



Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

MAY 2023

AMCP's Jennifer Mathieu Shares Tactics for Expanding Access to PDTs

Prescription Digital Therapeutics (PDTs) are software-based therapies that are reviewed and authorized by the FDA. These products are available by prescription only, but the lack of a statutorily defined coverage category for PDTs in Medicare and Medicaid inhibits patients' access to these innovative treatments. Given lawmakers' unfamiliarity with the benefits PDTs provide to patients, Jennifer Mathieu, AMCP's Senior Vice President of Professional & Government Affairs, discussed strategies for eliminating confusion in a Politico article published on May 15. In the article, Mathieu shares AMCP's intent to hold a PDT demonstration day on Capitol Hill for legislators and their staff. The demonstration aims to offer lawmakers tangible examples of PDT products and how they function. The article also mentions the Access to PDTs Act of 2023 (S. 723/H.R. 1458), which will add PDTs to the list of services and products eligible for coverage under Medicare and Medicaid and direct CMS to establish product-specific Healthcare Common Procedure Coding System codes.

Read the full Politico [article](#).

[Let your Members of Congress know](#) you support the Access to PDTs Act of 2023.



What can **COSENTYX**[®] do for your patients?

[See the data](#) ▶

11/22 243347

Eye On Washington

ICYMI: Law CPE Sessions from AMCP 2023 Now Available on AMCP Learn

AMCP 2023, hosted from March 21 to 24, brought thousands of managed care decision-makers to San Antonio, Texas for four days of continuing pharmacy education (CPE) sessions, keynote presentations, networking opportunities, and satellite symposia. During the meeting, AMCP's Government Affairs team presented accredited Federal and State Legislative & Regulatory Updates sessions. CommonHealth Solutions LLC's Melissa Andel also guided an accredited session on [The Inflation Reduction Act: From the Outside Looking In](#) (available until May 31). All three legislative and regulatory sessions, along with other CPE presentations from AMCP 2023, are available free to members on AMCP Learn. These sessions must be completed for CPE credit before December 31, 2024.

Visit [AMCP Learn](#) to view CPE sessions from AMCP 2023.

AMCP Submits Comments on Race and Ethnicity Statistical Standards

Advocacy Tip

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

On Jan. 27, the Office of Management and Budget (OMB) published a notice and request for comments entitled “Initial Proposals for Updating OMB’s Race and Ethnicity Statistical Standards.” Given AMCP’s Strategic Priority of Addressing Health Disparities in Medication Use and Access, the organization submitted comments on April 27 which specifically address data collection as it relates to health equity. Within the letter, AMCP supports updating OMB Directive 15, recommends listening to the voices of those who want their identity to be presented in data collection, and offers findings from the AMCP Health Disparities Advisory Group. AMCP also urges OMB to expand its data standards proposals beyond race and ethnicity to become as inclusive as possible.

Read AMCP’s [comment letter](#).

CMS Issues Final Medicare Part D DIR Reporting Guidance

On May 3, 2023, the Centers for Medicare & Medicaid Services (CMS) provided final guidance for Medicare Part D sponsors on reporting direct and indirect remuneration (DIR) data for contract year (CY) 2022. CMS clarified that payments and adjustments resulting from risk-sharing arrangements related to supplemental coverage of Part D drugs should be reported as DIR. CMS is also requiring the amount reported in the DIR #8 field to include any pharmacy price concessions applied at the point of sale. Part D sponsors can begin to submit the 2022 DIR Submission Information and upload the Summary 2022 DIR Report and Detailed 2022 DIR Report on June 1. The deadline for submissions is 11:59pm PT on Friday, June 30.

For more information, please see the [May 3, 2023 DIR Guidance memo from HPMS](#).

Register Your Organization for the AMCP IRA Workshop Series

Beginning in August 2023, AMCP will host a series of half-day virtual workshops geared to address the impact of the Inflation Reduction Act (IRA) on pharmacy practice. By joining the workshop series, organizations will gain access to stakeholder insights into the implementation of IRA’s health care provisions. Attending organizations will specifically hear from health care decision-makers about their own strategies for accommodating the law’s drug price negotiation, inflationary rebate, and Part D redesign provisions. This opportunity allows organizations to position themselves in the center of the rapidly changing conversation around one of the largest pieces of health care legislation since Medicare Part D was established.

[Join the IRA Workshop Series today.](#)



What can
COSENTYX®
do for your
patients?

[See the data ▶](#)

11/22 243347