AMERICAN ACADEMY OF FAMILY PHYSICIANS

December 2, 2020

Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 136,700 family physicians and medical students across the country, I write in response to the notice of proposed rulemaking (NPRM) on Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) requirement, as published in the November 4, 2020 version of the *Federal Register*.

In the NPRM, the Department of Health and Human Services (HHS) proposes to implement sunset provisions so that all regulations in Titles 21, 42, and 45 of the Code of Federal Regulations (CFR) will automatically expire if they are not reviewed within a certain timeline. These Titles contain all regulations governing the agencies within HHS, including but not limited to the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Health Resources and Services Administration (HRSA) and the programs that each of these agencies administer. HHS proposes that these regulations will expire at the latest of either:

1) Two calendar years after the year that this proposed rule first becomes effective,
2) Ten calendar years after the year that the regulation first went into effect, or
3) Ten calendar years after the last year in which HHS assessed and, if review is required, reviewed the regulation.

More specifically, the Department proposes to require that all regulations are assessed for their impact on a substantial number of small entities. For those that are deemed to have a significant impact, HHS will have to more formally review them to determine whether they should continue without change or should be amended or rescinded. If the review is not performed within the time periods outlined above, the regulation will expire. Notably, this would require that almost 2,500 regulations will need to be assessed in the two-year period after the SUNSET rule becomes effective or risk automatic expiration.

The AAFP is concerned about the impact that this proposed rule could have on agencies' ability to respond to the worsening COVID-19 pandemic and administer the health care coverage, payment, and public health programs that family physicians and their patients depend on. While the AAFP supports efforts to reduce the regulatory burdens on physicians and recognizes the potential value of retrospective review, we believe this rule will increase regulatory complexity and lead to disruptions for a myriad of health care stakeholders. The rule also threatens to harm public health if critical regulations were to automatically sunset. Thus, **we recommend that HHS rescind the proposed rule.**

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States, insurance issuers, physicians, and other health care professionals all rely on existing regulations and the regulatory process in order to serve patients. Patients themselves also rely on clear regulatory guidance on the safety of food and medications, as well as health care coverage programs. For example, the Affordable Care Act was passed more than ten years ago and many of the ensuing regulations have not been amended since they were first finalized. If these regulations were to automatically expire, it would create confusion for states and issuers administering qualified health plans and Medicaid coverage to the expansion population.[1] Similarly, the regulations implementing the Medicare Drug, Improvement, and Modernization Act, which created Medicare Part D, first went into effect in 2005.[2] Since some sections of these regulations have not been updated since they went into effect, the stability of the Part D program could also be at risk if regulations were to automatically expire. This could ultimately obstruct beneficiaries' ability to obtain their medications and have a negative impact on their health.

The FDA produces many regulations each year that are vital to ensuring public safety. We performed a search of the *Federal Register* and found that 76 FDA regulations went into effect in 2009. Among several other policies, these regulations improve access to investigational treatments, prevent salmonella, and improve oversight of lab tests for respiratory viruses.[3,4,5] If any of these regulations were to expire, companies developing and handling pharmaceuticals, cosmetics, and food would no longer be compelled to comply with long-standing safety regulations.

In addition to causing disruption and uncertainty, the AAFP is concerned that this rule will interfere with agencies' ability to perform their essential functions and promulgate important new regulations. Many of these functions are of even greater importance now, as our nation faces a growing COVID-19 case load and must undertake the process of reviewing and distributing new vaccines and therapeutics. If this proposed rule were implemented as proposed, we believe that the agencies administering health programs would be overburdened and the patients, physicians, and other stakeholders they serve will be negatively impacted. The AAFP is particularly concerned that Indigenous people, rural residents, and other medically underserved populations will disproportionately bear the impact of this regulation, given the agencies that are governed by Titles 21, 42, and 45. We are committed to eliminating racial and other inequities in health care and strongly recommend that HHS strive toward the same goal.

HHS conducted a sample study of existing regulations to determine the cost of this proposal. The Department estimates that the reviews and assessments required in the first two years after this rule is finalized will take between 30,000 and 78,000 hours of agency staff time, likely at the same time as HHS continues to respond to and recover from a public health crisis.[6] We also note that this is an unfunded mandate, and agencies will be required to dedicate staff and funds from their limited budgets to performing assessments and reviews instead of furthering the health of the public.

The AAFP is concerned that such a significant undertaking will detract from the administration of vital health care programs and we do not believe the proposed timeline is necessary to achieve the statutory requirements of retrospective review. The Regulatory Flexibilities Act (RFA) already requires each federal agency to develop a plan for the periodic review of rules with a significant economic impact. The RFA does not provide for the sunsetting of regulations that are not reviewed. We instead recommend that HHS prioritize mitigating the impact of the pandemic and ensuring high-quality, affordable health care for all Americans.

Given the significant impact it will have on agency functions and the potential downstream impact on family medicine practices and patients, we do not believe this rule should be finalized as proposed. The AAFP urges HHS to rescind this NPRM.

Thank you for the opportunity to comment on the NPRM. Should you have any questions, please contact Meredith Yinger, Senior Regulatory Strategist, at (202) 235-5126 or myinger@aafp.org.

Sincerely,

Gary L. LeRoy, MD, FAAFP

Gary LeRoy, MD, FAAFP
Board Chair

[1]Department of Health and Human Services. Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans. 2011. Available at: https://www.federalregister.gov/documents/2011/07/15/2011-17610/patient-protection-and-affordable-care-act-establishment-of-exchanges-and-qualified-health-plans

[2]Centers for Medicare and Medicaid Services. Medicare Prescription Drug Benefit. 2005. Available at: https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit

[3]Food and Drug Administration. Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation. 2009. Available at: https://www.federalregister.gov/documents/2009/07/09/E9-16119/prevention-of-salmonella-enteritidis-in-shell-eggs-during-production-storage-and-transportation

[4]Food and Drug Administration. Medical Devices: Immunology and Microbiology: Classification of Respiratory Viral Panel Multi-plex Nucleic Acid Assay. 2009. Available at: https://www.federalregister.gov/documents/2009/10/09/E9-24432/medical-devices-immunology-and-microbiology-devices-classification-of-respiratory-viral-panel

[5]Food and Drug Administration. Expanded Access to Investigational Drugs for Treatment Use. 2009. Available at: https://www.federalregister.gov/documents/2009/08/13/E9-19005/expanded-access-to-investigational-drugs-for-treatment-use

[6]Retrieved from the Regulatory Impact Analysis (Section VI) of the proposed rule.