



September 16, 2020

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

Re: Department of Health and Human Services Proposed Rule: Good Guidance Practices (RIN 0991–AC17)

Dear Secretary Azar:

Thank you for the opportunity to submit comments on the Good Guidance Practices notice of proposed rulemaking (NPRM) issued by the Department of Health and Human Services (HHS).

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 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 principles¹ 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 strongly support efforts to increase transparency and opportunities for meaningful public comment on important policies that impact the health and wellbeing of the patients we represent. However, we are concerned that the proposed rule could have unintended consequences on policies impacting healthcare coverage that could ultimately harm patients with serious and chronic health conditions. We therefore urge HHS to withdraw this proposed rule.

The Department fails to provide adequate detail about key provisions of the NPRM, making it impossible for us to conduct a thorough analysis about its impact on the populations we serve and provide meaningful comments. For example, the definition of what constitutes guidance for the purposes of this rule is poorly defined, making it difficult for our organizations to fully understand the breadth of policies and guidance that would be impacted by the proposed rule. Additionally, many important policy documents impacting patients' coverage under the Affordable Care Act have been jointly issued by HHS and agencies such as the Internal Revenue Service, Department of Labor, and Department of Treasury. It is unclear from this proposed rule how guidance issued jointly by these Departments will be treated.

Under the proposed rule, current HHS guidance not submitted to a new repository by November 16, 2020 would automatically be rescinded. This would allow HHS to withdraw policies in a manner that directly contradicts efforts to improve transparency and public input. There are a wide range of policy documents – including discussion papers, informational bulletins, fact sheets, Frequently Asked Questions, State Medicaid Director letters and many others – that may meet the definition of guidance under the proposed rule and therefore impact access to quality and affordable healthcare coverage for patients with serious and chronic conditions. Our organizations are concerned that some of these important policies could be rescinded without notice or public scrutiny and that this process could create confusion among healthcare stakeholders, including state and local governments, private health plans, drug and device manufacturers, and the health care providers our patients rely on.

It is also unclear to our organizations how the Department and its agencies would be able to comply with the rule's requirements on such a short timeline. Guidance and other directives provided by this and previous Administrations are often iterative and develop over extended periods of time. Across the many operating divisions and agencies under HHS, the volume of information that would need to be reviewed, sorted, and then filed with the repository by November 16, 2020 seems unmanageable. By not providing an adequate time for agencies and operating divisions to thoughtfully provide review and recommendations, the Department is forcing errors that could have real and serious implications for the populations we serve.

Our organizations are also concerned about the shortened comment period for this proposed rule. The initial comment period was less than 30 days, which provides insufficient time to fully consider this complex proposal and its potential consequences for patients with serious and chronic conditions. Additionally, if HHS plans to implement this proposal by November 16, 2020 (the deadline for submitting guidance to the repository), the Department will not have sufficient time to consider the public comments submitted. We are concerned that important guidance documents could simply be overlooked in this rushed process and be rescinded, even if inadvertently.

Again, our organizations agree that transparency and public input in the regulatory process can be improved. For example, our organizations were deeply disappointed when CMS submitted Medicaid block grant guidance to the Office of Information and Regulatory Affairs (OIRA) for review, held meetings with interested stakeholders (including a number of our organizations) expressing serious concerns about the proposal and subsequently withdrew it from OIRA, yet still released block grant guidance through a State Medicaid Director letter in January 2020.² However, there is no evidence that this proposal would address this type of practice.

Our organizations urge you to withdraw the proposed rule. We are committed to working with you on proposals that will improve transparency and public input on important policies impacting patients with serious and chronic health conditions.

Sincerely,

American Cancer Society
Cancer Action Network
American Heart Association
American Kidney Fund
American Liver Foundation
American Lung Association
Alpha-1 Foundation
Arthritis Foundation
CancerCare
Chronic Disease Coalition
Cystic Fibrosis Foundation
Epilepsy Foundation
Family Voices
Hemophilia Federation of America
Leukemia & Lymphoma Society
Lutheran Services in America
Mended Hearts & Mended Little Hearts
Muscular Dystrophy Association
National Alliance on Mental Illness
National Coalition for Cancer Survivorship
National Health Council
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
Susan G. Komen
The AIDS Institute
WomenHeart: The National Coalition for Women with Heart Disease

¹ Healthcare reform principles. Available at:

<https://cqcengage.com/mda/file/kSgnXK91pJZ/052820%20Healthcare%20Principles42logos.pdf>.

² CMS, Dear State Medicaid Director (Jan. 20, 2020) (SMD # 20-001),

<https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>.