Regulation Review

Just an Average $13 Billion Regulation

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Today, the administration revealed a $13 billion proposed rule with every cabinet agency participating in the release. When the executive summary is four-and-a-half pages long and every agency is involved in crafting the language, you know

you've created a regulatory masterpiece. This 131-page behemoth would aim to amend the "Federal Policy for the Protection of Human Subjects," and despite its costs, would somehow reduce burdens and ambiguity.

BREAKDOWN

- Costs: $13.3 billion ($1.3 billion annually at a seven discount rate)
- Benefits: $2.6 billion ($291 million annually at a seven discount rate)
- Paperwork Hours: 12.1 million

ANALYSIS

Since 1991, there has been a "common rule" for treating human subjects who volunteer for research. During this time, according to the administration, there has been a change in the scope and type of research involving volunteers. To address these changes, all cabinet agencies have joined to better protect human subjects and enhance informed consent.

For example, informed consent documents are to be shortened and clarified so that volunteers no longer feel overwhelmed by legal jargon. Informed consent would also be required for secondary research with biospecimens, even if the investigator cannot identify the donor. Finally, these policies would extend to all clinical trials, regardless of the funding source.

At $13.3 billion, if finalized, it would rank as the tenth most expensive regulation since 2009, which is remarkable considering few outside of the health care industry have discussed the measure. This year, it will rank as the fourth most expensive rulemaking by net present value and the costliest by annual burden. What's more, it obviously imposes more costs than benefits: with a ratio of 4.4:1, somewhat inappropriate for an administration that prizes high net benefit rules.

Although the rulemaking doesn't list a specific affect entity, if one assumes the measure will primarily affect "Scientific Research," here are the ten most affected states (accounting for 60 percent of the facilities), assuming net present value costs:

Affected State	Cost (in $ millions)
California	$2,661
Massachusetts	$811
Texas	$699
New York	$697
Florida	$649
Maryland	$559
Virginia	$500
Pennsylvania	$491
North Carolina	$471
New Jersey	$443

As with most industries, California is the leader, and likely to bear the largest costs, but Massachusetts sits in second. Dwarfed by California in population, Massachusetts boasts more than 1,000 research facilities, more than Texas and New York. Maryland was another surprise entry in the top ten, even though it has the smallest population in this sample.

SMALL BUSINESS IMPACT

The administration concludes that the average institution will bear more than $150,000 in new annual costs because of the measure. Although this is an extraordinary sum for a single entity, the analysis finds that most entities don't fit the definition of small business. Thus, this measure likely does not impose a significant economic impact on a substantial number of small entities.

UNFUNDED MANDATES

Although this proposed rule will easily cost more than $1.3 billion annually, the administration concluded that it does not impose unfunded mandates of at least $141 million. There does not appear to be a concise reason for denying that the rule will impose substantial unfunded mandates on private entities or states.

CONCLUSION

It’s odd, even in the regulatory world, to have a rulemaking joined by all cabinet agencies. It’s even rarer for a proposed rule to impose more than $13 billion in costs and 12 million paperwork hours. This rulemaking seems to have something for everyone: huge costs, massive scope, and uncertain burden reductions. It has helped to push 2015 regulatory burdens past $150 billion.