December 22, 2020

The Hon. Alex Azar, Secretary

U.S. Department of Health and Human Services

200 Independence Avenue SW

Washington, DC 20201

**Re: RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations Timely**

Dear Secretary Azar:

We are writing on behalf of the Council of Academic Family Medicine (CAFM) which collectively includes family medicine medical school and residency faculty, community preceptors, residency program directors, medical school department chairs, research scientists, and others involved in family medicine education.

We appreciate the opportunity to provide comments on the Department of Health and Human Services (HHS) proposed rule, “Securing Updated and Necessary Statutory Evaluations Timely” (hereinafter referred to as the “Regulations Rule”) and specifically changes to 42 CFR parts 400–429 and parts 475– 499 or the Medicare portion of the rule. The proposed rule would retroactively impose an expiration provision on most HHS regulations and establish “assessment” and “review” procedures to determine which, if any, regulations should be retained or revised. The Regulations Rule is an ill-conceived proposal that would create tremendous administrative burden for HHS and would wreak havoc across a broad swath of Department programs and regulated entities such as Medicare. We urge HHS to immediately withdraw this proposed rule.

**The proposed rule would create tremendous administrative burden for HHS**

HHS asserts that the Regulations Rule will promote “accountability, administrative simplification [and] transparency. . . .”[[1]](#footnote-1) In fact, the proposed rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic. HHS itself estimates that the proposed rule would cost nearly $26 million dollars over 10 years, needing 90 full-time staff positions to undertake the required reviews.[[2]](#footnote-2) Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old.[[3]](#footnote-3) However, these estimates likely underestimate the time and money involved in the review process, and do not accurately account for complications that may arise.

The Regulations Rule would adversely affect HHS’s ability to focus on the administration of current programs, to issue new regulations, and appropriately review current regulations that need modification. In addition, several regulations implementing important parts of the Affordable Care Act are approaching their ten-year anniversary. Regulations like these would need to be reviewed within the next two years, or they would expire. However, the underlying law still exists, even if the regulations expire.

Especially during crisis situations like COVID-19, it is critically important that HHS have the flexibility and bandwidth to shift focus and respond quickly to immediate needs.

**The current rule would wreak havoc across all HHS programs**

The greater danger posed by the Regulations Rule is that important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time- consuming review process would summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies.

For example, one of the most positive regulations related to primary care training was the inclusion of an exception to the teaching physician rules for primary care education. This policy, commonly called the primary care exception (§ 415.174 Exception: Evaluation and management services furnished in certain centers) was implemented in 1996 – and remains critically important today.

The exception allows, under certain restricted circumstances, the “teaching physician” to supervise a resident (a training physician) immediately after a patient visit, rather than the typical mandate that the supervision occur during the patient encounter. The purpose is to allow the trainee to develop a continuity relationship with the patient and to be viewed by the patient as their physician, while still ensuring supervision by, and payment of, the teaching physician. This has been a very successful part of the training of family medicine residents, and if it were to be rescinded without review it would wreak havoc on the training of primary care physicians, causing disruption, additional costs and administrative burden.

**The proposed rule is unnecessary and HHS does not have the authority to propose automatic expiration dates on almost all regulations.**

The Regulations Rule claims that automatic expiration dates give HHS the incentive necessary to conduct regular assessments of existing regulations and comply with the Regulatory Flexibility Act (RFA). First, HHS agencies already commonly update regulations when needed. HHS’ contention that it needs to “incentivize” regulation review by imposing a mandatory rescission is simply not supported by the facts.[[4]](#footnote-4)

Further, the RFA requires each 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.”[[5]](#footnote-5) However, nothing in this forty-year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations.

In fact, this proposal is contrary to the Administrative Procedure Act’s (APA) requirements for rulemaking. In the APA, Congress established clear procedures and standards for agencies seeking to modify or rescind a rule. The APA requires agencies to go through the same rulemaking process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment.[[6]](#footnote-6)

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expired.[[7]](#footnote-7) We do not dispute that federal agencies can later amend existing regulations. However, the Regulations Rule would modify thousands of separate, distinct rules across HHS in a single stroke, in violation of the APA. HHS’ attempt to apply a blanket amendment to 18,000 regulations violates the APA’s requirements that review of an existing rule take place on an individual basis, requiring specific fact-finding relevant to the individual rule that the agency wants to amend,

**Conclusion**

The Regulations Rule is simply an attempt to destroy duly promulgated regulations, by retroactively imposing an arbitrary end date to duly promulgated regulations. This rule is unnecessary, will wreak havoc in current HHS programs, and will tie the hands of the incoming Administration by detracting from critical issues like the COVID-19 pandemic, to undertake this time-consuming process. We strongly oppose this rule and urge HHS to withdraw it immediately.

Thank you for the opportunity to comment on this important issue. If you have further questions, please contact Hope Wittenberg Director, Government Relations at 202-986-3309 or hwittenberg@stfm.org

Sincerely,



Steven R. Brown, MD

President

Association of Family Medicine Residency Directors



Tricia C. Elliott, MD

President

Society of Teachers of Family Medicine



Allen Perkins, MD, MPH

President

Association of Departments of Family Medicine



Gillian Bartlett, PhD

President

North American Primary Care Research Group

1. 85 Fed. Reg. 70104. [↑](#footnote-ref-1)
2. 85 Fed. Reg. 70116. [↑](#footnote-ref-2)
3. 85 Fed. Reg. 70112. To be specific, HHS states that “because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480.” *Id.* [↑](#footnote-ref-3)
4. 85 Fed. Reg. 70099, 70106. [↑](#footnote-ref-4)
5. 5 U.S.C. 610(a) (In the case of the RFA, periodically is defined as 10 years, unless such review is not feasible, in which case the review can be extended another 5 years). [↑](#footnote-ref-5)
6. 5 U.S.C. § 551(5);*see also* Maeve P. Carey, Specialist in Government Organization and Management, *Can a New Administration Undo a Previous Administration's Regulations?*, Congressional Research Service (Nov. 21, 2016), <https://fas.org/sgp/crs/misc/IN10611.pdf> (“In short, once a rule has been finalized, a new administration would be required to undergo the rulemaking process to change or repeal all or part of the rule.”); Office of Information and Regulatory Affairs, Office of Management and Budget, The Reg Map 5 (2020) (noting that “agencies seeking to modify or repeal a rule” must follow the same rulemaking process they would under the APA). [↑](#footnote-ref-6)
7. 85 Fed. Reg. 70104, fn 85 & 86, citing to separate, specific rulemakings modifying interim final rules implementing mental health parity and foreign quarantine provisions, respectively. [↑](#footnote-ref-7)