



[Submitted electronically to: cures.rfi@mail.house.gov]

August 2, 2024

The Honorable Diana DeGette
U.S. House of Representatives
Energy & Commerce
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, MD
U.S. House of Representatives
Energy & Commerce
2313 Rayburn House Office Building
Washington, DC 20515

Dear Congresswoman DeGette, and Congressman Buchson,

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to your request for information (RFI) regarding the proposed Cures 2.0 and the 21st Century Cures Act.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists and pharmacy personnel in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA applauds your continuing leadership in modernizing our nation's coverage and healthcare delivery systems through Cures 2.0. One of our key priorities is to expand the utilization of pharmacist services to help individuals and communities in underserved areas to increase patient care. APhA shares appreciation for the progress made on multiple fronts in advancing several Cures 2.0 proposals through legislation or executive action to help meet the original goals of Cures. APhA further agrees that additional provisions included in the latest version of Cures 2.0 are still necessary to advance healthcare delivery in the United States. Accordingly, APhA respectfully requests the re-inclusion and addition of the following provisions in the next version of the Cures 2.0 legislation:

Include and Update Previous Sec. 408 Language - Medicare Coverage for Pharmacogenetic Consultations/Medicare Coverage for Consultations

As you know, pharmacogenomics addresses how an individual's DNA influences the response to a medication. As medication experts, pharmacists are well suited to interpret pharmacogenomic testing and determine which medication is best suited for each individual

patient. A recent [retrospective study](#) of Medicare-eligible health plan members in the Teachers' Retirement System Kentucky demonstrated that, when combined with comprehensive medication management (CMM) services, pharmacogenomic testing can improve appropriate drug selection, support drug adherence, and reduce adverse drug events (ADRs)—which ultimately resulted in better patient outcomes and considerable cost savings. The services included patient education, genetic testing, pharmacist review, and a comprehensive medication action plan. Direct medical charges decreased in the intervention group by approximately \$7,000 per patient overall, or an average of \$218.82 per patient per month. During the study's 32 months, cost savings totaled \$37 million.

Accordingly, APhA strongly recommends reincluding the provisions and making the following changes/updates to this section of the legislation:

Change “qualified clinical pharmacist” to “qualified pharmacist.”

“(3) QUALIFIED ~~CLINICAL~~ PHARMACIST.—The term ‘qualified ~~clinical~~ pharmacist’ means an individual—

“(A) ~~with a doctoral degree in pharmacy;~~

“(B) ~~who is licensed or otherwise authorized under State law or Federal law to furnish consultations as a pharmacist in the State in which such individual furnishes consultations;~~

“(C) ~~has appropriate pharmacy specialty certifications or appropriate training, as determined by the Secretary; and~~

“(D) meets other qualifications as specified by the Secretary.”.

Considerations:

- Recommend removing “clinical” as there is not an accepted definition of a clinical pharmacist.
- Pharmacists with a Bachelor’s in Pharmacy and the appropriate training are delivering these services and should not be excluded; therefore, PharmD should be removed.
- The updated language should also consider providing flexibility for telehealth consultations/services in other states per state authority.

Include H.R. 1770 to Protect Seniors’ Access to Critical Pharmacist-Provided Public Health Testing and Immunization Efforts

With the federal Public Readiness and Emergency Preparedness (PREP) Act authorities for pharmacist-provided care expiring at the end of December 2024, key provisions that empowered pharmacists to order tests, treat patients, and provide immunizations will expire removing many of these vital healthcare providers from the U.S. public health system. In particular, the ending of these flexibilities will have a disproportionate impact on individuals

covered by Medicare as many Medicaid programs and private insurers have already taken steps to allow pharmacists to continue providing these services. The current language of section 1861(s) of the Social Security Act prohibits the Centers for Medicare and Medicaid Services (CMS) from paying a pharmacist for these public health services. If not enacted into law in this Congress, APhA recommends the inclusion of H.R. 1770, the Equitable Community Access to Pharmacist Services Act, which you both cosponsor, in Cures 2.0 to address support our nation's public health infrastructure and the inclusion of pharmacists in the public health workforce.

Establish a Chief Pharmacy Officer within CMS

Pharmacists play a critical role in the U.S. public health system. Additionally, prescription medications are fundamental to maintaining the health of millions of Americans. The unaffordability of medications is a top issue facing Congress and the respective agencies, especially CMS, the agency that administers the Part D program. During the COVID-19 pandemic, the professional societies representing pharmacists regularly found it difficult to communicate to and throughout the Department of Health and Human Services' (HHS) and CMS' bureaucracy. While we appreciate the efforts of CMS to work with pharmacy, many challenges could have been avoided by the establishment of a central office – a Chief Pharmacy Officer - as CMS did by establishing the offices of the Chief Medical Officer and Chief Dental Officer. The creation of such an office would also bring CMS in line with standard operating practices for other health insurers and health systems where such positions are commonplace. Accordingly, APhA strongly recommends including legislative language in Cures 2.0 to establish this position.

Thank you for the opportunity to comment on the Cures 2.0 RFI. We would once again like to commend you for your leadership on these issues and would be happy to assist in any manner we can.

Please contact Doug Huynh, JD, APhA Director of Congressional Affairs, at dhuyh@aphanet.org if you have any additional questions.

Sincerely,

A handwritten signature in black ink that reads "Michael Baxter". The script is cursive and fluid, with the first letters of each word being capitalized and prominent.

Michael Baxter
Vice President, Federal Government Affairs