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December 4, 2020

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

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

Dear Secretary Azar:

On behalf of Prevent Blindness and the millions of people of all ages whom we represent across the country, including those who live with low vision, vision impairment, and those who have or are at risk for vision-related eye diseases; we appreciate the opportunity to respond to the Department of Health and Human Services (HHS) Notice of Proposed Rulemaking titled, "Securing Updated and Necessary Statutory Evaluations Timely (SUNSET). These written comments are in follow-up and reiteration to oral comments presented at a November 23, 2020 public hearing.

Prevent Blindness is the nation's leading nonprofit, voluntary organization committed to preventing blindness and preserving sight. We strive to improve our nation's vision and eye health by enhancing state and community capacities through our core competencies of early detection, improved access to eye care, patient empowerment, care coordination, public policy, research, advocacy, public awareness, and health education. As well, protecting and expanding access to sight-saving care is our priority for patients across the age continuum. Our policy goal is to see programs put in place that reduce America's burden of preventable vision loss and eye disease to protect and enhance Americans' quality of life, well-being, economic independence and productivity, and reduce health care costs through improved outcomes.

Prevent Blindness Position on SUNSET

Our concerns with these proposed policies focus on the impact that this provision would have on people who are living with low vision, blindness, or vision loss and impairment due to a range of chronic conditions that are co-morbid or consequential to vision health. ***After due consideration of the impacts of the policies proposed in this rule, we strongly object to its implementation and we urge HHS to withdraw it immediately.*** We also strongly object to the truncated 30-day comment period, which is insufficient time for stakeholders to gauge and determine the potentially harmful impacts of a rule possessing this broad of scope.

We are deeply alarmed at the impact to the Medicaid and Children's Health Insurance Program (CHIP), which are often times the only source of vision and eye health care for children, non-elderly adults, those who live with a disability, and aging Americans. The cumulative affects of these proposals coupled with the tradition of the Department's use of regulations and sub-regulatory guidance (such as the August 2020 "Good Guidance" proposal) over the course of this Administration directed at states, providers, managed care plans, and beneficiaries would place Americans at great risk of accessing care that could protect and even save their vision.

We understand the need to review and examine as needed existing rules to determine their effectiveness and issue program updates through the established rulemaking channels that provide for public input and feedback. However, these channels already exist. HHS already periodically reviews and updates its regulations. For example:

- HHS annually reviews and updates the Notice of Benefits and Payment Parameters for insurance exchanges and issuers and the Basic Health Program's funding methodology to update requirements based on new information and data.
- HHS also annually reviews and updates certain Medicare regulations to reflect policy and technical changes and new program parameters.
- In 2016, HHS revised the 2002 regulations governing Medicaid managed care, modernizing the regulations to reflect updated practices.

As such, this attempt almost surely undermines any meaningful effort to update regulations where needed in the future, and would impede appropriate stakeholder engagement as the public would be forced to address unnecessary administrative reviews instead of working as partners with HHS to improve program outcomes.

Summary of Provisions

As outlined, HHS is proposing to retroactively impose an expiration provision on most HHS regulations, and establish "assessment" and "review" procedures to determine which, if any, regulations should be retained or revised. Specifically, the proposed rule would provide that HHS automatically expire regulations at the later of two years after SUNSET would take effect, ten years following the regulation's promulgation, or ten years after HHS reassesses, and if necessary, reviews the regulation. As stated, to preserve a regulation, HHS would first need to assess whether the regulation has a significant impact upon a substantial number of "small entities." Should an impact be determined to exist, HHS would need to review the regulation to determine whether it should continue without any changes or should be amended or rescinded. The rule sets the standard for reviews, and requires HHS staff to consider factors such as the need to continue the rule and its complexity, the nature of public complaints or comments received concerning the rule, and the extent to which the rule overlaps, duplicates, or conflicts with other federal rules.

This approach is an ill-conceived proposal that would wreak havoc across a broad swath of Department programs and regulated entities, including Medicaid and Medicare and the Centers for Disease Control and Prevention (CDC).

SUNSET Impact on Vision and Eye Health Access

Vision and eye health enables many aspects of daily living no matter your age, racial and ethnic background, or socio-economic status. People with vision impairment are more likely to experience other chronic conditions, including diabetes, hearing impairment, heart problems, hypertension, joint symptoms, low back pain, and stroke as well as falls, injury, motor vehicle collisions, depression, social isolation, diminished health-related quality of life, and premature death. Diabetes, one of the most common chronic diseases among adults, can lead to vision loss through diabetic retinopathy and diabetic macular edema, and increases risk for cataracts and glaucoma. All of these trends are massive cost-drivers to the national health care system, and have the potential to cause disruptions in a patient's health, well-being, and financial independence if not addressed ahead of time through programs at HHS that extend access to preventive eye care, conduct critical surveillance of major eye diseases, and focus on closing disparities in access to care across minority populations and age groups.

The overall cost of vision problems to our country is $172 billion annually, and without significant intervention, are projected to increase to $717 billion by 2050 as our population continues to age. The proposals within this rule would absolutely contribute to the realization

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of these projections by jeopardizing early detection and cost-effective treatments that could prevent lifelong vision impairment or permanent loss of vision and the enormous costs of living without sight.

Additionally, as we continue to manage and respond to the serious COVID-19 pandemic, we are seeing several impacts of the virus on people who live with vision loss and eye disease. Many of the circumstances that surround vision loss and eye disease—including the presence of chronic disease, disparities along racial and ethnic lines, socioeconomic circumstances, and age—are at the intersection of COVID-19 and its most serious consequences. In addition, several conditions that are associated with the most serious complications of COVID-19 are analogous to vision and eye health, including diabetes, heart problems, depression and social isolation, longer hospitalization and readmission[1], and need for long-term care. Early COVID-19 surveillance data[2] from the CDC indicates that 30% of patients with COVID-19 also had diabetes and 4.8% of patients had a neurologic or neurodevelopmental disability (including visual impairment). This same study also indicates that people over the age of 50 represented the highest prevalence of COVID-19 and, based on available data, 33% of COVID-19 patients are Hispanic, 22% are black, and 1.3% are Native American/Alaska Native, illustrating the intersection between vision and eye health, underlying health indicators, and COVID-19. These trends indicate the need to divert resources *toward* solving these problems, not diverting them away from solving them.

HHS asserts that this rule will promote "accountability, administrative simplification [and] transparency. . . ." In fact, the proposed rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic. HHS itself estimates that the proposed rule would cost nearly $26 million dollars over 10 years, needing 90 full-time staff positions to undertake the required reviews. Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old. However, these estimates likely underestimate the time and money involved in the review process, and do not accurately account for complications that may arise. If implemented, this rule would adversely affect HHS's ability to focus on the administration of current programs, to issue new regulations, and appropriately review current regulations that need modification.

We are alarmed that HHS would choose to divert scarce resources away from programs that will enable us to prevent avoidable vision loss through robust national surveillance of vision loss and eye disease and the impacts of the COVID-19 pandemic to instead focus staff resources and attention on ushering through the burdensome proposals of this harmful rule.

In addition, several regulations implementing important parts of the Affordable Care Act are approaching their ten-year anniversary, like the Medicaid cost-sharing rule. Regulations like these would need to be reviewed within the next two years, or they would expire. However, the underlying law still exists, even if the regulations expire. Without the cost-sharing rule, states would not have clear guidance on how to implement cost-sharing amounts. Regulations play an important role in implementing HHS policies and programs including safety net programs such as Medicaid and the Children's Health Insurance Program (CHIP), which provide health coverage—including, in many states, vision and eye care— for over 75.5 million people, including 36.6 million children. The ACA includes essential health benefits, which require insurers to provide benefits within a set of 10

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[1] Morse AR, et al. *JAMA Ophthalmol*. 2019;doi:10.1001/jamaophthalmol.2019.0446. Accessed 20/01/23 from: https://www.ncbi.nlm.nih.gov/pubmed/30946451

[2] Coronavirus Disease 2019 Case Surveillance – United States, January 22 – May 30, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm6924e2.htm?s_cid=mm6924e2_w

essential categories that includes chronic disease management and pediatric vision care. We have concerns that destabilizing these regulations that specifically determine the benchmarks states may use to establish the services and level of care provided in a marketplace plan's essential health benefit category will lead to uncertainty for states setting these annual rules and weaken a needed patient protection and standard of care. A strong regulatory framework provides states the clarity they need to run these programs on a day-to-day basis, gives providers and managed care plans guidance as to their obligations, and explains to beneficiaries what their entitlement means. The Regulations Rule would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process.

The bigger danger posed by this rule is that it would effectively disengage critical stakeholders from their proper role in the governing of our country and important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time consumer review process would summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies. For example, multiple insurance affordability programs including Medicaid and CHIP rely on regulations at 42 C.F.R. § 435.603 to determine financial eligibility using Modified Adjusted Gross Income (MAGI) methodologies. If this regulation were to simply disappear, programs would be free to redefine MAGI household and income counting rules, with no standards, consistency, or accountability. Arbitrarily rescinding large swaths of regulations would wreak havoc in HHS programs, leading to untold harm to the millions of people who rely on those programs.

Conclusion

Prevent Blindness reiterates our opposition to this rule, and our position that HHS withdraw it immediately. Please do not hesitate to contact Sara D. Brown, Director of Government Affairs, at (312) 363-6031 or sbrown@preventblindness.org if you or your staff would like to discuss these issues.

Sincerely,

Jeff Todd
President and CEO
Prevent Blindness