



Week in Regulation

Organ Transplant Proposal Leads Otherwise Quiet Week

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Last week, the eyes of the policy and political world turned to Congress' return from its recess and the presidential election debate. The rules that landed in the pages of the Federal Register gave little reason to focus on the regulatory landscape. There were nine rulemakings with some kind of quantifiable economic impact. The most significant action was a proposed rule from the Department of Health and Human Services (HHS) seeking to implement a 2013 law on organ transplant standards. Across all rulemakings, agencies published \$1.7 billion in total costs and added 79,936 annual paperwork burden hours.

REGULATORY TOPLINES

- Proposed Rules: 28
- Final Rules: 55
- 2024 Total Pages: 75,354
- 2024 Final Rule Costs: \$1.24 trillion
- 2024 Proposed Rule Costs: \$120.4 billion

NOTABLE REGULATORY ACTIONS

The most consequential action of the week was the [proposed rule](#) from HHS regarding “Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act.” As the title suggests, the proposal seeks to implement provisions of the HOPE Act, a 2013 law that amended relevant statute “to eliminate the prohibition in the United States on transplantation of organs from persons with HIV, allowing transplantation of these organs if certain requirements are satisfied.” The law also includes the provision that “the Secretary may lift the research and IRB [institutional review board] requirements if the Secretary has determined that participation in such clinical research, as a requirement for such transplants, is no longer warranted.” This proposed rule represents such a determination. Under this new determination, HHS estimates annual “Net costs associated with organ transplants; costs associated with organ transplant centers reading and understanding the rule, reviewing policies and procedures, and training staff” of \$154 million (or roughly \$1.4 billion over a 10-year period), but also expected benefits for the affected population in terms of the quality and length of life as their treatment shifts from dialysis to transplants.

TRACKING THE ADMINISTRATIONS

As we have already seen from [executive orders and memos](#), the Biden Administration will surely provide plenty of contrasts with the Trump Administration on the regulatory front. And while there is a general expectation that the current administration will seek to broadly restore Obama-esque regulatory actions, there will also be areas

where it charts its own course. Since the AAF RegRodeo data extend back to 2005, it is possible to provide weekly updates on how the top-level trends of President Biden’s regulatory record track with those of his two most recent predecessors. The following table provides the cumulative totals of final rules containing some quantified economic impact from each administration through this point in their respective terms.

TRACKING THE ADMINISTRATIONS

REGULATORY ACTIVITY FROM INAUGURATION DAY TO SEPTEMBER 13TH (Year 4)

	FINAL RULES	FINAL RULE COSTS	PAPERWORK HOURS
BIDEN 2021	1015	\$1.68T	324.8M
TRUMP 2017	1113	-\$96.4B	291.5M
OBAMA 2009	1384	\$327.2B	263.4M

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With the main action from last week coming in the form of a proposed rule, the Biden Administration’s to-date

final rule totals had only a modest upward shift. Costs increased by \$219 million and paperwork by roughly 75,000 hours, due primarily to a Securities and Exchange Commission (SEC) rule. There was virtually no movement in the Trump-era totals. Meanwhile, the Obama Administration saw costs and paperwork surge by \$4.8 billion and 3.3 million hours, respectively. The main driver of these trends was the SEC rule (that would subsequently be overturned in court) on “Conflict Minerals” – a rulemaking that would somewhat awkwardly be one of the **costliest actions** emanating from Dodd-Frank “even though it had nothing to do with the financial crisis” that inspired the financial reform law.

TOTAL BURDENS

Since January 1, the federal government has published \$1.36 trillion in total net costs (with \$1.24 trillion in new costs from finalized rules) and 113.2 million hours of net annual paperwork burden increases (with 47.6 million hours coming from final rules).

