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VIA ELECTRONIC SUBMISSION

January 4, 2020

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

Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar:

The Medicare Rights Center (Medicare Rights) appreciates this opportunity to comment on Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) proposed rule. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals.

The COVID-19 public health emergency continues to demonstrate the need for reliable access to health care, especially for older adults and people with disabilities. The pandemic makes it crucial to protect Medicare's ability to provide guaranteed coverage and meet the changing and urgent needs of the populations it serves. The Department of Health and Human Services (HHS) also must have the bandwidth to shift focus and respond quickly to immediate and emergent issues. Thousands of lives are at stake.

The SUNSET proposed rule would unnecessarily impose retroactive expiration provisions on most Medicare regulations, which would leave beneficiaries, providers, payers, professionals, advocates, and the general public on constantly shifting ground, unable to rely on finalized rules or to predict which regulatory requirements will be extant in any given year. Such a proposal, if put into effect, would

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undermine stability, increase burdens, and cause chaos. We also expect that it would cause payers and providers to refuse to participate in Medicare, leading to access issues for beneficiaries.

The proposed rule would establish assessment and “review” procedures to determine which, if any, regulations should be retained or revised. In the absence of such procedural steps, the rules would expire, no matter their age, significance, or how many stakeholders may be relying on them. This would leave a void where even the most longstanding regulations once stood. This could mean a reversion to an earlier regulation in some cases—if that earlier regulation had already gone through the procedures—or could mean a lack of regulation at all, leaving stakeholders scrambling to interpret statutes on their own. HHS blithely asserts that stakeholders would not be left in the dark and would be both able to see what rules are under review and able to suggest additional rules for review. But this information would not reduce uncertainty. Knowing whether HHS is reviewing a rule is different from knowing what HHS will choose to do. Further, stakeholders suggesting HHS review a rule does not force HHS to review it.

In addition, the sheer administrative burden that such a system would create for HHS would be immense. Each year, HHS promulgates many Medicare rules, each designed to meet a need in the program. Coupled with the hundreds of rules from other HHS agencies and programs, no administration would be able to thoroughly review each one prior to its sunset, leading to critical Medicare regulations expiring with no guarantee that anything would take their place. This could include rules about eligibility, process, coverage, payment, and beneficiary protections.

Our callers already face issues when rules change or are misinterpreted by providers and plans. For example:

- Many providers still do not understand that the therapy caps were eliminated.
- Some providers do not understand whether they can bill for telehealth.
- Some providers do not know the rules around Qualified Medicare Beneficiary improper billing protections. Similarly, plans often do not know about the requirement to make sure their in-network providers do not improperly bill Qualified Medicare Beneficiaries.
- Providers often misunderstand rules around Durable Medical Equipment and can especially struggle regarding requirements for prior authorization documentation of power mobility devices.
- Some providers do not know how to order services under the home health benefit or are unaware of the limits.
- Providers and plans both are often not aware of rules around frequency and requirements for coverage for Positron Emission Tomography scans.
- Many skilled nursing facilities do not understand the COVID-19 PHE flexibility around the SNF 100-day extension.

These examples show that there is already uncertainty and confusion for providers and plans—even for rules of long standing—and this confusion can affect people with Medicare, by interfering with their

access to care, leaving them with higher than necessary bills, or forcing them to pursue lengthy appeals processes. Adding to this confusion by arbitrarily expiring rules could easily throw the Medicare system into disarray, which would not benefit the people Medicare is meant to serve, or its plans and providers. This is a dangerous and ill-conceived idea that would create a problem rather than solving one.

In addition, 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. As this administration knows,¹ the APA requires agencies to go through the same rulemaking process to revise or rescind an existing rule as they would for a new rule, with public notice and the opportunity to comment.² In *Department of Homeland Security v. Regents of the University of California*, the Supreme Court found a rescission of guidance that had only a post hoc justification as arbitrary and capricious. If this proposal were enacted, rules would expire without even a post hoc justification. Instead, there would only be agency silence and inaction.

While we agree that HHS can add end dates, or certain conditions whereby a previously promulgated rule would expire,³ the agency's SUNSET proposal goes well beyond that authority. It would modify dozens of separate, distinct Medicare rules in a single stroke, embedding expiration dates without any demonstrated attention to the specifics of the rule in question. Such blanket changes are thoughtless, arbitrary, and capricious.

While we appreciate that Medicare elements of the rule have been given a 60-day comment window, we also strongly object to the expired 30-day comment period for non-Medicare regulations. This is utterly insufficient for a rule of with such a broad scope and potentially devastating effects.

For each these reasons, we urge you to rescind this unnecessary, counterproductive, and improper rule in its entirety.

Thank you again for this opportunity to provide comment. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Senior Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

Sincerely,

¹ *Department of Homeland Security v. Regents of the University of California*, 591 U.S. ____ (2020).

² 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).

³ 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.

Fred Riccardi

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