December 4, 2020

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

Re: Securing Updated and Necessary Statutory Evaluations Timely (RIN 0991–AC24, Docket No. HHS–OS–2020–0012)

Dear Secretary Azar:

Thank you for the opportunity to comment on proposed rule, Docket No. HHS–OS–2020–0012, "Securing Updated and Necessary Statutory Evaluations Timely," RIN 0991-AC24.

The undersigned organizations represent millions of patients facing serious, acute, and chronic health conditions across the country. Our organizations have a unique perspective on what patients need to prevent disease, cure illness, and manage chronic health conditions. Our diversity enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion. We urge the Department of Health and Human Services (HHS) to make the best use of the knowledge and experience our patients and organizations offer in response to this proposed rule.

In March of 2017, our organizations agreed upon three overarching principles[1] to guide any work to reform and improve the nation's healthcare system. These principles state that: (1) healthcare should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit (EHB) package.

Our organizations urge the Department to immediately withdraw the proposed rule. The proposed rule's impact on programs that provide coverage to millions of Americans, including those who are low-income, people of color and individuals with pre-existing conditions, is unacceptable to our organizations. In addition to the broad and indiscriminate reach of this proposal, the Department's truncated 30-day comment period is insufficient and demonstrates a lack of seriousness in evaluating regulations that govern how and when individuals and families can obtain the coverage they need to maintain and improve their health. Instead of undermining the operation of these health coverage programs and regulation of the individual health insurance market for millions of our nation's most vulnerable in the middle of a pandemic, the Department should continue to implement its existing Final Retrospective Review Plan, adopted in August 2011 and posted on the Department's website.[2]

The Department proposes to use automatic expiration of rules as a forcing mechanism to compel, within the next two years, the assessment and, if applicable, the review of nearly all Departmental regulations that have been in force for more than 10 years. The imposition of such a mechanism would significantly disrupt the ability of the Centers for Medicare & Medicaid Services (CMS) to administer critical healthcare programs such as Medicaid, the Children's Health Insurance Program (CHIP), and the Affordable Care Act (ACA) over the next two years. Our organizations offer the following comments in opposition to the proposed rule:

Authorities Exist for Periodic Review of Regulations

The Department has an existing mechanism for periodic review of significant regulations and does not need to implement this proposed rule, which unnecessarily jeopardizes key programs, to phase out or update regulations. In August 2011, the Department issued a Final Retrospective Review Plan to implement Executive Order 13563.[3] The Plan has five goals: (1) streamline or eliminate unjustified costs and burdens; (2) increase transparency in the retrospective review process; (3) increase opportunities for public participation; (4) set clear retrospective review priorities; and (5) strengthen analysis of regulatory options. Between January 2012 and February 2016, the Department issued ten updates on the regulatory reviews it conducted.[4] The preamble to the proposed rule does not contain any reference to the Department's August 2011 plan or to any of the updates, nor does it justify why the plan is ineffective or why the updates were discontinued in 2016.

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[1] Consensus Health Reform Principles. Available at: https://www.lung.org/getmedia/aafde78d-da8f-4067-ad6a-6b3429fac1b9/100720-healthcare-principles43logos.pdf.

[2] https://www.hhs.gov/open/retrospective-review/index.html

[3] https://wayback.archive-it.org/org-745/20141203143033/http:/www.hhs.gov/open/execorders/13563/hhs_final_retrospective_review_plan_8-19-11_4.pdf

[4] https://www.hhs.gov/open/retrospective-review/index.html

The Rule Creates Unnecessary Confusion

If implemented, the proposed rule would create uncertainty for Federal regulations that are essential to the management of healthcare programs including Medicaid, CHIP, and the Marketplace. These programs are the source of health insurance coverage for millions of people with serious and chronic conditions. As a result, our organizations are deeply concerned about the uncertainty this rule would create for the patients that we represent.

The Medicaid and CHIP programs are complex, federal-state health insurance programs that affect not only millions of beneficiaries, but also all of the states and territories, tens of thousands of providers, and hundreds of managed care plans. The Marketplace facilitates the enrollment of millions of consumers across all of the states into private coverage sold by dozens of insurers, while the private insurance regulations promulgated by HHS establish the ground rules for coverage in the broader individual and group health insurance markets on which millions more individuals depend.

Each of these stakeholders has an interest in—and legitimate expectation of—stability in the federal regulatory guidance on which they rely in administering or participating in these programs and markets. By providing for automatic expiration if CMS does not conduct timely assessments and reviews, the proposed rule's forcing mechanism would unnecessarily and illegally create uncertainty on the part of stakeholders as to whether they should continue to rely on federal regulations for policy and operational guidance.

The Proposed Rule is Inconsistent with Federal Statute

The authority for issuing Medicaid and CHIP regulations is found in section 1102 of the Social Security Act, which expressly directs the Secretary of HHS to issue regulations "not inconsistent with this Act, as may be necessary to the efficient administration of the "functions with which [s/he] is charged under this Act." This section does not give the Secretary the authority to write automatic expiration dates into regulations. In fact, the risk of automatic expiration if an assessment and review is not conducted within a specified time frame is flatly inconsistent with the "efficient administration" of Medicaid and CHIP. It would force CMS to engage in an endlessly repeating and highly inefficient cycle of assessments of all regulations and reviews of those determined to have a significant economic impact upon a substantial number of small entities.

The preamble to the proposed rule repeatedly cites the Regulatory Review Act at 5 U.S.C. 610 as authority for the forcing mechanism. Our organizations believe this to be a clear misreading of the statute. Section 610 does not require, much less authorize, the blanket imposition of automatic expiration dates on almost all regulations, as the proposed rule would do. Section 610 only requires that agencies have a "plan for the periodic review of rules that have or will have a significant economic impact upon a substantial number of small entities." That is exactly what the Department already has in the form of its August 2011 Final Retrospective Review Plan.

The Proposed Rule is Wasteful

The proposed rule will force HHS to divert limited staff resources to reviewing long-standing regulations over the next two years, disrupting its administration of Medicaid, CHIP, and the Marketplace during the coronavirus pandemic. If the proposed rule is issued in final form in January 2021, any regulation issued

before 2013 would have to be assessed and, if applicable, reviewed before the end of 2023, or it would automatically expire. The proposed rule would define "regulation" as a section of the Code of Federal Regulations. It does not explain how many Medicaid, CHIP or Marketplace regulations CMS would need to assess and, if necessary, review over the next two years.

The regulations implementing the Medicaid program are found at 42 CFR Parts 430 to 436, 438, 440-442, 447, and 455-456. These 14 parts alone contain 1,044 separate CFR sections. Most of those sections are at least ten years old, which means that they would each have to be assessed and, if necessary, reviewed before 2023, or they would expire. The remaining eight parts contain hundreds more sections. The regulations implementing the CHIP program are found in 42 CFR Part 457. That part has over 155 separate sections, the large majority of which were promulgated over ten years ago. In short, these "regulations" represent long-standing policy on which stakeholders have been relying on – in some cases, for over a decade. The proposed rule would require that, over the next two years, CMS assess and, if necessary, review in the neighborhood of a thousand Medicaid and CHIP regulations in order to avoid or postpone their automatic expiration. Setting this expectation, understanding that the Department does not have sufficient resources to appropriately facilitate this process, is unreasonable and unacceptable.

Key provisions of the ACA affecting states, consumers, providers, and insurers would soon be up for review and require regular review and updates to ensure coverage options and consumer protections remain in place. Rules establishing health insurance marketplaces — the sole place where individuals can access federal financial assistance — were issued and updated regularly in the years following the ACA's enactment in 2010. The market reforms governing individual and group market coverage would also come under review. Under the proposed rule, unless the agency performed an affirmative act to prevent the expiration of these regulations, the result of the proposed rule would be to put at risk guaranteed issue and renewal of coverage, broad protections for people with preexisting conditions and comprehensive coverage requirements, among other key regulations implementing the ACA.

A review of these regulations would be an indefensible waste of resources, especially in the midst of the COVID-19 pandemic. The preamble states at p. 70111: "The Department recognizes that this proposed rule requires the Department to undertake certain tasks. But the Department believes that retrospective review of regulations should be a priority, and is willing to commit the necessary resources towards performing the Assessments and Reviews." In the midst of a pandemic, when Medicaid, CHIP and Marketplace coverage are so important to the communities most at risk, including people of color, people with disabilities, and many low-wage health care workers, we disagree that "performing the Assessments and Reviews" of hundreds of current program regulations "should be a priority" for HHS and CMS. The priority for CMS over the next two years should be ensuring Medicaid and CHIP coverage are operating as effectively as possible in making COVID-19 testing, treatment, and vaccinations available to all Americans, and ensuring continued federal protections for all people who need the guarantees of the ACA to buy and maintain private coverage.

Conclusion

The Department should withdraw this proposed rule and continue the periodic review of regulations it conducted between 2012 and 2016. Given the broad scope and potential harm of this proposal, the

Department's truncated 30-day comment period was insufficient. The proposed forcing mechanism would disrupt the operation of healthcare programs including Medicaid, CHIP, and the Marketplace by creating regulatory uncertainty for stakeholders, and it would divert CMS resources from what should be the highest priority: ensuring that these programs respond effectively as possible to the pandemic.

Thank you again for the opportunity to comment on the proposed rule. Please contact Hannah Green of the American Lung Association at hannah.green@lung.org if you have any questions or if we can be of further assistance.

Sincerely,

American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
American Kidney Fund
ALPHA-1 Foundation
Arthritis Foundation
Asthma and Allergy Foundation of America
CancerCare
Cancer Support Community
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
Leukemia & Lymphoma Society
Muscular Dystrophy Association
National Alliance on Mental Illness
National Patient Advocate Foundation
National Health Council
National Hemophilia Foundation
National MS Society
National Organization for Rare Disorders
Pulmonary Hypertension Association
Susan G. Komen
The AIDS Institute
United Way Worldwide