



December 4, 2020

Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

On behalf of the American College of Physicians (ACP), I am writing to express our strong opposition to the proposed rule “Securing Updated and Necessary Statutory Evaluations Timely”, and urge that it be withdrawn. ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 163,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP is deeply concerned that this rule will be burdensome and, in fact, increase regulatory complexity. This rule would create a continual change in the regulatory environment requiring entities subject to HHS regulations to keep track of rules that would continue to stay in place and rules that would sunset. This proposed rule’s most detrimental impact is that it would enable essential regulations that protect patients and that are imperative to the effectiveness of the myriad programs under HHS regulatory authority, including Medicare, Medicaid, CHIP, CDC, HRSA, FDA, and others, to expire. This decision would demonstrate an extraordinary, unnecessary, and inefficient use of departmental resources and would be an irresponsible stewardship of public funds.

Additionally, the resource demands would be both time consuming and costly for HHS agencies at a time when resources could be better used to support patients, physicians, and other clinicians — thereby making this rule potentially harmful to patients. If HHS is unable to dedicate the needed resources to conduct the necessary assessments and reviews, rules would expire and cause major harm. For example, if Medicaid regulations were left to expire, this would make it hard, if not impossible, for states to properly administer their Medicaid programs, potentially harming millions of people who rely on such benefits to cover care for their acute and chronic conditions. There is also the potential to disrupt work on program operations and force delays in adopting health care priorities because of the need to redirect staff to review existing regulations.

For the FDA, which issues hundreds of regulations per year, the resource demand would be enormous. To fulfill the requirements of this proposed rule, staff would have to review every regulation to determine if it impacts small entities, and then draft justifications for retaining the regulations, which could paralyze FDA functions related to writing and reviewing new regulations.

ACP strongly urges HHS not to move forward, and to instead withdraw this proposed rule. Given the thousands of regulations implemented by HHS, a required review every ten years of each one, or automatically sun-setting that regulation, is simply not feasible. The Regulatory Flexibility Act (RFA), 5 U.S.C. 610 and various executive orders cited already provide adequate opportunity for regulation review. This rule would likely impede HHS efforts to meaningfully update regulations where needed, since it would force HHS to devote staff time to the unnecessary reviews it would mandate. 5 U.S.C. 610 (a) requires each federal agency to “publish a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.” According to this provision, a review is required every 10 years unless that is “not feasible”. Further, in cases where that 10-year review is deemed not feasible, the provision 5 U.S.C. 610 allows the review period be extended up to five more years. The proposed rule would not allow for such contingencies, which could lead to harm rather than the desired outcome of reducing administrative burden. The Regulatory Flexibility Act does not provide for regulations to automatically sun-set if the issuing agency does not review them.

ACP takes seriously the need for HHS to efficiently and effectively administer the Medicare programs that provide health care coverage for America’s elderly and most vulnerable patient populations; the Medicaid and CHIP programs that provide health insurance for millions of Americans, including some low-income people, families and children, pregnant women, the elderly, and people with disabilities; and the many other Agency programs that impact American lives. To make these programs work, physicians, other clinicians, states, and managed care plans need stability and predictability from the Agency.

The College greatly appreciates the concern of HHS for small entities and the impact regulation may have on them. ACP hopes HHS will take into account these concerns and the strain that this proposed rule may cause to our health systems and disrupt each aspect of the clinical experience and workflow. If you have any questions or would like additional information, please contact Brian E. Outland, Director, Regulatory Affairs at boutland@acponline.org or 202-261-4544.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline W. Fincher MD". The signature is written in a cursive, flowing style.

Jacqueline Fincher, MD, MACP
President
American College of Physicians