



## Week in Regulation

# Significant Non-Coronavirus Regulation Out of FDA

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As long as COVID-19 looms over daily life, the response of a subset of government agencies will be of particular importance. The Food & Drug Administration (FDA) is among that core group. In a bit of twist, however, last week brought some regulatory news out of FDA that was not (directly, at least) connected to the pandemic. A major regulation on cigarette package warning labels finally hit the Federal Register, in turn pushing the regulatory budget further to the cost side. Across all rulemakings, agencies published \$1.2 billion in total net costs and added 1.5 million hours of annual paperwork.

## REGULATORY TOPLINES

- 2020 Proposed Rules: 35
- 2020 Final Rules: 82
- 2020 Total Pages: 16,202
- 2020 Final Rule Costs: \$4.5 billion
- 2020 Proposed Rule Costs: \$3.7 billion

## TRACKING THE REGULATORY BUDGET

The FDA's [final rule](#) on cigarette labels was the most significant rulemaking of the week. Under the Family Smoking Prevention and Tobacco Control Act, a package of cigarettes needs to include "color graphics depicting the negative health consequences of smoking." With this rule, FDA has established "11 new textual warning label statements and accompanying color graphics," manufacturers can include. The agency estimates that this additional requirement brings roughly \$1 billion in net present value costs. As of [the week before last](#), the running fiscal year (FY) 2020 regulatory budget tally stood at roughly \$2.5 billion. These additional costs represent a 40 percent increase on the cost side of the ledger.

The Trump Administration expects to reach \$51.6 billion in cumulative net savings in [FY 2020](#). To date in the fiscal year, agencies have finalized 67 deregulatory actions and 21 regulatory actions, totaling \$3.5 billion in quantified total net costs.

## THIS WEEK'S REGULATORY PICTURE

This week, the White House aims to better coordinate federal agency operations in the wake of COVID-19.



*Via CDC*

On March 17, Office of Management and Budget (OMB) acting director Russell Vought issued a [memorandum](#) to all federal agencies formally directing agencies to “thoughtfully manage all our resources in a way that aligns with our desired outcome of slowing the transmission of COVID-19.” The memorandum outlines several ways in which agencies should identify non-critical activities and direct those resources toward the response to the coronavirus.

Of most interest to those following regulatory policy is the directive to “[c]onsider streamlining regulations and approval processes for critical services, including issuing general waivers policies and delegating decision-

making where appropriate.” This directive will have two effects.

The most immediate effect is that agencies will move to waive requirements. In addition to those featured [last week](#), agencies are waiving certain regulations. The Department of Housing and Urban Development announced a [moratorium](#) on foreclosures and evictions at Federal Housing Administration-insured properties. The Department of Health and Human Services waived rules prohibiting doctors from working across state lines, in a move announced by Vice President Mike Pence on March 18. Many of these actions would have had a greater effect on curbing COVID-19 had they been made sooner but are still important steps as the federal government ramps up its response.

The second effect is on the capacity of agencies to continue rulemaking on regulations not related to COVID-19. While the exact ramifications are too early to know, it is likely to reduce both regulatory and deregulatory actions in the months ahead. This could have an effect on what regulations make the possible “deadline” for avoiding the streamlined procedures of the Congressional Review Act, which as of now would appear to be mid-May (this could be extended if Congress is in session more days than expected in August and after Labor Day).

While the Trump Administration has already finalized many of its major priorities like the repeal of the Clean Power Plan, revising Waters of the United States, and issuing a new overtime rule, some priorities remain. The largest of these is the Safer Affordable Fuel-Efficient Vehicles rule, currently under review at OMB’s Office of Information and Regulatory Affairs, and the Council of Environmental Quality’s proposed National Environmental Policy Act rules. The OMB memorandum may delay these rules and others.

## TOTAL BURDENS

Since January 1, the federal government has published \$8.2 billion in total net costs (with \$4.5 billion in finalized costs) and 16 million hours of net annual paperwork burden increases (with 1.6 million hours due to final rules). [Click here](#) for the latest Reg Rodeo findings.

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Total Number of  
Regulations  
Finalized

**77**

Total Finalized Cost

**\$4.5b**

Paperwork Hours

**1,591,863**