



## Week in Regulation

# Massive Proposed Rules Dominate the Week

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With the end of the fiscal year (FY) 2020 regulatory budget window closing in, there was negligible change to the final rule tally. Rather, the bulk of last week's regulatory activity came from proposed rules. Proposals regarding food safety recordkeeping and the legal status of independent contractors had estimated economic impacts in the billions of dollars, albeit in different directions. Across all rulemakings, agencies published \$3.6 billion in total net costs and added 10.9 million hours of annual paperwork.

## REGULATORY TOPLINES

- Proposed Rules: 49
- Final Rules: 69
- 2020 Total Pages: 60,606
- 2020 Final Rule Costs: -\$121.8 billion
- 2020 Proposed Rule Costs: \$14.6 billion

## TRACKING THE REGULATORY BUDGET

The rulemaking with the most significant economic impact was a proposed rule from the Food & Drug Administration (FDA). The [proposal](#) regarding “Requirements for Additional Traceability Records for Certain Foods” would implement provisions of the Food Safety Modernization Act that require more rigorous reporting requirements in order to better ascertain the spread of foodborne illnesses. FDA pins its “primary estimate” at roughly \$5.1 billion in total costs, but also explores the possibility of a high-end cost estimate of nearly \$30 billion.

The most significant *deregulatory* action came from the Department of Labor (DOL). The [proposed rule](#) regarding “Independent Contractor Status Under the Fair Labor Standards Act” would further clarify the legal difference between an “independent contractor” and an “employee.” The American Action Forum examined the details of the proposal [here](#). DOL estimates that this proposal could yield roughly \$3.2 billion in present-value savings. It should be emphasized, however, that both of the above rulemakings are merely proposed rules and therefore do not apply to the FY 2020 regulatory budget.

The Trump Administration expected to reach \$51.6 billion in cumulative net savings in [FY 2020](#). To date in the fiscal year, agencies have officially published 132 deregulatory actions and 46 regulatory actions, totaling \$171.7 billion in quantified total net cost savings.

# THIS WEEK'S REGULATORY PICTURE

This week, the Department of Health and Human Services (HHS) removes financial barriers to living organ donation.



**FEDERAL REGISTER**  
The Daily Journal of the United States Government



 Rule

## Removing Financial Disincentives to Living Organ Donation

A Rule by the Health and Human Services Department on 09/22/2020



Source: <https://www.federalregister.gov/documents/2020/09/22/2020-20804/removing-financial-disincentives-to-living-organ-donation>

On September 22, HHS published a [final rule](#) in the Federal Register that it believes will increase organ donation from living donors by removing costly disincentives that can prevent some individuals from donating. The rule fulfills a directive from [Executive Order 13,879](#) signed in 2019.

Specifically, the rule expands the scope of expenses incurred during a living organ donation that are eligible for reimbursement from the Living Organ Donation Reimbursement Program. That program aims to reimburse expenses for those that may incur a financial hardship in their role as a living donor if they cannot be reimbursed by a state program, their health insurance, or the organ recipient. Previously, only medical expenses were covered. The new rule allows certain non-medical expenses, such as lost wages or payments for a caregiver to a dependent child, to be reimbursed by the program.

The same day, HHS also issued a [notice](#) on the Living Organ Donation Reimbursement Program guidelines, which set income qualifications for program eligibility. Those guidelines increased eligibility from those with income less than 300 percent of the federal poverty level to 350 percent.

According to HHS, there were 7,397 living organ donations in 2019, or about 19 percent of all organ donations. Though HHS did not offer a specific anticipated increase, it expects living organ donations to increase because studies have shown that reimbursement programs increase living organ donation by anywhere from 14 to 65

percent. There is also evidence that income plays a role in living organ donor transplant rates.

## TOTAL BURDENS

Since January 1, the federal government has published \$107.2 billion in total net cost savings (with \$121.8 billion from finalized rules) and 278.5 million hours of net annual paperwork burden increases (with 227.2 million hours due to final rules). [Click here](#) for the latest Reg Rodeo findings.

