



September 16, 2020

Re: Good Guidance Practices, Document ID: HHS-OS-2020-0008-0001

To Whom It May Concern:

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG) – a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV- and hepatitis C-related health care and support services. We are writing in response to this Notice of Proposed Rulemaking, *Good Guidance Practices*, in which the Department of Health and Human Services (“HHS”) proposes to issue regulations concerning the agency’s release and maintenance of guidance documents (the “proposed rule”).

While HHCAWG understands the importance of transparency and accountability in the use of guidance documents, is generally in favor of making government guidance readily available to the public in an organized manner, and supports measures that foster stakeholder engagement through public notice and comment, the proposed rule fails to achieve these goals. Furthermore, the proposed rule fails to adequately explain key provisions, making it impossible for HHCAWG to assess and provide meaningful comments on the full impact of this proposed rule in the short 30-day comment period. Accordingly, we urge HHS to withdraw the proposed rule in its entirety.

**The proposed rule’s guidance repository may lead to the arbitrary recession of important documents**

HHCAWG is primarily concerned about the effect this may have on guidance documents that the HIV and HCV communities have relied on to secure access to necessary, lifesaving medical care and treatment. We are concerned that this proposed rule will lead to rescission of guidance documents that are critical to people living with HIV, hepatitis, and other chronic conditions. We support, as a general principle, the creation of a centralized, searchable guidance repository. 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 allow the rescission of guidance simply by arbitrarily omitting it from a designated repository by the arbitrarily-designated date of November 16, 2020. For months, HHS personnel have been reviewing

guidance documents, with no indication of what documents are slated for rescission, what standards apply, or any opportunity for the public to weigh in. We adamantly oppose wholesale rescission of guidance documents arbitrarily excluded from the repository without meaningful stakeholder engagement and consideration of each document's relevance, or without demonstrating why rescinding specific guidance, without issuing more current or relevant guidance to replace it, is in the best interest of affected communities, specifically underserved or vulnerable communities such as those affected by HIV and hepatitis.

HHS has not adequately explained the process by which documents are identified to be uploaded to the repository. HHCAWG is concerned that this lack of transparency will result in important documents being overlooked and inadvertently rescinded. We understand that rescission of outdated guidance may be helpful to the public in many ways. However, in addition to lacking a clear standard for rescission of documents, the proposal also does not specify whether rescinded documents would be replaced with guidance that is more relevant and current. We are therefore concerned that this proposal, rather than promoting clarity about federal policies and efficient administration of government programs, will result in complex questions about government programs simply being left unanswered altogether.

For example, Health Resources and Services Administration (HRSA) guidance implementing the Ryan White HIV/AIDS Program ("RWHAP") is critical for the program's effective operation. The RWHAP serves more than half a million people each year and more than half of people in the United States with an HIV diagnosis. In 2018, a record 87.1% of clients receiving medical care through RWHAP achieved viral suppression, highlighting the key role that RWHAP plays in providing care and treatment to people living with HIV and achieving the ambitious goals articulated in the Administration's *Ending the HIV Epidemic: A Plan for America* initiative.<sup>1</sup> As one example of the potential harm of this proposed rule, a quick search in HHS' Guidance Portal at <https://www.hhs.gov/guidance/> reveals that only one HRSA RWHAP Policy Clarification Notice (PCN)—PCN #18-01—is included in the portal. Many of the organizations represented by HHCAWG, as well as staff in every state's RWHAP, regularly rely on these PCNs to ensure that RWHAP clients receive timely access to the services they need to achieve and maintain viral suppression. We are very concerned that only one PCN is currently included in the portal, and fear that this proposed rule will lead to rescission of PCNs and other guidance documents that are critical to the administration of RWHAP and, therefore, to the fight against HIV.

The proposed rule includes a lengthy process for reinstating rescinded guidance which, in addition to being vague, is also impractical. Such a process is time consuming, burdensome, and causes uncertainty among the public and regulated entities. Additionally, advocates and policy analysts at organizations such as those represented by HHCAWG rely on the ability to immediately access guidance documents that enable us to effectively serve our populations; our work will be significantly and needlessly burdened if we are required to undergo a lengthy

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<sup>1</sup> HRSA Announces Highest HIV Viral Suppression Rate in New Ryan White HIV/AIDS Program Client-Level Data Report (Dec. 11, 2019), <https://www.hiv.gov/blog/hrsa-announces-highest-hiv-viral-suppression-rate-new-ryan-white-hiv-aids-program-client-level-0>.

petition process any time we discover that a guidance document has been rescinded. Much of our work includes timely responding to organizations serving people on the ground who often need real-time technical assistance to serve immediate needs of people living with HIV or hepatitis. Delays in providing such assistance can lead to devastating individual and public health outcomes if consumers lose coverage or access to care while we await access to a guidance document. Guidance documents are critical to our work in that they enable us to understand complex questions related to administration of government programs. Wholesale, arbitrary rescission of guidance documents will hamper our ability to effectively serve people living with HIV and hepatitis.

Additionally, the guidance repository in its current form located at <https://www.hhs.gov/guidance/> is insufficient to meet the needs of members of the public, including organizations represented by HHCAWG, that rely on these documents to answer specific and complex questions. If HHS intends to remove guidance documents from topical webpages and instead make them available exclusively through a single searchable repository, that repository should be indexed in a more sophisticated and useful manner—for example, the repository should include a more comprehensive list of topics, more precise titles and subtitles, and informative categories and sub-categories to help the public understand the different types of available guidance and the entities to which they apply.

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

Far from the stated goal of increasing clarity on guidance for both stakeholders and members of the public, the proposed rule obfuscates the definition of guidance. HHS notes that the content rather than format of a document dictates whether it would be considered guidance. While HHS provides some examples of what would qualify as guidance as well as what would be considered exempt, HHS severely confuses its definition of guidance by including material contained within non-guidance documents. 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.

This definition is so vague as to be unworkable. HHS does not provide any examples of guidance that is actually hidden within non-guidance, nor does it specify the manner in which it purports to identify when or where this has occurred. As stated above, HHCAWG is concerned about the potential arbitrary recessions this may create for guidance organizations represented by HHCAWG rely on. Furthermore, HHCAWG questions how HHS or members of the public are to discern an agency's intent when it issues a document upon which affected parties choose to rely.

For example, the Center for Consumer Information and Insurance Oversight (CCIIO) created a series of templates and review documents 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.<sup>2</sup> HHCAWG has relied on these documents as one way to assess whether issuers are providing adequate, nondiscriminatory coverage of HIV and viral hepatitis medications. While these documents were created for CCIIO's internal use during the QHP certification process, issuers rely on these when creating their plan benefit designs. It is not clear if these review templates would be considered guidance under the proposed rule.

### **The 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 "significant" guidance issued after November 16<sup>th</sup>, 2020 will have notice and comment requirements applied and 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. While HHCAWG 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 individuals and communities that we serve 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.

HHCAWG appreciates your thoughtful consideration of our comments. If you have questions or would like to discuss further, please contact HHCAWG co-chairs HHCAWG Co-Chairs Phil Waters with the Center for Health Law and Policy Innovation at [pwaters@law.harvard.edu](mailto:pwaters@law.harvard.edu), Amy Killelea with the National Alliance of State and Territorial AIDS Directors at [akillelea@nastad.org](mailto:akillelea@nastad.org), or Rachel Klein with The AIDS Institute at [rklein@tmail.org](mailto:rklein@tmail.org).

Respectfully submitted by the undersigned organizations:

ADAP Educational Initiative  
AIDS Action Baltimore  
AIDS Alabama  
AIDS Alliance for Women, Infants, Children, Youth & Families  
AIDS Foundation of Chicago  
AIDS Research Consortium of Atlanta

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<sup>2</sup> CCIIO, Qualified Health Plan Certification, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/ghp>

AIDS Resource Center of Wisconsin  
AIDS United  
American Academy of HIV Medicine  
APLA Health  
Bailey House, Inc.  
Communities Advocating Emergency AIDS Relief (CAEAR)  
Community Access National Network (CANN)  
Georgia AIDS Coalition  
Harm Reduction Coalition  
HealthHIV  
HIV Dental Alliance, Atlanta  
HIV Medicine Association  
Housing Works  
Legal Council for Health Justice  
Los Angeles LGBT Center  
Michigan Positive Action Coalition  
Minnesota AIDS Project  
National Alliance of State and Territorial AIDS Directors  
National Coalition of STD Directors  
National Latino AIDS Action Network  
NMAC  
Positive Women's Network - USA  
Project Inform  
Rocky Mountain CARES  
San Francisco AIDS Foundation  
SisterLove  
Southern AIDS Coalition  
Southern HIV/AIDS Strategy Initiative  
The AIDS Institute  
Thrive Alabama  
Treatment Access Expansion Project  
Treatment Action Group