



December 22, 2021

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal (HHS-OS-2020-0012; RIN: 0991-AC24)

Dear Secretary Becerra:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) appreciate the opportunity to comment on the Department's proposed repeal of the final rule entitled *Securing Updated and Necessary Statutory Evaluations Timely* (SUNSET), HHS-OS-2020-0012; RIN: 0991-AC24.

CPR is a coalition of more than 50 national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain their maximum level of health and independent function. CPR is comprised of organizations that represent patients – as well as the providers who serve them – who are frequently in need of medical rehabilitation services in a variety of settings, including inpatient rehabilitation hospitals, skilled nursing facilities, outpatient clinics, physician and therapy offices, and in the home.

Overview

In the final SUNSET rule issued on January 19, 2021, the Department of Health and Human Services (HHS) set an automatic expiration date for regulations issued by the agency, unless a staff assessment determines that a regulation should be maintained. Under the final rule, regulations would expire ten years after their final issuance date, and HHS would have two years after the SUNSET rule's effective date to review rules already older than ten years to determine whether they should expire or be renewed. The staff assessments would require a determination that the regulation has a significant economic impact on a substantial number of small entities. The assessment would also require a comprehensive review of any continued need for the regulation, complaints about the regulation, the complexity of the regulation, any duplicative or conflicting regulations, and whether circumstances favor amending or rescinding the rule.

In response to the proposed SUNSET rule, CPR provided [comments](#) expressing concern about the suggested regulatory process, the expected and substantial burden on agency staff, and the likely erosion of the regulatory framework that was designed over the years to protect patients. In October 2021, the Department proposed to repeal the SUNSET rule on the grounds that “it would significantly alter the operations of HHS with considerable repercussions for a diverse array of stakeholders.” Additionally, the Department now notes that the process the previous Administration used to promulgate the SUNSET rule was “extremely unusual, if not unprecedented,” and that the vast majority of stakeholders strongly opposed the rule. The Department states that the originally finalized rule rested on a flawed understanding of the amount of Departmental resources that would be required to conduct the required reviews, significantly underestimating the staff time that would be required and thus the likelihood that regulations might simply expire without a retrospective analysis. Based on the Department’s own assessment, this proposal to repeal the rule will save time, human resources, and an estimated \$75.5 million in annual cost savings and allow the Department to focus on carrying out “mission-critical objectives.”

CPR strongly supports the repeal of the SUNSET rule and commends HHS for working towards the modernization of regulations that promote public health through a targeted process. We offer additional comments in support of this withdrawal below.

I. The Proposed Process Was Too Broad

As illustrated in the Coalition’s initial comment letter, the SUNSET rule would have unnecessarily threatened the existence of thousands of rules, many of which have been integrated into a regulatory framework that regulates benefits and access to care for patients in need of medical rehabilitation as well as overall health and human services. The existing rulemaking process already provides for updates and revisions to existing regulations through public notice-and-comment periods, which allow stakeholders to offer input on how certain populations would be impacted by the changing regulatory framework. A mandatory and indiscriminate focus on the review of all older regulations would make it more difficult to concentrate on targeted regulatory changes with a more distinct purpose of promoting public health. As such, CPR agrees with the Department’s contention that the SUNSET rule does not support the Department’s mission to promote health and welfare.

II. SUNSET Requirements Would Hamstring the Administration

A retroactive review of all the Department’s regulations would be extremely resource intensive and time consuming, as the Department now recognizes. Implementation of the final rule would require at least an initial review of an estimated 17,200 regulations and more detailed review of nearly 4,000 regulations, with even the low-end estimate of Departmental staff time required at nearly 78,000 hours per year during the first five years after the rule’s effective date. The Department notes that this would likely require additional hiring of non-government experts to complete the reviews. By contrast, the Department now projects that withdrawing the SUNSET rule as proposed would save the federal government between \$10 and \$25 million dollars per year on an annualized basis over ten years.

CPR agrees with the Department’s statement that the rule rested on a “flawed understanding of the resources required for this undertaking.” The intense resource requirement would increase the likelihood that regulations would not be reviewed by the two-year deadline, threatening the potential expiration by default of critical regulations simply because the agency could not complete this new charge. Further, dedicating such a significant amount of agency resources towards these reviews would greatly impact the Department’s ability to combat the COVID-19 pandemic, develop new regulations to improve HHS programs, and conduct targeted efforts to improve the Code of Federal Regulations.

III. Blanket Expiration of Regulations Could Harm Patients

CPR does not oppose the idea of amending regulations through a structured review process and understands that reviews are necessary to modernize regulations. In the past, the Coalition has advocated for the revision and removal of several regulations impacting patients and stakeholders who provide care services. However, as noted in our initial comment letter, the SUNSET rule does not appropriately distinguish between regulations that are legitimately outdated and those that provide structure and protections to the existing health care system and its patients. The arbitrary expiration and review process increases the possibility that patients will be negatively impacted. Further, as noted by the Department, the unpredictable nature of a regulation’s expiration would create uncertainty for stakeholders, which could interfere with care delivery and product development, not to mention the significant time and resources required for stakeholders to monitor the regulatory review process and provide comment on the numerous expected analyses.

We strongly urge the Administration to move forward with the proposed repeal of the SUNSET rule to ensure that patients and HHS programs are not threatened by the arbitrary expiration of existing rulemaking. CPR will continue to engage with HHS and other federal agencies to ensure that outdated or inappropriate regulations are addressed through a targeted and reasonable process.

We greatly appreciate your consideration of our comments on this proposal. Should you have any further questions regarding this comment letter, please contact Peter Thomas or Joe Nahra, coordinators of CPR, by e-mailing Peter.Thomas@PowersLaw.com and Joseph.Nahra@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the Coalition to Preserve Rehabilitation

ALS Association
American Academy of Physical Medicine & Rehabilitation
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Occupational Therapy Association

American Physical Therapy Association
American Speech-Language-Hearing Association
American Spinal Injury Association
American Therapeutic Recreation Association
Association of Academic Physiatrists
Association of Rehabilitation Nurses
Association of University Centers on Disabilities
Brain Injury Association of America*
Center for Medicare Advocacy*
Christopher & Dana Reeve Foundation*
Clinician Task Force
Disability Rights Education and Defense Fund
Epilepsy Foundation
Lakeshore Foundation
Falling Forward Foundation*
The Michael J. Fox Foundation for Parkinson's Research
National Association for the Advancement of Orthotics & Prosthetics
National Association of State Head Injury Administrators
National Athletic Trainers' Association
National Disability Rights Network
National Multiple Sclerosis Society*
Rehabilitation Engineering and Assistive Technology Society of North America
Spina Bifida Association
United Cerebral Palsy
United Spinal Association*

**** CPR Steering Committee Member***