Federation of American Hospitals®

Charles N. Kahn III
President and CEO

December 17, 2021

The Honorable Xavier Becerra
Secretary
U.S. 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; Proposal to Withdraw or Repeal; 86 Fed. Reg. 59,906 (Oct. 29, 2021)

Dear Secretary Becerra:

The Federation of American Hospitals (FAH) is the national representative of more than 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 areas across 46 states, plus Washington, D.C and Puerto Rico. Our members include 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 the opportunity to submit these comments to the Department of Health and Human Services (HHS or the Department) regarding the *Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal* (SUNSET or Proposed Rule), published in the *Federal Register* on October 29, 2021.

The FAH commends HHS' reconsideration of the feasibility, operability, and prudence of the SUNSET Final Rule, published in the *Federal Register* on January 19, 2021 (86 Fed. Reg. 5,694) (Final Rule), as well as its review of the process through which the rule was finalized. In doing so, the Department re-establishes its dedication to addressing pressing public health matters as its priority, protecting the public by preserving the efficient operation of the federal health care programs, mitigating the economic impact of burdensome regulations, and preserving the legitimacy of the administrative process.

The FAH understands that the Final Rule purported to encourage streamlining of the regulatory process by mandating a deadline-driven, retrospective review of all the Department's regulations. However, the FAH strongly agrees with the Department's suggestion, reached after its extensive review and analysis of the Final Rule and comments from the original proposed rulemaking (Original Proposed Rule),[1] that withdrawal of the Final Rule will best serve both the public's needs and mission of the agency. As we stated in our prior comments regarding the Original Proposed Rule, implementation of the Final Rule would cause a diversion of substantial resources of HHS, providers, and stakeholders and would have a tremendous and wide-ranging impact on stakeholders and the administrative process. For all the reasons described in our prior comments, attached for your convenience, we believe that withdrawal of the Final Rule would be an act of public service that would positively impact HHS, providers, stakeholders, and the public far more than the implementation of the Final Rule.

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

The Final Rule would have been ill-advised and ill-timed had it gone into effect. Its proposed effective date, if it had not been delayed by the Department's action because of pending legal challenges to the rule, would have been in March 2021, in the middle of the COVID pandemic in the United States. The COVID pandemic has caused more than 780,000 deaths in our country,[2] and has stretched our country's health care infrastructure—and its providers and the Department—to its limits. Any diversion of HHS' and health care stakeholders' resources from the pandemic response to properly responding to and attempting to implement the Final Rule would undermine providers' ability to provide needed care to patients.

We strongly agree with the Department's analysis in the Proposed Rule that the Final Rule contained a substantial underestimation of the resources that would be required for its implementation. Moreover, its implementation would result in an unprecedented diversion of resources during these unprecedented times. As we noted in our response to the Original Proposed Rule, as important as are HHS' efforts toward regulatory reform, these activities and actions should allow prioritization of the activities and actions needed to support our health care system at this critical time.

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[1] *Securing Updated and Necessary Statutory Evaluations Timely*, 85 Fed. Reg. 70096 (proposed Nov. 4, 2020).

[2] Centers for Disease Control and Prevention, *United States, At A Glance,* COVID DATA TRACKER (Dec. 3, 2021 at 3:44 AM), https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

Truncated Comment Period Made Meaningful Review and Collaboration Impossible

The FAH firmly supports HHS' scrutiny of the adverse impact due to the Original Proposed Rule's 30-day comment period. The truncated comment period did not permit enough time for industry stakeholders to conduct a meaningful review of the Original Proposed Rule with proper discussion, consideration, and a cooperative deliberative process between the Department and stakeholders. Instead, overburdened stakeholders were required to rapidly develop their analyses and submit comments based on limited and condensed deliberation.

As we set forth in our response to the Original Proposed Rule, the abbreviated comment period for the Original Proposed Rule turned the regular administrative process, with opportunity for notice and comment rulemaking, on its head by allowing only cursory analysis and evaluation of the rule.

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

Throughout its consideration of the Original Proposed Rule, the FAH remained receptive to the Department's foundational proposition that there should be a process for evaluating and reviewing its regulations to ensure that they remain relevant, beneficial, and necessary. However, the FAH maintains that proper use of the processes established in the Administrative Procedure Act (APA) is the most effective and judicious method to accomplish this end. The Final Rule, as we originally commented, uses a sword to eradicate irrelevant regulations where excision by scalpel may be more appropriate and effective.

We agree with HHS' revised analysis that the danger created by the Final Rule is that, given the time and resource constraints faced by the Department, it may lead to the unintended situation in which a wide range of regulations and guidance could be eliminated, not only because they had been methodically assessed and reviewed by the Department and judged to be no longer necessary or effective, but because HHS simply does not have the resources to address them. We agree with the discussion in the Proposed Rule that the possibility of automatic expiration of HHS regulations, and the actual expiration of HHS regulations could harm the public.

In contrast, the APA sets forth a fair and efficient process for the public to recommend regulations to update or revise.[3] Its efficacy has been thoroughly vetted and its body of jurisprudence is well-established. It requires the Department's authority to establish regulations be exercised in a manner that is thoughtful, deliberate, and seriously considers all commenters' perspectives. In contrast, the Final Rule risks erasing decades of guidance that is relied upon by stakeholders and businesses to guide their investments in their work and ensure a level playing field for all. Upending this system with a regulation as sweeping as the Final Rule would introduce

[3] 5 U.S.C. § 553(e).

a level of ambiguity and confusion into the health care industry that would be unnecessary, detrimental, and ill-advised.

HHS' current regulatory review structure and processes maintain certainty in uncertain times for providers, stakeholders, and the health care industry as a whole, and implementation of the Final Rule would inject significant and detrimental instability into the rulemaking process. We strongly urge HHS to withdraw the Final Rule.

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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 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) 624-1500.

Sincerely,