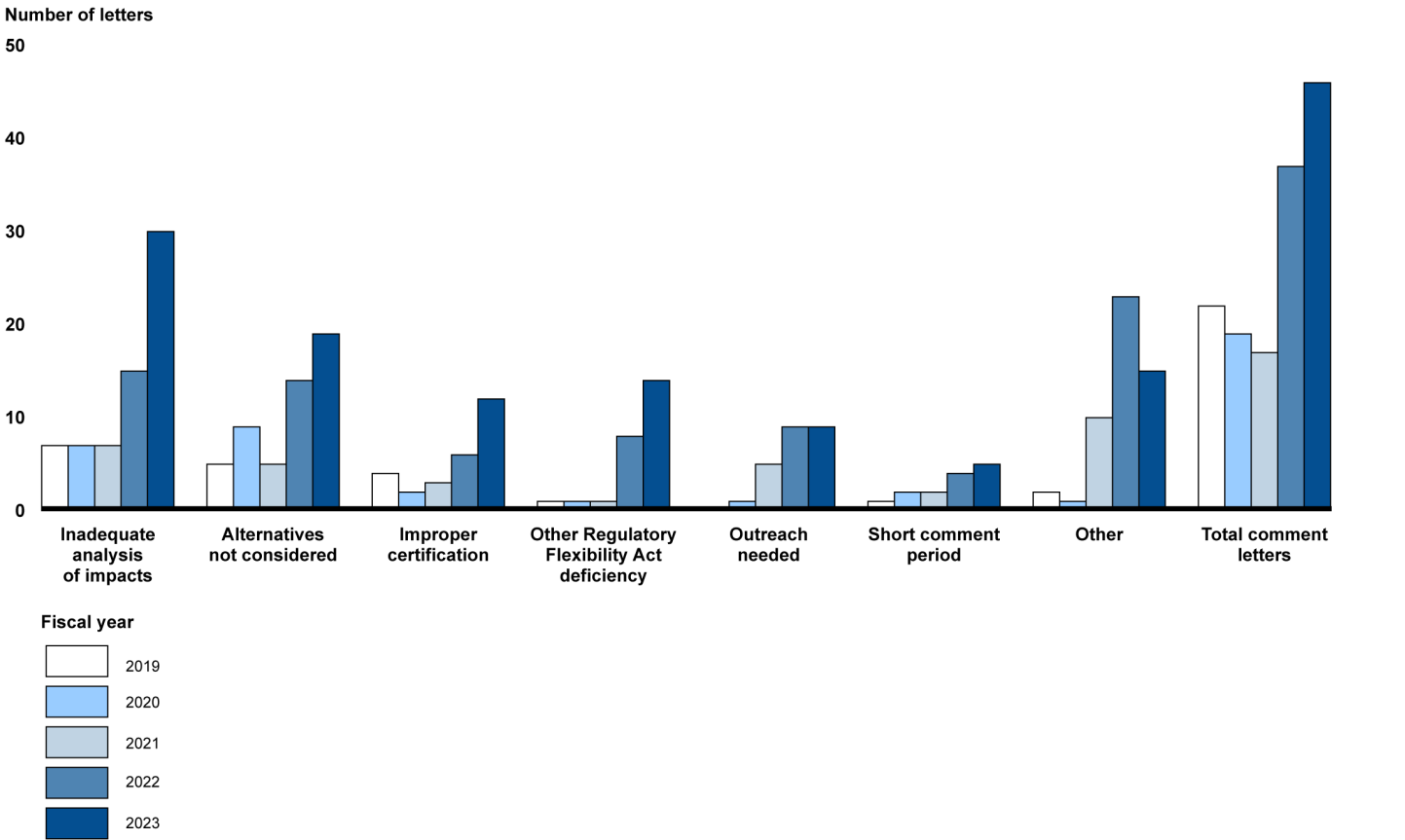
The Regulatory Flexibility Act (RFA) designates certain responsibilities to the Small Business Administration's Chief Counsel for Advocacy, including monitoring and reporting on agency compliance with RFA. To address this mandate, the Office of Advocacy publishes annual reports evaluating agency compliance with RFA and Executive Order 13272.<sup>1</sup> Figure 6 shows the total number of comment letters Advocacy sent during fiscal years 2019 through 2023, as well as the main issues identified in the letters. The most frequently cited issues during this period were (1) inadequate analysis of impacts, (2) alternatives not considered, (3) improper certification, (4) other RFA deficiency, (5) outreach needed, (6) short comment period, and (7) other. A comment letter may contain more than one issue.

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<sup>1</sup>Exec. Order No. 13272, *Proper Consideration of Small Entities in Agency Rulemaking*, 67 Fed. Reg. 53461 (Aug. 16, 2002).

Appendix III: Most Frequently Cited RFA  
Compliance Issues in Office of Advocacy  
Annual Reports, Fiscal Years 2019–2023

Figure 6: Most Frequently Cited Regulatory Flexibility Act Compliance Issues in Office of Advocacy Annual Reports, Fiscal Years 2019–2023



Source: GAO analysis of Office of Advocacy compliance reports. | GAO-25-106950

Note: A comment letter can contain more than one issue.

# Appendix IV: Agencies That Received Training or Comment Letters from the Office of Advocacy, Fiscal Years 2019–2023

The Small Business Administration’s Chief Counsel for Advocacy is responsible for monitoring and reporting on agency compliance with the Regulatory Flexibility Act (RFA) and providing training. Table 8 lists the 57 agencies that received comment letters or training on RFA compliance in fiscal years 2019–2023, as identified in Advocacy’s annual reports.

**Table 8: Agencies That Received Regulatory Flexibility Act Training or Comment Letters from the Office of Advocacy, Fiscal Years 2019–2023**

Agency	FY 2019		FY 2020		FY 2021		FY 2022		FY 2023	
	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter
Agricultural Marketing Service	—	—	—	L	—	—	—	—	—	—
Agricultural Marketing Service, Livestock and Poultry Program	—	—	T	—	—	—	—	—	—	—
Agricultural Marketing Service, Specialty Crop Program	—	—	T	—	—	—	—	—	—	—
Alcohol and Tobacco Tax and Trade Bureau	—	L	—	—	—	—	—	—	T	L
Animal Plant and Health Inspection Service	—	—	—	L	—	—	—	L	T	—
Army Corps of Engineers	—	L	—	—	—	L	T	L	—	—
Board of Governors of the Federal Reserve System	—	—	—	—	—	—	—	—	—	L
Bureau of Ocean Energy Management	—	—	—	—	—	—	—	L	—	L
Centers for Medicare & Medicaid Services	—	—	T	—	T	—	—	L	—	—
Chemical Safety and Hazard Investigation Board	—	—	T	—	—	—	—	—	—	—
Citizenship and Immigration Services	—	L	—	—	—	—	—	—	—	L

Appendix IV: Agencies That Received Training  
or Comment Letters from the Office of  
Advocacy, Fiscal Years 2019–2023

Agency	FY 2019		FY 2020		FY 2021		FY 2022		FY 2023	
	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter
Consumer Financial Protection Bureau	—	L	—	L	—	—	—	L	—	L
Consumer Product Safety Commission	—	—	—	—	—	—	—	L	—	L
Council on Environmental Quality	—	—	—	—	—	—	—	L	—	L
Department of Agriculture	—	—	—	—	—	L	—	—	—	—
Department of Commerce	—	—	—	—	—	L	—	—	—	—
Department of Defense	—	L	—	—	—	—	—	—	—	—
Department of Education	—	L	—	—	—	—	T	L	—	—
Department of Energy	—	L	—	—	T	L	—	L	—	L
Department of Housing and Urban Development	—	—	—	—	T	—	—	—	—	—
Department of Justice, Civil Rights Division	—	—	—	—	T	—	—	—	—	—
Department of Labor	—	L	—	—	—	L	—	L	—	L
Department of Labor, Wage and Hour Division	—	—	—	—	T	—	—	—	—	—
Department of the Interior	—	—	—	—	—	—	—	L	—	L
Department of State	—	—	—	—	—	—	—	—	T	—
Department of the Treasury	T	—	—	—	T	—	—	—	—	—
Department of Veterans Affairs	T	—	T	—	—	—	—	—	—	—
Employee Benefits Security Administration	—	—	—	—	—	—	T	—	—	—
Environmental Protection Agency	—	L	—	L	—	L	—	L	—	L



**Appendix IV: Agencies That Received Training  
or Comment Letters from the Office of  
Advocacy, Fiscal Years 2019–2023**

Agency	FY 2019		FY 2020		FY 2021		FY 2022		FY 2023	
	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter
Federal Acquisition Regulation Council	—	—	—	—	—	—	—	—	—	L
Federal Aviation Administration	—	—	—	—	T	—	T	—	—	—
Federal Communications Commission	—	—	—	L	—	—	T	L	—	—
Federal Deposit Insurance Corporation	—	—	—	L	—	—	—	—	—	L
Federal Emergency Management Agency	T	—	—	—	—	—	—	—	—	—
Federal Energy Regulatory Commission	—	—	—	—	—	—	—	—	T	—
Federal Housing Finance Agency	—	—	—	—	—	—	—	—	—	L
Federal Motor Carrier Safety Administration	—	L	—	L	T	—	—	—	—	—
Federal Railroad Administration	T	—	—	—	—	—	—	L	T	L
Federal Trade Commission	—	L	—	—	—	—	—	L	T	L
Financial Crimes Enforcement Network	—	—	—	—	—	—	—	L	—	L
Food and Drug Administration	—	—	—	L	—	L	—	—	—	L
Food and Nutrition Service	—	L	—	—	—	—	—	—	—	—
Food Safety and Inspection Service	—	—	T	—	—	—	—	—	—	—
Forest Service	T	—	—	—	—	—	—	L	—	—
Internal Revenue Service	—	—	—	—	—	—	—	L	—	L
Mine Safety and Health Administration	—	—	—	—	—	—	T	—	—	L

**Appendix IV: Agencies That Received Training  
or Comment Letters from the Office of  
Advocacy, Fiscal Years 2019–2023**

Agency	FY 2019		FY 2020		FY 2021		FY 2022		FY 2023	
	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter	Received training	Received comment letter
National Credit Union Administration	—	—	—	—	—	—	—	—	—	L
National Labor Relations Board	T	—	—	—	—	—	T	—	—	L
National Marine Fisheries Service	—	—	—	L	—	—	—	L	—	L
Nuclear Regulatory Commission	—	—	—	—	T	—	—	—	—	—
Office of Information and Regulatory Affairs	—	—	—	—	—	—	—	—	—	L
Office of Management and Budget	—	—	—	—	—	L	—	—	—	—
Office of the Comptroller of the Currency	—	—	—	L	—	—	—	—	—	L
Securities and Exchange Commission	—	—	T	—	—	—	T	L	—	L
Small Business Administration	—	L	—	—	—	—	T	—	—	—
U.S. Coast Guard	T	—	—	—	—	—	—	—	T	—
U.S. Fish and Wildlife Service	—	—	—	L	—	—	—	L	—	L

FY = Fiscal year; T = Received training; L = Received comment letter; — = Did not receive

Source: GAO analysis of Office of Advocacy reports. | GAO-25-106950

# Appendix V: Comments from the Department of Energy



Department of Energy  
Washington, DC 20585

February 11, 2025

Ms. Jill Naamane  
Director  
Financial Markets and Community Investment  
U.S. Government Accountability Office  
441 G Street N.W.  
Washington, DC 20548

Dear Ms. Naamane:

The Department of Energy (DOE) appreciates the opportunity to comment on the Government Accountability Office's (GAO) draft report titled, *Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance (GAO-25-106950)*.

GAO's draft report contained one recommendation for potential enhancements to the Department's policies and procedures. DOE's regulatory processes currently comply with all applicable statutory requirements, and the Office of General Counsel coordinates closely with DOE programs to provide guidance applicable to individual rulemakings. However, the Department is reviewing the requirements and recommendations identified in the GAO report to assess whether additional internal DOE guidance would be beneficial.

DOE notes also that GAO's report contains inaccurate information regarding DOE's regulatory processes. Notably, the report does not correctly characterize the Regulatory Flexibility Act (RFA) analysis the Department performed for specific rules. The report also does not recognize the Department's process for identifying benefits to small businesses or correctly characterize the Department's guidance relating to the consideration of small entities. The Department has separately provided detailed technical comments to address these concerns.

GAO should direct any questions to Ami Grace-Tardy, Assistant General Counsel for Legislation, Regulation and Energy Efficiency, at [ami.grace-tardy@hq.doe.gov](mailto:ami.grace-tardy@hq.doe.gov).

Sincerely,

JOCELYN  
RICHARDS

Digitally signed by  
JOCELYN RICHARDS  
Date: 2025.02.11  
15:25:24 -05'00'

Jocelyn Richards  
Acting General Counsel

Enclosure

Enclosure

**Management Response  
GAO Draft Report:  
Regulatory Flexibility Act: Improved Policies for Analysis and  
Training Could Enhance Compliance (GAO-25-106950)**

**Recommendation 1:** The Secretary of Energy should revise Energy's Regulatory Flexibility Act policies and procedures to incorporate statutory requirements and elements recommended by the Office of Advocacy, the Office of Management and Budget, and the Government Accountability Office (GAO) for conducting certification and regulatory flexibility analyses, such as considering beneficial and indirect impacts on small entities.

**DOE Response:**

The Department of Energy's (DOE) regulatory processes currently comply with all applicable statutory requirements, and the Office of General Counsel coordinates closely with DOE programs to provide guidance applicable to individual rulemakings. However, the Department is reviewing the requirements and recommendations identified in the GAO report to assess whether additional internal DOE guidance would be beneficial.

After receiving GAO's final report, DOE will specify any specific actions taken or planned in the Congressional letter required by 31 U.S.C 720.

# Appendix VI: Comments from the Environmental Protection Agency



OFFICE OF POLICY  
WASHINGTON, D.C. 20460

January 14, 2025

Mr. Alfredo Gomez  
Director  
Natural Resources and Environment  
U.S. Government Accountability Office  
Washington, DC 20548

Dear Mr. Gomez:

Thank you for the opportunity to review and comment on the Government Accountability Office's draft report, "Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance" (GAO-25-106950). The purpose of this letter is to provide the U.S. Environmental Protection Agency's response to the draft report's findings, conclusions, and recommendation for EPA.

The GAO reviewed EPA final rules, and those of three other agencies, published in fiscal years 2022 and 2023 that were deemed significant under Executive Order 12866. The GAO also reviewed policy and guidance of the four agencies related to the RFA and regulatory analysis, and the training activities of the Small Business Administration's Office of Advocacy. In general, the GAO found that the four agencies met their statutory obligations under the Regulatory Flexibility Act (RFA), but that in some cases agency analyses were not consistent with some of the SBA Office of Advocacy's suggested practices for RFA analyses. The report also asserts that regulatory flexibility analyses were sometimes inconsistent with Office of Management and Budget (OMB) and GAO's generally suggested elements for conducting broader regulatory and economic analyses.

The EPA takes its obligations under the RFA seriously. I fully agree with the finding that EPA is meeting the statutory requirements of the RFA. In fact, SBA Office of Advocacy's RFA guidance highlights EPA regulatory flexibility analyses as good examples, and also highlights EPA guidance as an example of an agency that has "developed criteria for determining whether a particular economic impact is significant."<sup>1</sup> In many ways, especially with regard to the process EPA undertakes for rules that may have a significant economic impact on a substantial number of small entities, the EPA goes above and beyond what is statutorily required.<sup>2</sup>

<sup>1</sup> See p.19, p.42 and p.49 of Small Business Administration, Office of Advocacy, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (August 2017), available at <https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/rfa-basics/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/>.

<sup>2</sup> See Chapters 2 and 5 of U.S. Environmental Protection Agency, Office of Policy, Regulatory Management Division, *EPA's Action Development Process: Final Guidance for EPA Rulewriters: Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act* (November 2006), available at <http://www.epa.gov/rfa/documents/Guidance-RegFlexAct.pdf>.

The EPA also takes its regulatory analysis seriously. When a full regulatory analysis of an EPA rule is required, as was the case for most rules reviewed for this GAO report, the RFA certification analysis or the regulatory flexibility analysis are just one part of the broader regulatory analysis encompassing many issues that inform and support EPA decisions about regulatory options for the rule. In many cases, the analytical elements highlighted in GAO's draft report as absent from EPA's RFA-related analysis are included elsewhere in EPA's broader regulatory analysis for the rule, or would not contribute substantially to an understanding of how to minimize the rule's impacts on regulated small entities (the goal of the RFA) or to maximize the net benefit of the rule to society (the goal of E.O. 12866). The impacts on small entities are important, and are one of the many aspects of a rule, along with other major economic and policy implications, that must be considered by agency decision-makers.

EPA believes that the analysis of benefits and of indirect impacts are best analyzed within the context of the broader regulatory analysis where they can be balanced with all the effects of a given rule, both negative and beneficial. In addition, the EPA interpretation of "significant impacts" under the RFA that excludes beneficial impacts and indirect impacts is supported by court findings. SBA Advocacy's RFA guidance acknowledges that in a case under the National Environmental Policy Act a full environmental impact statement "does not need to be prepared if the only impact of the project will be beneficial." The same SBA Advocacy guidance also notes several court cases support excluding indirect impacts from RFA analyses and that the RFA requires analysis of small entity impacts only when the rule directly regulates small entities.

Finally, EPA notes a disconnect in the application of OMB and GAO general regulatory analysis guidance to the conclusions and recommendations in the draft report about analysis specifically for RFA. There is acknowledgement in a footnote that the OMB and GAO guidance documents are not specific to RFA, but in the main body of the report many of the "key elements" that are highlighted as missing from agencies' RFA analyses are included in the rule's broader regulatory/economic analyses. Those elements are not "missing," they are just not included in analytical work that specifically addresses (and already meets) RFA requirements.

Please find enclosed additional specific technical comments EPA is providing on the GAO's draft report.

Below is the GAO's one recommendation to the EPA and EPA's response to the recommendation.

**GAO Recommendation:**

"The Administrator of EPA should revise EPA's Regulatory Flexibility Act policies and procedures to more fully incorporate elements recommended by the Office of Advocacy, OMB, and GAO for conducting certification and regulatory flexibility analyses, such as considering beneficial and indirect impacts on small entities." (Recommendation 4)

**EPA Response:**

The EPA plans on updating its Regulatory Flexibility Act guidance at a time when resources allow. As part of that update EPA will consider relevant guidance from other agencies, and we expect that EPA's RFA guidance will remain focused on RFA-related analyses that address statutory requirements.

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**Appendix VI: Comments from the  
Environmental Protection Agency**

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Thank you for the opportunity to review this draft report. Please contact Stuart Miles-Mclean (Miles-Mclean.Stuart@epa.gov) if you have any questions or need additional information.

Sincerely,

**ADRIANA  
HOCHBERG**  
Digitally signed by  
ADRIANA  
HOCHBERG  
Date: 2025.01.14  
16:51:56 -05'00'  
Adriana Hochberg  
Acting Associate Administrator

Enclosures

cc: EPA GAO Liaison Team

# Appendix VII: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

January 13, 2025

Jill Naamane  
Director, Financial Markets and  
Community Investment  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Ms. Naamane:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"REGULATORY FLEXIBILITY ACT: Improved Policies for Analysis and Training Could Enhance Compliance"** (GAO-25-106950).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

*Melanie Anne Egorin*

Melanie Anne Egorin, PhD  
Assistant Secretary for Legislation

Attachment



**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN  
SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT  
ENTITLED - REGULATORY FLEXIBILITY ACT: IMPROVED POLICIES FOR  
ANALYSIS AND TRAINING COULD ENHANCE COMPLIANCE (GAO 25-106950)**

The Department of Health & Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

**Recommendation 2**

The Secretary of Health and Human Services should revise HHS's Regulatory Flexibility Act policies and procedures to more fully incorporate elements recommended by the Office of Advocacy, OMB, and GAO for conducting certification and regulatory flexibility analyses, such as considering beneficial and indirect impacts on small entities.

**HHS Response**

HHS concurs with the recommendation. HHS is continuing its efforts to update and provide transparency on the Department's policies and procedures related to the Regulatory Flexibility Act, including the certification process and development of regulatory flexibility analyses. We anticipate new directives and analytic guidance on regulatory review and analysis in calendar year 2025 and will reflect those requirements in any updates to our policies and procedures. HHS will update GAO on its progress to address the recommendation.

# Appendix VIII: Comments from the Small Business Administration



U.S. SMALL BUSINESS ADMINISTRATION  
WASHINGTON, DC 20416

January 16, 2025

Daniel Garcia-Diaz  
Managing Director  
Financial Markets and Community Investment  
U.S. Government Accountability Office

Dear Mr. Garcia-Diaz:

Thank you for providing the U.S. Small Business Administration (SBA) with the opportunity to comment on the Government Accountability Office (GAO) draft report titled, "Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance" (25-106950).

The Regulatory Flexibility Act (RFA) was enacted in 1980 in response to concerns about the effect that federal regulations can have on small entities, such as small businesses, small governmental jurisdictions, and certain not-for-profit organizations. The SBA's Office of Advocacy provides RFA compliance training to federal agencies.

GAO's draft report examines Centers for Medicare & Medicaid Services' (CMS), the Department of Energy's (Energy), the Environmental Protection Agency's (EPA), and the SBA's RFA analyses for 2022 – 2023 rules and the extent to which Advocacy has provided RFA training, among other objectives.

GAO's draft report issues one recommendation for the Administrator of the SBA. The SBA's level of concurrence with justification, planned remediation activities, and estimated remediation timeframes are described below. The Office of Advocacy will provide a separate comment letter in response to the draft report and GAO's two proposed recommendations for the Office of Advocacy.

**Recommendation 1** – *The Administrator of SBA should develop and implement policies and procedures for complying with the Regulatory Flexibility Act.*

**SBA Response:**

The SBA partially agrees with this recommendation. In addition to the policies and procedures developed by the SBA's Office of Advocacy, the agency has developed and implemented streamlined policies and procedures for review of rules and their associated regulatory economic analysis, including analysis required by the Regulatory Flexibility Act. These policies and procedures are outlined in the SBA's Framework and Guidelines for Regulatory Economic Analysis, regular trainings, and technical assistance for all staff working on rules. All policies and procedures are documented and made available internally, and the SBA plans to make these policies and procedures publicly available in accordance with Executive Order 13272. Given the SBA's existing policies and procedures, the SBA proposes that the recommendation be revised to state the following: *The Administrator of SBA should publish its policies and procedures for complying with the Regulatory Flexibility Act on its public website.*

The SBA estimates that it can remediate the above recommendation by making policies and procedures for complying with the Regulatory Flexibility Act publicly available on the SBA's website within 180 days.

Sincerely,



**Dr. Anna Calcagno**

Director, Office of Strategic Management and Enterprise Integrity (OSMEI)  
SBA Statistical Official  
SBA Chief Data Officer  
SBA Deputy Performance Improvement Officer  
Office of Performance, Planning, and the Chief Financial Officer (OPPCFO)  
U.S. Small Business Administration

# Appendix IX: Comments from SBA's Office of Advocacy, January 17, 2025



January 17, 2025

VIA ELECTRONIC SUBMISSION

Ms. Jill Naamane, Director  
Financial Markets and Community Investment  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Re: Draft Report, *Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance (GAO-25-106950)*

Dear Director Naamane,

The Office of Advocacy (Advocacy) appreciates the opportunity to review and comment on the draft Government Accountability Office (GAO) report *Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance (GAO-25-106950)*. Because Advocacy is an independent office within the Small Business Administration (SBA), Advocacy's comments are limited to Recommendations 5 and 6 concerning Advocacy's Regulatory Flexibility Act (RFA) training program. Advocacy understands that SBA will be providing a separate response concerning recommendations involving its programs and activities. Advocacy accepts GAO's recommendations concerning its RFA training program and will implement those recommendations in a timely manner. That said, Advocacy would like to take the opportunity to provide additional detail about its RFA training program and other efforts to promote RFA compliance by federal agencies.

## **I. Background**

### **A. The Office of Advocacy**

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the SBA that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

409 3rd Street SW / MC 3110 / Washington, DC 20416  
Ph 202-205-6533 / [advocacy.sba.gov](https://advocacy.sba.gov)

The Regulatory Flexibility Act (RFA),<sup>1</sup> as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>2</sup> 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, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.<sup>3</sup> Additionally, section 609 of the RFA requires the Consumer Financial Protection Bureau (CFPB), the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA) to conduct special outreach efforts through a review panel (often referred to as a SBREFA panel).<sup>4</sup> The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.<sup>5</sup> If a rule will not have a significant economic impact on a substantial number of small entities, agencies may certify the rule.<sup>6</sup> The agency must provide a statement of factual basis that adequately supports its certification.<sup>7</sup>

The RFA directs the Chief Counsel for Advocacy to monitor and report on federal agencies' compliance with the law. In addition, Executive Order 13272 imposes certain requirements on federal agency rulemaking and requires Advocacy to report on agency compliance with that executive order. Advocacy produces an annual report to Congress and the Office of Management and Budget to fulfill these mandates.<sup>8</sup>

#### **B. Advocacy's Training Program**

Executive Order 13272, issued in 2002, requires, among other things, Advocacy to "provide training to agencies on compliance with the [RFA]."<sup>9</sup> This mandate was issued primarily to recognize the importance of Advocacy's participation in the rulemaking process and to help ensure improved RFA compliance by federal agencies. Advocacy has been fully compliant with this directive, has had a robust RFA training program in place since 2003, and has trained thousands of federal officials on RFA compliance. In fact, since the training program's inception in 2003, Advocacy has trained every cabinet level department, 85 separate component agencies and offices, and 24 non-cabinet agencies. Advocacy has also provided RFA training to other interested groups, such as congressional staff members and small business trade associations, so they can better understand the RFA and more effectively participate in the rulemaking process.

However, one challenge with the Executive Order is that while Advocacy is required to provide RFA training to federal agencies, the agencies are not obligated to accept or participate in it. However, through diligent effort and outreach, Advocacy has trained agencies that write the

<sup>1</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

<sup>2</sup> Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).

<sup>3</sup> 5 U.S.C. § 603.

<sup>4</sup> *Id.* § 609.

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

<sup>6</sup> *Id.* § 605(b).

<sup>7</sup> *Id.*

<sup>8</sup> Copies of Advocacy's annual RFA reports can be found at <https://advocacy.sba.gov/category/resources/annual-reports-on-the-rfa/>.

<sup>9</sup> Exec. Order No. 13,272, 67 Fed. Reg. 53,461 (Aug. 16, 2002).

most impactful rules and have the greatest impact on small entities. By targeting agencies that have the greatest impact on small businesses, Advocacy's training program has been effective.

Advocacy's training sessions are typically 3 hours long and give participants hands-on training on how to comply with the RFA and associated requirements to assess small business impacts. Each training session is tailored to the agency being trained. Advocacy's training team includes a lead trainer and the regulatory economist and attorney who works on that agency's rules. The training includes exercises and examples of actual rules to refresh and reinforce the attendees' knowledge and understanding of the RFA. The training also incorporates information about the Administrative Procedure Act, Executive Order 12866 (*Regulatory Planning and Review*), and other relevant statutes to put the RFA in its proper context within the rulemaking process.

One of the most important themes throughout the training is that agencies should involve Advocacy as early as possible so that any RFA issues or deficiencies can be flagged and corrected. By engaging Advocacy early, agencies can avoid errors in RFA compliance and produce better analyses. Advocacy has found that the training program has resulted in a greater willingness by agencies to share early draft documents with Advocacy and rely on Advocacy as a resource. This has led, in turn, to better compliance with the RFA.

As part of the RFA training program, Advocacy provides participants with a copy of its RFA compliance guide.<sup>10</sup> The guide provides a step-by-step, detailed outline of what the RFA requires and what agencies must do to comply with the statute. It also details relevant case law and real-world examples of compliant RFA analyses for reference. Advocacy also maintains resources on its website on data sources to use when conducting RFA analyses that is available for all agencies.<sup>11</sup>

Advocacy has received positive feedback on its training program from agency participants and continues to revise and update its RFA guidance and the format of the training based on agency feedback.

## II. GAO's Recommendations

The draft report includes two recommendations concerning Advocacy's RFA training program. Advocacy accepts GAO's recommendations and will implement these recommendations as soon as possible. Advocacy is providing additional detail and context concerning its RFA training program to better inform GAO's recommendations and put it in proper context.

<sup>10</sup> U.S. SMALL BUS. ADMIN. OFFICE OF ADVOCACY, A GUIDE FOR GOVERNMENT AGENCIES: HOW TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT, (Aug. 2017), <https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf>.

<sup>11</sup> U.S. Small Bus. Admin. Office of Advocacy, *RFA Data Resources for Federal Agencies*, <https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/rfa-basics/rfa-data-resources-for-federal-agencies/> (last updated June 4, 2024).

**A. GAO Recommendation: The Chief Counsel of the Office of Advocacy should develop and implement policies and procedures for providing training to agencies on RFA compliance, including mechanisms to identify agencies most in need of training and agencies that have not received the training for an extended period.**

Advocacy accepts this recommendation and commits to developing and implementing formal policies and procedures concerning its RFA training program. Advocacy already identifies agencies that are most in need of training or have not received it for an extended period. However, since a process was not formally documented, it could not be demonstrated properly. Despite not having written procedures in identifying agencies in need of training, Advocacy has still been effective at achieving its training objectives.

Advocacy keeps records of when agencies receive training and how many agency officials participate in each training. These trainings are also reported in the RFA annual reports, along with a list of every agency, sub-agency, and office trained since the training program's inception in 2003.

While Advocacy may not have trained every rule-writing agency according to the Administrative Conference of the United States (ACUS) list in the draft report, Advocacy is confident that it has trained the agencies that affect small entities the most, including all cabinet departments and most of the sub-agencies that write rules that impact small entities. However, Advocacy commits to reevaluating this list to determine whether there are additional agencies that issue regulations that impact small entities but have not yet received training. Given Advocacy's small staff and limited resources, Advocacy has focused on those agencies that issue regulations that have the biggest impact on small entities. After reviewing the list of 87 agencies listed by GAO as those not formally trained as part of the training program, Advocacy has initially found that many of those agencies do not write rules that significantly impact small entities or do not issue regulations frequently. For example, agencies such as the National Archives and Records Administration, Office of Personnel Management, Merit Systems Protection Board, and Office of Special Counsel primarily issue policies concerning actions of agencies and federal employees and do not impact small entities. Therefore, Advocacy does not consider these agencies priorities for RFA training, nor have these entities requested training by Advocacy. However, Advocacy will gladly provide training to any agency upon request.

Further, in Advocacy's experience, the agencies that are the most knowledgeable about the RFA are ones in which Advocacy has the most contact with. This is especially true for the three agencies that are subject to convening SBREFA panels (EPA, OSHA, and CFPB). Advocacy notes that EPA in particular has perhaps the most extensive agency guidance and procedures for complying with the RFA. Indeed, EPA was one of the three pilot agencies Advocacy worked with to develop its RFA training program following the issuance of Executive Order 13272 because of EPA's extensive experience with the RFA and SBREFA at the time.

While the draft report focuses on Advocacy's formal training program, Advocacy is continuously engaged with congressional staff members, agency personnel, trade association representatives, and OMB's Office of Information and Regulatory Affairs through its daily

interactions and engagement. Advocacy has also provided RFA compliance briefings and presentations to these groups. Advocacy also discusses the RFA in its regulatory roundtables, where agency officials are frequent speakers and attendees. While these sessions are not counted in Advocacy's formal training count, many agency personnel attend and participate in discussion.

Regarding training not being targeted at agencies that need training most or ones who Advocacy has filed public comments with, a comment letter may not always be written due to an issue with RFA compliance. Writing a comment letter is just one of many instances that may prompt Advocacy to offer training to an agency. Advocacy staff may identify RFA deficiencies during the interagency review process, which will often prompt Advocacy to offer training to the agency at that time. Additionally, because Advocacy staff maintain close relationships with the agencies, Advocacy is often aware when agencies experience changes in staff that may prompt Advocacy to offer training. Further, there have been instances where agencies have approached Advocacy to request training.

As previously stated, Advocacy provides RFA compliance assistance through more than just formal training. Advocacy staff actively promote RFA compliance in all their regular interactions with agencies. Advocacy has strong relationships with its agency counterparts and provides feedback on RFA compliance on each individual rule it reviews. Advocacy encourages agencies to provide draft documents before a rule enters the formal interagency review process. By providing feedback early in the process, Advocacy has resolved potential RFA issues prior to publication. Agencies will often reach out to Advocacy with specific questions about RFA issues, such as defining significant impact and substantial number of small entities, the proper definition of a small business, or the potential use of an alternative size standard. Advocacy considers all these interactions as part of its effort to promote RFA understanding and compliance.

Finally, Advocacy is sometimes unsuccessful in providing training at some agencies because we do not frequently engage with them or they do not write many rules. Very few agencies have declined training, but it is sometimes a challenge to actually schedule it. While Executive Order 13272 tasks Advocacy with providing the training, there is no corresponding requirement for agencies to accept it. Regardless, Advocacy continues its outreach efforts and targets those agencies that write the most significant rules for small entities, or those that have not been trained for an extended period of time. Advocacy will redouble its efforts to identify agencies that have not been trained and offer training to those agencies that write the most impactful rules and the rules that small entities care most about.

**B. GAO Recommendation: The Chief Counsel of the Office of Advocacy should develop one or more performance goals that more clearly link with its strategic objective of training rulemaking officials throughout the government.**

Advocacy accepts this recommendation. This training performance metric is set in collaboration with the Office of Management and Budget (OMB). Advocacy fully commits to working with



the OMB to explore new and appropriate metrics for RFA training performance goals that better reflect compliance with the Executive Order and the needs of federal agencies. As noted in the draft GAO report and in Advocacy's RFA annual reports, Advocacy has met its performance goal of training at least 100 agency officials annually every year since the RFA training program began in 2003. Advocacy is fully committed to continuing this history of success.

Further, since Advocacy began conducting online training during the COVID-19 pandemic, we have seen a substantial increase in the number of agency staff trained. Advocacy is now implementing a hybrid training model of online and in-person training that has resulted in a record-breaking 515 agency officials from 17 agencies trained in FY 2024. Advocacy's hybrid training allows us to reach agencies officials we might not otherwise reach in an in-person environment in Washington, DC, including agency personnel in regional and field offices across the country. Additionally, Advocacy has found that field offices often have more direct interactions with small entities that would be impacted by their regulations. Advocacy has received positive feedback from agencies for the flexibility in training format and venue that is most conducive to the agency and for focusing on particular aspects of the RFA relevant to the rules they are working on.

### III. Conclusion

Advocacy accepts GAO's recommendations regarding its RFA training program and will implement these recommendations as soon as possible. Advocacy also hopes that the additional information and context on its RFA outreach activities has provided a fuller view of its role in advancing RFA compliance and serving as a resource for agencies on RFA issues. Advocacy is pleased to continue to fulfill its mission of offering training to agencies and others, including GAO and all interested in RFA compliance. On the issue of small business impacts of regulations, it is unfortunate that the majority of economically significant rules sampled in GAO's report were certified as not having a significant economic impact on a substantial number of small entities. Advocacy believes this illustrates a core issue with agency compliance with the RFA not addressed in the report. For most economically significant rules, agencies are not exploring alternative regulatory approaches that could lower small business regulatory burden. This limits a useful tool to make regulations more cost effective for small businesses.

If you have any questions or require additional information, please contact me or Stephanie Fekete, Director of Interagency Affairs, at (202) 205-6888 or [stephanie.fekete@sba.gov](mailto:stephanie.fekete@sba.gov).

Sincerely,

//signed//

Major L. Clark, III  
Deputy Chief Counsel  
Office of Advocacy  
U.S. Small Business Administration

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# Appendix X: Comments from SBA's Office of Advocacy, February 28, 2025



February 28, 2025

VIA ELECTRONIC SUBMISSION

Ms. Jill Naamane, Director  
Financial Markets and Community Investment  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Re: Draft Report, *Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance (GAO-25-106950)*

Dear Director Naamane,

The Office of Advocacy (Advocacy) appreciates the opportunity for additional time to provide supplementary comments on the draft Government Accountability Office (GAO) report *Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance (GAO-25-106950)*. As stated in our first letter on January 17, 2025, Advocacy concurs with GAO's recommendations concerning its RFA training program and will implement these recommendations by continuing existing efforts to expand the training program.

However, Advocacy believes GAO has missed an opportunity to adequately assess agency compliance with the Regulatory Flexibility Act (RFA). In these comments, Advocacy will provide further context on RFA compliance issues to increase understanding of where and when agencies fall short and the policy implications of not complying with the RFA. Advocacy appreciates the ability for new leadership to weigh in on this important issue so it can be carried out effectively and ensure that GAO, Congress, and the public can be best informed.

## **I. Background**

### **A. The Office of Advocacy**

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the SBA that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the Small Business Administration (SBA) or the Administration.

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The Regulatory Flexibility Act (RFA),<sup>1</sup> as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>2</sup> 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, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.<sup>3</sup>

Additionally, section 609 of the RFA requires the Consumer Financial Protection Bureau (CFPB), the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA) to conduct special outreach efforts through a review panel (often referred to as a SBREFA panel).<sup>4</sup> The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.<sup>5</sup> If a rule will not have a significant economic impact on a substantial number of small entities, the agency head may provide a certification.<sup>6</sup> The agency must provide a statement of factual basis that adequately supports its certification.<sup>7</sup>

The RFA directs the Chief Counsel for Advocacy to monitor and report on federal agencies' compliance with the law. In addition, Executive Order 13272 imposes certain requirements on federal agency rulemaking and requires Advocacy to report on agency compliance with that executive order. Advocacy produces an annual report to Congress and the Office of Management and Budget to fulfill these mandates.<sup>8</sup>

## **II. Additional Comments Regarding Advocacy's Promotion of RFA Compliance and GAO's Recommendations Regarding Advocacy's Training Program**

As previously stated in our comment letter, Advocacy has implemented a robust RFA training program since 2003. We have trained thousands of federal officials on RFA compliance. However, Advocacy still encounters challenges with its training program.

### **A. There is a lack of enforcement for agency participation in RFA training.**

Advocacy constantly updates its training program based on feedback from participants and issues with agencies' RFA compliance that Advocacy staff encounter. Since Advocacy began conducting online training during the COVID-19 pandemic, we have seen a substantial increase in the number of agency staff trained. Advocacy has further enhanced the program by implementing a hybrid model of online and in-person training. As a result, Advocacy trained 515 agency officials from 17 agencies trained in FY 2024, which is almost four times as many people

<sup>1</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

<sup>2</sup> Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).

<sup>3</sup> 5 U.S.C. § 603.

<sup>4</sup> *Id.* § 609.

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

<sup>6</sup> *Id.* § 605(b).

<sup>7</sup> *Id.*

<sup>8</sup> Copies of Advocacy's annual RFA reports can be found at <https://advocacy.sba.gov/category/resources/annual-reports-on-the-rfa/>.

trained in FY 2023 and the highest number on record for the office, and more than five times higher than Advocacy's OMB-established performance objective.<sup>9</sup>

However, while Executive Order 13272 requires Advocacy to provide training to agencies on compliance with the RFA, the agencies are not obligated to accept or participate in it. Despite Advocacy offering training to agencies, and striving to be as flexible and accommodating as possible, agencies commonly decline, fail to respond, or cancel training after it has been scheduled. Additionally, Advocacy has no mechanism to control who participates in the training. We rely on agencies to ensure the participants in the training are appropriate representatives who work on the RFA.

**B. GAO's conclusion that Advocacy's lack of formal training policies and procedures has resulted in agencies not being adequately equipped to comply with the RFA is misplaced.**

Advocacy is committed to developing formal policies and procedures and will reevaluate its performance standards in conjunction with OMB based on GAO's recommendations. That said, Advocacy cautions that developing formal internal procedures for the RFA training program will not resolve all RFA issues. Despite Advocacy's continued success in consistently exceeding our OMB approved performance objectives of training 100 agency officials per year, Advocacy continues to encounter RFA compliance problems at federal agencies, including agencies that have participated in the training program.

Instead, Advocacy has found that we are more successful at addressing RFA issues by engaging with agencies early in the process on each individual regulation. Executive Order 13272 and the RFA require agencies to submit draft rules and initial regulatory flexibility analyses (IRFAs) to Advocacy prior to publication in the Federal Register.<sup>10</sup> When agencies work with Advocacy early in the process (often before interagency review under Executive Order 12866), they are generally more compliant with the RFA. However, across almost all agencies, this early engagement at the draft stage is an underutilized process. Frustratingly, many agencies do not notify Advocacy of their rules until after they are published. A more thorough investigation may have shown this to be a method to strengthen agency compliance with the RFA.

As an example of early engagement, Advocacy, as an independent office, is part of SBA's internal clearance process for its draft rules covering SBA programs and regulations, a process completed prior to a rule being submitted to OIRA for interagency review. Most of the time, RFA issues can be resolved with SBA at this stage. As a result, Advocacy rarely writes letters to SBA on RFA compliance issues because such issues are already addressed at an early stage and can be remedied through frequent communication and interaction.<sup>11</sup> In addition, Advocacy's engagement with the FAR Council and participation on the Civilian Agency Acquisition Council often results in early review of draft regulations. Advocacy is not always successful at resolving all RFA issues through this early review of FAR Council regulations, but early review of these rules has resulted in better RFA compliance. Advocacy continues to promote early involvement

<sup>9</sup> In FY 2023, Advocacy provided training to 139 agency officials across 9 federal agencies.

<sup>10</sup> Exec. Order No. 13,272, § 3(a), 67 Fed. Reg. 53,461 (Aug. 16, 2002); 5 U.S.C. §§ 603(a), 609(b)(1).

<sup>11</sup> The last letter Advocacy wrote to SBA was on August 22, 2019.

with agencies on their regulatory activities as a successful method of resolving RFA compliance problems, but agencies do not often accept the offer.

### **III. The RFA Is an Analytical Statute, Not Just a Procedural Requirement**

Although the RFA does not impose substantive constraints on agency decision-making, it does require proper analysis and agency consideration. At the draft proposed stage, agencies must analyze the small business impacts to either certify a rule is not expected to have a substantial economic impact on a significant number of small entities or complete an initial regulatory flexibility analysis. This is done best through a process that promotes high-quality analysis and includes proper consideration of small entity impacts into decision-making. Unfortunately, GAO's report did not review underlying problems with the quality and adequacy of RFA analysis and failed to address the substantive issues with agency RFA compliance.

#### **A. Advocacy's RFA guidance outlines the minimum requirements for RFA compliance**

GAO treated Advocacy's guidance as the "gold standard" for RFA compliance, whereas Advocacy believes our RFA guidance outlines the minimum requirements agencies must meet to be considered fully compliant with the RFA. Advocacy's guidance is based on over 40 years of experience overseeing compliance with the RFA, legislative history of the RFA, and court decisions interpreting the RFA, and should not be viewed as optional.

#### **B. Certifications that do not include an adequate factual basis are not considered to be compliant with the RFA by the Office of Advocacy**

GAO's draft report states that the sampled certifications generally met RFA requirements. However, to meet the requirement of a proper certification in the RFA, the certification must include a "statement of factual basis." According to our guidance, "Advocacy interprets the 'factual basis' requirement to mean that, at a minimum, a certification should contain a description of the number of affected entities and the size of the economic impacts and why either the number of entities or the size of the impacts justifies the certification."<sup>12</sup> GAO identifies several rules that fall short of what Advocacy would consider an adequate factual basis for certification, yet incorrectly classifies them as generally RFA compliant.

Advocacy is concerned that GAO's findings may be misinterpreted by agencies and cause them to further improperly certify rules. In order to certify that a rule will not have a significant impact on a substantial number of small entities, an agency's factual basis must demonstrate how many small entities would be affected and what the effect is. It must also show that this effect is not significant and the number affected is not substantial, supported by reasonably stated criteria. This necessitates a reasonable numeric estimate of the small entity impact compared against relevant financial measures of affected small entities. For example, an estimated annual compliance cost of \$100 to affected small entities making \$100,000 in annual revenue represents 0.1% of revenue. This shows the impact is low and not significant by a standard of significance

<sup>12</sup> U.S. SMALL BUS. ADMIN. OFFICE OF ADVOCACY, A GUIDE FOR GOVERNMENT AGENCIES: HOW TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT 13, (Aug. 2017), <https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf>.

of 1 to 3% of revenue.<sup>13</sup> In practice, these key statistics are not always calculated and the supporting reasoning for the certification is not fully quantified, which results in an inadequate certification.

Agencies must conduct an IRFA whenever they cannot certify the rule. The certification states that the rule *will not* have a significant impact on a substantial number of small entities. If the rule may have a significant impact but the agency is not certain or has incomplete data, it must do an IRFA because it cannot certify as a matter of fact that the impact will not be significant. This highlights that agencies must do an IRFA if their threshold analysis yields significant impacts or unclear impacts, or whether they think something may change in the resultant final rule that impacts the impact on small entities. The only instance where a rule can be certified is when the agency can certify as a matter of fact that it will not be significant. An IRFA allows agencies to explore policy options to minimize small business compliance costs so that a more compliant, tailored, and cost-effective rule can be issued that does not impose unintended or unnecessary regulatory burden on an important part of the economy. When an agency fails to issue an IRFA that adequately considers small business relief provisions, rules may be more costly than necessary, less effective, and provide fewer net benefits.

**C. IRFAs and FRFAs must include all required elements to be compliant with the RFA**

GAO's draft report states that the sampled IRFAs and final regulatory flexibility analyses (FRFAs) generally met RFA requirements. However, to meet the requirement of a section 602 and 603 of the RFA, the IRFAs and FRFAs must include all required elements. The elements for an IRFA are:

1. A description of the reasons why action by the agency is being considered.
2. A succinct statement of the objectives of, and legal basis for, the proposed rule.
3. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.
4. A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.
5. An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.
6. A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes, and which minimize any significant economic impact of the proposed rule on small entities.

GAO identifies several rules that do not include each element yet still classifies the rules as generally compliant with the RFA. Rules that do not include all elements of the IRFA are not RFA compliant. Advocacy advises agencies that elements 1 and 2 can draw from sections of the preamble where this is often explained. Elements 3 and 4 pertain to the number of affected small entities and estimated impact most likely analyzed in the certification threshold analysis and

<sup>13</sup> *Id.*

should be expanded on in an IRFA. Element 5 provides important insight for affected small entities and relies on agencies understanding how their new rule may relate to other rules small entities are already complying with. Element 6 is the most important element which agencies should devote time and attention towards. A detailed impact assessment from Elements 3 and 4 can inform a targeted scope of element 6 to potentially reduce disproportionate compliance costs to the most impacted. Typically, the smallest small entities are most impacted on costs to revenue basis and warrant the most consideration for regulatory relief where possible according to agency objectives.

The quality of the alternatives the agencies assess is an important factor in RFA compliance. Many IRFA alternatives assessed do not qualify as “significant” alternatives under the RFA. As our guidance states, alternatives should be cost minimizing, feasible, and meet the agency’s objective. Alternatives that are at a higher stringency or costs than the proposed provisions do not comply with the RFA since they do not “minimize any significant impact of the proposed rule on small entities.” Additionally, a no action alternative is sometimes used, but is not a compliant IRFA alternative. No action is captured in the agency’s baseline estimate and policy options are measured for impact (costs and benefits) against this baseline.

The quality of IRFA alternatives is important in assessing agency compliance, but unfortunately this was not assessed by GAO. Further, to illustrate this shortcoming, to Advocacy’s knowledge, none of the final rules from the sample adopted a small business alternative reducing their costs of compliance. However, GAO did not highlight this fact. Advocacy believes agency assessments can be improved to be more effective in informing decisionmakers within the agency on small business regulatory flexibility. Advocacy believes improving assessment and consideration of small business regulatory alternatives is the biggest potential area for agencies to improve their RFA compliance.

#### **IV. GAO’s Findings Regarding Agency Compliance with the RFA**

##### **A. Economically significant rules are likely to be economically significant to small businesses.**

In the report, GAO examines 195 significant final rules from four executive branch agencies. 142 of them (73 percent) were certified as not having a significant impact on a substantial number of small entities. Advocacy finds this statistic alarming. As mentioned in Advocacy’s first response letter and expanded here, rules deemed to be economically significant for their total impact on the economy are likely to be economically significant to small businesses as well. Small businesses account for over 99 percent of all businesses and are represented in every geographic area and industry of the U.S. economy.

Many of those 142 certifications are likely to be improper due to either agencies underestimating the economic impact on small entities or agencies undercounting the number of impacted small entities. In their analysis, GAO failed to assess the accuracy and quality of the agency estimates. It is not likely that a rule having an annual effect on the economy of \$100 million or more would not significantly impact a substantial number of small businesses as well. While it is conceivable that an economically significant rule could not impose a significant economic impact on a



substantial number of small businesses, that it much more likely to be the rare exception based on the composition of small entities and the broader economy. There are some exceptions, including when a small business is not subject to the rule's requirements such as when state governments are affected or small businesses are exempted from the rule, but these exceptions very likely do not occur 73 percent of the time. Advocacy does not have access to the sampled rules, but in our own brief search of final significant rule certifications from this time period of the selected agencies, we found several instances of certifications that lacked an adequate factual basis.

Agencies have access to publicly available data from the Census Bureau, which annually publishes the number of small entities in each industry. These statistics can be used to estimate the number of affected small entities. Agencies should estimate the costs of the rule's provisions on a small entity based on the time and resources expended to complete the activities and requirements of the rule, as is similarly done in other required regulatory analyses. In areas where there are knowledge gaps, agencies can make informed, reasoned assumptions based on the best available information or seek comment from small businesses and Advocacy for input. And in those cases, the assumptions should be clearly stated. When significant impacts are discovered, they can be remedied through the consideration of alternative provisions for small entities through an initial regulatory flexibility analysis. Falling short of these actions does not demonstrate compliance with the RFA. This was another lost opportunity in GAO's report.

**B. Sample selected does not adequately reflect the scope of the RFA**

The federal government issues thousands of regulations each year. In FY 2022 and FY 2023, the years studied in the report, 5,775 final regulations were issued, and another 4,023 regulations were proposed.<sup>14</sup> Advocacy reviews up to an estimated 1,500 different regulatory proposals, notices of regulatory activity, regulatory guidance, or final rules each year, as resources allow. In FY 2022 and FY 2023, executive branch agencies issued 310 significant rules, including 127 economically significant rules, which do not include rules from independent agencies that are also subject to the RFA.<sup>15</sup>

GAO only reviewed significant rules from four agencies across two recent years. Because regulations are so numerous, it is difficult to find a sample that is representative of the overall total. Advocacy understands how limited time and resources may prevent a complete evaluation. However, the sample misses several important aspects of RFA compliance. The conclusion that agencies are mostly in compliance with the RFA, as assessed from an unrepresentative small sample, all the while clear compliance issues remain, hinders Advocacy's ability to ensure that regulators follow the RFA.

While the agencies selected by GAO (i.e., SBA, CMS, DOE, and EPA) may have had the most RFA eligible rules in the time period, they are not necessarily the agencies small businesses often have the most regulatory concerns with. Since the RFA directs agencies to understand and consider reducing regulatory burden on small businesses, Advocacy believes an assessment of

<sup>14</sup> The George Washington Univ. Regul. Stud. Ctr., *Reg Stats*, [https://regulatorystudies.columbian.gwu.edu/reg-stats/#rules\\_Fed\\_Reg\\_by\\_prez\\_year](https://regulatorystudies.columbian.gwu.edu/reg-stats/#rules_Fed_Reg_by_prez_year) (last accessed Feb. 27, 2025).

<sup>15</sup> *Id.*



other federal agencies that impose greater regulatory burden on small businesses would have made for a better sample to illustrate how well the RFA is working to bring regulatory flexibility to small businesses. As is, the report shows whether selected agencies followed procedure but does not ascertain the extent to which agencies appropriately relieved small businesses of disproportionately burdensome regulation. The purpose of the RFA is to provide small entities regulatory flexibility when warranted not to perform perfunctory analysis.

Since 2017, the top agencies to which Advocacy wrote comment letters expressing small business concerns were EPA, CFPB, DOL, and CPSC. According to the National Small Business Association, the types of regulations with most regulatory burden were tax, health care and health insurance, and payroll and employee compensation.<sup>16</sup> The federal agencies small business respondents reported the most regulatory difficulties with were IRS, DOL, EPA, OSHA, and HHS. Small businesses expressed most difficulty with the complexity of rules, cost of compliance, difficulty interpreting and understanding rules, and the volume of existing rules. Along with EPA, OSHA and CFPB were deemed to be SBREFA panel agencies by Congress, presumably because Congress recognized that their regulatory actions can significantly impact small businesses.

Based on Advocacy's reports on agency compliance with the RFA, Advocacy believes that GAO should have focused on other agencies or expanded its scope to include more than four agencies. The CFPB is a clear candidate for this investigation due to the frequency that Advocacy sends letters to the CFPB and the fact that it is an agency subject to additional RFA procedures as a SBREFA panel agency. Additionally, DOL is one of the top agencies to which Advocacy has sent letters, citing severe underestimation of regulatory compliance costs in many cases. According to Table 7 in the draft report, GAO also noted that DOL had the fourth highest number of significant final rules subject to RFA requirements during FY 2022 and FY 2023. Further, as a subagency of DOL, OSHA is another agency that is subject to SBREFA panels. The sample selected fails to represent the regulatory activity that impacts small businesses the most.

**C. GAO's analysis of EPA's rules during the selected time period does not provide a comprehensive analysis of RFA compliance**

In the draft report, GAO did not analyze any IRFAs or FRFAs from EPA because the agency certified every rule during the selected timeframe and scope would not have a significant economic impact on a substantial number of small entities. GAO cannot conclude that EPA is complying fully with the RFA without examining their RFA requirements under an IRFA and SBREFA panel. According to Appendix II, Table 7 of the draft report, EPA published 21 final rules that were considered significant, which GAO found were all certified. Advocacy is alarmed that all EPA rules considered economically significant were certified as not having a significant economic impact on a substantial number of small entities. Advocacy recognizes there are exceptions but expects most rules require an IRFA.

Further, GAO found that two EPA certifications did not describe small entities affected by the rule. Additionally, GAO cited one EPA rule where EPA could not estimate the number of small

<sup>16</sup> NAT'L SMALL BUS. ASS'N, 2017 NSBA SMALL BUSINESS REGULATIONS SURVEY 4 (2017), [https://www.nsbaadvocate.org/files/ugd/fec11a\\_97ac56aea7a84821a7c1991c17fa008c.pdf](https://www.nsbaadvocate.org/files/ugd/fec11a_97ac56aea7a84821a7c1991c17fa008c.pdf).

entities affected due to several data limitations. When an agency cannot adequately describe the small entities affected by a rule in a certification, the agency has not met the requirements for an adequate factual basis supporting a certification. Therefore, in such a case, the agency must conduct an IRFA. GAO should not have concluded that those certifications were RFA compliant.

**D. GAO's findings are inconsistent with Congress, Advocacy, small business advocates, and GAO's own reports**

GAO's draft report concludes that the agencies generally complied with the RFA. However, Congress, Advocacy, and even GAO have found that agencies fail to comply with the RFA.

For example, the House Committee on Small Business conducted its own investigation into agency compliance with the RFA and published its findings in 2024.<sup>17</sup> The Committee concluded that overall, most agencies are failing to comply with the RFA's requirements. The Committee reviewed more than 100 proposed and final rules and sent letters 66 letters to 34 different federal agencies. The Committee found four main issues with agencies' RFA compliance:

- Agencies often improperly certified rules.
- Agencies often underestimate both the costs and the number of impacted small businesses when conducting an RFA analysis.
- Agencies repeatedly fail to appropriately assess if a rule is duplicative or conflicts with other rules.
- Some agencies did not comply with congressional oversight.

Advocacy believes that the Committee's more comprehensive investigation of agency compliance with the RFA government wide is more representative than GAO's assessment of four agencies. The Committee's investigation appears to have focused more on rules that would have a significant impact on small businesses rather than what rules were considered significant under EO 12866.

Further, the Committee's findings are consistent with Advocacy's comment letters and reports to Congress on agency compliance with the RFA. According to Advocacy's annual reports, the top RFA issues cited in Advocacy's comment letters are inadequate analysis of small entity impacts and failure to consider significant alternatives. Advocacy has also cited improper certifications in many letters.

Additionally, in a 2023 report, the National Federation of Independent Businesses (NFIB) identified and reviewed 28 RFA deficiencies between January 2021 and January 2023 stemming from Advocacy comment letters.<sup>18</sup>

<sup>17</sup> HOUSE COMM. ON SMALL BUS., REGULATORY FLEXIBILITY ACT (RFA) REPORT: AGENCIES' NONCOMPLIANCE WITH THE RFA (2024), [https://smallbusiness.house.gov/uploadedfiles/05.22.2024\\_-\\_house\\_committee\\_on\\_small\\_business\\_rfa\\_report.pdf](https://smallbusiness.house.gov/uploadedfiles/05.22.2024_-_house_committee_on_small_business_rfa_report.pdf).

<sup>18</sup> ROB SMITH, NAT'L FED'N OF INDEP. BUS., THE REGULATORY FLEXIBILITY ACT: TURNING A PAPER TIGER INTO A LEGITIMATE CONSTRAINT ON ONE-SIZE-FITS-ALL AGENCY RULEMAKING (May 2023), <https://strgnfibcom.blob.core.windows.net/nfibcom/NFIB-RFA-White-paper.pdf>.

GAO has also found in previous investigations that agencies have not complied with the RFA. For example, GAO published a report in 2018 analyzing RFA compliance at six financial regulators (Board of Governors of the Federal Reserve System, Office of the Comptroller of the Currency, Federal Deposit Insurance Corporation, Securities and Exchange Commission, Commodity Futures Trading Commission, and Consumer Financial Protection Bureau).<sup>19</sup> In the report, GAO found “several weaknesses” with the RFA analyses. For certifications, GAO found that the “factual basis provided for many . . . certifications lacked key information . . . for understanding the analyses regulators used to support their conclusion.” Additionally, GAO noted that many RFA-required analyses had weaknesses and that regulatory flexibility analyses often included limited evaluation of costs and alternatives. GAO also investigated the agencies’ approach to RFA-required retrospective review under section 610 of the RFA, which was not done in the current draft report.

GAO’s conclusion that agencies are compliant with the RFA conflicts with other reports, including their own prior report. GAO’s agency recommendations should be reflective of and responsive to the compliance issues found in these reports.

#### **V. Conclusion**

Advocacy appreciates working with GAO on this important issue and is glad for the opportunity to comment fully on the draft report. As previously stated in our first letter, Advocacy concurs with GAO’s recommendations regarding its RFA training program and will implement these recommendations expeditiously. We understand the importance of RFA training because it is one step toward agency compliance. However, in practice, many federal agencies do not give proper consideration to small businesses during regulatory development. It is our hope that GAO’s work on this issue, Advocacy’s feedback, and the resultant report lead to improved outcomes for small businesses who rely on Advocacy and federal agencies to consider their needs when they regulate.

If you have any questions or require additional information, please contact me or Stephanie Fekete, Director of Interagency Affairs, at (202) 205-6888 or [stephanie.fekete@sba.gov](mailto:stephanie.fekete@sba.gov).

Sincerely,

//signed//

Chip Bishop  
Deputy Chief Counsel  
Office of Advocacy  
U.S. Small Business Administration

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<sup>19</sup> U.S. GOV’T ACCOUNTABILITY OFF., GAO-18-256, FINANCIAL SERVICES REGULATIONS: PROCEDURES FOR REVIEWS UNDER REGULATORY FLEXIBILITY ACT NEED TO BE ENHANCED (2018).

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# Appendix XI: GAO Contact and Staff Acknowledgments

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## GAO Contact

Jill Naamane at [naamanej@gao.gov](mailto:naamanej@gao.gov).

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## Staff Acknowledgments

In addition to the contact named above, Paige Smith (Assistant Director), Sarah Garcia (Analyst in Charge), Charlene Calhoon, Matthew Curtis, Steven Flint, John Karikari, Jill Lacey, Alice Lin, Alberto Lopez, Jennifer Schwartz, and Jena Sinkfield made key contributions to this report.

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