



Charles N. Kahn III  
President and CEO

December 4, 2020

VIA electronic submission at <http://www.regulations.gov>

Mr. James Lawrence  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: RIN 0991-AC24, Department of Health and Human Services Securing Updated and Necessary Statutory Evaluations Timely**

Dear Mr. Lawrence:

The Federation of American Hospitals (FAH) appreciates the opportunity to submit these comments to the Department of Health and Human Services (HHS or the Department) regarding the *Department of Health and Human Services Securing Updated and Necessary Statutory Evaluations Timely* (Proposed Rule), published in the *Federal Register* on November 4, 2020 (85 Fed. Reg. 70096). The FAH is the national representative for over 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural America. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates HHS' ambitious initiative to enhance its implementation of section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 610, and various executive orders, and improve accountability and the performance of its regulations. The Department has established goals of ensuring that regulations are timely and relevant, increasing accountability and transparency, and mitigating the economic impact of burdensome regulations on small businesses, nonprofits, and governmental jurisdictions.<sup>1</sup>

---

<sup>1</sup> 5 U.S.C. § 601(7) (defining a "small entity" as a "small business," "small organization," or "small governmental jurisdictions" as defined previously in §§ 601(3), 601(4), and 601(5) of this section).

The FAH understands that the Proposed Rule is meant to support these efforts by requiring a deadline-driven retrospective review of all of the Department's regulations that have a significant economic impact upon a substantial number of small entities for undue administrative complexity, continued relevance, and performance measurement. However, the FAH encourages the Department to postpone consideration of the Proposed Rule until the COVID-19 public health emergency (PHE) is no longer consuming HHS' and health care industry stakeholders' attention and straining national resources. Implementation of the Proposed Rule would cause a diversion of substantial resources of HHS and health care providers and would have a tremendous and wide-ranging impact on stakeholders, small entities, and the administrative process. We believe that industry stakeholders need more time than allotted in the comment period to review, quantify, and respond to the significant impact of the Proposed Rule, particularly in the midst of the PHE. The FAH urges HHS to withdraw the Proposed Rule as it is still possible for the Department to accomplish similar ends through use of the Administrative Procedure Act.

### ***Timing of the Proposed Rule Diverts HHS and Health Care Industry Resources from Addressing the COVID-19 Pandemic***

As the Department is well aware, hospitals are facing incredible challenges this year. Our members continue to make great efforts to ensure that they are providing quality care to the patients in their communities throughout the COVID-19 PHE. Whether preparing for a possible surge of, or caring for, COVID-19 patients, or addressing the economic strain of maintaining critical health care services, our members have been impacted significantly by the PHE. During the PHE it has become clear how important it is for hospitals to have readily accessible guidance from HHS to assist our members in responding to these current challenges.

The FAH is concerned that the diversion of health care stakeholder resources required to properly respond to, and possibly implement, the myriad of regulatory and operational changes as a result of this Proposed Rule in the midst of the PHE would leave patients and providers in a precarious position. Every day, hospitals treat more patients afflicted with COVID-19 than the day before. Despite the unprecedented amount of resources and effort required from providers and hospitals to address the PHE, our members believe that responding to this Proposed Rule is important to make the Department aware of the possible significant and protracted impact on patients and hospital operations.

Although HHS has expressed a continuing and laudable focus on improving and streamlining its regulations, the FAH feels strongly that the timing is inappropriate. A more comprehensive response to the Proposed Rule will take time and effort that our members do not have in the midst of the PHE. If the Proposed Rule is finalized during the PHE, our members will be stretched to properly monitor and respond to publications in the Federal Register and to review and submit suggestions to the HHS website under any implemented final version of the Proposed Rule. Thus, the FAH urges the Department to delay consideration and implementation of the Proposed Rule.

Similarly, it seems that a diversion of manpower and other resources from HHS at this time to promulgate, finalize, and implement any version of the Proposed Rule during the PHE would be misguided. HHS's role in resolving this pandemic is crucial. The Department is both the nation's leader and its clearinghouse for vaccine development, COVID-19 testing, the approval of new treatments, and the administration of grants imperative to ensuring the safe and continued operations of hospitals and health care facilities. As important as they are, HHS' efforts towards regulatory reform should allow prioritization of the activities and actions needed to support our health care system at this critical time.

### ***Truncated Comment Period Makes Meaningful Review and Collaboration Impossible***

The FAH believes that a thirty-day comment period for a rule of this magnitude is insufficient. A review of the Proposed Rule by industry stakeholders should be conducted in a meaningful way with proper discussion and consideration. This is simply not possible to achieve in thirty days during a widespread and deadly pandemic.

Moreover, the FAH is concerned that pushing forward with finalizing the Proposed Rule without allowing time for, and seriously taking into account, the views, recommendations, and constructive input of stakeholders could be risky for the entire health care system. The ramifications of finalizing a Proposed Rule this far-reaching that has not been properly vetted and, where appropriate, improved upon through the cooperative deliberation of HHS and the health care and public health communities could be harmful to hospitals, providers, and patients. The administrative process is designed to encourage collaboration between the public and HHS to develop the best possible regulation to govern the industry while complying with applicable law. The abbreviated comment period for the Proposed Rule serves to turn the regular administrative process on its head, allowing only cursory analysis and evaluation of the rule and little, if any, meaningful feedback to HHS and consideration of that feedback by HHS.

### ***The Proposed Rule's Goals Could Be Accomplished Through a More Nuanced Mechanism or Existing Processes***

In the Proposed Rule, HHS seeks to create a system to assess, review, and revise or discard regulations that it deems no longer relevant or beneficial. However, the possible broad rejection of large swaths of regulations under this Proposed Rule uses a sword to eradicate irrelevant regulations where excision by scalpel may be more appropriate and effective. It also duplicates processes already established by the Administrative Procedure Act (APA) to accomplish the same ends.

Rather than reviewing and updating each rule individually, HHS proposes the possible elimination of regulations by instituting an artificial deadline for the regulatory assessment and review process that must be completed for many important rules to be sustained. The FAH is concerned that this may be too aggressive to achieve the intended purpose.

The proposal is far too broad and risks expunging successful and useful rules along with rules that are less so. In this instance, the FAH believes that the risk is greater than the reward in that rules governing, for example, the Medicare and Medicaid programs, quality of care initiatives, and reimbursement, could easily be eliminated, either by mistake of the calendar or because HHS simply does not have the time and manpower necessary to complete such a daunting job by the self-imposed, artificial deadline. Such overreach would have real, detrimental, and lasting ramifications for beneficiaries, hospitals, providers, and other stakeholders seeking HHS' guidance in administering programs. Implementation of the proposal would force upon HHS a false choice in prioritizing rules to assess and review when instituting such a time-sensitive process is not necessary. With more time and a nuanced approach, we believe that the Department, stakeholders, industry leaders, providers, and advocates could together develop a more effective and balanced process to accomplish the Department's desired goals and could supplement the practices and procedures required by the APA.

Congress has already structured its preferred process for developing and discharging regulations through the APA. The APA prescribes procedures to update, revise, and/or expire existing regulations through notice and comment rulemaking.<sup>2</sup> Further, the APA sets forth a fair and efficient process for the public to recommend regulations to update or revise.<sup>3</sup> The Proposed Rule duplicates much of what already exists - in precise and tested guidance supported by statute and a well-established body of jurisprudence - under the APA. The depth and breadth of the body of law supporting and interpreting the APA lends certainty to small entities, large businesses, providers, and hospitals as they identify which regulations and their impacts should be factored into the cost of doing business. The FAH strongly asserts that upending this system with a regulation as sweeping as the Proposed Rule would introduce a level of ambiguity and confusion into the health care industry that would be unnecessary, detrimental, and ill-advised.

At a time when hospitals are under extraordinary stress to respond to the COVID-19 pandemic, we are strained to respond to this Proposed Rule as comprehensively as we would like. The PHE is not the appropriate time to set forth a wide-reaching administrative mechanism that threatens to upend many of the regulations the health care industry relies upon everyday - particularly when the industry would have such an abbreviated timetable to respond and make recommendations, and when long-established processes already exist to accomplish the same ends.

We strongly urge HHS to withdraw the Proposed Rule and to issue another notice of proposed rulemaking on this topic when providers, leaders, and stakeholders have the resources to actively participate in the administrative process and provide the valuable assessments, comments, and recommendations essential to developing an effective system to accomplish the established goals of the Department.

---

<sup>2</sup> See generally 5 U.S.C. § 500 et seq.

<sup>3</sup> 5 U.S.C. § 553(e).

The FAH appreciates the opportunity to comment on this Proposed Rule. We look forward to continued partnership with HHS to streamline the Department's regulatory catalogue in a manner that ensures that only the most relevant and effective regulations remain as guidance.

If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. Reinhart". The signature is fluid and cursive, with a large initial "A" and "M".