



Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

SEPTEMBER 2023

Access to PDTs Act of 2023 Discussed in a House Energy & Committee Hearing

On Sept. 19, the House Energy & Commerce Subcommittee on Health discussed the Access to Prescription Digital Therapeutics (PDTs) Act of 2023 ([H.R. 1458](#)) during a hearing titled “Examining Policies to Improve Seniors’ Access to Innovative Drugs, Medical Devices, and Technology.” AMCP thanks Energy & Commerce Committee Chair Rep. Cathy McMorris Rodgers (R-WA) and Health Subcommittee Chair Rep. Brett Guthrie (R-KY) for including the Access to PDTs Act of 2023 in the list of bills discussed during the hearing. AMCP also thanks Representatives Kevin Hern (R-OK), Mike Thompson (D-CA), Bill Johnson (R-OH), and Doris Matsui (D-CA) for their original co-sponsorship of and continued advocacy for the bill. During the hearing, CMS’ Acting Chief Medical Officer Dr. Dora Hughes responded to a question on PDTs from Rep. Johnson by sharing PDTs’ potential to address medication access issues for Medicare and Medicaid beneficiaries. AMCP is eager to work with CMS to expand access to these innovative therapies and continues to urge Members of Congress to pass the Access to PDTs Act of 2023.

[Tell your Members of Congress to pass the Access to PDTs Act of 2023.](#)

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AMCP Comments on Coverage with Evidence Development Proposed Guidance

On June 22, CMS released a proposed guidance document titled "Coverage with Evidence Development," which addresses the factors CMS considers in making national coverage determinations (NCDs) using the coverage with evidence development (CED) paradigm. Given AMCP's commitment to providing patients with timely access to valuable and potentially lifesaving treatment, AMCP responded with comments on Aug. 21. In the comment letter, AMCP applauds CMS for addressing diversity in clinical trials, and urges the agency to consider more stringent standards for health equity in CED clinical trials.

[Read the full comment letter.](#)

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Adam Colborn Discusses AMCP's Legislative & Regulatory Priorities for 2023

As Members of Congress return to Washington D.C. following the August recess, AMCP's Director of Government Affairs, Adam Colborn, discussed the progress of AMCP's 2023 policy priorities during an episode of the AMCP Podcast Series — *Listen Up!*. In the podcast, Colborn explains the challenges and success in advocating for AMCP's top legislative priority, the Access to PDTs Act of 2023 ([S. 723/H.R. 1458](#)). "Our biggest obstacle is just getting folks to understand what a PDT is," Colborn states. "We held a Demo Day on the Hill... and we had 10 PDT manufacturers bring in their products and display them and demo them directly with congressional staff" he explains, adding that the demonstrations were "really helpful in our pursuit of co-sponsors." Colborn also addressed AMCP's secondary and tertiary legislative priorities; the Medicaid VBPs for Patients Act ([H.R. 2666](#)) and the Equitable Community Access to Pharmacist Services Act ([S. 2477/H.R. 1770](#)), as well as the top regulatory priority, implementation of

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the Inflation Reduction Act.

[Listen to the full podcast episode.](#)

Now Available: AMCP's Inflation Reduction Act Resource Center

While CMS already unveiled the first 10 drugs slated for Medicare price negotiation on Aug. 29, managed care pharmacists' role in implementing the monumental Inflation Reduction Act (IRA) is just beginning. That's why AMCP created the new IRA Resource Center, a central repository for up-to-date IRA information and guidance released by CMS, as well as educational resources and collaborative opportunities to unravel the law's healthcare provisions with other managed care pharmacy professionals. Of note, AMCP held a session titled "Keeping Up With IRA" during the Aug. 29 eLearning Day, with a recording of the session now available in the Resource Center and on AMCP Learn. The IRA Resource Center also features information on the upcoming "Understanding the Fundamentals of IRA and Its Impact" pre-conference program at AMCP Nexus on Oct. 16, as well as the second IRA Workshop Series event which will take place on Nov. 9.

[Browse the full IRA Resource Center.](#)

2023 Call for AMCP Committee Applications Now Open

AMCP's volunteer member committees are an integral part of the association's work, as they complete assigned tasks and offer guidance to AMCP staff in a variety of subject areas. These committees are extremely

active, and committee members committee member can expect to spend a minimum of six days per year (not including travel time) attending AMCP-related meetings and performing committee activities, including committee meetings and conference calls. Committee members can also expect to spend an average of one to two hours per week reading AMCP material, preparing for AMCP activities, and communicating with AMCP members. AMCP's committee year starts at the AMCP Annual Meeting in April and runs for one year. Individuals may serve three consecutive terms on the same committee. Members who are interested and/or experienced in the legislative and regulatory space are encouraged to apply for the [Legislative and Regulatory Action](#) or [Public Policy Committees](#). Committee applications are due by 5:30pm ET on Nov. 1.

Learn about the roles and responsibilities of other [AMCP committees](#).