

December 31, 2020

Alex Azar, II, Secretary of Health and Human Services
c/o James Lawrence, Office of the General Counsel
U.S. Department of Health and Human Services

Re: Securing Updated and Necessary Statutory Evaluations Timely

Docket No. HHS-OS-2020-0012

Dear Secretary Azar:

The Public Health Law Center is pleased to submit these comments to the Department of Health and Human Services (Department) on its Proposed Rule entitled “Securing Updated and Necessary Statutory Evaluations Timely.” The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation’s diet, encourage physical activity, protect the nation’s public health infrastructure, and promote health equity.

We strongly oppose the Proposed Rule, which would violate the Administrative Procedure Act, weaken the Department’s ability to regulate public health and welfare, and have a detrimental impact on public health regulation. The Department should abandon the Proposed Rule for the following reasons:

- Broadly imposing automatic expiration of Department regulations violates the Administrative Procedure Act (APA).
- Automatic expiration of regulations without adherence to APA procedural requirements or reasoned deliberation by the Department would likely be found in violation of statutory requirements and arbitrary and capricious.
- A sunset of nearly all Department regulation undermines congressional intent in ensuring periodic review under the Regulatory Flexibility Act (RFA).
- The sweeping proposed changes would create substantial uncertainty in public health and welfare regulation.
- Implementing burdensome, agency-wide changes under the Proposed Rule diverts Department resources at a time the country is confronting a national public health crisis in the COVID-19 pandemic.

For these reasons, and those raised in public comments submitted by numerous commenters finding the Proposed Rule in violation of the APA, unduly burdensome on the Department, and harmful to public health regulation, we urge the Department to abandon the Proposed Rule.

I. Broadly Imposing Automatic Expiration Dates on Department Regulation Violates the Administrative Procedure Act.

The Proposed Rule's broad imposition of expiration dates across entire swaths of Department regulations violates the Administrative Procedure Act. Broadly imposing expiration dates for regulations without Department consideration of the Proposed Rule's impact on individual regulations or programs is arbitrary and capricious. Further, the automatic expiration of a regulation under the Proposed Rule undermines APA rulemaking requirements and would also likely be found arbitrary and capricious.

A court reviewing agency action shall "hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The agency must "articulate a satisfactory explanation for its action, including a 'rational connection between the facts found and the choice made.'" *Motor Vehicles Mfr. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983). Agency action is arbitrary and capricious when the agency does not provide a satisfactory explanation for its action or "entirely fail[s] to consider an important aspect of the problem." *Id.*, at 43, 50. In addition, "when its prior policy has engendered serious reliance interests . . . a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *FCC v. Fox Television Stations*, 556 U.S. 502, 515-16 (2009).

The Department attempts to satisfy these requirements by explaining that its proposal to use expiration dates would motivate compliance with existing review requirements under the RFA, without providing a satisfactory explanation regarding how it would address the sunset's effect on individual regulations affected by the Proposed Rule. Further, the Department does not provide a reasoned explanation for its departure from prior policy with respect to the thousands of regulations it proposes to sunset. The Department completely fails to consider potential disruption of programs and cohesive regulatory schemes and inconsistency with congressional directives. By way of example, automatic expiration of regulations would threaten the Food and Drug Administration's long-standing regulatory schemes protecting public health and safety by placing nutritional standards, food labeling requirements, food safety regulations, and commercial tobacco control regulations at risk of unreasoned rescission and result in the FDA's failure to fulfill its regulatory responsibilities in these areas.

The Department also entirely fails to consider that promulgating a rule that does not examine the individual impacts of expiration and recklessly positions the Department for future violations of the APA is arbitrary and capricious and in violation of the APA.

Moreover, automatic expiration of a regulation without individualized consideration undermines the APA's rulemaking requirements. Rulemaking under the APA applies to the repeal of a rule and requires public notice and an opportunity for public comment. 5 U.S.C. §§ 551(5), 553. "Revocation constitutes a reversal of the agency's former views as to the proper course" and "[w]hile the agency is entitled to change its view on [a matter], it is obligated to explain its reasons for doing so." *Motor Vehicles Mfr. Ass'n v. State Farm*, 463 U.S. 29, 41, 56 (1983). "[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change" and "[g]enerally, one aspect of that explanation would be a justification for rescinding the regulation . . ." *Id.* at 42, 52. Automatic expiration of a regulation for lack of agency affirmative action is arbitrary and capricious on its face for lack of explanation and a total failure to consider the issue. The Department argues it may impose an expiration on the occurrence of a condition, yet the condition the Department has chosen would violate the APA. If the Department does not perform an affirmative action to prevent expiration of a regulation, the Department would fail to articulate a satisfactory explanation for its expiration, making the agency action arbitrary and capricious. For these reasons, lack of agency action resulting in arbitrary expiration likely violates the Administrative Procedure Act.

II. The Proposed Rule Undermines the Department's Compliance with the RFA.

In the Proposed Rule, the Department's stated purpose is "to enhance the Department's implementation of section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 610 . . . and improve accountability and the performance of its regulations." 85 FR 70097. However, the Department's Proposed Rule does not further the Department's implementation of the RFA. In fact, the Department's Proposed Rule undermines congressional intent in requiring review under the RFA in at least two ways. Further, as explained below, the Department errs in making an unsupported assumption that instituting an expiration for regulations under its purview would be incentive to follow the law.

One way in which the Proposed Rule undermines congressional intent is by defeating the requirement of ensuring agency review of rules affecting small entities. The RFA requires periodic review of rules that have a "significant economic impact of the rules upon a substantial number of such small entities." 5 U.S.C. § 610(a). The RFA requires agencies to create a plan to fulfill their periodic review

requirements and does not require or grant agencies authority to broadly institute expiration dates for all regulations to achieve this purpose.

In fact, automatic expiration of Department regulations frustrates the RFA's purpose of review "to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities." 5 U.S.C. § 610(a). If Department regulations expire in the absence of assessment or review, the Department cannot conduct required review under the RFA. The Proposed Rule does not address that the Department's wide-ranging rule frustrates Congress's intent for the RFA to ensure agency review of rules that affect small entities.

In fact, automatic expiration may even inappropriately sunset rules that increase economic impact on small entities. The Proposed Rule does not sufficiently address this concern. The Department merely states that this is unlikely because "members of the public will remind the Department if the Review deadline is nearing"—imposing economic impacts on small entities and attempting to delegate its legal responsibilities under the RFA to the public. 85 FR 70117.

A second way in which the Proposed Rule undermines congressional intent is the Department's failure to observe that Congress limited the scope of the RFA to ensure agencies periodically review a narrow subset of their regulations. The Proposed Rule does not consider that the Department may be impeding its ability to conduct reviews under the RFA by instituting added procedural requirements and broadly applicable regulatory sunsets. Creating procedural requirements for assessment and arbitrary expiration dates pertaining to all of its regulations will likely divert agency resources from RFA review. Expiration dates are particularly contrary to effectuating RFA compliance because the Department will need to prioritize assessing rules without any impact on small entities simply due to their imminent expiration, rather than using Department resources efficiently to focus on rules requiring the Department's review under the RFA.

Moreover, the Department errs in the assumption that automatic expiration and revocation will incentivize Department compliance with the RFA. The Department is already required to conduct periodic review under the RFA. It is an impermissible and harmful assumption that the Department would be incentivized to fulfill existing legal obligations by threatening expiration of public health and welfare regulations that would directly impact the public, not the Department.

III. The Proposed Rule Creates Substantial Uncertainty in Public Health and Welfare Regulation and Is Antithetical to the Purpose of Regulation.

The wide-ranging proposed changes would create substantial uncertainty in public health and welfare regulation. Agency regulation establishes standards, methods, processes, and programs that collectively further public health and welfare, build on the expertise of the agency and the public, and work in tandem to create a strong, cohesive, and consistent body of regulation. Government entities, individuals, organizations working in public health and welfare, and regulated industries rely on the Department's adherence to these processes to ensure their ability to participate in agency rulemaking processes and to provide predictability in regulation that guides their activities. The imposition of arbitrary automatic sunsets in the Proposed Rule would thwart the Department's ability to fulfill its essential functions it is relied on to perform. The Proposed Rule allows regulations to expire without the Department's reasoned consideration or public input—threatening its carefully crafted fabric of regulation with an unreasoned and unpredictable patchwork.

IV. Our Recommendation

In consideration of the above concerns—and concern of diverting Department resources to implement the Proposed Rule's sweeping changes when the country is confronting a national public health crisis in the COVID-19 pandemic—we strongly urge the Department abandon the Proposed Rule.

Respectfully,



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