



Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

MARCH 2023

The Access to Prescription Digital Therapeutics Act of 2023 is Introduced

On March 9, the Access to Prescription Digital Therapeutics (PDTs) Act of 2023 (S. 723/H.R. 1458) was introduced by Senators Jeanne Shaheen (D-NH), Shelley Moore Capito (R-WV), Marsha Blackburn (R-TN), and Cory Booker (D-NJ) and Representatives Kevin Hern (R-OK), Mike Thompson (D-CA), Bill Johnson (R-OH), and Doris Matsui (D-CA). The bill adds PDTs, which are software-based therapies authorized by the FDA and available by prescription only, to the list of services and products eligible for coverage under Medicare and Medicaid. It also authorizes CMS to establish payment methodologies and product-specific Healthcare Common Procedure Coding System codes for PDT reimbursement. In a press release applauding the bill's introduction, AMCP CEO Susan Cantrell explains that "The Access to Prescription Digital Therapeutics Act will ensure Americans have timely and efficient access to treatments that will help address their conditions and improve their peace of mind." AMCP proudly supported the previous iteration of the bill (S. 3791/H.R. 7051) introduced in the last session of Congress and will continue as a leading advocate for authorizing coverage of PDTs.

[Read AMCP's press release.](#)

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Member Benefit! Monitor COVID-19 PHE Guidance with Regulatory NewsBREAKs

In January, President Biden announced that the ongoing COVID-19 Public Health Emergency (PHE) declaration would expire on May 11. Since the announcement, officials within the Department of Health and Human Services have released regular guidance explaining which pandemic-era protections would be wound down as a result of the PHE ending and which protections would remain in place. As the federal government releases additional guidance, stay up to date with the latest information from AMCP's Regulatory NewsBREAK communications. Regulatory NewsBREAKs are delivered directly to member inboxes following the release of pertinent information by federal agencies.

ACCESS TODAY

Eye On Washington

AMCP Submits Comments on CMS Advance Notice for 2024

On Feb. 1, CMS released an Advance Notice of planned changes in the Medicare Advantage (MA) capitation rate methodology and risk adjustment methodology applied under Part C of the Medicare statute for Calendar Year

Advocacy Tip

Stay up-to-date: Read AMCP's [Letters, Statements and Analysis](#) on all legislation and

2024. Following the release of this information, AMCP responded with a comment letter on March 6. In the letter, AMCP supports the Administration's goal to align a core set of measures across quality rating and value-based care programs through the agency's proposed Universal Foundation. AMCP's comments also applaud CMS' commitment to advancing health equity and encourage the agency to adopt updates to HEDIS measures that replace exclusionary language with inclusive, gender-affirming language.

[Read AMCP's full comment letter.](#)

AMCP Joins Pharmacy Organizations in Letter on the COVID-19 PHE

In addition to monitoring the latest updates on the winding down of the COVID-19 Public Health Emergency (PHE), AMCP also joined 11 other pharmacy organizations in a sign-on letter advocating for the continued access to certain critical patient care services delivered by pharmacists under the PHE. Dated March 3, the letter requests clarification on the continuation of several flexibilities provided by the PHE, including reimbursement for testing, vaccination, and treatment of uninsured patients, reimbursement for pharmacist-provided services under the PREP Act, expanded access to telehealth services, access to treatment for opioid-use disorder, and Hospital-at-Home programs. The continuation of these services would assist not only in combatting the next phase of the COVID-19 pandemic but in tackling future public health emergencies as well.

[View the sign-on letter.](#)

AMCP Comments on Proposed Rule Regarding Interoperability and Prior Authorization

Earlier this month, AMCP submitted comments in response to a December 2022 Notice of Proposed Rulemaking (NPRM) from CMS regarding improvements to interoperability and prior authorization (PA) processes for Medicare Advantage organizations, Medicaid managed care plans, state Medicaid agencies, Children's Health Insurance Program agencies, and other related entities through the Medicare Promoting Interoperability Program. AMCP's comments support including drug PA information on Application Programming Interfaces (APIs), as long as they don't conflict with existing PA requirements. AMCP also applauds CMS for considering the impact of technology on health equity and supports the use of an opt-out option for the Provider Access API.

[Read AMCP's full comment letter.](#)

regulation impacting managed care pharmacy.



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