

**Calendar No. 448**

115TH CONGRESS }  
2d Session }

SENATE

{ REPORT  
115-271 }

GUIDANCE OUT OF DARKNESS ACT

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R E P O R T

OF THE

COMMITTEE ON HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS  
UNITED STATES SENATE

TO ACCOMPANY

S. 2296

TO INCREASE ACCESS TO AGENCY GUIDANCE DOCUMENTS



JUNE 7, 2018.—Ordered to be printed

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Mr. JOHNSON, from the Committee on Homeland Security and  
Governmental Affairs, submitted the following

**R E P O R T**

[To accompany S. 2296]

[Including cost estimate of the Congressional Budget Office]

The Committee on Homeland Security and Governmental Affairs, to which was referred the bill (S. 2296) to increase access to agency guidance documents, reports favorably with an amendment in the nature of a substitute, and recommends that the bill, as amended, do pass.

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**I. PURPOSE AND SUMMARY**

S. 2296, the Guidance out of Darkness, or “GOOD” Act, seeks to provide greater transparency and accountability of guidance documents, which agencies use to provide regulated entities and the public with assistance in interpreting existing law and understanding agency policies. The bill requires agencies to post all guidance—including items such as memos, “Dear Colleague” letters, bulletins, directives, or anything that can be considered a policy statement or interpretation—on the website regulations.gov and publish a hyperlink on the internet website of the agency that provides access to the guidance documents.

## II. BACKGROUND AND NEED FOR LEGISLATION

Agency guidance documents serve four primary purposes: (1) explaining new regulations; (2) responding to stakeholder questions; (3) clarifying existing policies; and (4) sharing leadership priorities and initiatives.<sup>1</sup> Some have raised concerns about agencies issuing guidance when they should undertake rulemaking and some regulatory experts have observed that “no one actually knows how many guidance documents exist, or how to find them all.”<sup>2</sup> Hence some observers have used the term “regulatory dark matter,” to refer to the Federal administrative policymaking that occurs through guidance documents.<sup>3</sup> This bill seeks to remedy that by providing greater transparency and accountability of guidance documents.

In 1997, the Food and Drug Administration (FDA) created an agency policy regarding good guidance practices.<sup>4</sup> Later that year, Congress mandated certain aspects of the FDA’s good guidance practices through the Food and Drug Administration Modernization Act of 1997 (FDAMA).<sup>5</sup> A decade later, the Office of Management and Budget (OMB) recognized the public concern regarding access to guidance documents and a lack of a formal process and issued government-wide “Good Guidance Practices.”<sup>6</sup> The OMB Good Guidance Practices bulletin established policies and procedures for all departments and agencies in regards to the development, issuance, and use of “significant guidance documents.”<sup>7</sup>

The bulletin stated that as the scope and complexity of regulatory programs have grown, so has the issuance of guidance documents.<sup>8</sup> With the increase in the usage of guidance documents, OMB determined that “clear and consistent agency practices for developing, issuing, and using guidance documents” were necessary.<sup>9</sup> The bulletin goes on to state that “[w]ell-designed guidance docu-

<sup>1</sup> Government Accountability Office, *Guidance Documents from Federal Agencies*, GAO–15–368 (May 18, 2015).

<sup>2</sup> Paul Noe, *Shining the Light on Regulatory Dark Matter: Due Process and Management for Agency Guidance Documents*, Am. Forest & Paper Ass’n (Feb. 6, 2018), <http://www.afandpa.org/media/blog/blog/2018/02/06/shining-the-light-on-regulatory-dark-matter-due-process-and-management-for-agency-guidance-documents>.

<sup>3</sup> This term was first coined by Clyde Wayne Crews Jr. See Clyde Wayne Crews, *Mapping Washington’s Lawlessness: A Preliminary Inventory of “Regulatory Dark Matter,”* Competitive Enter. Inst. (Dec. 9, 2015), <https://cei.org/content/mapping-washington%E2%80%99s-lawlessness> (citing Mathew Fancis, *First Planck Results: The Universe is Still Weird and Interesting*, Ars Technica (Mar. 21, 2013) (Astrophysicists have concluded that ordinary visible matter . . . make[s] up only a tiny fraction of the universe . . . Instead, dark matter and dark energy make up most of the universe, rendering the bulk of existence beyond our ability to directly observe)).

<sup>4</sup> Paul R. Noe & John D. Graham, *Due Process and Management for Guidance Documents: Good Governance Long Overdue*, 25 Yale J. on Reg. 103 (2008), <https://regproject.org/wp-content/uploads/Paul-Noe-Due-Process-and-Management-for-Guidance-Documents.pdf>.

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

<sup>6</sup> *Id.*

<sup>7</sup> Off. of Mgmt. & Budget, Exec. Off. of the President, OMB Memorandum M–07–07, *Issuance of OMB’s “Final Bulletin for Agency Good Guidance Practices”* (Jan. 18, 2007), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2007/m07-07.pdf> (The bulletin defines this term as “a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to: (i) Lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; or (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; or (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866, as further amended.”).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 1.

ments serve many important or even critical functions”<sup>10</sup> including in providing assistance in interpreting existing law or providing greater clarity through a policy statement.<sup>11</sup> However, not all guidance is well-designed nor does all guidance receive the careful consideration under consistent procedures for regulatory development and review and therefore the bulletin established general policies and procedures for developing, issuing, and using significant guidance.<sup>12</sup>

One procedure in particular, to aid in public access to the development and issuance of significant guidance documents, established that agencies would maintain a current electronic list of all significant guidance documents on their agency websites, within 30 days of issuance.<sup>13</sup> The agency list would be searchable and include the name of the guidance document, the docket number, and the issuance and revision dates.<sup>14</sup>

In March 2016, the U.S. Government Accountability Office (GAO) examined opportunities to enhance transparency and oversight of the rulemaking process.<sup>15</sup> GAO stated “concerns have been raised about the level of oversight for agencies’ guidance, whether agencies seek feedback from affected parties on guidance, and how to ensure that agencies do not issue guidance when they should undertake rulemaking.”<sup>16</sup> GAO found that a sample of departments varied in the degree to which they complied with OMB’s requirements for significant guidance.<sup>17</sup> As agencies continue to issue guidance, processes to promote transparency and accountability of departments and agencies are integral to the public debate.

Regulated entities, Congress and the government oversight community remain uncertain of the breadth of existing guidance documents. This uncertainty can have real effects on regulated parties.

S. 2296 seeks to establish a baseline transparency standard for guidance, broadly defined, which will facilitate more accountability. In turn, greater accountability and transparency will inform the public, while also providing a necessary check on regulatory agencies. As one regulatory expert stated, “[r]equiring vastly more disclosure, ensuring that federal agencies post all guidance documents online is a sensible and essential step to beginning to hold federal agencies accountable for their actions.”<sup>18</sup>

### III. LEGISLATIVE HISTORY

Chairman Ron Johnson (R-WI) introduced S. 2296 on January 11, 2018. Senators James Lankford (R-OK) and Joni Ernst (R-IA) later joined as cosponsors. The bill was referred to the Committee on Homeland Security and Governmental Affairs. The Committee considered S. 2296 at a February 14, 2018 business meeting.

<sup>10</sup>*Id.* at 2 (citing Off. Of Mgmt. & Budget, Exec. Off. Of the President, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities*, 72–74 (2002)).

<sup>11</sup>*Id.*

<sup>12</sup>*Id.*

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

<sup>14</sup>*Id.*

<sup>15</sup>U.S. Gov’t Accountability Off., GAO–16–505T, *Federal Rulemaking: Opportunities Remain for OMB to Improve the Transparency of Rulemaking Processes* (2016), <https://www.gao.gov/assets/680/676081.pdf>.

<sup>16</sup>*Id.*

<sup>17</sup>*Id.*

<sup>18</sup>Clyde Wayne Crews, *Wayne Crews Responds to GOOD Act*, Competitive Enter. Inst. (Jan. 11, 2018), <https://cei.org/content/wayne-crews-responds-good-act>.

During the business meeting, Chairman Johnson offered an amendment in the nature of a substitute which was adopted by voice vote *en bloc* as modified. The amendment clarified the definition of guidance and also specified the manner in which guidance documents would be posted to a central website. Senators present for the vote were Johnson, Portman, Paul, Lankford, Enzi, Hoeven, Daines, McCaskill, Heitkamp, Peters, Hassan, Harris, and Jones.

The Committee ordered S. 2296 as amended reported favorably *en bloc* on February 14, 2018, by voice vote. Senators present for the vote were Johnson, Portman, Lankford, Enzi, Hoeven, Daines, McCaskill, Heitkamp, Peters, Hassan, Harris, and Jones.

#### IV. SECTION-BY-SECTION ANALYSIS OF THE BILL, AS REPORTED

##### *Section 1. Short title*

This section establishes the short title of the bill as the “Guidance Out Of Darkness Act” or the “GOOD Act.”

##### *Section 2. Definitions*

This section defines “agency” as those defined under section 551 of title 5 of United States Code.

This section also defines “guidance document” as an agency statement of general applicability, other than a rule, that does not have the force or effect of law; and that is designated by an agency official as setting forth a policy on statutory, regulatory, or technical issue, or an interpretation of a statutory or regulatory issue. Such a document may include a memorandum; a notice; a bulletin; a directive; a news release; a letter; a blog post; a no-action letter; and combination thereof.

This section also states that the term “guidance document” shall be construed broadly to effectuate the purpose and intent of the bill, and shall not be limited to the illustrative list of documents put forward in Section 2(A)(ii).

##### *Section 3. Publication of guidance documents on the Internet*

This section requires all guidance documents published by an agency to be published in a single location on the Internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note)—commonly referred to as regulations.gov. Each agency must publish a hyperlink on the Internet website of the agency that provides access to the guidance documents. Agencies must publish the guidance documents in accordance with this bill on the date on which an agency issues the guidance document.

This section also requires each agency to publish, no later than 180 days after the date of enactment, and in accordance with requirements of the bill, any guidance document in effect on that date.

This section also requires agencies to maintain information on the same Internet website concerning rescinded guidance.

#### V. EVALUATION OF REGULATORY IMPACT

Pursuant to the requirements of paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee has considered the regulatory impact of this bill and determined that the bill will have no regulatory impact within the meaning of the rules. The

Committee agrees with the Congressional Budget Office's statement that the bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

VI. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, March 26, 2018.*

Hon. RON JOHNSON,  
*Chairman, Committee on Homeland Security and Governmental Affairs, U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 2296, the GOOD Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Matthew Pickford.

Sincerely,

KEITH HALL,  
*Director.*

Enclosure.

*S. 2296—GOOD Act*

S. 2296 would amend federal law to require agencies to post their regulatory guidance documents online. Typically, such documents explain how regulations are interpreted by the agency but are not themselves legally binding. Agencies often disseminate such guidance to the public in memorandums, notices, bulletins, directives, news releases, letters, blog posts, or speeches.

Federal policies require agencies to post important information online and to promote open and transparent government. According to the Government Accountability Office, many agencies already provide guidance documents to the public using websites, email, meetings, social media, mass media, and newsletters. Thus, CBO estimates that implementing the bill would have no significant cost.

Enacting S. 2296 could affect direct spending by some agencies because they are authorized to use receipts from the sale of goods, fees, and other collections to cover operating costs. Therefore, pay-as-you-go procedures apply. Because most agencies can make adjustments to the amounts collected as operating costs change, CBO estimates any net changes in direct spending by those agencies would be insignificant. Enacting the bill would not affect revenues.

CBO estimates that enacting S. 2296 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

S. 2296 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act.

The CBO staff contact for this estimate is Matthew Pickford. The estimate was approved by H. Samuel Papenfuss, Deputy Assistant Director for Budget Analysis.

VII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

Because S. 2296 would not repeal or amend any provision of current law, it would make no changes in existing law within the

meaning of clauses (a) and (b) of paragraph 12 of rule XXVI of the Standing Rules of the Senate.

