



APhA

2215 Constitution Avenue, NW • Washington, DC 20037-2985

August 12, 2019

U.S. Department of Health and Human Services
Office for Civil Rights
Attn: Section 1557 NPRM
Hubert H. Humphrey Building, Room 509F
200 Independence Ave. SW
Washington, DC 20201

[Submitted electronically to www.regulations.gov]

Re: Nondiscrimination in Health and Health Education Programs or Activities [HHS-OCR-2019-0007]

Dear Sir/Madam:

APhA is pleased to submit these comments regarding the Department of Health and Human Services' (HHS) Proposed Rule, *Nondiscrimination in Health and Health Education Programs or Activities* (hereinafter, the "Proposed Rule"). Founded in 1852 as the American Pharmaceutical Association, APhA represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physician office practices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services.

The Office for Civil Rights, Office of the Secretary, Department of Health and Human Services (HHS), (hereinafter, "OCR") issued the Proposed Rule to implement Section 1557(c) of the Affordable Care Act (ACA), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. APhA appreciates HHS's efforts to gather information from stakeholders regarding nondiscrimination in health care settings.

I. Scope of Coverage

The Proposed Rule indicates entities principally engaged in the business of health care would need to comply with Section 1557 for any program or activity it engages in. Alternatively, entities not principally engaged in the business of health care would need to comply with Section 1557 only for the programs or activities for which it receives Federal financial

assistance. The Proposed Rule provides examples of entities principally engaged in the business of health care (e.g., hospitals, nursing facilities, hospices, community health centers and physical therapists). However, the Proposed Rule does not provide additional information regarding circumstances where an entity is not primarily engaged in the business of health care or shed light on how an entity could make such a determination. APhA seeks clarity from HHS regarding the scope of coverage.

II. Meaningful access for individuals with limited English proficiency (LEP)

APhA appreciates the additional flexibility granted in the Proposed Rule, particularly pertaining to the development of a written LEP plan and specific technical requirements which may be burdensome for small, resource-constrained entities to develop and/or implement. APhA agrees with HHS that in many circumstances, foreign language speakers can rely on a clear audio transmission for effective communication as opposed to the video remote interpreting standards that were outlined in the final rule being the only option.

In addition, APhA agrees that an individualized case-by-case assessment of the four factors specified in the Proposed Rule that covered entities can consider may be beneficial when determining the extent of their need to provide language assistance services.¹ APhA encourages HHS to provide education to entities regarding this new framework to help covered entities reevaluate how they will provide language assistance services in accordance with the flexibility provided in the Proposed Rule, once finalized. Given the changes required in the 2016 Final Rule, it will be important for entities to be provided with the educational resources to help them utilize the flexibility provided in the Proposed Rule.

III. Effective Communication for Individuals with Disabilities

APhA recognizes the small margins small businesses, particularly those on which independent community pharmacies operate. Therefore, an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees would likely be helpful. However, it is important to note some pharmacies, for example, may have more than 15 employees. Therefore, it may be helpful for HHS to consider reevaluating this number to better reflect current realities within small businesses who may be challenged with adhering to the rule once finalized.

¹ The four factors noted in the Proposed Rule are: (1) The number or proportion of LEP individuals eligible to be served or likely to be encountered in the eligible service population. (2) The frequency with which LEP individuals come in contact with the entity's health program, activity, or service. (3) The nature and importance of the entity's health program, activity or service. (4) The resources available to the entity and costs.

IV. Taglines, Notices, Language Access Plans and Video Interpretation Standards

As noted above, APhA appreciates HHS's efforts to provide health care entities with additional flexibility. The changes regarding taglines and notices will be helpful for some pharmacists who raised concerns regarding space requirements, including those taglines in publications and in postings placed within pharmacies, and other burdens associated with the taglines and notices.

V. Cost of the Final Rule

APhA appreciates HHS's desire to better understand the cost of the Final Rule, as imposed in 2016. While APhA does not have specific cost information, we note the estimated costs related to pharmacy-related communications is likely underestimated. As noted in the proposed rule, the Department relied on estimates from the Pharmaceutical Care Management Association (PCMA), which obtained an estimate based on the number of beneficiaries from its member organizations. Since these communications were from pharmacy benefit managers, APhA notes pharmacies, other health care facilities, and pharmacists also provide pharmacy-related communications, and not all individuals served within pharmacies may have health benefit coverage provided by PCMA members.

VI. Resources and Education

When HHS finalized Section 1557, certain resources and educational materials (e.g., fact sheets) were made available by HHS. APhA strongly encourages HHS to update the resources and educational materials once the Proposed Rule is finalized. While APhA also provides education and outreach to members, our members appreciate resources provided by HHS that will help them utilize the flexibility provided in the Proposed Rule once finalized.

In addition, as regulatory flexibility is being provided, APhA is sensitive to the needs of individuals with disabilities and LEP who may have relied on certain resources and information being available. APhA encourages HHS to make clear which specific resources and information were found to be most beneficial to help inform future compliance decisions. HHS may also consider making available grants and other resources to exempted entities that are financially constrained but interested in providing such resources to patients. In addition, given today's restrained healthcare provider compensation environment, we request a review by HHS of the cost to providers for these services and requiring coverage of these costs within provider reimbursement models.

Thank you for the opportunity to provide information on this important issue. APhA and our members are committed to increasing patient access to health care and improving care. If

you have any questions or require additional information, please contact Jenna Ventresca, JD, Associate Director of Health Policy, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO