March 27, 2018

[Submitted electronically to www.regulations.gov]

Mr. Roger Severino
Director, Office of Civil Rights (OCR)
U.S. Department of Health and Human Services (HHS)
Attention: Conscience NPRM, RIN 0945–ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Proposed Rule (Docket ID number HHS–OCR–2018–0002)

Dear Mr. Severino:

The American Pharmacists Association (APhA) appreciates the opportunity to submit our comments on HHS's "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Proposed Rule" (the "Proposed Rule"). Founded in 1852 as the American Pharmaceutical Association, APhA represents 64,000 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, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA supports HHS's efforts to clarify OCR authority for federal enforcement of the established laws protecting the freedoms of conscience and religious exercise protected by the First Amendment to the U.S. Constitution and Federal statutes (collectively referred to in the Proposed Rule as ''Federal health care conscience and associated anti–discrimination laws").[1]

APhA appreciates HHS's concern that the public and many health care providers and entities are largely uninformed of conscience protections afforded to individuals and institutions.

[1] Church Amendments (42 U.S.C. 300a–7), Coats-Snowe Amendment (42 U.S.C. 238n), Consolidated Appropriations Act, 2017 (Pub. L. 115–31, Div. H, Tit. V, sec. 507(d) (the Weldon Amendment) and at Div. H, Tit. II, sec. 209), (ACA) related to assisted suicide (42 U.S.C. 18113), the ACA individual mandate (26 U.S.C. 5000A(d)(2)), and other matters of conscience (42 U.S.C. 18023(c)(2)(A)(i)–(iii), (b)(1)(A) and (b)(4)), Counseling and referral for certain services in Medicaid or Medicare Advantage (42 U.S.C. 1395w– 22(j)(3)(B) and 1396u–2(b)(3)(B)), Advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406), Helms Amendment ((22 U.S.C. 7631(d), Consolidated Appropriations Act, 2017, Pub. L. 115–31, Div. J, Title VII, sec. 7018), hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)), vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)), and religious nonmedical health care (e.g., 42 U.S.C. 1320a–1, 1320c–11, 1395i–5 and 1397j–1(b)).

We agree that these protections extend the conscience rights and self-determination to all, including health care providers. APhA's support of conscience rights protections is reflected in our House of Delegates (HOD) policy, which states:

> "APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient's access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal."[2]

Due to their application to pharmacists and pharmacies that receive reimbursement directly or indirectly from HHS for the provision of pharmacy services, our comments focus on the conscience provision of the Church Amendments (42 US.S.C 300a–7(d)).[3]

I. Balancing Patient & Provider Rights

APhA's policy recognizes the need to establish systems to ensure patient access to necessary medications while supporting the ability of pharmacists to refuse to participate in procedures to which they have moral or religious objections. The Department states the Proposed Rule will not limit patient access to health care and is merely designed to protect the conscience rights of health care providers and entities. To ensure HHS achieves its goal, APhA recommends HHS revise the Proposed Rule to acknowledge that health care providers and entities may establish systems to help meet patients' health care needs. APhA has long recommended that prior to serving any patient, pharmacists discuss objections they may have with their supervisor and develop ways to honor these personal convictions while also meeting the needs of patients.

II. Assurance and Certification of Compliance

APhA appreciates HHS trying to find the appropriate balance in the Proposed Rule between protecting the health care workforce and avoiding undue administrative burden on providers and health care entities. While HHS proposes to lessen the assurance and certification reporting requirements for sub-recipients by making them exempt, the Department notes that Section 88.4(c) also contains several important exceptions from the proposed requirements for written assurance and certification of compliance. One of these exceptions is for "[p]hysicians, physician offices, and other health care practitioners participating in Part B of the Medicare program." It is important to note that while pharmacies and pharmacists participate in the Medicare program, primarily in Part D, but also in Part B (e.g., certain immunizations). However, many of the Part B statutory provisions and regulations do not include pharmacists or pharmacies as health care providers, eligible clinicians or other similar terms,[4] and therefore,

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[2] JAPhA 38(4):417 July/August 1998) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2010) (Reviewed 2015). Pg. 48. Available at: http://www.pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf

[3] "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions." *See*, 42 U.S.C. § 300a–7(d). Available at: https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapVIII-sec300a-7.pdf

[4] HHS does include pharmacists in other terms used in the Proposed Rule. *See,* pg. 3893 "Thus, the Department's proposed inclusion of the terms ''health care professional'' and ''health care personnel'' is intended, for example, to cover pharmacists,

pharmacists may not be covered by this exception. Accordingly, APhA requests HHS clarify that pharmacists and pharmacies are included in provisions applicable to other recipient or sub-recipient providers, entities or practitioners, when applicable.

Thank you for the opportunity to provide comments on the Proposed Rule. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

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

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs
The Honorable Alex Azar, Secretary, HHS
Conscience and Religious Freedom Division, OCR, HHS

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nurses, occupational therapists, public-health workers, and technicians, as well as psychiatrists, psychologists, counselors, and other mental health providers, but the definition does not enumerate these health care job categories because they are reasonably included in such terms."