U.S. House of Representatives
Committee on Oversight and Government Reform
Trey Gowdy, Chairman

Shining Light on Regulatory Dark Matter

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Executive Summary

The growth of the number and cost of federal regulations imposes an increasing economic and administrative burden on the American economy. The Code of Federal Regulations now contains more than one million “regulatory restrictions,” which are command terms such as shall and must.¹ Accounting for the exact cost of regulations is complicated—though estimates range from hundreds of billions of dollars to over two trillion dollars.² While the associated costs are inexact, it is clear the scope and effect of regulations on our economy is vast.

Meanwhile, the volume of regulatory guidance is even less clear.³ Regulatory guidance is an agency’s statement of policy or interpretation of a statute or regulation, and it comes in many forms—memoranda, bulletins, circulars, manuals, and a wide variety of other agency documents.⁴ Though regulatory guidance does not have the force and effect of law, these lesser-known government documents can have significant effects on the public and can alter the behavior of regulated parties. While the Office of Management and Budget (OMB) has required agencies to maintain a public inventory of significant guidance for more than a decade, many agencies fail to keep a definitive list of significant guidance documents. In many cases, the agencies fail to even identify certain guidance documents as significant in the first place.⁵

The ubiquitous and nebulous character of agency guidance prompted the Committee to conduct oversight in an effort to expose this regulatory “dark matter.” On December 8, 2017, and January 11, 2018, the Committee requested information from 46 federal agencies on their use of guidance, including how many guidance documents were issued over the prior ten years. The Committee also requested data related to compliance with applicable requirements for each such document. Agency responses were illuminating.

⁵ Reg. Dark Matter, supra note 3.
This report compiles information produced by agencies in response to the Committee’s request. The Committee compiled an initial inventory totaling more than 13,000 guidance documents, with substantially more documents available on agency websites or online databases. Many agencies were able to produce a complete inventory of guidance documents, including some agencies which identified thousands. Most responding agencies also indicated their respective regulatory reform task forces plan to evaluate guidance documents under the requirements of Executive Orders 13,771 and 13,777.

However, many responses to the Committee’s inquiry show significant problems with regulatory guidance practices. As an initial matter, many agencies were simply unable to provide a complete response, including several major regulatory agencies like the Department of Interior (DOI or Interior). After three months, nearly half of all agencies surveyed were unable to provide a complete inventory of guidance documents. Several agencies were unable to produce information for even a single guidance document.

The data provided show agencies fail to comply with the Congressional Review Act and applicable executive orders and directives, like Executive Order 12,866 and the Office of Management and Budget’s Good Guidance Bulletin. The data also show some agencies neither understand nor apply this definition of guidance, despite it being issued more than 10 years ago.

Federal agencies, particularly those that embraced the Administration’s call for regulatory reform and retrospective review in Executive Orders 13,771 and 13,777, are moving in the correct direction, but more can be done. To create permanent reform, agencies should address the deficiencies highlighted in this report and develop a culture of transparency and accountability for all regulatory actions, regardless of whether statutorily required notice and comment procedures apply. For those agencies that have not yet done so, the establishment of effective information management, particularly inventorying agency guidance assets, should be the first step.
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Findings

1. **The universe of guidance documents is vast and expanding.** Agencies provided information on more than 13,000 guidance documents issued since 2008. This represents only a portion of the complete universe of guidance documents.

2. **The federal government does not maintain a complete inventory of guidance documents.** The Committee found agencies generally do not maintain a complete inventory of guidance documents. The Committee requested “a list of all guidance documents issued by your agency since January 1, 2008,” to include the title and form of the guidance, date of issuance, the issuing office or component, and whether the guidance was submitted for review. Of the 46 agencies that received the Committee’s request, only a few were able to produce a comprehensive list of guidance documents within two weeks, which showed the vast majority of agencies do not keep a current database of guidance documents. Over the course of three months:
   - Twenty-seven agencies fully responded, including two agencies that did not issue any guidance documents during the period in question.
   - Eleven agencies partially responded, eight of which are continuing to produce material responsive to the request.
   - Eight agencies did not produce any information about their guidance documents.

3. **Agencies are confused with respect to the definition of guidance.** Some agencies are unable to understand or effectively apply the OMB definition of guidance:
   - The Department of Health and Human Services (HHS) stated unless the Committee “placed meaningful limits on the definition,” HHS would “be unable to respond in [a] meaningful and productive way.” The Department stated the OMB definition was “elusive” and “too broad to provide meaningful boundaries.”
   - The Department of Defense (DOD) reported issuing just five guidance documents since 2008. Many additional documents that meet OMB’s definition of guidance, however, are available on various DOD websites.
   - The Securities and Exchange Commission (SEC) reported issuing only 19 guidance documents since 2008. Many more are available on the Commission’s website.

4. **Agencies are largely not compliant with the Congressional Review Act (CRA).** Of the more than 13,000 guidance documents identified for the Committee, only 189 were submitted to Congress and the Government Accountability Office (GAO) in accordance with the CRA. Agencies may not be effectively identifying significant guidance documents or submitting all required guidance to the Office of Information and Regulatory Affairs (OIRA) for review. Agencies reported 536 significant guidance documents, but only 328 were reported to have been submitted to OIRA for review.
Introduction

Clyde Wayne Crews, an expert in regulatory policy at the Competitive Enterprise Institute, coined the term “regulatory dark matter” to describe all the sub-regulatory activity in the federal regulatory state. The phrase, as he explains, is an allusion to the concept that what can be seen of the regulatory state is the equivalent to what can be seen in the universe. Planets and stars and other types of ordinary “visible matter” account for only about five percent of the matter in the universe. On the other hand, ninety-five percent of the universe is comprised of dark matter and dark energy, which are poorly understood and cannot be directly observed. Similarly, sub-regulatory activities—meaning policies and legal interpretations established outside of the rulemaking process—account for the vast majority of the regulatory state, but the nature and scope of those activities are unknown, as are the burdens on taxpayers and businesses.

The line between regulations and guidance is hazy. Law provides little clarity, as the Administrative Procedure Act defines “rule” in such a way as to bring both within its bounds. Generally, however, when an agency intends to promulgate a policy that will have the force and effect of law, the agency issues a regulation through the notice and comment process. Regulations with the force and effect of law are often called “legislative rules.” Legislative rules differ from interpretive rules and agency statements of policy in that the latter two do not have the force and effect of law, and are therefore exempt from the notice and comment requirement.

Guidance generally covers the latter two categories: statements of policy and interpretative rules. Statements of policy include agency statements issued to advise the public, prospectively, of how the agency plans to exercise its authority or to inform the public how it may comply with the law and applicable regulations. Interpretative rules are statements from an agency that are issued to advise the public of how the agency interprets the statutes it administers and the regulations it has promulgated.

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10 See Id.
12 See COLE & GARVEY, supra note 9; Robert A. Anthony, Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like—Should Federal Agencies Use Them to Bind The Public, 41 DUKE L.J. 1311, 1325 (1992) (“A policy statement is an agency statement of substantive law or policy, of general or particular applicability and future effect, that was not issued legislatively and is not an interpretive rule.”) (internal citations omitted).
13 See COLE & GARVEY, supra note 9; Anthony, supra note 12 (“An interpretive rule is an agency statement that was not issued legislatively and that interprets language of a statute (or of an existing legislative rule) that has some tangible meaning.”) (internal citations omitted).
In 2007, the Office of Management and Budget established a government-wide policy for guidance documents in the “Final Bulletin for Agency Good Guidance Practices” (Good Guidance Bulletin). The Good Guidance Bulletin defined guidance as a statement of general applicability and future effect that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.\(^\text{14}\) The Good Guidance Bulletin also established requirements for agencies issuing significant guidance. A significant guidance document is one that may: (1) lead to an annual effect on the economy of $100 million or more; (2) create serious inconsistency or otherwise interfere with regulatory actions of another agency; (3) materially affect the budget; or (4) raise novel legal or policy issues.\(^\text{15}\) Agency requirements for significant guidance documents include establishing a written approval process, maintaining an online list of such documents, and providing a public feedback mechanism.\(^\text{16}\)

**Use and Effect of Guidance**

Agencies prefer guidance to legislative rules because they are more flexible, easier to promulgate, and can be written in plain language to be more accessible to the average person.\(^\text{17}\) A recent report by Professor Nicholas Parrillo published by the Administrative Conference of the United States (ACUS) stated agencies tend to prefer guidance because it is less time and resource intensive.\(^\text{18}\) However, the question of whether and how often to issue guidance versus a legislative rule is more complex than a simple determination of which is easier. Guidance can place a burden on regulated entities, and in some cases guidance can be more difficult to understand than the underlying regulation it was intended to clarify, particularly for small entities who may lack the resources to hire compliance professionals.\(^\text{19}\)

However, insufficient guidance can be problematic for industry as well.\(^\text{20}\) Regulated entities want to know how to comply with applicable laws and guidance documents help the regulated entities understand how the regulatory enforcement officials view the law.\(^\text{21}\) This combination of ease of use and necessity results in the proliferation of regulatory dark matter. According to the Parrillo report, “There is no comprehensive compilation of guidance, but everyone agrees its volume is oceanic.”\(^\text{22}\) Although, as Crews notes, “If thousands of regulations and directives were not a fact of life, there would exist less of a ‘need’ [for guidance].”\(^\text{23}\)

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\(^\text{14}\) Good Guidance Bulletin, *supra* note 4 at Sec. I(3). The Good Guidance Bulletin excludes “regulatory actions” as defined in Executive Order 12866, which is an action that promulgates or leads to the promulgation of a rule or regulation.

\(^\text{15}\) Good Guidance Bulletin, *supra* note 4 at Sec. I(4).

\(^\text{16}\) Good Guidance Bulletin, *supra* note 4 at Sec. II-III.


\(^\text{18}\) *Id.* at 31.


\(^\text{21}\) *Id.* at 30.

\(^\text{22}\) *Id.* at 35.

The D.C. Circuit Court of Appeals commented on the expansive use and unintended consequences of guidance documents in Appalachian Power Co. v. EPA. The court invalidated a guidance document because they found the document to have the force and effect of law. When contemplating the broader issue of agency guidance practices, the court said:

The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as the years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in the regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.24

The court made this statement in 2000, though the use of regulatory guidance has continued relatively unabated—save for some regulatory reform efforts such as the 2007 Good Guidance Bulletin and other executive policies, like the Department of Justice’s decision to limit its reliance on guidance documents.25

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A Hazy View of Executive Agency Guidance Practices

To better understand the scope of agency guidance, the Committee asked 46 agencies for information about guidance documents issued over the last 10 years, including agencies tasked with enforcing laws concerning the environment, financial transactions, education, and public health. In addition to basic information about each guidance, the Committee also requested information to provide context around the role of guidance and the process for issuing guidance at each agency, such as:

- the form of guidance;
- the issuing agency or office;
- an indication of whether the guidance was considered significant;
- an indication of whether the guidance was submitted to OIRA for review;
- an indication of whether the guidance was submitted to Congress and the GAO as required by the Congressional Review Act; and
- an indication of whether the guidance had been or would be reviewed by the agencies Regulatory Reform Task Force if the agency was covered under Executive Order 13,771.


27 Letter from Trey Gowdy, Blake Farenthold, Jim Jordan, Mark Meadows & Gary Palmer, Chairman & Representatives, H. Comm. on Oversight & Gov’t reform, to 40 agency heads (Dec. 8, 2017) (on file with the Committee); See Appendix A for a copy of the letter.
As of March 7, 2018, 25 agencies had provided a complete list of guidance documents and the other information requested.\(^{28}\) Eight agencies are in the process of producing information responsive to the Committee’s request.\(^{29}\) In total, these agencies have produced information about more than 13,000 guidance documents.

However, over the course of three months, some agencies were not able to produce information to the Committee. Eight agencies responded with a commitment to produce information, but did not.\(^{30}\) Two agencies had no guidance to report.\(^{31}\) Three other agencies produced information so substantially incomplete as to raise questions about the adequacy of those agencies’ information management practices.\(^{32}\)

To date—with nearly half of the agencies either having not produced information or having produced information on only a portion of their guidance documents issued over the previous decade—the Committee obtained information for more than 13,000 guidance documents. This total does not account for guidance documents available online on agency websites in database form when a list was not provided to the Committee.

**Congressional Review Act: A Second Look**

The *Congressional Review Act* (CRA) is an important tool of Congressional oversight, allowing the legislative branch to review and overturn the regulatory actions of federal agencies.\(^{33}\) Agencies are required to report every rule to Congress and the Government Accountability Office (GAO) before the rule can take effect.\(^{34}\) Upon receipt, Congress may invalidate a rule by passing a resolution of disapproval, through an expedited process.\(^{35}\) For the purposes of the CRA, “rule” is an expansive term.\(^{36}\) According to GAO, guidance documents are

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\(^{29}\) These agencies are the: Department of Justice, Department of Housing and Urban Development, National Archives and Records Administration, Small Business Administration, Department of the Treasury, Department of Agriculture, Federal Depository Insurance Corporation, and Environmental Protection Agency.

\(^{30}\) These agencies are the: Department of Commerce, Federal Communications Commission, Federal Trade Commission, Department of Energy, Department of the Interior, Department of State, Department of Transportation, and United States Agency for International Development.

\(^{31}\) These agencies are the Postal Regulatory Commission and the United States Postal Service.

\(^{32}\) These agencies are the Department of Health and Human Services, Department of Homeland Security, and the Office of Personnel Management.


\(^{35}\) *See* 5 U.S.C. § 802.

CRA-eligible rules so long as they constitute: “(1) an agency statement, (2) of future effect, and (3) designed to implement, interpret, or prescribe law or policy.”37

Since the CRA’s enactment, Congress has relied upon its expedited processes to invalidate 16 rules.38 The CRA requires each agency that promulgates a rule to submit to each house of Congress a report containing a copy of the rule, a concise statement describing the rule, and the proposed effective date of the rule.39 A rule which must be submitted in this manner cannot take effect if it has not been submitted.40 Congress then has a prescribed period of time during which it may pass a joint resolution disapproving of the rule.41 If such a joint resolution is passed and signed by the President, the rule is invalidated and treated as if it had never been issued.42 A rule that is disallowed may not be reissued in substantially the same form and a new rule that is substantially the same cannot be issued unless specifically authorized by a new act of Congress.43

The information obtained by the Committee shows, of the more than 13,000 guidance documents identified, agencies sent only 189 to Congress and GAO in accordance with the CRA. To be sure, not all of the more than 13,000 guidance documents disclosed to the Committee necessarily qualify as a rule under the CRA.44 However, many of these guidance documents would likely qualify as rules under CRA’s capacious definition.

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40 Id.

41 5 U.S.C. § 801(a)(3)-(5). However, these rules that do take effect may still be voided within the prescribed timeframe and will be treated as though they never took effect.


44 While expansive, the definition of a rule under CRA is not all-encompassing. Only agency statements of general applicability that prospectively implement law or policy, or prescribe or interpret law or policy are covered. See GAO B-329272, supra note 37, at 5. Agencies may make statements that are guidance but would not be considered a rule under the CRA, such as guidance of particular applicability, and are therefore exempt from the submission requirement. See 5 U.S.C. § 804(3).
Compliance with Executive Order 12,866 and Other Executive Branch Policy

OMB relies on the Office of Information and Regulatory Affairs (OIRA) to be the principal entity responsible for regulatory review. Under Executive Order 12,866, OIRA serves as the President’s regulatory traffic cop, reviewing proposed regulatory actions to ensure agencies are complying with applicable law and policies.\(^{45}\) The review process typically manifests as a back and forth between the agency and OIRA, and may begin prior to the formal submission of the rule.\(^ {46}\) At the conclusion of the process, OIRA may sign off on the rule or return it to the agency for further consideration.\(^ {47}\) The OIRA review process has been shown to improve regulatory analysis.\(^ {48}\)

The mandate contained in Executive Order 12,866 also means OIRA has the authority to review significant guidance documents, which are considered significant regulatory actions under the order.\(^ {49}\) A significant guidance document is one likely to have an annual impact on the economy of $100 million or more, interfere with the activities or regulations of another agency, materially alter the budget impact of certain programs, or raise novel legal or policy issues.\(^ {50}\)


\(^{47}\) EO 12866, supra note 45.


\(^{49}\) See EO 12866 supra note 45; see also OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, M-09-13, MEMORANDUM FOR THE HEADS AND ACTING HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES (Mar. 4, 2009).

\(^{50}\) Good Guidance Bulletin, supra note 4, at Sec. I(4).
Independent regulatory agencies are exempt from submitting rules and guidance to OIRA under EO 12,866.\textsuperscript{51} The exemption does not prevent OIRA from reviewing material developed by independent regulatory agencies; for example, OIRA reviews Unified Agenda submissions and Paperwork Reduction Act information collection requests from independent regulatory agencies.\textsuperscript{52} While the President has the authority to expand OIRA’s review to independent regulatory agencies, the President has not done so and the Committee’s review of compliance with EO 12,866 is limited to guidance from non-independent regulatory agencies.

The information obtained by the Committee shows the agencies identified 536 significant guidance documents out of more than 13,000 guidance documents issued by non-independent agencies reviewed by the Committee. Agencies submitted only 328 guidance documents to OIRA for review—not all 536 significant guidance documents were submitted to OIRA. This discrepancy suggests either some confusion about what constitutes a significant guidance document, or weaknesses in the process, or unclear expectations about the submission of guidance.

**Agency Guidance Practices: The Bright Spots**

The information obtained by the Committee also showed positive developments in agency guidance practices. Some agencies were able to produce information for significant numbers of guidance documents. Other agencies disseminate their guidance on their websites and maintain repositories of guidance documents, in some cases going beyond the Good Guidance Bulletin’s requirement that significant guidance documents be posted in this manner.\textsuperscript{53}

\textsuperscript{51} See EO 12866 supra note 45 at Sec. 3(b).

\textsuperscript{52} See 42 U.S.C. § 3502(1) (2016).

\textsuperscript{53} See Good Guidance Bulletin, supra note 4, at Sec. III(1).
Internal Tracking

In response to the Committee’s request, two agencies, the Department of Education and the Department of Labor, provided information on more than 6,000 guidance documents—nearly half of the guidance documents listed in response to the entirety of the Committee’s request to 46 federal agencies. Despite this sizeable amount of information, these two agencies were able to fully respond to the Committee’s request. Education and Labor’s ability to respond completely and promptly indicates the use of effective information management policies and adherence to those policies, allowing the agencies to effectively track and inventory policies and legal interpretations in use at the agencies. The recent regulatory reform Executive Orders may also be a contributing factor, as they require agencies to identify guidance documents that may be appropriate for rescission or repeal, which of course first requires the agency to inventory such guidance documents.

Dissemination of Guidance

In response to the Committee’s request, most agencies provided individual hyperlinks to webpages where the guidance documents can be found online. Some agencies maintain easily identifiable and navigable online repositories for their guidance documents on their websites—including some that place all guidance documents in their online repositories instead of only significant guidance documents, as is required by the Good Guidance Bulletin.

Agency Guidance Practices: In Need of Improvement

The information obtained by the Committee also showed some areas where there is a clear need for government-wide improvement, like CRA compliance, but certain agencies demonstrated more serious deficiencies in their understanding of the limited requirements of guidance procedures. Specifically, certain agency responses indicated a systemic confusion or lack of familiarity with the underlying concept of guidance. The Committee’s request letter explained the wide variance of practices among agencies, but provided a citation to the OMB Good Guidance Bulletin for purposes of establishing a consistent and long-used definition. However, agencies still struggled with the response.

Responses from the Department of Defense (DOD) and the Securities and Exchange Commission (SEC) suffered similar defects. DOD and SEC reported issuing five and nineteen guidance documents respectively over the last ten years.

54 For the productions of these agencies, see infra Appendix I and Appendix J.
57 See Letter from John H. Gibson II, Chief Management Officer, Dep’t of Def., to Trey Gowdy, Chairman, H. Comm. on Oversight & Gov’t Reform (Dec. 20, 2017) (on file with the Committee); See Letter from Bryan Wood, Director, Securities and Exchange Comm’n. Off. of Legis. & Intergovernmental Affairs, to Trey Gowdy, Mark
DOD oversees a procurement program which in recent years has exceeded $115 billion annually, and an overall departmental budget which has in recent years exceeded $595 billion annually. DOD utilizes several hundred thousand individual buildings; more than 5,000 locations, sites, or bases; and over 30 million acres of land. The Department spends more money and employs more people on an annual basis than Wal-Mart, Exxon-Mobil, General Motors, and Ford. Understanding the enormous economic and employment footprint of the Department, Committee staff questioned DOD’s assertion the Department only issued five guidance documents in the past ten years.

After consulting with contracting experts and conducting a web search, Committee staff found numerous additional documents online, issued by DOD and appearing to qualify as guidance, most of which are available on the Department’s websites. Some examples include:


Similarly, SEC oversees the issuance of securities and the American stock and option markets. The period for which the Committee requested data covered one of the largest financial crises in history. A cursory search by Committee staff turned up well in excess of 19 guidance documents and interpretations on SEC’s website. Some examples include:

- A database of Staff Accounting Bulletins, eight of which were issued within the timeframe identified by the Committee, available at https://www.sec.gov/interps/account.shtml.

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Meadows, Jim Jordan, Gary J. Palmer, & Blake Farenthold, Chairman and Representatives, H. Comm. on Oversight & Gov’t Reform (undated) (on file with the Committee).


59 Budget outlays for DOD totaled $595.72 billion in FY 2016, $594.13 billion in FY 2017, and is projected to be $646.82 billion in FY 2018. See DOD FY2018, supra note 58.


61 Id.


A collection of compliance and disclosure interpretations, with more than thirty issued within the timeframe identified by the Committee, available at https://www.sec.gov/divisions/corpfin/cfguidance.shtml#sas.67

The failures of these agencies to identify guidance readily available on their agency websites, suggests they may be unclear on what constitutes guidance under OMB’s definition. The OMB Bulletin does not require independent agencies to comply, so it is plausible that SEC may be unfamiliar. On the other hand, DOD has had more than ten years to seek clarification if the Department lacked certainty about the definition. However, the concerns about DOD and SEC pale in comparison to the Department of Health and Human Services (HHS).

Agency Guidance Practices: More Work to be Done

The Department of Health and Human Services accounts for nearly a quarter of federal outlays and administers more grant dollars than all other federal agencies combined.68 In the past three fiscal years, budgetary outlays for HHS have accounted for more than $1.1 trillion on an annual basis.69 Federal outlays during this period totaled $3.85 trillion in FY 2016, $3.98 trillion in FY 2017, and an estimated $4.17 trillion in FY 2018.70

Despite the significant federal resources devoted to the Department, HHS has a history of struggling with basic requirements in the Good Guidance Bulletin. In 2015, GAO issued a report on guidance practices focused on four agencies, one of which was HHS.71 GAO reported HHS (1) had no written guidance procedures; (2) did not provide easy online access to significant guidance on a departmental website; (3) did not provide an opportunity for public feedback on guidance documents; and (4) was unable to determine the number of significant guidance documents issued by HHS.72

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69 See HHS FY18, supra note 58.
70 See Historical Tables, supra note 68.
72 Id. at 44-45.
On December 22, 2017, HHS responded to the Committee’s request. The response described the Regulatory Reform Task Force, information previously provided to the Committee in testimony during a November 2017 joint subcommittee hearing. The response further identified three Department websites that contain guidance documents: one at HHS.gov, one at FDA.gov, and one at CMS.gov. Information about those websites follows, from most useful to least.

Your letter requested information on the guidance documents that have been issued since January 1, 2008. Guidance documents directed externally are readily available in most cases:

- HHS.Gov/Regulations. The Department’s regulatory web portal provides information and guidance on a number of Department policies, including the Health Insurance Portability Accountability Act, the Health Information for Economic and Clinical Health Act, and final rules by operating division as well as significant guidance documents.

- FDA.Gov/RegulatoryInformation/Guidances. The FDA provides a searchable database of guidance documents.

- CMS.Gov/Regulations-and-Guidance/Regulations-and-Guidance.html. CMS provides public links to manuals, regulations, policies, and information for the different types of providers in the Medicare and Medicaid systems.

Figure 1: December 22, 2017 HHS Response

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75 Id.
The FDA is required by law to maintain a publicly available comprehensive list of guidance.\(^\text{76}\) FDA is also required to establish written procedures for developing guidance, provide an opportunity for public comment for certain guidances, and maintain an appeals process for guidance.\(^\text{77}\) According to GAO, the Good Guidance Bulletin was informed by FDA’s guidance practices.\(^\text{78}\)

The link HHS provided in December to FDA’s guidance repository was, by far, the most responsive part of the Department’s answer to the Committee. FDA’s website includes a searchable database of more than two thousand final guidance documents, with links to each document. The Department, however, did not provide any indication of which guidance documents were significant, whether any were submitted to OIRA for review, whether any were submitted to GAO and Congress in compliance with CRA, or whether the Regulatory Reform Task Force has reviewed or has plans to review any of the documents.

\(^\text{78}\) GAO-15-368, \textit{supra} note 8, at 4.
The Centers for Medicare and Medicaid Services (CMS) was confusing, to say the least. The webpage was titled “Regulations & Guidance” and seemed to provide links to material that could possibly be relevant. However, under the heading “Guidance” at the top of the page, CMS provides a list of links which include: (1) Advisory Committees, (2) CMS Records Schedule, (3) CMS Small Business Administration Ombudsman, (4) CMS Small Entity Compliance Guides, (5) Executive Order Guidance, (6) Manuals, (7) Privacy Act System of Records, (8) Privacy Office, (9) Transmittals, and (10) Rulings.

The “Advisory Committees” link directs to a page about advisory committees, the “Privacy Office” link directs to a page about the privacy office, and the “CMS Small Business Administration Ombudsman” link directs to the Ombudsman’s webpage. None of those appear to provide any information other than general information about their intended subjects, and no guidance documents.

The “Executive Order Guidance” link directs to the CMS webpage that provides information about the since-rescinded Executive Order 13,422, which established some guidance requirements for agencies under the Bush Administration.

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CMS last modified that page on October 24, 2016, which is well over five years after the Bush-era EO was rescinded.\textsuperscript{85} This site, however, provides at least some information about guidance documents. According to the webpage, “At present, there are approximately 37,000 documents on the CMS website and many, perhaps most of these, include guidance.”\textsuperscript{86}

The webpage also offers the public an opportunity to submit comments, directing readers to “click on the FAQs link located under Tools at the bottom of the page and then click on the Submit Request link at the top of the page to submit your comment.” However, there is no “Tools” at the bottom of the page.

The Department of Health and Human Services (HHS)

https://www.hhs.gov/regulations

In its response to the Committee, the Department stated, “The Department’s regulatory web portal provides information \textit{and guidance} on a number of Department policies.”\textsuperscript{87} The third and final link HHS provided, however, does not appear to have any connection to guidance documents. In fact, the webpage does not contain the word “guidance.”\textsuperscript{88}

Requests for Additional Information from HHS

In light of the Department’s outsized portion of the federal budget and the serious deficiencies with respect to the Department’s response, Committee staff requested additional information, which was met with resistance. During the course of the Committee’s engagement with the Department, it became clear the Department suffered from the lack of any internal tracking mechanism for existing guidance documents or any central planning process for the development and promulgation of guidance documents.\textsuperscript{89}

\textsuperscript{86} Executive Order Guidance, supra note 82.
\textsuperscript{87} Clark Letter, supra note 72 (emphasis added).
\textsuperscript{89} See Email from Dir. for Oversight & Investigations, Dep’t of Health & Human Serv., to majority staff, H. Comm. on Oversight & Gov’t Reform (Feb. 22, 2018 6:08 p.m.) (on file with the Committee) (explaining there is no internal document and the production of responsive documents could exceed 100,000 pages).
On February 15, 2018 Assistant Secretary for Legislation Matthew Bassett informed the Committee: “Inasmuch as most HHS guidance documents that are labeled as such are available on-line, HHS replied on December 22” and “there is no universally accepted definition of ‘guidance document.’”\textsuperscript{91} The letter also stated the Good Guidance Bulletin’s definition of guidance “was too broad to provide meaningful boundaries to an otherwise elusive term” and without any “meaningful limits on the definition of ‘guidance document,’ [HHS] will be unable to respond in a meaningful and productive way.”\textsuperscript{92}

\textit{Signs of Progress at HHS}

Shortly after the February 15 letter from HHS Assistant Secretary for Legislation Matthew Bassett, HHS provided a response to a question from Rep. Mark Meadows during a November 14, 2017, subcommittee hearing.\textsuperscript{93} At the hearing, Rep. Meadows asked each of the three witnesses for information about the catalogue of guidance material at each agency. Unable to provide even a general estimate of the universe of guidance documents at HHS, the Department’s Associate Deputy Secretary agreed to provide a “plan of action on how [HHS is] going to address that request” within 14 days.\textsuperscript{94}

On February 26, 2018, more than three months after the hearing, HHS provided a 14-day “Action Plan for Guidance Document Survey,” detailing a two to three month process of identifying and compiling guidance at HHS.\textsuperscript{95} In assembling the list, HHS “will be tracking any guidance documents that match the GGP Bulletin (§I(3)) definition of ‘guidance document.’”\textsuperscript{96}

\textit{Conclusion and Recommendations}

The Committee found some agencies are largely in compliance with applicable law and statutes regarding the issuance of guidance, while other agencies have considerable deficiencies and shortcomings in their guidance processes, indicated by the disparity between the reported number of significant guidance documents and the reported number of guidance documents submitted to OIRA for review. The rate at which agencies did not submit their guidance documents to Congress and GAO, as is often required by the CRA, also suggests agencies are unaware of certain statutory mandates. Those agencies which have not produced a response to the Committee simply may not know what guidance they have issued and whether it was issued in accordance with applicable law.

\textsuperscript{91} Letter from Matthew Bassett, Assistant Sec’y for Legis., Dep’t of Health & Human Serv., to Trey Gowdy, Chairman, H. Comm. on Oversight & Gov’t Reform (Feb. 15, 2018) (on file with the Committee).

\textsuperscript{92} Bassett Letter, supra note 89.

\textsuperscript{93} Regulatory Reform Task Forces Check-In: Part II Before the Subcomm. on Healthcare, Benefits, and Administrative Rules and the Subcomm. on Intergovernmental Affairs of the H. Comm. on Oversight and Gov’t Reform, 115th Cong. (2017).

\textsuperscript{94} Id.

\textsuperscript{95} Email from Dir. for Oversight & Investigations, Dep’t of Health & Human Serv., to majority staff, H. Comm. on Oversight & Gov’t Reform (Feb. 26, 2018 4:32 p.m.) (on file with the Committee).

\textsuperscript{96} Id.
The following recommendations would introduce a measure of discipline and improve transparency with respect to how federal agencies process and track guidance documents:

1. **Congressional Review Act Compliance.** Agencies should comply with the CRA. The low rate at which agencies reported submitting guidance documents from the past decade to Congress and GAO in accordance with the CRA suggests agencies are unclear on what is required of them by the statute. When there is a lack of clarity about whether a guidance document should be submitted to Congress and GAO under the CRA, agencies should seek guidance from GAO and Congress.

2. **Online Repositories.** All agencies should follow the examples of agencies like the Consumer Financial Protection Bureau\(^\text{97}\) and the Department of Labor\(^\text{98}\) to make their guidance documents available in an online repository, complying with both the letter and the spirit of the Good Guidance Bulletin. Such publishing would alleviate the burden on regulated entities of seeking out new guidance documents issued by their regulators by placing the onus on the regulators to assemble and organize these documents. To advance transparency goals, a legislative solution could include a reporting requirement for agencies to post all guidance documents in a centralized location, such as a repository or library maintained on agency websites.

3. **Mandate Effective Guidance Practices.** Congress should consider legislation to codify existing requirements in executive directives, such as the Good Guidance Bulletin, which may improve Congressional oversight of agency regulatory activities and prevent future administrations from rescinding these directives at will. The Good Guidance Bulletin requires agencies to adopt best practices, like having written procedures for the issuance of significant guidance documents,\(^\text{99}\) requiring disclosure of certain information like the issuing agency or office and the date of issuance,\(^\text{100}\) maintaining an online database of significant guidance documents,\(^\text{101}\) and soliciting input from stakeholders and the public on significant guidance documents.\(^\text{102}\)

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\(^{98}\) Sub-agencies and offices at the Department of Labor list policy and guidance documents on their respective websites. See, e.g., Compliance Assistance, [MINE SAFETY & HEALTH ADMIN.](https://www.msha.gov/compliance-enforcement/compliance-assistance#policy) (last visited Mar. 2, 2018).

\(^{99}\) Good Guidance Bulletin, *supra* note 4, Sec. II(1).

\(^{100}\) *Id.* at Sec. II(2).

\(^{101}\) *Id.* at Sec. III(1).

\(^{102}\) *Id.* at Sec. III(2).
Appendices

Appendix A: Letter to Agencies
Appendix B – QQ: Productions of the Agencies

1. Appendix B – Consumer Financial Protection Bureau
2. Appendix C – Commodities Futures Trading Commission
3. Appendix D – Consumer Product Safety Commission
4. Appendix E – Chemical Safety Board
5. Appendix F – Department of Homeland Security
6. Appendix G – Department of Defense
7. Appendix H – Department of Justice
8. Appendix I – Department of Labor
9. Appendix J – Department of Education
10. Appendix K – Equal Employment Opportunity Commission
11. Appendix L – Department of Energy
12. Appendix M – Environmental Protection Agency
13. Appendix N – Export-Import Bank
15. Appendix P – Federal Election Commission
16. Appendix Q – Federal Energy Regulatory Commission
17. Appendix R – Federal Housing Financing Agency
18. Appendix S – Federal Labor Relations Authority
19. Appendix T – Federal Maritime Commission
20. Appendix U – General Services Administration
21. Appendix V – Department of Health and Human Services
22. Appendix W – Department of Housing and Urban Development
23. Appendix X – Department of the Interior
24. Appendix Y – Merit Systems Protection Board
25. Appendix Z – National Archives and Records Administration
26. Appendix AA – National Aeronautics and Space Administration
27. Appendix BB – Nuclear Regulatory Commission
28. Appendix CC – National Transportation Safety Board
30. Appendix EE – Pension Benefit Guaranty Corporation
31. Appendix FF – Postal Regulatory Commission
32. Appendix GG – Railroad Retirement Board
33. Appendix HH – Small Business Administration
34. Appendix II – Securities and Exchange Commission
35. Appendix JJ – Social Security Administration
36. Appendix KK – Department of State
37. Appendix LL – Surface Transportation Board
38. Appendix MM – Department of Transportation
39. Appendix NN – Department of the Treasury
40. Appendix OO – Department of Agriculture
41. Appendix PP – United States Postal Service
42. Appendix QQ – Department of Veterans Affairs