September 16, 2020

The Honorable Seema Verma  
Administrator, Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244  


Dear Administrator Verma:

The AIDS Institute, a national non-profit organization dedicated to supporting and protecting health care access for people living with HIV/AIDS, viral hepatitis, and other chronic health conditions, is concerned about the impact the Department of Health and Human Services’ (HHS) Notice of Proposed Rulemaking, titled “Good Guidance Practices,” will have on programs that provide services to people with HIV, and the policies that govern access to health care for vulnerable populations. The AIDS Institute appreciates the opportunity to submit comments on the proposed rule, but must acknowledge the 30-day comment period is much too short to fully assess the impact of this complex rule.

The AIDS Institute supports efforts to improve transparency and accountability in the use of guidance documents, and generally favors making government guidance readily available to the public in an organized manner and in such a way that fosters stakeholder engagement through notice and comment processes; however, the proposed rule fails to achieve these goals. Additionally, the proposed rule lacks clarity on several key provisions, making it difficult to understand the true intent and the operational. Therefore, we urge HHS to withdraw the proposed rule in its entirety.

The proposed rule poses a risk to the rescission of important guidance documents

The proposed rule roughly outlines a general process by which guidance documents must be uploaded to a designated repository by November 16, 2020; any guidance that is not included in the repository by that date is considered omitted. The creation of a centralized, searchable guidance repository is a commendable step towards transparency and government accountability. However, The AIDS Institute is concerned that this proposed rule will lead to the rescission of guidance documents that are critical to people living with HIV, hepatitis, and other chronic conditions. The HIV and hepatitis communities, like many other healthcare stakeholders, rely on guidance to ensure access to necessary, lifesaving medical care and treatment. Administrative guidance provides clarity and direction to the public about important programs, policies, and rules. Given the importance of guidance to members of the public who confront difficult and complex questions about legal obligations and the administration of government programs, it is extremely problematic to rescind guidance simply by arbitrarily omitting it from a designated repository without establishing a public review or oversight process.
HHS has not provided any indication of what documents are slated for rescission nor adequately outlined the process and standards by which current guidance is being evaluated for inclusion in the repository. The lack of transparency will undoubtedly result in important documents being overlooked and inadvertently omitted. We understand that rescission of outdated guidance may be helpful to the public in many ways. We believe that the public or key stakeholders must have an opportunity to engage in the review process before guidance documents are excluded from the repository and considered null and void. Additionally, the proposal also does not specify whether rescinded documents would be replaced with guidance that is more relevant and current. Rather than promoting clarity about federal policies and efficient administration of government programs, this proposed rule will result in complex questions about government programs simply being left unanswered altogether.

Despite including a lengthy description for reinstating rescinded guidance, the process remains vague; however, it can be discerned that the process described is impractical. Such a process is time consuming, burdensome, and causes uncertainty among the public and regulated entities. For patient advocates, policy analysts, and program administrators, immediate access to guidance documents is imperative to effectively serve the HIV and hepatitis communities. The process described seems to needlessly burden the public with a lengthy petition process when it is discovered that a guidance document has been omitted from the repository. Guidance documents are critical to the work public health professionals do by interpreting agency policy and complex questions related to administration of government programs. Placing the burden on the public through this untenable process can easily be avoided if the arbitrary, wholesale rescission of guidance were not included in this proposed rule.

**The proposed rule creates confusion as to what constitutes guidance**

The AIDS Institute notes that the proposed rule introduces confusion to the definition of guidance. HHS states the content rather than format of a document determines whether it is considered guidance, and several examples are provided. However, then the counterintuitive explanation that guidance could be contained within non-guidance documents creates significant confusion. HHS notes that even if a document is addressed to *specific parties*, if it nonetheless contains a general statement of relevant policy or interpretation intended to have future effect by guiding the conduct of other regulated parties, then the document would also be guidance. No examples of guidance that is actually hidden within non-guidance are provided, nor does it specify the manner in which it purports to identify when or where this has occurred. This definition is so vague as to be unworkable. The AIDS Institute is concerned about the lack of clarity regarding definitions and processes throughout the proposed rule that will have far-reaching and long-lasting, harmful effects on the HIV community’s ability to work effectively or efficiently.

**Proposed rule creates unnecessary burdensome process for issuing guidance**

In addition to the vague description for what constitutes guidance, we are greatly concerned about the lack of clarity around “significant” guidance and the process outlined for future issuance. The proposed rule states that guidance issued after November 16th, 2020 will have notice and comment requirements applied, and guidance deemed “significant” will be subjected to a stringent review process. Guidance is intended to be a streamlined method for outlining agency policy and assisting in the interpretation and implementation of regulations, and is not intended to supplant rule making. Subjecting guidance to the rigorous review process required for rule making is counterproductive to the purpose of issuing guidance documents. Working as designed, guidance has allowed agencies to adapt when necessary and
to quickly disseminate directions to programs in times of crisis, such as during the onset of the COVID-19 pandemic and throughout the year. This has ensured patients living with, and at heightened risk for HIV and hepatitis can continue to get access to life-saving treatment and care without delays.

**Examples of potential impact on guidance governing HIV programs and policies**

Service providers through the Ryan White HIV/AIDS Program (RWHAP) rely heavily on guidance, including policy clarification notices (PCN), for program operations to ensure timely delivery of care and treatment to clients living with HIV. Based on a search of [https://www.hhs.gov/guidance/](https://www.hhs.gov/guidance/) we are concerned that only one PCN is currently included in the portal, and worry that this proposed rule will leave out the numerous other PCNs and guidance documents that are critical to the administration of RWHAP and, therefore, to the fight against HIV.

Another example that impacts the HIV and hepatitis community are templates and review documents the Center for Consumer Information and Insurance Oversight (CCIIO) created for health insurance issuers applying for Qualified Health Plan (QHP) certification, including a prescription drug benefit review tool to ensure that prescription drug coverage complies with nondiscrimination, essential health benefits, and other requirements.1 The AIDS Institute reviews plans’ prescription drug formularies to ensure issuers are not applying discriminatory benefit designs that would discourage HIV and viral hepatitis patients from selecting their plans. While the documents were created for CCIIO’s internal use during the QHP certification process, issuers rely on these when creating their plan benefit designs, and we utilize them to evaluate the plans. It is not clear if these review templates would be considered guidance under the proposed rule.

While The AIDS Institute supports efforts to improve transparency, reduce duplication, and increase government accountability, the proposed rule creates confusion by failing to provide specificity around key terms and processes and inserting unnecessary, burdensome procedures. We believe that the HIV and hepatitis communities will be harmed by this proposed rule and will undermine the Administrations’ initiative to End the HIV Epidemic. We urge you to withdraw this rule.

We sincerely appreciate your time and consideration and look forward to continuing to work with you to improve the lives and well-being of people living with HIV and viral hepatitis. Feel free to reach out to Stephanie Hengst, shengst@taimail.org, or Rachel Klein, rklein@taimail.org.

Sincerely,

Stephanie Hengst
Manager, Research & Advocacy
The AIDS Institute

---

1 CCIIO, Qualified Health Plan Certification, [https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp](https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp)