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Report to Congressional Requesters

December 2020

FEDERAL RULEMAKING

Selected EPA and HHS Regulatory Analyses Met Several Best Practices, but CMS Should Take Steps to Strengthen Its Analyses

GAO-21-151

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GAO Highlights

Highlights of GAO-21-151, a report to congressional requesters

Why GAO Did This Study

EO 13771 generally requires executive agencies to identify two rules for repeal for each new rule issued. Since EO 13771 went into effect in 2017, executive agencies have taken regulatory actions expected to generate over $50 billion in savings to society. Quality regulatory analysis provides agency decision makers and the public with a thorough assessment of the benefits and costs of different regulatory options.

GAO was asked to review regulatory analyses for rules finalized under EO 13771. For selected agencies, this report examines (1) how the calculated economic effects of selected rules differed, if at all, from those of rules they modified; and (2) the extent to which agencies met best practices in analyzing the economic effects of selected rules for which monetized costs exceed monetized benefits.

GAO reviewed analyses for 11 rules—and the rules they modified— finalized by EPA and HHS, the two agencies that finalized the most economically significant EO 13771 rules through fiscal year 2019. GAO compared analyses to selected best practices in GAO's *Assessment Methodology for Economic Analysis*.

What GAO Recommends

GAO recommends that CMS take steps to ensure its future regulatory analyses are consistent with best practices for analyzing alternatives, assessing important effects, and providing transparency. EPA said it appreciated GAO's findings. HHS generally agreed with the report, and CMS agreed with the recommendation directed to it.

View GAO-21-151. For more information, contact Yvonne D. Jones at (202) 512-6806 or jonesy@gao.gov.

What GAO Found

GAO reviewed 11 Executive Order (EO) 13771 rules—five significant Environmental Protection Agency (EPA) rules and six economically significant Department of Health and Human Services (HHS) rules. Seven of the 11 rules modified (i.e. repealed, amended, or delayed) existing rules (see table). GAO found that analyses for most of the seven rules monetized the same types of benefits and costs as analyses for the rules they modified, an indicator of consistency in the regulatory analyses. For example, one EPA rule modified an earlier rule that had established requirements for chemical risk management programs. EPA monetized anticipated changes to industry compliance costs for both rules. Where agencies monetized similar types of benefits and costs for both reviewed rules and modified rules, the value of some estimates differed, in part, because agencies had updated analytical assumptions, such as the number of entities subject to requirements or relevant wage data.

Topics and Characteristics of 11 Environmental Protection Agency (EPA) and Department of Health and Human Services (HHS) Rules Selected for Review

Agency	Topics	Modified existing rule(s)	Monetized costs exceeded benefits
EPA	Risk management programs	●	○
	Railroad ties as non-waste fuels	●	○
	Chemical data reporting	●	●
	Mercury reporting	○	●
	Effluent from dental offices	○	●
HHS, FDA	Food labeling	●	○
	Agricultural water requirements	●	●
HHS, CMS	End-stage renal disease treatment	●	●
	Home health quality reporting	●	●
	Patient discharge planning	○	●
	Diabetes prevention and appropriate use of imaging services	○	●

Legend: ● = Yes; ○ = No

Source: GAO analysis of EPA, Food and Drug Administration (FDA), and Centers for Medicare & Medicaid Services (CMS) data. | GAO-21-151

Regulatory analyses for eight of the 11 rules GAO reviewed projected that monetized costs would exceed monetized benefits, though each identified other factors that may have led decision makers to determine that the total benefits justified the total costs, such as important, non-quantified effects. These eight analyses met about half of the selected best practices for economic analysis. However, some analyses developed by HHS's Centers for Medicare & Medicaid Services (CMS) did not fully meet best practices associated with analyzing regulatory alternatives, assessing important effects, and providing transparency. It is particularly important that agencies develop quality analyses for economically significant rules, such as those finalized by CMS. By meeting these best practices, CMS could help the public and other parts of government provide effective feedback and mitigate potential conflict with entities affected by rules. It could also help CMS assess whether a rule's benefits justify the costs.

Contents

Abbreviations

Assessment Methodology	*GAO Assessment Methodology for Economic Analysis*
CMS	Centers for Medicare & Medicaid Services
EO	Executive Order
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FR	*Federal Register*
HHS	Department of Health and Human Services
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget

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December 17, 2020

The Honorable Jerrold Nadler
Chairman
Committee on the Judiciary
House of Representatives

The Honorable Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform
House of Representatives

The Honorable Harley Rouda
Chairman
Subcommittee on Environment
Committee on Oversight and Reform
House of Representatives

Federal regulations are one of many tools that agencies use to implement laws aimed at achieving national goals, such as improving the economy and protecting the health and safety of the public and the environment. While regulations or rules—terms that we use interchangeably in this report—can generate substantial benefits to society, they can also have costs to industry, government, or the public.[1] To manage the overall costs of complying with federal regulations, Executive Order (EO) 13771, issued on January 30, 2017, requires executive agencies to offset the costs associated with each new regulation by eliminating the costs associated with at least two existing regulations, unless prohibited by law.[2]

[1]Rules are legally binding requirements, and are established by agencies pursuant to statutory authority. The *Code of Federal Regulations* annual edition is the codification of the general and permanent rules published in the *Federal Register* by agencies of the federal government. We use the terms regulations, rules, and actions interchangeably in this report.

[2]Exec. Order. No. 13771, *Reducing Regulation and Controlling Regulatory Costs*, 82 Fed. Reg. 9339 (Feb. 3, 2017). For the purposes of this order, agency means any executive department, military department, government corporation, government controlled corporation, or other establishment in the executive branch, but does not include independent regulatory agencies. 44 U.S.C. § 3502(1), (5).

Under EO 13771, agencies must annually provide their best approximation of the total costs or savings associated with each new rule or repealed rule to the Office of Management and Budget (OMB), among other requirements. New rules include those that establish new regulatory requirements and those that repeal, amend, or delay existing regulatory requirements. According to OMB, from between February 2017 through the end of fiscal year 2019, executive agencies finalized more than 440 rules with an estimated $50.9 billion in net cost savings to society (in 2019 dollars).[3]

Agencies have long been required to evaluate the benefits and costs of regulatory actions to assess whether a proposed rule's benefits justify its costs.[4] Quality regulatory analysis allows decision makers to evaluate different regulatory options using a common measure and provides government agencies, Congress, and the public with important information about the potential effects of rules. These potential effects may include monetized effects, including projected cost-savings associated with repealing, amending, or delaying existing rules. They may also include some effects that may be difficult to monetize or quantify but should still be accounted for, such as changes to quality of life or ecological health. In addition, quality regulatory analyses can ensure the public has information needed to provide agencies with effective feedback that can be used to improve regulatory approaches, mitigate potential conflict with affected entities, and reduce costs associated with delays or litigation.

OMB's Office of Information and Regulatory Affairs (OIRA) compiles information on and summarizes agencies' regulatory reform progress, including the number of EO 13771 rules and estimated net cost savings.

[3]According to OMB, agencies' calculations of cost savings for EO 13771 include effects agencies label as costs and cost savings and does not include those labeled as benefits. OMB guidance on EO 13771 accounting directs agencies to consider only those effects listed as costs and cost savings in prior economic analyses. As such, effects labeled as benefits—as opposed to cost savings, for example—should not be included in EO 13771 accounting.

[4]EO 12866, *Regulatory Planning and Review*, requires agencies to submit to OIRA an assessment of the potential benefits and costs of significant regulatory actions. Regulations are classified as significant if they result in a $100 million or greater effect on the economy in any given year, raise novel legal or policy issues, or meet certain other criteria. EO 12866 requires agencies to include additional information in their assessments of rules projected to result in $100 million or greater effects (i.e., the subset of significant rules defined as economically significant). 58 Fed. Reg. 51735 (Oct. 4, 1993).

However, less is known about how agencies have approached their regulatory analyses for those actions subject to the order.[5]

You asked us to review recent deregulatory actions to better understand agencies' estimates of economic impacts under EO 13771. This report examines the extent to which selected agencies have (1) finalized EO 13771 rules that repealed, amended, or delayed existing rules, and how, if at all, the calculated economic effects of those rules differed from the existing rules; and (2) met relevant best practices for economic analysis in their assessments of EO 13771 rules for which the agencies projected that the monetized costs would exceed the monetized benefits.

We selected for our review the Department of Health and Human Services (HHS) and the Environmental Protection Agency (EPA) because they are the two executive branch agencies that finalized the largest number of rules that were economically significant, including at least one regulatory and one deregulatory action, from fiscal year 2017 through fiscal year 2019 that were EO 13771 rules.[6] To select agencies for inclusion in our review, we used data from OIRA's regulatory reform reports as well as data from OMB's Reginfo.gov database to identify the agencies that finalized the greatest number of economically significant EO 13771 rules between February 3, 2017, when the executive order went into effect, and September 30, 2019, the most recent data available from OIRA's reports at the time of our review. We used OMB's Reginfo.gov database to identify which of the EO 13771 rules were economically significant.

Using OIRA's regulatory reform reports and OMB's Reginfo.gov database, we compiled a list of significant and economically significant

[5]EO 12866 assigns OIRA responsibility for ensuring federal rules issued by agencies, other than independent regulatory agencies, follow executive order requirements for regulatory analysis. "Independent regulatory agencies" refer to the boards and commissions identified as such in the Paperwork Reduction Act of 1995. 44 U.S.C. § 3502(5). The Securities and Exchange Commission is one example of an independent regulatory agency.

[6]OMB defines an EO 13771 regulatory action as a significant regulatory action or guidance document that has been finalized and imposes total costs greater than zero. OMB defines an EO 13771 deregulatory action as an action that has been finalized and has total costs less than zero. In this report, we refer to rules (but not guidance) that meet OMB's definition of EO 13771 regulatory action or EO 13771 deregulatory action as EO 13771 rules. Our review focused on rules, not guidance documents. Office of Management and Budget, *Reducing Regulation and Controlling Regulatory Costs*, M-17-21 (Washington, D.C.: 2017).

EO 13771 rules that EPA and HHS finalized between February 3, 2017, and April 30, 2020. In selecting rules for review, we prioritized rules that were economically significant. We excluded rules (1) that would not otherwise be considered economically significant if transfers were excluded from the economic analysis (i.e. remaining benefits or costs were less than $100 million); or (2) were under judicial review at the time of our review.[7] In applying these criteria, all economically significant EPA rules were excluded from our review. As a result, we supplemented our selection of EPA rules by randomly selecting rules finalized by EPA that were significant but not economically significant.

We reviewed a total of 11 EO 13771 rules. This total included six economically significant HHS rules–two finalized by the Food and Drug Administration (FDA) and four finalized by the Centers for Medicare & Medicaid Services (CMS). It also included five significant EPA rules. While these 11 rules provide insights into specific rulemaking processes and procedures that form the basis of our report, our findings regarding these rules cannot be generalized to make conclusions about other rules outside of our review.

For both objectives, we reviewed standardized information about each rule published in the *Federal Register* as well as information from publicly available regulatory analyses. Because some rules included several distinct provisions, for both objectives we focused our review on those provisions for which agencies identified monetized benefits or costs, excluding transfers.[8]

For our first objective, we determined that seven of the EO 13771 rules—three EPA, two FDA, and two CMS—had "modified" (i.e., repealed, amended, or delayed) existing rules. We collected regulatory analysis documentation for these seven rules and for the rules they modified. We then examined the extent to which the regulatory analyses for the seven rules and the rules they modified generally calculated benefits and costs consistently, including whether the agencies documented differences. In

[7]Transfers are monetary payments that shift resources from one party to another, such as payments from the government to private entities. Transfers do not change the total resources available to society.

[8]For rules that include multiple distinct provisions, *Circular A-4* directs agencies to analyze the benefits and costs of those provisions separately.

examining modified rules, we focused only on provisions affected by the EO 13771 rules.

For our second objective, we determined that analyses for eight of the EO 13771 rules—three EPA, one FDA, and four CMS—projected that monetized costs would exceed monetized benefits.[9] For each of the eight rules, we reviewed related regulatory analyses and documentation to assess the extent to which agencies' analyses for relevant provisions (i.e., those for which agencies monetized benefits, costs, or both) were consistent with selected best practices for economic analysis,[10] as discussed in our *Assessment Methodology for Economic Analysis* (Assessment Methodology) and relevant OMB and agency guidance.[11] We focused our assessment on rules for which straightforward comparisons of monetized information alone may not have provided sufficient information for decision makers to determine that these rules' total benefits were likely to justify the total costs. It is important for agencies to develop quality analyses for such rules because they may provide agencies with particularly important opportunities to assess and summarize information about a variety of considerations, such as the importance of nonmonetized effects, to assist officials in assessing whether the rules' total benefits are likely to justify the total costs. For more detail on our scope and methodology, see appendix I.

We conducted this performance audit from March 2020 to December 2020, 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.

[9]This subset includes four rules that we reviewed for our first objective because they modified existing rules.

[10]In conducting our review of selected rules, we did not evaluate their legal adequacy, and we express no view on the policy choices they contain.

[11]GAO, *Assessment Methodology for Economic Analysis*, GAO-18-151SP (Washington, D.C.: April 2018). This methodology provides a framework for assessing the sufficiency of economic analyses, including regulatory benefit-cost and cost-effectiveness analyses. We developed this methodology by synthesizing economic concepts identified by consulting with experts on economic analysis and in federal and international agency guidance.

Background

Executive Orders and Guidance for Regulatory Analysis

Several executive orders and OMB guidance documents provide agencies with direction and, depending on the type of rule being promulgated, requirements for the development of regulatory analysis.

EO 12866, *Regulatory Planning and Review.* This order, issued in 1993, sets forth a regulatory philosophy and set of principles that, to the extent permitted by law and where applicable, encourage federal agencies to assess benefits and costs of their proposed and final rules. It also directs agencies to consider available regulatory alternatives in all rules, including the alternative of not regulating, and generally select those alternatives that maximize net benefits, to the extent permitted by statute. EO 13771 and other executive orders reaffirm this philosophy and these principles. EO 12866 also establishes more specific requirements for some rules.

- For significant rules, agencies are required to include (1) a reasonably detailed description of the need for regulatory action and an explanation of how the regulatory action will meet that need, and (2) an assessment of the potential benefits and costs of the regulatory action.[12]
- For economically significant rules, agencies are further required to include (1) an assessment, including the underlying analysis, of the benefits and costs anticipated from the regulatory action, with, to the extent feasible, a quantification of those benefits and costs; and (2) an assessment, including the underlying analysis, of benefits and costs of potentially effective and reasonably feasible alternatives to the planned regulation, as well as an explanation of why the planned regulatory action is preferable to the identified alternatives.[13]

OMB Circular A-4. This circular, issued in 2003, provides guidance and best practices to federal agencies for determining the potential effects (i.e., benefits and costs) of new rules.[14] *Circular A-4* offers a framework for how agencies can analyze the benefits and costs of a proposed rule, but generally does not prescribe the specific assumptions or values to

[12]EO 12866, § 6(a)(3)(B).

[13]EO 12866, § 6(a)(3)(C).

[14]Office of Management and Budget, *Circular A-4*: Regulatory Analysis, (Washington, D.C., 2003).

use in analyzing the potential effects of rules. This flexibility is intended to allow agencies to apply the framework to their particular rules and regulated entities. OIRA uses *Circular A-4* as the primary guidance in reviewing regulatory analyses.

M-17-21. This guidance, issued by OMB in April 2017, is for federal agencies to use in implementing EO 13771 and defines regulatory and deregulatory actions under the order.[15] It also addresses requirements related to discount rates, identifying baselines for regulatory analyses and treating unquantified costs and cost savings.[16] Guidance for these requirements is generally consistent with *Circular A-4*.

Accounting Methods under EO 13771. This additional guidance, also issued by OMB, provides executive agencies with information on calculating the economic effects of rules to ensure consistent and comparable accounting of costs and cost savings.[17] For example, this guidance requires agencies to assume a rule is permanent and that its economic effects will continue in perpetuity.

EPA Regulations and EPA and HHS Internal Guidance Governing Regulatory Analysis

Both EPA and HHS have documented internal guidance that describes how officials should develop regulatory analyses to support and inform policy decisions and meet the requirements prescribed by the executive orders and OMB guidance described above. According to the agencies, this guidance applies to all rules the agencies finalize, including those that repeal prior rules.

EPA's *Guidelines for Preparing Economic Analyses* provides guidance on analyzing the economic effects of rules, including when to monetize, quantify, and qualitatively assess benefits.[18] Consistent with EO 12866,

[15]Office of Management and Budget, *Guidance Implementing Executive Order 13771, Titled "Reducing Regulation and Controlling Regulatory Costs*," M-17-21 (Washington, D.C.: 2017).

[16]When the benefits and costs of a rule will occur in the future, agencies are to determine the present value of future benefits and costs by applying an appropriate discount rate—the rate used to convert benefits and costs occurring in different time periods to a common present value. The discount rate adjusts future values based on the observation that people usually prefer receiving an amount of money today rather than receiving the same amount in the future.

[17]Office of Management and Budget, *Accounting Methods under Executive Order 13771*.

[18]EPA, *Guidelines for Preparing Economic Analyses* (Washington, D.C.: December 2010, updated May 2014).

EPA's guidelines emphasize that all benefits and costs of a rule should ideally be expressed in monetary terms whenever possible, but should still be included in the analysis if they cannot be monetized or quantified.

In June 2020, EPA published a notice of proposed rulemaking in the *Federal Register* to codify existing and new procedures EPA would be required to take when promulgating all future significant rules under the Clean Air Act.[19] EPA proposes to require each future rule promulgated under the Clean Air Act to present a summary of total benefits and costs in the rule's preamble. EPA also proposes to require an additional summary of the benefits and costs that pertain to the specific objective of the Clean Air Act provision or provisions under which the rule is promulgated. According to EPA, past analyses have generally presented benefits as aggregated totals. EPA has stated these totals do not clearly distinguish between benefits attributable to specific pollution reductions or other goals targeted by the specific statutory provision(s) authorizing the regulations and other welfare effects that are not the primary objective of the statutory provisions. As of December 8, 2020, this rule had not yet been finalized.

The HHS Assistant Secretary for Planning and Evaluation's *Guidelines for Regulatory Impact Analysis* also provides guidance to assist component agencies, such as CMS and FDA, in conducting economic analyses that meet the goals of executive orders.[20] Consistent with *Circular A-4, HHS'* guidelines emphasize the need to consider regulatory alternatives and report estimated benefits and costs using both a 3 and a 7 percent discount rate.

[19]Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process. 85 Fed. Reg. 35612 (June 11, 2020).

[20]HHS, *Guidelines for Regulatory Impact Analysis* (Washington, D.C.: January 2017).

Analyses of EO 13771 Rules and the Rules They Modified Were Found to Have Monetized Similar Effects

Most of the Regulatory Analyses Monetized the Same Types of Benefits and Costs

Seven of the 11 EO 13771 EPA and HHS rules we reviewed—three EPA, two FDA, and two CMS rules—included provisions that modified previously finalized rules.[21] For these seven rules and most of the rules they modified, we found that agencies monetized anticipated industry costs or cost savings due to changes in compliance or information reporting requirements. For the two FDA EO 13771 rules and the rules they modified, FDA also monetized benefits and costs associated with projected changes in health outcomes. EPA and CMS also qualitatively described, but did not monetize or quantify, potential health, environmental, and other effects in analyses for a subset of rules we reviewed and rules they modified. OMB requires agencies to monetize or quantify the important effects of rules, whenever possible, or to qualitatively describe those effects. Assessing important effects similarly for related rules—such as EO 13771 rules and those they modified—can help achieve analytical consistency and help decision makers and the public better understand the effects of agencies' proposed changes to regulations.

EPA

For rules we reviewed and rules they modified, EPA monetized the anticipated costs or cost savings of complying with regulatory requirements and discussed other effects qualitatively. For example, EPA's December 2019 Risk Management Program rule and the rule it modified both monetized costs or cost savings associated with developing

[21]Of these seven rules, four are EO 13771 deregulatory actions, and three are EO 13771 regulatory actions. These EO 13771 determinations are based on whether or not a rule is expected to have net cost savings. Our review focused on the provisions that modified prior rules and for which agencies monetized estimated costs or benefits. Generally, estimating benefits and costs in monetary terms allows for the comparison of different types of benefits and costs in the same units and the calculation of net benefits (i.e., benefits minus costs) for comparing alternatives. Our review of prior rules focused on provisions modified by rules we selected for review. See appendix II for a complete summary of the rules we reviewed, including their EO 13771 classifications, and rules they modified.

risk management programs and holding public meetings. The 2019 rule removed some risk management program requirements established by the earlier, modified rule, thereby reducing estimated compliance costs. Table 1 summarizes the benefits and costs EPA monetized in its regulatory analysis for each rule we reviewed and each rule they modified.

Table 1: Benefits and Costs the Environmental Protection Agency (EPA) Monetized for Reviewed Rules and the Rules They Modified

	Federal Register citation		Monetized benefits and costs		
Reviewed rule provisions	**Reviewed rule**	**Modified rule**	**Reviewed rule only**	**Modified rule only**	**Both reviewed rule and modified rule**
Chemical data reporting requirements under the Toxic Substances Control Act	85 Fed. Reg. 20122 (Apr. 9, 2020)	76 Fed. Reg. 50816 (Aug. 16, 2011)	None	None	Rule familiarization, industry compliance costs, agency administrative costs
Risk management programs for accidental chemical releases under the Clean Air Act	84 Fed. Reg. 69834 (Dec. 19, 2019)	82 Fed. Reg. 4594 (Jan. 13, 2017)	None	None	Rule familiarization, industry compliance costs, information availability
Addition of other treated railroad ties to list of categorical non-waste fuels	83 Fed. Reg. 5317 (Feb. 7, 2018)	76 Fed. Reg. 15456 (Mar. 21, 2011)	Rule familiarization, industry compliance costs	Not applicable[a]	Not applicable

Source: GAO analysis of selected and modified EPA rules and regulatory analyses. | GAO-21-151

[a]EPA did not conduct a discrete regulatory analysis for this rule. According to EPA officials, EPA considered the effects of this rule when assessing the effects of rules it promulgated at the same time but those effects cannot be disaggregated for our review.

EPA analyses for rules we reviewed also qualitatively described effects it did not monetize or quantify. EPA similarly qualitatively described but did not monetize those effects in analyses of modified rules. According to *Circular A-4* and agency guidance, agencies are to qualitatively describe or quantify benefits and costs when those effects cannot be monetized.

In its April 2020 Chemical Data Reporting rule, which modifies data reporting requirements for manufacturers of certain chemical substances, EPA stated that it anticipates the modifications will provide EPA and the public with additional and higher-quality information for evaluating chemical risks. The agency described these effects on information availability and quality in its regulatory analyses for the 2020 rule and the 2011 rule it modified. Similarly, the agency stated it was unable to

quantify the potential increase in probability of chemical accidents occurring due to the 2019 Risk Management Program rule. The 2017 rule it modified also described, but did not monetize, the anticipated decrease in chemical accidents due to the original provisions.

We were unable to compare the regulatory analyses for EPA's 2018 Other Treated Railroad Ties rule and the 2011 rule it modified because EPA did not conduct a discrete regulatory analysis for the 2011 rule.[22] The 2011 rule established a process for determining which nonhazardous secondary materials should be considered solid waste when used as fuels or ingredients in combustion units. The final rule stated that the agency assessed the effects of the rule when developing analyses for related rules finalized at the same time. Costs to the regulated community and benefits to human health and the environment were captured in those related analyses, according to the final rule.

The 2018 rule reclassifies certain railroad ties as nonwaste fuels. In doing so, EPA projects industry will no longer incur costs associated with either landfilling railroad ties and purchasing alternative fuels, or processing the ties in accordance with the Clean Air Act. EPA also qualitatively discussed potential cost savings due to entities not using fossil fuels for combustion. The agency stated it did not assess overall health and environmental effects of the rule and such effects could be positive or negative.

FDA

FDA estimated that both of the rules we reviewed, which delayed the implementation dates of nutrition and food safety rules, would result in the same compliance and health effects as the original rules but reduce the magnitude of those effects.[23] Table 2 summarizes the benefits and costs FDA monetized in its regulatory analysis for each rule we reviewed and each rule it modified.

[22]Additions to List of Categorical Non-Waste Fuels: Other Treated Railroad Ties. 83 Fed. Reg. 5317 (Feb. 7, 2018). Identification of Non-Hazardous Secondary Materials That Are Solid Waste. 76 Fed. Reg. 15456 (Mar. 21, 2011).

[23]Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably be Consumed at One Eating Occasion; Dual Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates. 83 Fed. Reg. 19619 (May 4, 2018); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E. 84 Fed. Reg. 9706 (Mar. 18, 2019).

Table 2: Benefits and Costs the Food and Drug Administration (FDA) Monetized for Reviewed Rules and the Rules They Modified

	Federal Register citation		Monetized benefits and costs		
Reviewed rule provisions	**Reviewed rule**	**Modified rule(s)**	**Reviewed rule only**	**Modified rule only**	**Both reviewed rule and modified rule**
Nutrition facts labels and serving sizes	83 Fed. Reg. 19619 (May 4, 2018)	81 Fed. Reg. 33742 (May 27, 2016)	None	None	Industry compliance costs, consumer health benefits
—	—	81 Fed. Reg. 34000 (May 27, 2016)	None	None	See above[a]
Agricultural water requirements for certain produce	84 Fed. Reg. 9706 (Mar. 18, 2019)	80 Fed. Reg. 74354 (Nov. 27, 2015)	None	None	Industry compliance costs, consumer health benefits

Source: GAO analysis of selected and modified FDA rules and regulatory analyses. | GAO-21-151

[a]FDA published a combined regulatory impact analysis for the two modified food labeling rules. As such, the monetized effects for both of the modified rules are the same.

FDA estimated that delaying these compliance dates would reduce the overall magnitude of both the industry costs and health benefits relative to the modified rules.[24] The cost savings (i.e., the reduced industry costs) associated with these rules included a delay in having to (1) relabel and reformulate products in accordance with the 2016 Nutrition Facts Label and Serving Size rules, and (2) test untreated ground agricultural water used to grow certain produce in accordance with the 2015 Standards for Growing, Harvesting, Packing, and Holding of Produce for Human

[24]Both FDA rules we reviewed are classified as EO 13771 deregulatory actions because the agency estimated both would result in cost savings using EO 13771 accounting requirements. The agency did not include the estimated annualized reduction in health benefits to consumers for each rule ($80 million for the 2018 food labeling rule, in 2016 dollars, and $96 million for the 2019 agricultural water rule, in 2017 dollars) in its EO 13771 calculations. FDA's estimates show that the 2018 rule would result in overall cost savings and the 2019 rule would result in overall costs when considering the monetized foregone health benefits. According to FDA officials, the agency considers economic effects it classifies as costs and cost savings (e.g., industry compliance costs) and does not consider public health benefits in its EO 13771 accounting, consistent with OMB guidance for EO 13771 accounting.

Consumption rule.[25] The reduced benefits—in this case, health benefits for consumers—were associated, in part, with delaying a reduction in the risk of illness from contaminated agricultural water that was anticipated to occur from implementing the 2015 rule.

CMS

Both CMS rules we reviewed, and two of four rules it modified, monetized costs associated with medical providers submitting information for agency quality assurance processes. Table 3 summarizes the benefits and costs CMS monetized in its regulatory analysis for each rule we reviewed and each rule they modified.

Table 3: Benefits and Costs the Centers for Medicare & Medicaid Services (CMS) Monetized for Reviewed Rules and the Rules They Modified

	Federal Register citation		Monetized benefits and costs		
Reviewed rule provisions	**Reviewed rule**	**Modified rule(s)**	**Reviewed rule only**	**Modified rule only**	**Both reviewed rule and modified rule**
Medicare Home Health Quality Reporting Program	84 Fed. Reg. 60478 (Nov. 8, 2019)	71 Fed. Reg. 65884 (Nov. 9, 2006)	Information collection requirements	None	None
Medicare End-Stage Renal Disease Quality Incentive Program	83 Fed. Reg. 56922 (Nov. 14, 2018)	82 Fed. Reg. 50738 (Nov. 1, 2017)	None	None	Provider information reporting costs
—	—	81 Fed. Reg. 77834 (Nov. 4, 2016)	Provider information reporting costs	None	None
—	—	79 Fed. Reg. 66120 (Nov. 6, 2014)	None	None	Provider information reporting costs[a]

Source: GAO analysis of selected and modified CMS rules and regulatory analyses. | GAO-21-151

[a]The Medicare End-Stage Renal Disease Quality Incentive Program 2018 rule removed two reporting measures originally introduced in the 2014 rule. The rule we selected for review monetized the cost savings associated with removing one of those two measures. The rule it modified monetized the costs associated with reporting the other measure. As a result, CMS calculated the same effect for the rule we reviewed and the rule it modified, but it calculated the effect for different provisions.

[25]Food Labeling: Revision of the Nutrition and Supplement Facts Labels. 81 Fed. Reg. 33742 (May 27, 2016); Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments. 81 Fed. Reg. 34000 (May 27, 2016); and Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. 80 Fed. Reg. 74354 (Nov. 27, 2015).

The two CMS rules we reviewed removed quality measures and amended a data quality assurance process for Medicare Home Health and End-Stage Renal Disease programs.[26] CMS updates these regulations annually and, in its Home Health and End-Stage Renal Disease rules finalized in 2019 and 2018, respectively, removed the quality measures as part of its Meaningful Measures Initiative. This initiative is part of CMS' efforts to implement EO 13771, according to CMS officials.[27] CMS did not monetize the effect of originally adding one of these measures to the Home Health program in 2006.

According to CMS officials, the agency calculated the associated provider cost when it originally developed the measure in 1998. In the other instance where CMS did not monetize the cost of provider information reporting, officials explained that CMS does not always monetize the effect of each provision it adds or removes in a given year, but the following year's estimate of industry burden reflects any program changes.

In addition to monetizing effects on industry, CMS qualitatively discussed some anticipated effects for rules we reviewed and rules they modified. For example, in its 2019 Home Health rule, CMS explained that it was removing a measure related to patient pain levels to reduce the unintended overprescription of opiates. When an agency does not monetize effects of a rule, this type of qualitative description of any anticipated costs or benefits can help the public better understand the agency's basis for finalizing the rule.

[26]Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements. 84 Fed. Reg. 60478 (Nov. 8, 2019). Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS. 83 Fed. Reg. 56922 (Nov. 14, 2018). See appendix II for more information on the modified CMS rules. We refer to CMS rules by the fiscal year in which they were finalized in the *Federal Register*. CMS refers to these annual rules by their effective year, which is the calendar year subsequent to final rule publication.

[27]According to CMS officials in February 2020, the agency had eliminated an estimated 18 percent of all industry-reported performance measures since starting the Meaningful Measures Initiative, with an estimated savings of $128 million and 3.3 million burden hours through 2020.

Changes in Analytical Assumptions Led to Some Benefit and Cost Estimates for EO 13771 Rules Differing from Modified Rules

While the regulatory analyses for the EO 13771 rules we reviewed generally monetized similar types of benefits and costs as the rules they modified, the values of some estimates differed. Values differed, in part, because agencies accounted for updates or changes in important assumptions in their analyses. Updating such information for new regulatory analyses and using similar analytical methods as for prior related rules can provide a more current assessment of a rule's effects for decision makers and the public, while ensuring analytical consistency. We identified several types of assumptions updated by agencies:

- **Wages.** Agencies used wage data to estimate the cost of time spent by industry personnel and agency staff to comply with regulations. For example, in its 2011 chemical data reporting rule, EPA estimated industry compliance costs, in part, by using industry-specific wage data from the Bureau of Labor Statistics and industry data submitted to EPA in 2002.

  EPA calculated wage rates in the 2020 chemical data reporting rule using the same sources, but using more recent Bureau of Labor Statistics data. As a result, EPA estimated the hourly wage of managerial workers at $48.73 in the 2020 rule and $43.22 in the 2011 rule (in 2018 and 2008 dollars, respectively).

- **Demographics.** To accurately estimate the number of entities that will be subject to a regulation, agencies referred to various demographic data. For example, in the 2020 and 2011 chemical data reporting analyses described above, EPA estimated the baseline number of entities that would be affected by the rule's provisions using data from an internal chemical data reporting database.

  However, in developing its analysis for the 2020 rule, EPA found that the number of affected entities had grown by approximately 1,600 since 2011, thereby increasing the magnitude of projected compliance costs.

- **Expansion of regulatory scope.** When modifying regulations, agencies may change regulatory requirements to expand the number of entities subject to those requirements. As a result, the scope of provisions the agency monetizes in one rule will differ from the original rule and generate different magnitudes of benefits or costs.

  For example, in its 2018 and 2017 End-Stage Renal Disease rules, CMS used the same wage data and time estimates to calculate the industry cost associated with submitting information to ensure data quality. However, the 2018 rule changed the scope of the data validation process. As a result, the number of entities required to

submit data and the amount of data required for submission both increased, thereby increasing the magnitude of costs associated with this provision.

HHS, EPA, and OMB documentation describe important variables that may necessitate that agencies update their assumptions for calculating economic effects over time, such as societal changes, economic growth, and technological advancements. For example, changing trends related to morbidity and mortality may necessitate that HHS update assumptions for analyzing the potential impacts of regulatory interventions related to health care.

Additionally, OMB's *Circular A-4* directs agencies to use the best available scientific, technical, and economic information when conducting their regulatory analyses. If new scientific data indicates the rate of emissions from a certain process is higher or lower than previously understood, for example, a new economic analysis for a rule affecting that process should reflect this new information. EPA's guidelines also describe the importance of establishing a new baseline for each regulatory analysis based on the current regulatory economy. Likewise, according to EPA officials, updates in scientific and technical information limit the usefulness of past analyses as a basis for estimating the effects of new rules.

Analyses for Which Monetized Costs Exceeded Benefits Met Several Best Practices, but CMS Partially Assessed Some Effects of Regulations

Regulatory analyses for the eight EO 13771 rules we reviewed—three EPA, one FDA, and four CMS—for which monetized costs exceeded monetized benefits met about half of the selected best practices for key elements of economic analysis related to Methodology, Scope and Analysis, and Transparency identified in our Assessment Methodology, though our assessments varied by agency.[28] Each analysis identified nonmonetized factors that may have influenced decision-making, such as non-quantified effects and the need to meet statutory requirements. This Assessment Methodology synthesizes concepts from a wide range of documents—including OMB circulars—on how economic analysis should be performed and provides a framework for assessing regulatory analyses. Using the Assessment Methodology, we assessed the analyses

[28]GAO-18-151SP. The key elements and best practices identified in our Assessment Methodology are not intended to be exhaustive or supplant or alter relevant federal and agency requirements for economic analysis. They simply serve to establish a sound framework for the assessment of economic analysis. For the purposes of our reporting, we use the "scope and analysis" category to present information on one selected best practice related to the "Objectives and Scope" key element and four selected best practices related to the "Analysis of Effects" key element.

for eight rules against nine selected best practices. A quality regulatory analysis consistent with these best practices can provide decision makers with important information needed to assess whether a rule's total benefits, including nonmonetized benefits, are likely to justify the total costs.

The annualized net monetized costs in the rules we reviewed ranged in magnitude from about $2 million for an EPA rule for mercury reporting requirements to about $220 million for the CMS rule finalizing revisions to patient discharge requirements for hospitals and home health agencies.[29] For rules we reviewed that contained multiple, distinct provisions, we did not assess analyses of provisions for which the agency did not identify monetized benefits or costs. None of the analyses we reviewed met all selected best practices.

EPA Analyses Met or Partially Met at Least Eight of Nine Selected Best Practices

EPA's analyses for the three significant rules we reviewed either met or partially met all of the selected best practices related to methodology as well as to scope and analysis. Two rules did not meet one of the best practices related to transparency; specifically, the best practice for quantifying how statistical variability affected estimates (see table 4). Although the EPA analyses we reviewed did not fully meet some selected best practices, it is unlikely that more rigorous analyses would have benefited EPA decision makers given that these rules were not determined to be economically significant. Therefore, more rigorous analyses may not have justified the additional resources required to conduct those analyses.

[29]Mercury; Reporting Requirements for the TSCA Mercury Inventory. 83 Fed. Reg. 30054 (June 27, 2018). Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care. 84 Fed. Reg. 51836 (Sept. 30, 2019).

Table 4: Assessment of Reviewed Environmental Protection Agency (EPA) Regulatory Analyses against Selected Elements and Best Practices for Economic Analysis

	Rule provisions		
Elements and best practices	Chemical data reporting requirements under the Toxic Substances Control Act	Reporting requirements for the Toxic Substances Control Act mercury inventory	Effluent limitations guidelines and standards for the dental category
Methodology			
Examining effects by comparing alternatives, using one as a baseline, unless otherwise justified	◓	◓	●
Scope and analysis			
Assessing important effects to the extent feasible	◓	◓	●
Using the concept of opportunity cost to monetize effects	●	●	●
Comparing alternatives using an appropriate outcome measure	●	◓	◓
Controlling for inflation and using appropriate discount rates	●	●	●
Focusing on effects that accrue to U.S. citizens and residents and using an appropriate time horizon	◓	◓	◓
Transparency			
Describing and justifying analytical choices, assumptions, and data used	●	●	●
Explaining implications of key limitations	◓	●	●
Quantifying how statistical variability affected estimates	○	○	●

Legend: ● = Met; ◓ = Partially met; ○ = Not met.

Source: GAO analysis of EPA data. | GAO-21-151

Consistent with our selected best practice for methodology, EPA's analysis for one rule examined effects by comparing alternatives, using one as a baseline.[30] EPA's analysis for two rules that revised reporting requirements for the Toxic Substances Control Act partially met this best practice because the agency analyzed one alternative for each rule, a "no-action" baseline representing the benefits and costs that would occur if the rule were not finalized.

Circular A-4 clarifies that agencies should consider appropriate and reasonable alternative approaches that may vary in terms of regulatory stringency, compliance dates, and enforcement methods, though the

[30]We did not assess whether baselines used for agency analyses were appropriate. Circular A-4 provides a framework agencies can use to develop appropriate baselines.

number of alternatives considered is ultimately up to the agency's discretion. EPA officials told us the agency considered only a "no-action" baseline alternative for the mercury inventory rule because the agency's planned regulatory approach was required by statute. According to agency officials, for that rule, the agency did not consider alternatives that would either have fallen short or exceeded the statute's requirements. *Circular A-4* states that agencies should describe the extent of regulatory discretion available to them if a rule results from a statutory directive. It also states that agencies should explore alternative regulatory approaches to the extent practical. However, given that both data reporting requirement rules are expected to impose annualized net costs of less than $3 million each, it is unlikely that analyzing other alternatives would have enabled EPA to identify opportunities that would have significantly reduced those net costs.

All three of EPA's analyses met two selected best practices for scope and analysis: (1) using the concept of opportunity cost to monetize effects, and (2) controlling for inflation and using appropriate discount rates. Each EPA analysis partially met at least two other best practices for scope and analysis:

- **Assessing important effects, to the extent feasible.** Our Assessment Methodology recommends that agencies quantify important economic effects where feasible. Where important effects cannot be quantified, it also recommends that agencies explain how they affect the comparison of alternatives. For the two rules that revised EPA chemical data reporting requirements for the Toxic Substances Control Act, EPA states that each rule will have benefits that are not quantified, such as improving information available on risks posed by toxic substances and informing efforts to mitigate these risks.

  In its analyses, however, EPA did not assess the importance of some of these potential effects. Similar to our Assessment Methodology, OMB guidance states that agencies should provide information on the key reasons why important effects cannot be quantified and provide relevant information, such as information about the likelihood, timing, and magnitude of nonquantified effects. Given that EPA finalized both these rules in response to statutory requirements and did not assess alternative regulatory approaches for either rule other than a no-action baseline, it is unlikely that more thorough assessments of nonquantified effects would have led the agency to choose a different regulatory approach.

- **Comparing alternatives using an appropriate outcome measure.** While all three analyses calculated and presented estimates using an appropriate outcome measure (net present value, annualized value, or a cost-effectiveness ratio), two analyses partially met this best practice because they did not compare these estimates across alternatives other than no-action baselines.[31]

  For example, EPA's analysis of the dental effluent limitation standards rule did not use an appropriate outcome measure to assess effects across alternative standards the agency considered, though EPA qualitatively explained why the agency's chosen regulatory approach was preferable to these alternatives.[32] Similarly, EPA's analyses for the mercury data reporting requirement rule did not assess alternatives other than a no-action baseline, though as noted above, it is not clear that assessing alternatives would have enabled the agency to identify better regulatory options.

- **Focusing on effects that accrue to U.S. citizens and residents and using an appropriate time horizon.** We found that analyses for all three rules focused on economic effects that accrue to U.S. citizens and residents. Our Assessment Methodology also recommends agencies calculate economic effects across a time horizon long enough to encompass a rule's important economic effects. OMB guidance for implementing EO 12866 states that 10 to 20 years is a standard time horizon for most agencies. In addition, OMB guidance for implementing EO 13771 generally requires that agencies use a perpetual time horizon for EO 13771 accounting purposes.[33] Because our Assessment Methodology is not intended to supplant EO requirements for economic analysis, we assessed whether analyses calculated effects using perpetual time horizons. For analyses that did not, we determined that these analyses partially met this best practice if they used time horizons long enough to

[31]Annualized benefits and costs represent the amortized value over the analysis period of the present value amounts. Under EO 13771, OMB has generally directed agencies to compute costs and cost savings in annualized or present value terms, over a perpetual time horizon, to ensure consistent and comparable accounting of costs and cost savings.

[32]Effluent Limitations Guidelines and Standards for the Dental Category. 82 Fed. Reg. 27154 (June 14, 2017).

[33]OMB guidance for implementing EO 13771 does not address whether agencies should publicly report EO 13771 calculations for individual rules. However, we reviewed analyses for this information because these calculations are used to assess agencies' compliance with EO 13771 and because analytical transparency is a key element of regulatory analysis. EPA has included this information in analyses for some EO 13771 rules, although not for the rules we reviewed.

encompass important economic effects. While analyses for none of the three rules calculated economic effects using a perpetual time horizon, we found that they did calculate benefits and costs across time horizons long enough to encompass important economic effects.

EPA analyses for all three rules met one or more of the selected best practices for transparency. In fact, analyses for all three rules met the best practice for describing and justifying analytical choices, assumptions, and data used. However, analyses for EPA's revisions to both chemical data reporting requirements and mercury reporting requirements did not quantify how statistical variability affected estimates.

EPA officials told us that they generally perform less rigorous analyses for rules that are not economically significant compared to those that are. Consistent with this approach, OIRA officials have previously told us that OIRA expects rules with greater economic effects to have more thorough assessments of benefits and costs than those expected to have lesser economic effects.[34] According to OIRA officials, this is because agencies must balance analytical rigor with resource limitations and other constraints.

None of the three EPA rules we reviewed were identified as economically significant by OMB. Specifically, EPA estimates that the chemical data reporting requirement rules would impose annualized net costs of less than $3 million each, while the dental office effluent rule would impose costs of about $55 million. As a result, it is unlikely that more rigorous analysis would have generated sufficient, additional information to both the public and agency decision makers to justify the additional resources.

FDA's Analysis Met or Partially Met Selected Best Practices

FDA's analysis for one economically significant rule that delayed agricultural water requirements for certain produce met the selected best practice for methodology as well as three best practices for scope and analysis, although it did not did not separately assess effects that potentially accrue beyond U.S. borders. In addition, FDA met one and partially met two selected best practices for transparency (see table 5). According to FDA, the agency delayed implementation of the agricultural water requirements to allow the agency additional time to respond to concerns surrounding the practicality of certain requirements. As a result, it is unlikely that fully meeting all selected best practices would have

[34]GAO, *Federal Rulemaking: Agencies Included Key Elements of Cost-Benefit Analysis, but Explanations of Regulations' Significance Could be More Transparent*, GAO-14-714 (Washington, D.C: Sept. 11, 2014).

provided sufficient, additional information to have altered the agency's decision-making.

Table 5: Assessment of Reviewed Food and Drug Administration (FDA) Regulatory Analysis against Selected Elements and Best Practices for Economic Analysis

	Rule provision
Elements and best practices	Agricultural water requirements for certain produce
Methodology	
Examining effects by comparing alternatives, using one as a baseline, unless otherwise justified	●
Scope and analysis	
Assessing important effects to the extent feasible	N/A
Using the concept of opportunity cost to monetize effects	●
Comparing alternatives using an appropriate outcome measure	●
Controlling for inflation and using appropriate discount rates	●
Focusing on effects that accrue to U.S. citizens and residents and using an appropriate time horizon	◓
Transparency	
Describing and justifying analytical choices, assumptions, and data used	●
Explaining implications of key limitations	◓
Quantifying how statistical variability affected estimates	◓

Legend: ● = Met; ◓ = Partially met; ○ = Not met; N/A = Not applicable.

Source: GAO analysis of FDA data. | GAO-21-151

Consistent with our selected best practice for methodology, FDA's analysis examined effects by comparing alternatives, using one of them as a baseline. FDA considered four alternative regulatory approaches that varied in terms of the scope of regulatory requirements whose effective dates would be delayed by the final rule.

FDA's analysis met three selected best practices for scope and analysis, and partially met the selected best practice of focusing on effects that accrue to U.S. citizens and residents and using an appropriate time horizon. Specifically, we found that FDA's analysis of delays to certain agricultural water requirements for produce acknowledged the rule would affect both foreign and domestic entities. *Circular A-4* guidance clarifies that agencies should report effects that accrue to U.S. citizens and residents separately from those that accrue beyond U.S. borders. FDA's

analysis did not report effects expected to accrue beyond U.S. borders separately, but did note that FDA did not expect the rule to have any significant effects on international trade.

With regard to transparency, FDA's analysis described and justified the analytical choices, assumptions, and data used. The agency partially met the selected best practice for explaining implications of key limitations. Specifically, FDA's analysis noted reasons why it may both overstate health benefits to society and costs to industry in complying with the rule. However, FDA did not analyze the implications of these limitations for estimated benefits and costs of other identified alternatives.

FDA also partially met the selected best practice for quantifying how statistical variability affected estimates because, although FDA developed a quantitative sensitivity analysis for its chosen regulatory approach, it did not develop similar analyses for alternative regulatory approaches. However, it is unlikely that fully meeting this or other selected best practices would have led FDA to pursue a different regulatory approach. This is because FDA primarily delayed certain agricultural water requirements due to considerations other than those assessed in the agency's regulatory analysis, such as potential foregone health benefits and industry compliance costs.

CMS Analyses Met about Half of the Best Practices, but Some Did Not Fully Assess Effects

CMS's analyses for four economically significant rules met some selected best practices, and either partially met or did not meet others, as shown in table 6. For example, analyses for two rules did not assess effects across alternatives other than a no-action baseline; analyses for three did not fully meet at least two best practices for scope and analysis, including assessing important effects to the extent feasible; and no analyses fully met the transparency best practice of quantifying how statistical variability affected estimates. It is particularly important that agencies develop high-quality regulatory analyses for economically significant rules. Because CMS analyses we reviewed did not meet these best practices, the public may not have been fully informed of the rules' potential benefits and costs, and decision makers may have lacked information needed to assess whether planned regulatory approaches were more cost beneficial than potential alternatives.

Table 6: Assessment of Reviewed Centers for Medicare & Medicaid Services (CMS) Regulatory Analyses against Selected Elements and Best Practices for Economic Analysis

	Rule provisions			
Elements and best practices	Home Health Quality Reporting Program	End-Stage Renal Disease Quality Incentive Program	Appropriate use criteria for imaging services and changes to Medicare Diabetes Prevention Program	Discharge planning requirements for hospitals and home health agencies
Methodology				
Examining effects by comparing alternatives, using one as a baseline, unless otherwise justified	●	◓	◓	●
Scope and analysis				
Assessing important effects to the extent feasible	◓	◓	◓	●
Using the concept of opportunity cost to monetize effects	●	●	●	●
Comparing alternatives using an appropriate outcome measure	◓	●	○	◓
Controlling for inflation and using appropriate discount rates	◓	◓	○	●
Focusing on effects that accrue to U.S. citizens and residents and using an appropriate time horizon	●	●	◓	●
Transparency				
Describing and justifying analytical choices, assumptions, and data used	◓	●	●	●
Explaining implications of key limitations	◓	●	●	◓
Quantifying how statistical variability affected estimates	○	○	◓	◓

Legend: ● = Met; ◓ = Partially met; ○ = Not met.

Source: GAO analysis of CMS data. | GAO-21-151

Two of four analyses for economically significant rules we reviewed met our selected best practice under methodology because they considered multiple, alternative regulatory approaches. Two other analyses partially met this best practice because they considered only a no-action baseline for at least one provision we reviewed and did not justify why additional alternatives were not considered. For example, for one rule, CMS identified and examined the effects of alternatives to a provision that made changes to the Medicare Diabetes Prevention Program.

However, CMS did not identify alternatives for another provision of the rule that established requirements for clinicians in consulting diagnostic

imaging services. CMS estimated this provision would increase compliance costs by about $296 million per year.[35] For a second rule, CMS did not consider alternative regulatory approaches other than a no-action baseline to a provision that modified performance measures for CMS's End-Stage Renal Disease Quality Incentive Program, which CMS estimated would generate about $5.5 million in annualized net costs across a perpetual time horizon.

CMS officials told us the agency may consider analyzing its chosen regulatory approach against a no-action baseline when the agency believes no other reasonable alternatives would fulfill the intent of the regulation. CMS's analyses for these provisions do not discuss or document the extent to which other alternatives available to the agency may or may not have fulfilled the intent of the regulation.

In its internal *Guidelines for Regulatory Impact Analysis,* HHS recognizes that agencies may sometimes be constrained in their consideration of alternatives. However, similar to our Assessment Methodology, HHS's guidelines also state any such limitations should be explicitly noted in an agency's regulatory analysis. CMS could more fully align its regulatory analyses with our selected best practice for methodology by assessing alternative regulatory approaches or explaining its reasons for not doing so.

Under the element of scope and analysis, CMS's analyses for each of the four CMS rules we reviewed used the concept of opportunity cost to monetize benefits and costs, but either partially met or did not meet at least one of the other four selected best practices.

- **Assessing important effects to the extent feasible.** Analyses for three rules did not explain why certain effects could not be quantified or how they might affect the comparison of alternatives. In its analysis of finalized requirements for clinicians in consulting diagnostic imaging services, CMS stated that the appropriate use criteria could assist clinicians in selecting imaging services that are most likely to improve health outcomes for patients based on their individual clinical presentations. However, the agency's analysis did not address why these benefits could not be quantified or assess the importance of

[35]Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. 82 Fed. Reg. 52976 (Nov. 15, 2017).

these benefits. Similarly, in its analysis of revisions to reporting measures for the End-Stage Renal Disease Quality Incentive Program, CMS stated that adopting a new medication reconciliation reporting measure would improve health outcomes for patients at dialysis facilities. The analysis provided contextual information on the magnitude of medication-related problems at dialysis facilities, but did not explain why CMS was unable to quantify the potential benefits of its planned changes.

- **Comparing alternatives using an appropriate outcome measure.** CMS's analysis for the rule that established appropriate use criteria for imaging services and made changes to the Medicare Diabetes Prevention Program did not meet this best practice. Although CMS's analysis for these provisions presented estimated net costs in annual terms over a 10-year period, the agency did not express these net costs in present value or annualized terms.

  Analyses for two rules partially met this best practice because they estimated the net costs of planned regulatory approaches relative to the baseline in annualized terms. However, the analyses did not compare annualized net costs with the estimates for other alternatives.

- **Controlling for inflation and using appropriate discount rates.** CMS's analysis for the rule that established imaging requirements and made changes to the Medicare Diabetes Prevention Program did not meet this best practice because the analysis did not provide sufficient information for us to determine whether CMS both (1) controlled for inflation by expressing benefits and costs in "real" terms and (2) used appropriate discount rates. For example, OMB guidance directs agencies to discount benefits and costs using both 3 percent and 7 percent rates.[36] For this rule, agency officials told us information provided to OIRA identified estimates developed using both discount rates, but the information is not in the agency's analysis.

  Analyses for two additional rules partially met this best practice because they controlled for inflation but presented estimates using only the 7 percent discount rate. According to CMS, the agency calculated effects for the Home Health Quality Reporting Program rule

[36]Benefits, costs, and discount rates expressed in real terms exclude the influence of inflation; those in nominal terms include the influence of inflation. Real benefits and costs are typically used to avoid the misleading effects of inflation. OMB *Circular A-4* directs agencies to use 3 percent and 7 percent in regulatory analyses. In addition, under EO 13771, OMB guidance directs agencies to compute costs and cost savings in annualized or present value terms, using a 7 percent discount rate and, unless otherwise justified, a perpetual time horizon.

using only the 7 percent discount rate based on HHS's and OMB's guidelines, which state that 7 percent should be the base measure. However, *Circular A-4* states that estimates should be calculated using both rates.

- **Focusing on effects that accrue to U.S. citizens and residents and using an appropriate time horizon.** CMS's analysis for appropriate use criteria for imaging services and changes to the Medicare Diabetes Prevention Program partially met this best practice because it did not calculate economic effects using a perpetual time horizon as generally required for EO 13771 accounting purposes.

With regard to the element of transparency, each CMS analysis partially met or did not meet at least one selected best practice. Our Assessment Methodology recommends analyses explain the implications of key limitations in the data used. Analyses for both the Home Health Quality Reporting Program and discharge planning requirement rules partially met this best practice because, although they provided some documentation of the quality of data used, these analyses did not document or discuss the extent to which limitations may or may not affect CMS's analysis.

All four CMS analyses either did not meet or partially met the selected best practice for quantifying how statistical variability of key data elements affected estimates because they either did not develop such analysis or did not use them to compare effects across alternatives. Officials told us they did not conduct sensitivity analyses for two rules because they were unable to identify alternative assumptions that could be applied. In its analyses for these rules, CMS did not discuss rationales for not conducting sensitivity analyses.

OMB and HHS guidance acknowledge that there must be a balance between analytical thoroughness and the practical limits of an agency's analytical capacity. Consistent with this approach, OIRA has previously told us it allows agencies to apply a rule of reason to determine whether it is appropriate to exclude certain aspects of regulatory analysis depending on resource limitations, data limitations, and sometimes, prohibitive statutory language.[37]

While OMB recognizes the need for flexibility in conducting regulatory analysis, OMB has also emphasized the importance of achieving a high

[37]GAO-14-714.

degree of transparency in methods and information.[38] Our Assessment Methodology likewise notes that an important benefit of a high-quality analysis is that the decision makers and the public can assess the structure of an analysis and the specific choices made by the authors. Analytical transparency and clear justifications for other methodological and scoping decisions are particularly important when analyzing the benefits and costs of rules expected to have economically significant effects on society. Without this information, decision makers and the public may not be sufficiently informed about the potential effects of planned regulations.

Conclusions

As federal agencies take regulatory actions to help achieve national goals, they strive to limit unnecessary regulatory burden. To do so, it is important that agencies develop high-quality regulatory analyses that provide decision makers with information needed to determine if the benefits of an action are likely to justify the costs.

We found that agencies generally monetized the same types of benefits and costs for the rules we reviewed and the rules they modified. We further found that differences in the values of some effects were attributable to updated analytical assumptions, such as changes to wages and regulatory scope. To the extent reasonable, efforts to identify similar effects and achieve reasonable analytical consistency between related new and existing rules, including through analyses of similar types of effects, can help decision makers and the public better understand the effects of agencies' proposed changes in regulations.

While we found that agency analyses we reviewed met some selected best practices for economic analysis, we also identified opportunities for CMS to improve its analyses of alternative regulatory approaches, assessments of important effects, and analytical transparency by applying best practices more fully.

Until CMS takes steps to ensure future analyses are consistent with best practices, the agency may be missing an opportunity to provide the public and other parts of government with important information about the agency's rationale for key decisions in analyzing rules' benefits and costs. Doing so could better ensure these groups have information necessary to

[38]OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 5365 (Feb. 5, 2002).

provide CMS with critical feedback that can be used to improve its regulatory approaches, mitigate potential conflict with entities affected by rules, and reduce costs associated with delays or litigation. Moreover, it could help ensure that agency decision makers have information needed to reassess existing rules to reduce regulatory burden, meet EO 13771 requirements, and make reasonable determinations that a given rule's benefits are likely to justify the costs.

Recommendation for Executive Action

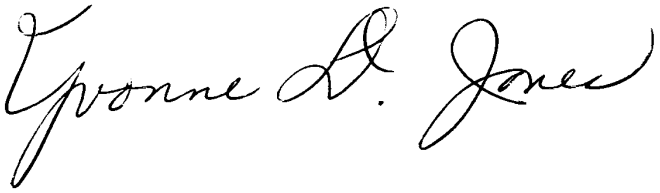
The Administrator of the Centers for Medicare & Medicaid Services should take steps to ensure future regulatory analyses are consistent with best practices, particularly with regard to (1) analyzing alternatives, (2) assessing important effects, and (3) ensuring analytical transparency. (Recommendation 1)

Agency Comments

We provided a draft of this report to HHS, CMS, FDA, EPA, and OMB for review and comment. In written comments provided by HHS and reproduced in appendix III, HHS generally agreed with our findings. CMS concurred with the recommendation directed to it and stated that the agency will develop and issue an agency-wide memo that will provide additional guidance on developing regulatory analyses in accordance with best practices. In written comments reproduced in appendix IV, EPA underscored the importance of regulatory analysis, and said it appreciated GAO's findings. EPA , HHS, and OMB provided technical comments that were incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Health and Human Services, the Administrator of the Centers for Medicare and & Medicaid Services, the Administrator of the Environmental Protection Agency, the Commissioner of Food and Drugs, and the Director of the Office of Management and Budget. In addition, the report will be 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 (202) 512-6806 or Jonesy@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.



Yvonne D. Jones
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Strategic Issues

Appendix I: Objectives, Scope, and Methodology

This report examines the extent to which selected agencies have (1) finalized rules under Executive Order (EO) 13771 that repealed, amended, or delayed existing rules, and how, if at all, the calculated economic effects of those rules differed from the existing rules; and (2) met relevant best practices for economic analysis in their assessments of EO 13771 rules for which the agencies projected that the monetized costs would exceed the monetized benefits.[1]

We selected for our review the Department of Health and Human Services (HHS) and the Environmental Protection Agency (EPA) because these are the two executive branch agencies that finalized the largest number of rules that were economically significant, including at least one regulatory and one deregulatory action, from fiscal year 2017 through fiscal year 2019 that were EO 13771 rules.[2] To select agencies for inclusion in our review, we used data from the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs' (OIRA) regulatory reform reports as well as data from OMB's Reginfo.gov database to identify the agencies that finalized the greatest number of economically significant EO 13771 rules between February 3, 2017, when the executive order went into effect, and September 30, 2019,[3] the most recent data available from OIRA's reports at the time of our review.[4] We

[1]EO 13771, issued on January 30, 2017, requires executive agencies to offset the costs associated with each new regulation by eliminating the costs associated with at least two existing regulations, unless prohibited by law.

[2]OMB defines an EO 13771 regulatory action as a significant regulatory action or guidance document that has been finalized and imposes total costs greater than zero. OMB defines an EO 13771 deregulatory action as an action that has been finalized and has total costs less than zero. In this report, we refer to rules (but not guidance) that meet OMB's definition of EO 13771 regulatory action or EO 13771 deregulatory action as EO 13771 rules. Our review focused on rules, not guidance documents. Office of Management and Budget, *Reducing Regulation and Controlling Regulatory Costs*, M-17-21 (Washington, D.C.: 2017) at 3–4.

[3]Regulations are classified as significant if they result in a $100 million or greater effect on the economy in any given year, raise novel legal or policy issues, or meet certain other criteria. Economically significant actions are the subset of significant rules that are expected to meet the $100 million threshold or have certain other adverse effects, including on the economy, public health, or state, local, or tribal governments.

[4]OIRA prepares annual summaries of executive branch departments' and agencies' compliance with EO 13771 for each fiscal year, beginning with 2017. These reports describe, by agency, the number of final regulatory and deregulatory EO 13771 actions, as well as the aggregate estimated costs or cost savings for those rules.

used OMB's Reginfo.gov database to identify which of the EO 13771 rules were economically significant.[5]

Using OIRA's regulatory reform reports and OMB's Reginfo.gov database, we compiled a list of significant and economically significant EO 13771 rules that EPA and HHS finalized between February 3, 2017, and April 30, 2020. To confirm the completeness and accuracy of the list, we cross-referenced our list with data from three other sources: (1) Reginfo.gov's regulatory review database; (2) information provided to us by HHS and EPA; and (3) our database on major rules submitted under the Congressional Review Act.[6] We concluded that the data were sufficiently reliable for our purposes of identifying selected agencies and rules for review.

In selecting rules for review, we prioritized rules that were economically significant. We excluded rules (1) that would not otherwise be considered economically significant if transfers were excluded from the economic analysis (i.e. remaining benefits or costs were less than $100 million) or (2) were under judicial review at the time of our review.[7] In applying these criteria, all of the economically significant EPA rules were excluded from our review. As a result, we supplemented our selection of EPA rules by randomly selecting rules finalized by EPA between February 3, 2017, and April 30, 2020, that were significant but not economically significant. We reviewed a total of 11 EO 13771 rules. This total included six economically significant HHS rules—two finalized by the Food and Drug Administration (FDA) and four finalized by the Centers for Medicare & Medicaid Services (CMS). It also included five significant EPA rules.[8] While these 11 rules provide insights into specific rulemaking processes

[5]OIRA's regulatory reform reports do not identify whether the EO 13771 rules are economically significant.

[6]A major rule is one that, among other things, has resulted in or is likely to result in an annual effect on the economy of $100 million or more. This is similar, but not identical to, the definition of an economically significant rule under EO 12866. The Congressional Review Act generally requires agencies to submit rules to both Houses of Congress and the U.S. Comptroller General before the rules can become effective. 5 U.S.C. § 801(a)(1)(A).

[7]Transfers are monetary payments that shift resources from one party to another, such as payments from the government to private entities. Transfers do not change the total resources available to society.

[8]We originally selected one economically significant EPA rule for review but excluded it after it came under judicial review during our review.

and procedures that form the basis of our report, our findings regarding these rules cannot be generalized to make conclusions about other rules outside of our review.

For both objectives, we reviewed standardized information about each rule published in the *Federal Register* as well as information from publicly available regulatory analyses.[9] Because some rules included several distinct provisions, for both objectives we focused our review on those provisions for which agencies identified monetized benefits or costs, excluding transfers.[10]

For our first objective, we determined that seven of the EO 13771 rules—three EPA, two FDA, and two CMS—had "modified" (i.e., repealed, amended, or delayed) existing rules. In some instances, the agency has issued multiple prior amendments to regulatory requirements. We used the final rule documentation for the seven rules we reviewed to identify the specific rule or rules they modified. We confirmed these determinations with EPA, FDA, and CMS. We next collected regulatory analysis documentation for both the seven EO 13771 rules and rules they modified. We then examined the extent to which the regulatory analyses for the seven rules and rules they modified generally calculated benefits and costs consistently, including whether the agencies documented differences. In examining modified rules, we focused only on provisions affected by the EO 13771 rules.

For our second objective, we determined that analyses for eight of the EO 13771 rules—three EPA, one FDA, and four CMS—projected that monetized costs would exceed monetized benefits. This subset includes four rules that modified existing rules and were assessed for our first objective. We focused our assessment on rules for which straightforward comparisons of monetized information alone may not have provided sufficient information to assist decision makers in determining that these rules' total benefits were likely to justify the total costs. It is important for agencies to develop quality analyses for such rules because they may provide agencies with particularly important opportunities to assess and

[9]For some rules, the published regulation included a section clearly identified as the complete regulatory analysis, which we reviewed. In cases where the regulation directed the public to a specific document—for example, a regulatory impact analysis available on regulations.gov—we reviewed those documents as well.

[10]For rules that include multiple distinct provisions, *Circular A-4* directs agencies to analyze the benefits and costs of those provisions separately.

summarize information about a variety of considerations, such as the importance of non-monetized effects, to assist decision makers

For each of the eight rules, we reviewed related regulatory analyses and documentation to assess the extent to which agencies' analyses for relevant provisions (i.e., those for which agencies monetized benefits, costs, or both) were consistent with selected best practices for economic analysis and relevant OMB and agency guidance.[11]

Our *Assessment Methodology for Economic Analysis* (Assessment Methodology) identifies five key elements of economic analysis: (1) objective and scope, (2) methodology, (3) documentation, (4) analysis of effects, and (5) transparency.[12] Each key element consists of economic concepts that represent best practices. Based on our review, analysis, and professional judgment, we selected a subset of the best practices that were most relevant to our objectives (see table 7 below). Although the other best practices in our Assessment Methodology are viewed as key to include in a full and complete economic analysis, we focused our review on these selected best practices because they related directly to analyses of benefits and costs.

[11]In conducting our review of selected rules, we did not evaluate their legal adequacy, and we express no view on the policy choices they contain.

[12]GAO, *Assessment Methodology for Economic Analysis*, GAO-18-151SP (Washington, D.C.: April 2018). We developed this methodology by synthesizing economic concepts identified by consulting with experts on economic analysis and in federal and international agency guidance. GAO-18-151SP provides a framework for assessing the sufficiency of economic analyses, including benefit-cost and cost-effectiveness analyses.

Table 7: Selected Elements and Best Practices for Economic Analysis

Selected elements	Selected best practices
Methodology	Examining effects by comparing alternatives, using one as a baseline, unless otherwise justified
Scope and analysis[a]	Assessing important effects to the extent feasible
—	Using the concept of opportunity cost to monetize effects
—	Comparing alternatives using an appropriate outcome measure
—	Controlling for inflation and using appropriate discount rates
—	Focusing on effects that accrue to U.S. citizens and residents and using an appropriate time horizon
Transparency	Describing and justifying analytical choices, assumptions, and data used
—	Explaining implications of key limitations
—	Quantifying how statistical variability affected estimates

Source: GAO. | GAO-21-151

[a]This category includes one selected best practice related to the "objective and scope" key element and four selected best practices related to the "analysis of effects" key element in the same category (five total). We present these selected best practices together for the purposes of our reporting.

For relevant provision(s) of each economic analysis, we assigned one of three mutually exclusive scores for each best practice:

- Met – The analysis has considered and properly dealt with the selected best practice.
- Partially met – The analysis has only partially considered and dealt with the selected best practice.
- Not met – The analysis has not considered or not properly dealt with the selected best practice.

For both objectives, we requested and reviewed information from HHS and EPA on rules and regulatory analyses in our review. We also contacted OMB in April 2020 to solicit OIRA's perspective on executive agencies' implementation of EO 13771. Informing us that it was engaged in responding to the Coronavirus Disease 2019, OMB met with us once on December 2, 2020 to respond to questions we submitted in April 2020.

We conducted this performance audit from March 2020 to December 2020 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.

Appendix II: Overview of Rules We Reviewed

We selected and reviewed 11 rules finalized by the Environmental Protection Agency and the Department of Health and Human Services since Executive Order 13771 went into effect in February 2017. For more information on our selection methodology, see appendix I.

Of the 11 rules we reviewed, we identified those which included provisions that (1) repealed, amended, or delayed existing rules and (2) had monetized costs that exceeded monetized benefits. See table 8 for a summary of these rules. Of the 11 rules, we found that seven included provisions that repealed, amended, or delayed an existing rule and eight had monetized costs that exceed the monetized benefits. Four of the 11 rules met both criteria.

Table 8: Eleven Department of Health and Human Services (HHS) and Environmental Protection Agency (EPA) Rules Selected for Review that Were Finalized Between February 2017 and April 2020

Agency	*Federal Register* citation	Reviewed rule title	Repealed, amended, or delayed an existing rule?	Monetized costs exceed monetized benefits?
CMS, HHS	82 Fed. Reg. 52976 (Nov. 15, 2017)	Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program*	○	●
CMS, HHS	84 Fed. Reg. 51836 (Sept. 30, 2019)	Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies*	○	●
CMS, HHS	83 Fed. Reg. 56922 (Nov. 14, 2018)	Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS; Correction*	●	●
CMS, HHS	84 Fed. Reg. 60478 (Nov. 8, 2019)	Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements*	●	●
FDA, HHS	83 Fed. Reg. 19619 (May 4, 2018)	Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving*†	●	○
FDA, HHS	84 Fed. Reg. 9706 (Mar. 18, 2019)	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E*†	●	●

Agency	*Federal Register* citation	Reviewed rule title	Repealed, amended, or delayed an existing rule?	Monetized costs exceed monetized benefits?
EPA	85 Fed. Reg. 20122 (Apr. 9, 2020)	TSCA Chemical Data Reporting Revisions Under TSCA Section 8(a)	●	●
EPA	82 Fed. Reg. 27154 (June 14, 2017)	Effluent Limitations Guidelines and Standards for the Dental Category	○	●
EPA	83 Fed. Reg. 30054 (June 27, 2018)	Mercury; Reporting Requirements for the TSCA Mercury Inventory	○	●
EPA	84 Fed. Reg. 69834 (Dec. 19, 2019)	Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act (December 19, 2019)†	●	○
EPA	83 Fed. Reg. 5317 (Feb. 7, 2018)	Additions to List of Categorical Non-Waste Fuels: Other Treated Railroad Ties†	●	○

Legend: ● = Yes; ○ = No

* = Rule is economically significant. Economically significant rules are those that are projected to have an annual economic effect more than $100 million or meet certain other criteria, such as having an anticipated adverse effect on the economy, public health, or State, local, or tribal governments.

† = Rule is an Executive Order 13771 deregulatory action. All other actions are Executive Order 13771 regulatory actions.

Source: GAO analysis of selected rules and regulatory analyses finalized by the Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), and EPA. | GAO-21-151

Table 9 summarizes the seven rules we reviewed that we found repealed, amended, or delayed provisions of at least one existing rule. We refer to those existing rules as “modified” rules. For more information on how we identified modified rules, see appendix I.

Table 9: Seven Department of Health and Human Services (HHS) and Environmental Protection Agency (EPA) Rules Selected for Review and Rules They Modified

Agency	Reviewed rule *Federal Register* citation	Reviewed rule title	Modified* rule title and *Federal Register* citation
CMS, HHS	83 Fed. Reg. 56922 (Nov. 14, 2018)	Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Accounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS	Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, 82 Fed. Reg. 50738 (Nov. 1, 2017)

Agency	Reviewed rule *Federal Register* citation	Reviewed rule title	Modified* rule title and *Federal Register* citation
—	—	—	Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model, 81 Fed. Reg. 77834 (Nov. 4, 2016)
, —	—	—	Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 79 Fed. Reg. 66120 (Nov. 6, 2014)
CMS, HHS	84 Fed. Reg. 60478 (Nov. 8, 2019)	Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements	Medicare Program; Home health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 205 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment, 71 Fed. Reg. 65884 (Nov. 9, 2006)
FDA, HHS	83 Fed. Reg. 19619 (May 4, 2018)	Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving	Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33742 (May 27, 2016)*
—	—	—	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts, 81 Fed. Reg. 34000 (May 27, 2016)*
FDA, HHS	84 Fed. Reg. 9706 (Mar. 18, 2019)	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354 (Nov. 27, 2015)*
EPA	83 Fed. Reg. 5317 (Feb. 7, 2018)	Additions to List of Categorical Non-Waste Fuels: Other Treated Railroad Ties	Identification of Non-Hazardous Secondary Materials That Are Solid Waste, (76 Fed. Reg. 15456 (Mar. 21, 2011)

Agency	Reviewed rule *Federal Register* citation	Reviewed rule title	Modified* rule title and *Federal Register* citation
EPA	84 Fed. Reg. 69834 (Dec. 19, 2019)	Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act (December 19, 2019)	Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, 82 Fed. Reg. 4594 (Jan. 13, 2017)
EPA	85 Fed. Reg. 20122 (Apr. 9, 2020)	TSCA Chemical Data Reporting Revisions Under TSCA Section 8(a)	TSCA Inventory Update Reporting Modifications; Chemical Data Reporting, 76 Fed. Reg. 50816 (Aug. 16, 2011)

Legend: * = Rule was delayed by the reviewed rule. No asterisk implies that the rule was amended by the reviewed rule.

Source: GAO analysis of selected rules and regulatory analyses finalized by the Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), and EPA. | GAO-21-151

Appendix III: 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

December 7, 2020

Yvonne D. Jones
Director, Strategic Issues
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Jones:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"Federal Rulemaking: Selected EPA and HHS Regulatory Analyses Met Several Best Practices, but CMS Should Take Steps to Strengthen Its Analyses"* (Job code 104220/GAO-21-151).

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

Sincerely,

Sarah C. Arbes
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — FEDERAL RULEMAKING: SELECTED EPA AND HHS REGULATORY ANALYSES MET SEVERAL BEST PRACTICES, BUT CMS SHOULD TAKE STEPS TO STRENGTHEN ITS ANALYSES (GAO-21-151)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report. HHS is committed to continuing to improve the development of high quality regulatory impact analysis to ensure it reflects best practices and addresses issues and requirements important to improving stakeholder experiences.

Executive Order (EO) 13771, entitled "Reducing Regulation and Controlling Regulatory Costs," was issued on January 30, 2017, directing all agencies to repeal at least two existing regulations for each new regulation and offset any costs imposed by new regulations while operating under a regulatory cost cap. In response to the EO, the Centers for Medicare & Medicaid Services (CMS) launched the "Patients over Paperwork" initiative in 2017.[1] Through this initiative, CMS established an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience. To date, the Patients over Paperwork initiative has yielded estimated savings of $6.6 billion to the medical community with a reduction of approximately 42 million hours of burden through 2021. In addition to the agency-wide initiative, CMS developed further guidance that summarized the EO and provided tools for developing regulatory impact analyses, in accordance with guidance issued by the HHS Assistant Secretary for Planning and Evaluation to assist HHS operating divisions in conducting economic analyses that meet the goals of the EO.

As part of the rulemaking process, CMS considers a number of factors, such as different options or alternatives considered for a proposed action. CMS also uses economic analyses to help determine whether the benefits of a regulation are greater than its costs, particularly for economically significant regulations that have an annual effect on the economy of $100 million or more in any one year. The public also plays an extremely important role by commenting on proposed rules and other documents that solicit public input, such as requests for information that sometimes lead to formal rulemaking.

As noted by the GAO, HHS and the Office of Management and Budget guidance acknowledge that there has to be a balance between analytical thoroughness and an agency's practical limits, capabilities, and timeliness. Therefore, in some cases it may be appropriate to exclude certain aspects of regulatory analysis depending on agency resource limitations, data limitations or prohibitive statutory language.

GAO's recommendation and HHS's response are below.

Recommendation

The Administrator of the Centers for Medicare & Medicaid Services should take steps to ensure future regulatory analyses are consistent with best practices, particularly with regard to (1) analyzing alternatives, (2) assessing important effects, and (3) ensuring analytical transparency.

[1] https://www.cms.gov/About-CMS/Story-Page/Patients-Over-Paperwork-fact-sheet.pdf

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — FEDERAL RULEMAKING: SELECTED EPA AND HHS REGULATORY ANALYSES MET SEVERAL BEST PRACTICES, BUT CMS SHOULD TAKE STEPS TO STRENGTHEN ITS ANALYSES (GAO-21-151)

HHS Response

CMS concurs with GAO's recommendation. In addition to the guidance CMS has already provided, we will develop and issue a CMS-wide memo that provides additional guidance on developing regulatory analyses in accordance with best practices, including those noted by GAO. The memo will emphasize the importance of analyzing alternatives and assessing important effects to ensure analytical transparency. CMS will also work with HHS Assistant Secretary for Planning and Evaluation to seek additional training on developing regulatory impact analyses.

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Appendix IV: Comments from the Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF POLICY

Dr. Yvonne Jones
Director, Regulatory Issues
Strategic Issues
U.S. General Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Dr. Jones:

Thank you for the opportunity to review and comment on GAO's draft report, "Selected EPA and HHS Regulatory Analyses Met Several Best Practices, but CMS Should Take Steps to Strengthen Its Analyses" (GAO 21-151). While the report did not offer any recommendations for EPA, I want to take this opportunity to underscore the importance of thorough, sound economic analysis to support EPA's rulemaking process.

The EPA stands behind the quality of the agency's benefit-cost analyses. Unfortunately, none of the EPA rules examined in the report were economically significant. If the GAO had reviewed economically significant EPA rules as initially planned, GAO would have found even more detailed benefit-cost analyses that are both thorough and consistent with the best economics and other sciences, relying on peer-reviewed literature and models. In preparing these detailed assessments of benefits and costs per E.O. 12866 and Circular A-4, the agency relies on the EPA *Guidelines for Preparing Economic Analyses* that have been thoroughly peer-reviewed by the EPA Science Advisory Board. The *Guidelines* address important subjects such as uncertainty, timing, and valuation of costs and benefits, and promote the consistent treatment of these issues in all economic analyses at the EPA. The *Guidelines* provide a sound scientific framework for performing economic analyses and ensure that EPA regulations not only contribute to a safe environment but also a healthy economy. We also ensure that our *Guidelines* are updated to reflect advances in economics, and thoroughly updated EPA *Guidelines for Preparing Economic Analyses* is currently in the final stages of SAB review.

EPA is proud of our detailed and careful calculation of costs and cost savings per E.O. 13771. In fact, the EPA Office of Inspector General praised our creation of a cost-accounting spreadsheet to standardize cost accounting for compliance with E.O. 13771 as a "noteworthy achievement." The agency's consistent and thorough cost calculations underpin the agency's transparent implementation of E.O. 13771.

I appreciate both GAO's consideration of the EPA's earlier feedback on the Statement of Facts and GAO's recognition that for the EPA rules covered in the report, "it is unlikely that more rigorous analysis would have generated sufficient, additional information to both the public and agency decision

makers to justify the additional resources." (p. 21) I am also gratified that the report acknowledges that the small sample of rules reviewed provides an indication of consistency in regulatory analysis.

Thank you again for the opportunity to review the draft report.

Sincerely,

BRITTANY BOLEN

Digitally signed by BRITTANY BOLEN
Date: 2020.12.04 13:11:12 -05'00'

Brittany Bolen
Associate Administrator

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Yvonne D. Jones at (202) 512-6806 or JonesY@gao.gov

Staff Acknowledgments

In addition to the contact named above, Danielle Novak (Assistant Director), J. Daniel Paulk (Analyst-in-Charge), Tim Guinane, Melanie Magnotto, Steven Putansu, Joe Santiago, Andrew J. Stephens, and Mackenzie D. Verniero made key contributions to this report.