

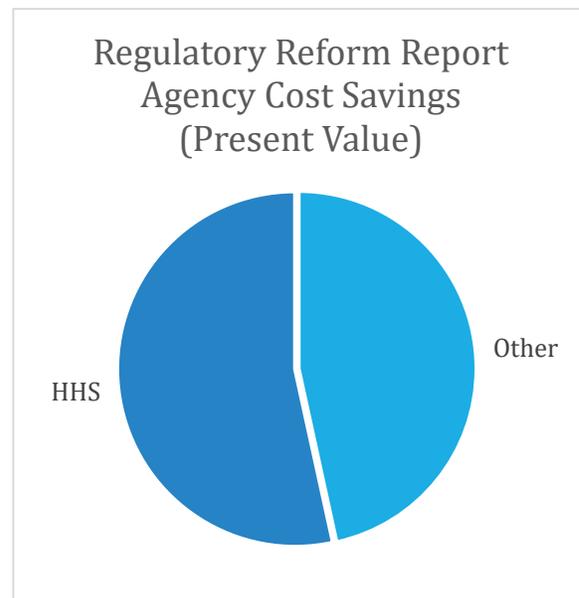
## Spotlight: HHS Entries in OIRA's Latest Regulatory Reform Report

Cutting red tape in the Medicare program delivers cost savings while other deregulatory efforts fall short

### Introduction

[Executive Order 13771](#) imposed new constraints on executive branch regulatory agencies, directing them to cut two rules for any new rule issued and to offset any costs imposed by new rules. The [Regulatory Reform Report](#) for fiscal year (FY) 2018, issued last month by the Office of Information & Regulatory Affairs (OIRA), provides an update on agency actions over the course of the year. It shows a present value estimate of \$23.4 billion in “overall regulatory costs” saved.

Of that \$23.4 billion, more than half came from a single agency: the U.S. Department of Health & Human Services (HHS). That agency also had 25 deregulatory actions and four regulatory actions in FY 2018. This Regulatory Insight unpacks these figures and finds that the Centers for Medicare and Medicaid Services (CMS) is shouldering the deregulatory burden for HHS by reducing Medicare paperwork, while the other HHS deregulatory initiatives fall short of providing the kind of regulatory relief that President Trump has promised.



### Understanding how these figures are calculated

A few points help put the contents of the report into perspective. First, OIRA [only counts those actions that have been completed](#), or “finalized,” so new proposed rules do not make it into the report.

*This insight reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.*

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Second, OIRA reports these cost and cost savings figures in present value. That means the figures represent the current value of the entire future stream of costs or cost savings. Last year, OIRA provided an [explanation for its accounting approach](#). The important distinction is that these are not annual cost or cost savings figures. OIRA's cost savings estimate of over \$23.4 billion on a present value basis converts to just over \$1.6 billion on an annualized basis. For HHS, the cost savings were \$12.5 billion present value or \$874 million annualized.

Third, under [OIRA's definitions](#), more types of activities count as “deregulatory actions” than as “regulatory actions.” For example, if an agency makes a discretionary change to a paperwork requirement that reduces burden (i.e., a change that does not require regulatory change), that can count as a “deregulatory action.” But, if an agency makes a discretionary change to paperwork that increases burden, that does not count as “regulatory action.” Although this leads to apples-to-oranges results in the total counts of regulatory and deregulatory actions, it does provide an incentive for the agencies to engage in behavior defined as deregulatory.

Last year, OIRA calculated its FY 2017 results by using the raw total of deregulatory actions to regulatory actions. That yielded an astonishing ratio of 22:1, which was the subject of several [skeptical commentaries](#) and ultimately received [three Pinocchios](#) from the Washington Post's Fact Checker. On the bright side, OIRA's FY 2017 and FY 2018 reports made the inputs into the counts transparent, which is always good news to a researcher. That has not immunized these results from [criticism](#), though, some of which is discussed below.

This year, OIRA presented the FY 2018 ratios in two ways. The first way captures all deregulatory actions and all regulatory actions; the same as it was done for FY 2017. It was 12:1 using this broader approach. The second way narrows the counts to those deregulatory and regulatory actions that were “significant” under EO 12866. This narrower approach is closer to an apples-to-apples comparison, which is more useful when trying to weigh the deregulatory and regulatory actions against each other. Using this approach, the ratio was 4:1.

## Unpacking the HHS numbers

The first step in understanding the agency-specific totals is to categorize the listed actions into those actions that yielded cost savings (i.e., those which are “deregulatory”),<sup>1</sup> and those which did not. The report notes that HHS contributed 25 deregulatory and four regulatory actions in the FY 2018 total, for a ratio of 6.25:1 using the broad approach. This was a quite a bit lower than the 12:1 ratio achieved by all of the agencies subject to EO 13771.

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<sup>1</sup> OIRA generally takes a “net” approach to cost changes within one regulatory action. “Where an agency combines such provisions, the cost impact (the difference between costs imposed and cost savings...) of such rules will generally determine whether such actions are EO 13771 regulatory actions that need to be offset, or EO 13771 deregulatory actions.” [Guidance Implementing Executive Order 13771](#) (M-17-21).

Crunching the numbers using the apples-to-apples approach, HHS reported 18 significant deregulatory actions and four significant regulatory actions, for a ratio of 4.5:1. Measured that way, HHS had a slightly higher ratio than the agencies as a whole (4:1). Upon closer inspection, four of the deregulatory actions characterized as significant were not actually reviewed by OIRA, and therefore the designations appear to be incorrect. Table 1 shows the adjusted ratio removing these four rules from the total for an adjusted ratio of 3.5:1.<sup>2</sup>

**Table 1: Two-for-One Performance (FY 2018)**

|   | HHS                                  | All Agencies* |
|---|--------------------------------------|---------------|
| Deregulatory Actions:<br>Significant Regulatory Actions             | 6.25:1                               | 12:1          |
| Significant Deregulatory Actions:<br>Significant Regulatory Actions | 4.5:1 (reported)<br>3.5:1 (adjusted) | 4:1           |

\*Agencies subject to EO 13771.

## Regulatory actions

The four regulatory actions emerged from three components of HHS. As shown in Table 2, two of them were required by law—either due to statute or compliance with a consent decree signed as part of litigation. The two discretionary rules seem to have been considered “regulatory” because they delayed a rule that would have conferred benefits if it had gone into effect.

**Table 2: HHS Regulatory Actions (FY 2018)**

| Sub-Agency        | Rule  | Annualized Costs                         | Annualized Benefits  | Type                       |
|-------------------|---|--|--|----------------------------|
| CMS <sup>1</sup>  | Physician Fee Schedule                          | \$296M (paperwork)                       | \$182M (cost savings to Medicare from diabetes prevention program) | Mandatory (statute)        |
| FDA <sup>2</sup>  | Health Care Antiseptics                         | \$2M (product reformulation and testing) | Unquantified (potential reduction to antibiotic resistance)        | Mandatory (consent decree) |
| OASH <sup>3</sup> | 6-Month Delay to the “Common Rule” <sup>4</sup> | \$46M (foregone benefits)                | \$7M (cost savings)  | Discretionary              |

<sup>2</sup> The author has requested clarification on this point and will update this Insight if appropriate.

|      |   |                           |                     |               |
|------|---|---------------------------|---------------------|---------------|
| OASH | Additional 6-Month Delay to the “Common Rule” | \$35M (foregone benefits) | \$6M (cost savings) | Discretionary |
|------|---|---------------------------|---------------------|---------------|

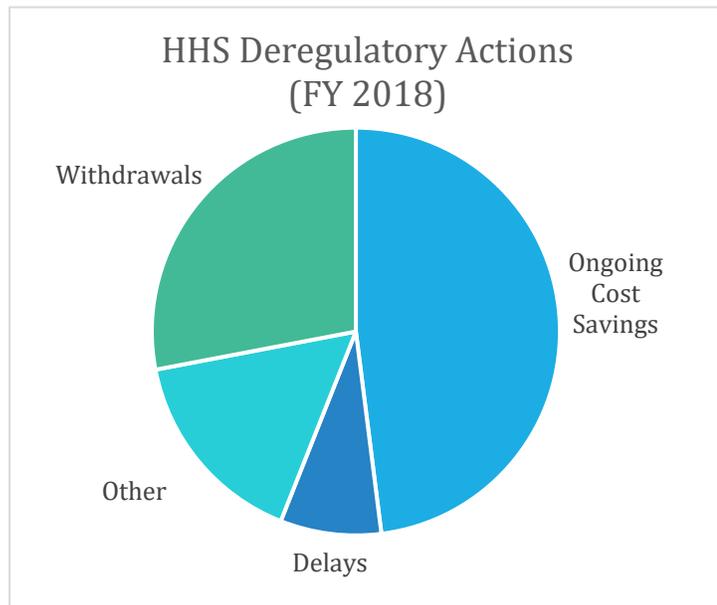
1. Centers for Medicare & Medicaid Services
2. Food & Drug Administration
3. Office of the Assistant Secretary for Health
4. The “Common Rule” is the Federal Policy for the Protection of Human Subjects, a joint rulemaking done by a large coalition of agencies.

## Deregulatory actions

Turning to the deregulatory actions, OIRA lists 25 for HHS. *Seven* were withdrawals of prior proposals, *four* contained either zero or unquantified cost savings, *two* were delays, and the remaining *12* account for the cost savings.

### Withdrawals

Seven of HHS’s 25 deregulatory actions were withdrawals of proposed rules that were issued in previous years. As noted above, when [OIRA defined those actions that would be](#)



[counted as “deregulatory.”](#) it included withdrawals of proposed rules if those proposed rules were published prior to January 20, 2017 (i.e., prior to the Trump Administration) and the withdrawals were published in the Federal Register.<sup>3</sup> This was a somewhat counterintuitive definitional choice, because proposed rules, by definition, are not yet in effect and therefore do not impose regulatory costs or confer any associated benefits. When it comes to new rulemaking, OIRA does not “count” new proposed rules as regulatory or deregulatory. This avoids double-counting that would occur when an agency proposed and then finalized an action.

So, why allow a deregulatory credit when withdrawing a proposed rule?<sup>4</sup> One explanation is to improve certainty for stakeholders. There is generally no set timeframe after which a proposed rule “expires” under the Administrative Procedure Act. This means that proposed rules can dangle for years with parties uncertain about when or whether the agency will finalize them. While the [Unified Agenda](#) gives clues about an agency’s future regulatory plans, the schedules provided

<sup>3</sup> M-17-21 page 4 (definition of “EO 13771 deregulatory action”). An agency does not receive any cost savings credit for a withdrawn proposed rule. *Id.*

<sup>4</sup> This approach is limited to proposed rules of prior administrations. It would create a perverse incentive if, in this Administration, an agency could issue a new proposed rule, which doesn’t “count” under OIRA’s definition of a regulatory action, only to withdraw it and have it count as a deregulatory action.

there are not binding, and there is nothing to stop an agency from extending the expected publication date of a final rule. One big exception is a provision from the Medicare Modernization Act of 2003, which sunsets certain Medicare proposed rules if the agency does not finalize them within 3 years.<sup>5</sup> Overall, there are not strong incentives to encourage an agency to formally withdraw a proposed rule. And some policy issues are so complex that they can legitimately take years for agencies to resolve. Meanwhile, the public is left wondering about the status of the rule. Regulatory uncertainty is often cited by regulated entities as something that hinders investment, so there are pro-innovation reasons for an agency to resolve uncertainty where it is able to do so. Therefore, allowing agencies to claim a deregulatory credit for withdrawing a proposed rule encourages an agency to withdraw actions it does not plan to finalize any time soon. And, under OIRA’s accounting rules, a re-issued proposed rule in the future would not “count” as a regulatory action until it is finalized, so the agency does not lose any ground as a result of the withdrawals.

Table 3 summarizes the seven HHS withdrawals for FY 2018, the oldest of which is from the George W. Bush Administration (2007) and the most recent of which is from the last full week of the Obama Administration (2017).

**Table 3: HHS Withdrawn Proposed Rules (FY 2018)**

| Sub-Agency       | Rule  | Proposed Date  | Withdrawal Date |
|------------------|---|----------------|-----------------|
| CMS <sup>1</sup> | Certification of Compliance for Health Plans                    | Jan. 2, 2014   | Oct. 4, 2017    |
| CMS              | Requirements for Prosthetics and Custom Orthotics               | Jan. 12, 2017  | Oct. 4, 2017    |
| CMS              | Revisions to Patient’s Rights                                   | Dec. 12, 2014  | Oct. 4, 2017    |
| CMS              | Part B Drug Payment Model                                       | Mar. 11, 2016  | Oct. 4, 2017    |
| FDA <sup>2</sup> | Data Falsification  | Feb. 9, 2010   | Sept. 28, 2018  |
| FDA              | Use of Materials Derived from Cattle                            | Jan. 12, 2007  | Sept. 28, 2018  |
| FDA              | Labeling for Food that has been Refused Admission into the U.S. | Sept. 18, 2008 | Sept. 28, 2018  |

1. Centers for Medicare & Medicaid Services

2. Food & Drug Administration

### *Deregulatory actions without quantified cost savings*

Four of the HHS deregulatory actions for FY 2018 had either zero or unquantified cost savings. This included three actions that removed old regulatory text that was no longer applicable<sup>6</sup> because, for example, the associated programs expired due to an act of Congress. Removing regulatory language that no longer applies because circumstances changed cleans up the list of existing federal regulations, and is considered a deregulatory action under OIRA’s guidance. But,

<sup>5</sup> [Medicare Modernization Act of 2003](#) § 902(a)(1). This also applies to interim final rules.

<sup>6</sup> Removing Outmoded Regulations Regarding the Ricky Ray Hemophilia Relief Fund Program (0906-AB13), Removing Outmoded Regulations Regarding the National Health Service Corps Program (0906-AB15), Removing Outmoded Regulations Regarding the Rural Physician Training Grant Program, Definition of “Underserved Rural Community” (0906-AB17).

like withdrawals, they do not yield any cost savings because under the status quo they were not imposing any costs. The last action contains a solely qualitative discussion of benefits, costs, and transfers.<sup>7</sup>

## ***Delays***

Two actions delayed effective dates. One delayed changes to a new reporting system.<sup>8</sup> Another delayed a compliance date for a new food labeling requirement.<sup>9</sup> Both provided short-term relief from impending regulatory changes, and as such are considered to be deregulatory. However, they are, by definition, short-term delays that do not provide ongoing cost savings, and therefore their contribution to the overall cost savings estimate is likely to be fairly low.<sup>10</sup>

## ***Deregulatory actions with quantified cost savings***

The categories of rules above all had zero, unquantified, or low savings estimates, which means that this last set of actions, 12 of them in total, is what must be driving the \$12.5 billion cost savings estimate (\$847 million annualized).

Although the information in the public domain (e.g., final rule preambles) shows that the agency quantified the cost savings, it is not enough to recreate the \$847 million figure from OIRA's report, because the data in the preambles are not sufficiently standardized. We can tell, however, that one was a paperwork reduction that did not require a regulatory change,<sup>11</sup> and the others were final rules, all of which involved at least some paperwork reduction.<sup>12</sup>

Eight of these actions made changes to the Medicare program. One of the largest changes was in the Medicare [home health care](#) rule, which removed 235 instances of data collection from a mandatory patient assessment and outcomes information system called [OASIS](#). The agency estimated that this will save 2.0 million burden hours per year, monetized at \$146 million per year.

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<sup>7</sup> Short-Term Limited Duration Insurance (0938-AT48).

<sup>8</sup> Adoption and Foster Care Analysis and Reporting System (0970-AC76).

<sup>9</sup> Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods (0910-AH92).

<sup>10</sup> This depends on how the value of a delay is calculated.

<sup>11</sup> Payment Collections Operations Contingency Plan (0938-1217).

<sup>12</sup> CY 2018 Home Health Prospective Payment System Rate Update, CY 2019 Case-Mix Adjustment Methodology Refinements, Value-Based Purchasing Model, and Quality Reporting Requirements (0938-AT01); CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (0938-AT03); Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019 (0938-AT08); CY 2019 Notice of Benefit and Payment Parameters (0938-AT12); CY 2018 Updates to the Quality Payment Program (0938-AT13); FY 2019 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (0938-AT24); Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2019 (0938-AT25); Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2019 Rates (0938-AT27); FY 2019 Inpatient Psychiatric Facilities Prospective Payment System--Rate and Quality Reporting Updates (0938-AT32); Religious Exemptions and Accommodations for Coverage of Certain Prevent Services Under the Affordable Care Act (0938-AT20); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (0938-AT46).

That is 13% of the overall burden from OASIS, which the agency [estimated to be 15.8 million hours](#) in 2016. Although the other FY 2018 Medicare rules had mostly smaller changes, this illustrates the potential impact of cutting paperwork.

## Putting it all together

The HHS entries in the FY 2018 Regulatory Reform Report provide a glimpse into how the Trump Administration's regulatory two-for-one initiative is playing out. Here are a few key takeaways.

### Little new regulatory activity

HHS issued very little new regulation in FY 2018. There were four regulatory actions, of which two were mandatory and two were characterized as regulatory because they delayed a previous rule that would have been beneficial. That is a [striking difference from what we have come to expect at this point in a new administration](#).

### The accounting rules matter

Understanding the bean-counting rules that go into producing these data is important. By allowing agencies to “count” more deregulatory actions than regulatory actions, OMB's guidance encourages agencies to take steps that they otherwise might not (e.g., removing regulations that are no longer in effect). A by-product of that choice, however, is that the counts can be misleading if taken out of their rather complicated context.

### Paperwork savings can really add up

HHS has been able to achieve some meaningful cost savings, but they have been concentrated in Medicare paperwork reductions. Medicare is a major federal program with a large paperwork footprint, and paperwork is a [frequent complaint](#) among health care providers. CMS's [Patients over Paperwork](#) initiative, which seems focused on Medicare, is an “internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience.” It dovetails with the goals of the regulatory two-for-one initiative, and may very well have positioned CMS to have the best deregulatory results in HHS for FY 2018.

### Potential for paperwork savings is immense and largely untapped

The Medicare program, though, is only one part of CMS, which also runs Medicaid, the Children's Health Insurance Program (CHIP), and oversees much of the individual market for health insurance (e.g., the Affordable Care Act reforms). These also have significant paperwork footprints and could benefit from review.

In addition, CMS is only one part of HHS. CMS only accounts for 14% of the overall paperwork burden imposed by HHS.<sup>13</sup> Two other agencies account for large shares of the paperwork totals: the Food & Drug Administration (14%) and the Office for Civil Rights (69%), which manages the health privacy and security standards commonly known as HIPAA.<sup>14</sup> This begs the question: Are these other HHS operating divisions planning to come to the table with initiatives that could make a dent in the 1.3 billion burden hours imposed by HHS every year?

Stepping back from HHS, the current inventory of paperwork burden imposed by all agencies is 11.3 billion hours per year.<sup>15</sup> Many ambitious deregulatory proposals would require statutory change, but discretionary paperwork burdens are one arena in which the Administration could reduce regulatory burdens without needing to go to Capitol Hill. As this Administration continues to search for deregulatory opportunities, it might consider digging deeper on paperwork.

## The other deregulatory entries fall short

As shown above, counting lots of types of actions as “deregulatory” might create good incentives to encourage agencies to do some regulatory housekeeping. The overall performance of HHS shows that this can add up to large “deregulatory” counts, but looking at the details shows that the count is not a proxy for the meaningful regulatory reform. Although they lead to large totals, actions like withdrawals of proposed rules, delays, and removing inactive regulatory text are simply not the kind of sweeping regulatory reform that would be needed to meet [President Trump’s promises to cut regulation back to 1960s levels](#).

## Conclusion

In sum, the HHS entries reveal a mixed bag of deregulatory results that [mirrors the overall performance of the government](#). On the one hand, HHS achieved targeted paperwork savings by cutting red tape in the Medicare program. On the other hand, many of its deregulatory initiatives fall short of providing the kind of regulatory relief that President Trump [promises with his rhetoric](#). Next year’s report will shed even more light on whether agencies have been able to close the gap between the rhetoric and the reality.

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<sup>13</sup> Paperwork statistics generated from summary data available at [reginfo.gov](http://reginfo.gov).

<sup>14</sup> HIPAA is the Health Insurance Portability and Accountability Act of 1996.

<sup>15</sup> Office of Information & Regulatory Affairs, Government-Wide Totals for Active Information Collections <https://www.reginfo.gov/public/do/PRARReport?operation=11> (as of Nov. 19, 2018).