



November 19, 2021

The Honorable Xavier Becerra
 Secretary
 Department of Health and Human Services
 200 Independence Avenue, SW
 Washington, DC 20201

Re: Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures (RIN 0991-AC29)

Dear Secretary Becerra :

Thank you for the opportunity to submit comments on the Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures issued by the Department of Health and Human Services (HHS). Our comments focus on the repeal of the final rule “Department of Health and Human Services Good Guidance Practices.” We support the Department’s decision to repeal the rule.

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 proposal.

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) health care should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) health care should be affordable, enabling patients to access the treatments they need to live healthy

¹ Healthcare reform principles. Available at: <https://www.lung.org/getmedia/24309f63-74e9-4670-8014-d59f21104cfd/092021-ppc-healthcare-principles-42-logos-final.pdf>

and productive lives; and (3) health care must be adequate, meaning health care 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, as we expressed in our comments on the proposed rule,² we are concerned that the final rule would have had unintended consequences on policies impacting healthcare coverage that could ultimately harm patients with serious and chronic health conditions. We therefore applaud HHS for withdrawing the final rule.

We were particularly concerned about the guidance repository as outlined by the previous administration. We agree with the Department that the provisions regarding the guidance repository are inappropriate and unnecessary. Under the final rule, HHS guidance is automatically rescinded simply by being left out of the repository. The repository provision allows HHS to withdraw policies in a manner that is contrary to improving transparency and public input. 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. If stakeholders cannot find a guidance in the repository, they will not know if it has been removed due to a policy change or is simply left out of the repository by human error or technical failures. 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 final rule and therefore impact access to quality and affordable healthcare coverage for patients with serious and chronic conditions. Our organizations are familiar with the guidance practices of the agencies with which we work most; adding a layer of a Department-wide guidance repository would only create confusion.

Finally, we also share the Department’s concern about the delay or prevention of the issuance of guidance documents and the unnecessary diversion of resources. The COVID-19 pandemic has shown the need for HHS to move quickly, especially when public health and human life are on the line. We agree with the Department that the final rule will harm HHS programs and the underserved populations that rely on them, and that this is especially true the Medicaid program. Organizations like ours rely on HHS guidance documents to support the people we serve in accessing health care. A confusing and burdensome process for HHS to issue and for us to find guidance documents would hinder these efforts.

Our organizations applaud you for withdrawing 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. For more information, contact Rachel Patterson at the Epilepsy Foundation at rpatterson@efa.org.

Sincerely,

Alpha-1 Foundation
ALs Association
American Cancer Society Cancer Action Network

² Comments on Good Guidance NPRM (September 16, 2020) [https://www.lung.org/getmedia/6b16f667-1d83-4fc8-a6dd-b36441c7d9f0/health-partner-comments-hhs-guidance-rule-\(final\).pdf](https://www.lung.org/getmedia/6b16f667-1d83-4fc8-a6dd-b36441c7d9f0/health-partner-comments-hhs-guidance-rule-(final).pdf)

American Heart Association
American Kidney Fund
American Lung Association
Arthritis Foundation
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
Muscular Dystrophy Association
National Alliance on Mental Illness
National Eczema Association
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
Susan G. Komen
The AIDS Institute