



Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW, Room 713F
Hubert H. Humphrey Building
Washington, DC 20201

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Headquarters

One Kaiser Plaza Suite 850
Oakland, CA 94612
Main 415-954-9988
Fax 510-419-0263
www.apiahf.org

Washington D.C. Office

1629 K Street N.W. Suite 400
Washington, D.C. 20006
Main 202-466-7772
Fax 202-466-6444

National Advocates for Asian
American, Native Hawaiian &
Pacific Islander Health

Re: Good Guidance Practices Proposed Rule; RIN 0991-AC17

September 16, 2020

Dear Secretary Azar:

The Asian & Pacific Islander American Health Forum (APIAHF) submits this comment letter in response to the Department of Health and Human Services (HHS) notice of proposed rule regarding "Good Guidance Practices" ("proposed rule"). We raise concerns about several issues impacting consumers, and particularly those who are racial and ethnic minorities, limited English proficient, have health literacy and literacy challenges and advocates working with and supporting those communities. **Overall, while APIAHF supports transparency and accountability, it strongly opposes the proposed rule as it would create burdensome and unnecessary procedural requirements to guidance documents and lead to the rescission of any guidance not included in the new repository, which is unprecedented and unnecessary.**

APIAHF is the nation's leading health policy organization working to advance the health and well-being of over 20 million Asian Americans, Native Hawaiians and Pacific Islanders (AA and NHPI) across the U.S. and territories. APIAHF works to improve access to and the quality of care for communities who are predominately immigrant, many of whom are limited English proficient, and may be new to the U.S. health care system or unfamiliar with private or public coverage. We have longstanding relationships with over 100 community-based organizations across 34 states and the Pacific, to whom we provide capacity building, advocacy and technical assistance. Since 2012, APIAHF and partners have worked to outreach to, educate and enroll 1 million consumers through Action for Health Justice (AHJ), a national collaborative of more than 70 AA and NHPI national and local community-based organizations and health centers.

As such, we have a strong understanding of the needs and barriers experienced by AA and NHPI communities across the country and the community based organizations working with them, and the impact that changes outlined in the proposed rule would have on those individuals and communities by creating substantial uncertainty and increasing regulatory burden on those communities.

30-Day Comment Period is Insufficient to Allow for Public Review and Comment

The proposed rule is cross-cutting, potentially impacting guidance issued across the entire agency with the possibility to create confusion about its impact and failing to achieve stated goals of transparency and accountability. A 30-day comment period is insufficient to allow for adequate public review, particularly in light of the current COVID-19 national emergency. APIAHF joins advocates nationwide in requesting that the department provide at least a 60-day period of notice and comment.

The Proposed Rule Fails to Achieve Its Stated Goals and Undermines Transparency

While we appreciate the goals of transparency and accountability, the proposed rule fails to achieve these goals.

Which documents constitute “guidance” and “significant guidance”

The proposed rule fails to adequately describe how the department will determine what documents constitute guidance and significant guidance, including what criteria will be considered and what process the department will use to categorize such documents. The proposed definition is vague and creates further confusion for what constitutes guidance and what does not. For example, the department does not explain how it will calculate any proposed costs associated with “significant guidance,” thus failing to articulate a standard. Further the department fails to explain the statutory basis for which it is applying notice and comment to significant guidance and how joint guidance from several agencies would be treated.

Rescinds guidance merely for failing to include it in a repository

The proposed rule would rescind guidance merely for omitting it from the designated repository, an unprecedented and unwarranted action given the role of guidance and the broad number of documents that could be impacted. We strongly oppose this proposal as the department should not rescind guidance without a public and collaborative process with clear standards for evaluating current guidance documents and outside of public view. In addition, the department should not rescind guidance that is already established without demonstrating, though clear criteria, why rescinding it is in the best interest of underserved and affected communities.

For example, APIAHF works with AA and NHPI communities who trace their heritage to more than 50 different countries and speak more than 100 different languages with distinct needs, challenges and assets. Since 1986, APIAHF has advocated for the issues of access to health care, quality health care, language access and detailed and accurate data to support the needs of AA and NHPI

communities. Advocates working with AA and NHPI communities and regulated entities operate with existing guidance that has been in effect, sometimes for decades. Rescinding such guidance, such as those impacting health programs in the Affordable Care Act, Medicaid, Medicare and language access, would harm these communities and regulated entities.

Members of the public will likely be confused if a guidance document appears on a HHS website, but is not included in the repository. It would not be apparent that such guidance is considered rescinded under this rule. Even if stakeholders petition to reinstate guidance omitted from the repository, such a process would be time consuming, burdensome, and cause uncertainty among the public and regulated entities. We therefore oppose these provisions.

Further, the proposed petition process provides no explanation for how such a petition will be considered and evaluated.

Disclaimer will create regulatory confusion and burden

By adding a disclaimer that all guidance lacks the force and effect of law, the proposed rule will create confusion and regulatory burden amongst consumers, members of the public and regulated entities about their rights and responsibilities. APIAHF has already documented numerous incidents from AA and NHPI advocates who have noted that recent immigrants and those with limited English proficiency are often unaware of their rights.

Proposed guidance process is burdensome and unnecessary

The guidance process should be streamlined and nimble, ensuring that there is clarity on implementing of existing regulations so that regulated entities and the public understand their rights and responsibilities. In contrast, the proposed rule creates burdensome requirements that have no place in the guidance process given that the rulemaking process already exists and includes notice and comment procedures.

The proposed process would create burden for the department and agencies/offices in responding to novel circumstances, such as the COVID-19 public health emergency, in which the department has issued several documents that would likely fall under the definition of guidance in the proposed rule, detailed [here](#), including disclosure of protected health information issued by OCR, human research protections related to COVID-19, among others.

For the reasons set forth above, and to ensure that AA and NHPI communities and advocates are able to access the essential services they need, we strongly urge the department to withdraw this rule. For questions, please contact Juliet K. Choi, APIAHF Executive Vice President and Chief of Staff at jchoi@apiahf.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kathy Ko Chin', followed by a horizontal line extending to the right.

Kathy Ko Chin,
APIAHF President & CEO