Consumer Federation of America

December 4, 2020

Alex Azar
U.S. Secretary of Health and Human Services
Washington, D.C.

RE: Proposed Rule: Securing Updated and Necessary Statutory Evaluations Timely

Online Submission via Regulations.gov

Dear Secretary Azar:

Consumer Federation of America (CFA) submits the following comments on the above referenced proposed rule. As we noted in our joint comments with Center for Science in the Public Interest and other consumer advocacy organizations, the Department of Health and Human Services (HHS) should extend the comment deadline for this rule and provide the public with the information necessary to meaningfully evaluate the proposal. CFA writes separately here to address the substance of the proposed rule more directly. CFA is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Over the years, CFA has advocated for many HHS food policies that are important to consumers and affect them in their everyday lives, such as the requirements for the nutrition facts panel, and the rules implementing the Food Safety Modernization Act. If implemented, the proposed rule could disrupt past progress on nutrition and food safety goals, and paralyze future work to protect consumers at HHS.

The proposed rule exhibits an ideological animus towards "regulation," much like President Trump's "2 for 1" regulations order, Executive Order 13771, which directs agencies to eliminate two regulations for every new one they create. Such policies rest on the premise that Americans need relief from burdensome government interference in their lives. Survey after survey, however, shows that Americans favor more, not less, government action to address problems ranging from internet privacy, to climate change, to labor rights, to food safety. According to a recent poll conducted by Data for Progress, "a majority of voters – including 62% of Republicans – think that regulations serve an important role in protecting the environment, keeping workers safe and ensuring a fair economy."[1] Another recent survey by the Pew Charitable Trusts finds that "nearly two-thirds of Americans believe the federal government should act more aggressively to combat climate change."[2]

[1] https://www.citizen.org/news/poll-71-of-voters-support-strong-regulation-to-protect-the-public/
[2] https://www.washingtonpost.com/climate-environment/2020/06/23/climate-change-poll-pew/

The proposed rule would inhibit government action, making HHS more passive in the face of bad actors that put consumers' lives at risk. It would add to existing retrospective review requirements for HHS, and divert significant resources to defending past agency actions, rather than crafting the solutions to meet today's challenges.

Yet the proposed rule utterly fails to marshal the evidence that would support such a radical approach. It emphasizes that several states have adopted "sunsetting" policies. Notably, those policies were passed by legislators, who were directly accountable to their constituent voters. But regardless, as the rule points out, scholars have documented how several states repealed their sunset laws after concluding that "sunset provisions quickly proved to be an expensive, cumbersome, and disappointing method for enhancing legislative control")." The proposed rule also cites reports from the Organisation for Economic Co-operation and Development,[3] which it claims contain foreign examples of similar regulatory "sunset" provisions. Needless to say, foreign regulatory systems are much different from that of the U.S. and evaluating the claims made in the proposed rule on the basis of a few OECD reports is very difficult. If for no other reason, HHS should extend the comment period so members of the public can familiarize themselves with the foreign regulatory systems that it purports to be emulating.

The proposed rule further contains several radical departures from established law that HHS should clarify. For example, the proposed rule abandons the Administrative Procedure Act's (APA's) definition of "rule." HHS proposes instead to evaluate the Code of Federal Regulations section by section, yet it also maintains that "The Department should in many cases perform a single Assessment (and, where required, a single Review) that considers all Regulations issued as part of the same rulemaking." This seems to create a situation ripe for well-funded special interests to pick off regulatory provisions and water down consumer and public health protections through a piecemeal process. HHS should provide more information on how it would guard against such an outcome, and the procedures that would apply to dictate which rules would be reviewed in "a single assessment" and which would be reviewed CFR section by CFR section.

The proposed rule also appears to conflict with the APA more generally. According to the proposed rule, "It complies with the APA to amend Regulations to add dates by which Regulations expire unless the Assessment and/or Review is timely performed." This is because "An agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date." But the proposed rule goes on to more or less concede that reviewing every entry in the Code of Federal Regulations would be impossible, and therefore, many "regulations" would expire if the proposal is finalized. In order to make sure we do not lose any really important rules, the proposed rule suggest that members of the public could use a website to submit comments asking for the Department to review a particular regulation "if the deadline for publishing an Assessment or Review is nearing and the Department has not yet announced that it has commenced the Assessment or Review." In other words, HHS seeks to outsource the heavy lifting of its regulatory reform mission to private citizens. This will clearly lead to many arbitrary and capricious results. Has HHS considered what types of regulations may be favored by such a process? Presumably regulations that favor narrow, powerful, moneyed interests will be brought to the

[3] The rule misidentifies the "OECD" as the "Office for Economic Co-Operation and Development."

attention of HHS regulators more often than protections for dispersed groups of consumers. How would HHS account for that dynamic?

The proposed rule indicates that the results of its undertaking to review all of its regulations that are over 10 years old within 2 years would result in myriad "final agency actions" where aggrieved interests, including big corporations, could challenge whether "the amendment, repeal, or affirmation of Regulations" or indeed, the determination that a regulation "does not have a significant economic impact upon a substantial number of small entities," was actually "arbitrary and capricious" under the Administrative Procedure Act. So even if HHS could manage to sort through all of its regulations and make informed, accurate decisions about which regulatory requirements are justified and which are not, it would then have to fend off a veritable tsunami of legal claims second-guessing those decisions. Has HHS estimated the burden of defending such lawsuits? Has the Department consulted with the Department of Justice about whether their lawyers would respond to the expected increase in workload?

The proposed rule requires HHS lawyers to review every single "regulation" for whether it "complies with applicable law." Since there are so many regulations to review in just two years, the Department will have to hire many new lawyers, and other specialists for conducting these reviews. The proposed rule cites an estimate that a total of between 20,160 and 44,900 hours will be spent on new Reviews, at a cost of roughly $244 per hour, or between $4,938,797 to $10,999,602. How did HHS arrive at these estimates? Presumably a great deal of analysis went into them, can the Department share that analysis with the public?

And why has HHS chosen to conceal nearly all of the "Regulatory Streamlining & Analysis" published by Deloitte consulting in March of 2019, that it cites in support of its proposed rule? The document is posted in the docket on regulations.gov., but with two of three bullet points in the "executive summary" slide apparently redacted, and all but 25 of the document's 170 pages blacked out completely. Why isn't that information being made available to the public? Why didn't HHS have a public meeting to discuss the Deloitte findings and solicit feedback on its regulatory reform ideas back in 2019?

According to HHS, "this proposed rule seeks to advance democratic values and apply the lessons learned from States, foreign jurisdictions, and the academic community." In keeping with this motivation, HHS should not rush to finalize this rule. Advancing democratic values takes time. The public, moreover, should have full access to the information necessary to evaluate the "lessons learned" behind this rulemaking.

Thank you for your consideration of these questions and concerns.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America