



AMCP Submits Comments on OMB Equity RFI

AMCP responded to a request for information (RFI) from the Office of Management and Budget (OMB) on advancing equity and support for underserved communities through government. Aligned with AMCP's strategic priority to address health disparities, AMCP's comments focused on changes to federal program enrollment to increase access to prescription drugs and health coverage. Continuous 12-month enrollment in Medicaid will help reduce gaps in coverage, which have been shown to negatively affect medication adherence. AMCP also recommends increasing automatic enrollment in the Low-Income Subsidy (LIS) Program in Medicare Part D which will help seniors access needed prescription drugs at more affordable costs.

[Read AMCP's comments.](#)

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Eye On Washington

President Biden Signs Executive Order on Increasing Competition

On July 9, President Biden signed an Executive Order (EO) titled "Promoting Competition in the American Economy," which included a section on increasing competition and lowering prices for prescription drugs. The EO focuses on promoting the use of biosimilars and improving the approval process for generics and biosimilars by making it more transparent, efficient, and predictable. It directs the Secretary of Health and Human Services (HHS) to provide educational materials and communications on biosimilars, to help facilitate the development of interchangeable products, and to work with the Federal Trade Commission to identify and address efforts to impede generic and biosimilar competition. While AMCP is extremely supportive of these efforts, the EO also includes language directing the Food and Drug Administration (FDA) to work with states to develop and implement drug importation programs, which AMCP has historically opposed.

[Read the Executive Order.](#)

CMS Opens National Coverage Determination Process for Aduhelm

This month, CMS began the National Coverage Determination (NCD) process for the recently approved and controversial Alzheimer's drug Aduhelm, which will determine if Medicare will cover the treatment and if so, for what population and under what conditions. Often, treatments are covered in Medicare through Local Coverage Determinations (LCDs), in which Medicare Administrative Contractors set coverage policy for their respective regions, which can lead to uneven coverage across the country. The NCD process, in contrast, sets coverage policy for the entire country. NCDs can be requested by third parties, but in the case of Aduhelm, CMS chose to open the process itself due to the potential cost to the Medicare program. Several health insurers have already indicated that they will not cover Aduhelm or will severely restrict the population for coverage. There will be two public comment opportunities on the NCD

Advocacy Tip

Stay up-to-date: Read AMCP's [Letters, Statements and Analysis](#) on all legislation and regulation impacting managed care pharmacy.

process; the first is open now with focus on the scientific evidence for coverage of Auhelm, and the second to follow when CMS issues a proposed NCD.

Read CMS's initial [National Coverage Analysis](#).

Congress Releases 21st Century Cures 2.0 Discussion Draft

Last month, Representatives Diana DeGette and Fred Upton released the initial [discussion draft](#) of the 21st Century Cures 2.0 legislation, a follow-up to 2016's 21st Century Cures Act. Cures 2.0 would, among other things, fund educational programs for caregivers on medication adherence, promote greater diversity in clinical trials, require FDA to submit a report to Congress on future challenges related to cell and gene therapies, allow for the use of real-world evidence in post-approval studies for accelerated approval drugs, and codify the Medicare Coverage of Innovative Technology (AMCP) rule at CMS.

AMCP supports these provisions and is drafting comments to share with Reps. DeGette and Upton. If you would like to share examples of caregiver education programs run by health plans or pharmacy benefit managers, please reach out to advocacy@amcp.org.

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