



December 4, 2020

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Alex M. Azar
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 [HHS-OS-2020-0012; RIN: 0991-AC24]

Dear Secretary Azar:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) appreciate the opportunity to comment on the Notice of Proposed Rulemaking 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 the 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 SUNSET rule, the Department of Health and Human Services (HHS) proposes to set an automatic expiration date for nearly all regulations issued by the agency, unless a detailed staff assessment determines that a regulation should be maintained. Rules would expire ten years after their final issuance date, and HHS would have two years from the SUNSET rule's effective date to review rules issued more than ten years prior to that date and determine whether to renew them or let them expire. The staff assessments would require a determination that the regulation has a significant economic impact on a substantial number of small entities and 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.

This sunset period would apply to most regulations issued by HHS, excluding those issued jointly with other agencies; those relating to military or foreign affairs functions; those relating to internal management, procurement or personnel matters; and those that cannot legally be rescinded. Annual payment update regulations for Medicare Parts A and B, such as the annual rules for the physician fee schedule and post-acute care provider settings, would also be excluded from the sunset period.

CPR strongly opposes the SUNSET rule on the grounds that the proposed process is overly broad, the requirements on agency staff would be onerous and prevent important, timely regulatory work, and the blanket expiration of regulations could significantly erode the regulatory framework established over decades to protect patients, especially those that our organizations represent. The risk of unintended consequences of this proposal cannot be overstated. In addition, a 30-day comment period is not nearly long enough to fully analyze the magnitude of the impact of this proposal. CPR, however, is not opposed to HHS modernizing specific aspects of its regulations that are outdated or not consistent with contemporary, effective clinical practices. We therefore encourage HHS to withdraw this rule and work towards appropriate modernization of its regulations through a more targeted process.

I. The Blanket Process Is Too Broad

While CPR does not oppose the concepts of regulatory modernization and targeted updates to outdated or onerous rules, we strongly oppose the overly broad process detailed in the SUNSET rule. This proposal would unnecessarily threaten the existence of thousands of rules, many of which have been refined through the years to construct a framework that has successfully regulated the health care industry for years or decades. The mandated reviews are unnecessary for many—or even a majority of—regulations under the scope of the SUNSET proposal, as the rulemaking process already provides for updates and revisions to existing regulations through periodic public notice-and-comment periods.

We have seen successes from previous, more targeted efforts for regulatory relief, including the Patients over Paperwork program. We encourage HHS to continue identifying specific solutions to regulatory concerns raised by patients and providers, rather than embarking upon a sweeping, unfocused review of decades worth of rulemaking. If HHS proceeds with this proposal, we believe these reviews would be rife with unintended consequences, including making it more difficult to focus on needed regulatory changes in distinct areas.

II. SUNSET Requirements Would Hamstring the Administration

The Department's own analyses estimate that the cost of implementing this regulation would be nearly \$26 million over ten years, utilizing the time of up to 90 full-time employees. HHS also notes that each review may take up to 100 hours to perform. This represents a significant administrative burden to be imposed on HHS, and we expect that many of these reviews could be much more costly than estimated. If the SUNSET rule is finalized as proposed, HHS estimates that the first two years alone would require review of approximately 2,500 rules.

Despite the Administration’s stated goals of executing HHS’ responsibilities “in a way that maximizes benefits, minimizes costs, and keeps up with the times,” this proposal runs counter to these objectives. The Department proposes to impose a “strong incentive” with this blanket sunset provision; however, this wide-ranging proposal would, in fact, hamper HHS’ ability to efficiently carry out its current duties as the key federal health care agency.

In the first two years after finalization of this regulation and beyond, the SUNSET rule would prevent the agency from devoting critical staff time and resources to combatting the COVID-19 pandemic, developing new regulations to improve HHS programs, and conducting targeted efforts to improve the Code of Federal Regulations. Especially during the transition period to a new Administration, it is critical that agency staff be available to carry out new and existing priorities in a timely fashion. Tying up agency personnel and regulatory expertise with unnecessary regulatory reviews would hamstring this process. If the Department is unable or unwilling to complete the full process of the mandated reviews for the many regulations that would be subject to expiration, these rules could simply expire without any replacement, potentially threatening the stable functioning of the Department.

III. Blanket Expiration of Regulations Could Harm Patients

As noted above, CPR does not oppose the idea of modernizing regulations through a targeted regulatory review process, and in fact has supported the rescission or revision of several regulations that we believed were outdated, burdensome, or otherwise stood in the way of our goals of increasing access to rehabilitative care. CPR in particular has advocated for the removal of unnecessary burden in post-acute care (PAC) regulations, including the modification of the “three hour rule” and adjustments to duplicative documentation requirements in the Inpatient Rehabilitation Facility (IRF) payment system; revision of the three-day prior inpatient stay requirement for Skilled Nursing Facility (SNF) admission; and expansion of the requirement for plan of care signatures for outpatient therapy services.

Additionally, we have long noted that the existing regulations covering access to skilled therapy services must be updated to reflect the national settlement in the *Jimmo v. Sebelius* litigation to codify the fact that skilled services are covered for Medicare beneficiaries not just to improve function, but to maintain or prevent deterioration in function. We have also advocated for the removal of the outdated and inappropriate “in the home” requirement for coverage of durable medical equipment (DME), which significantly limits the mobility devices available to beneficiaries with mobility disabilities.

However, this proposal does not appropriately distinguish between regulations that are legitimately out of date and due for reconsideration and those that provide structure to the existing health care system and are critical to the consumer and patient protections that have been built up over decades. Placing an all-encompassing, burdensome review process solely in the hands of agency staff with an unreasonably short timeframe raises the potential for serious upheaval of critical patient-centered regulations simply due to staff time and resource constraints.

In addition, a 30-day comment period is simply insufficient for stakeholders to comprehensively analyze and assess the proposed rule's ultimate impact. What is known is that this proposed regulation would have a stunningly comprehensive impact on virtually all HHS programs and thirty days does not provide an appropriate time period with which to understand its implications.

Additionally, this rule would impose significant uncertainty on agencies carrying out vital programs, such as Medicare, Medicaid, the Children's Health Insurance Program (CHIP), implementation of the Affordable Care Act, regulation of safety and effectiveness by the Food and Drug Administration, and many more. These programs are governed by longstanding regulations that have been refined and periodically updated for many years. The potential for eliminating many of these rules simply based on an arbitrary expiration date could make the administration of HHS programs chaotic, which is especially problematic during a period of ongoing uncertainty regarding the COVID-19 pandemic.

We strongly urge the Administration to withdraw this proposed rule to ensure that HHS programs are not summarily 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 rule. 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

American Academy of Physical Medicine and Rehabilitation
American Association of People with Disabilities
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Network of Community Options and Resources
American Occupational Therapy Association
American Physical Therapy Association
American Speech-Language-Hearing Association
American Spinal Injury Association
American Therapeutic Recreation Association
The Arc of the United States
Association of Rehabilitation Nurses
Association of University Centers on Disabilities

Brain Injury Association of America*

Center for Medicare Advocacy*

Clinician Task Force

Christopher & Dana Reeve Foundation*

Disability Rights Education and Defense Fund (DREDF)

Epilepsy Foundation

Falling Forward Foundation*

Lakeshore Foundation

The Michael J. Fox Foundation for Parkinson's Research

National Association for the Advancement of Orthotics and Prosthetics

National Association of Social Workers

National Association of State Head Injury Administrators

National Athletic Trainers' Association

National Council on Independent Living

National Disability Rights Network (NDRN)

National Multiple Sclerosis Society*

Paralyzed Veterans of America

Rehabilitation Engineering and Assistive Technology Society of North America

Spina Bifida Association of America

United Cerebral Palsy

United Spinal Association*

**** CPR Steering Committee Member***