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Eye on Capitol Hill

House Speaker Nancy Pelosi Introduces Drug Pricing Bill H.R.3

The latest development in the drug pricing debate in Washington is the introduction of a sweeping piece of legislation by House Speaker Nancy Pelosi (D-CA). Her bill, H.R.3, would give the HHS Secretary broad authority to negotiate prescription drug prices for Medicare and to extend the negotiated prices to the private market. Manufacturers that fail to reach agreement on pricing with the Secretary would be subject to significant penalties in the form of escalating excise taxes.

The Speaker's bill would also limit annual drug price increases by requiring manufacturers whose prices in Medicare Part B and Part D have risen more rapidly than inflation since 2016 to lower the price of the drug or rebate the entire amount above inflation back to the government.

The third major prong of Speaker Pelosi's bill is a significant redesign of the Medicare Part D drug benefit. The bill would cap patients' out-of-pocket costs in Part D at \$2,000 annually. The bill also would place greater financial responsibility during the catastrophic phase of the Part D benefit on health plans and pharmaceutical companies. Plans and manufacturers would assume far greater financial responsibility (50 percent and 30 percent, respectively) than they do at present, thereby reducing Medicare's financial responsibility to just 20 percent.

Key House committees have begun legislative hearings on the bill this week, and Speaker Pelosi's staff has indicated they want the House to vote on the measure before year's end.

A summary of the bill can be found [here](#). Read H.R.3 in its entirety [here](#)

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Legislative Update

Hill Days: AMCP Takes Message to House and Senate Offices

AMCP hosted a successful legislative day on Capitol Hill earlier in September, just as Congress was returning from summer recess to continue its ongoing drug pricing debate. A dozen AMCP members, along with staff, participated in more than 30 House and Senate office visits with lawmakers and health care aides. The meetings provided an opportunity for AMCP to educate targeted congressional offices on AMCP's key policy positions, and to explain the value of managed care pharmacy in the broader health care system. Discussions centered on preapproval information exchange (PIE) legislation and prior authorization. AMCP has heard from Hill staff since the visits, and will continue to follow-up with opportunities to advocate and be a resource on managed care pharmacy issues. Learn more about [AMCP legislative policy positions](#).

Regulatory Update

SAMHSA Issues New Proposed Rule to Modernize 42 CFR Part 2

The Substance Abuse and Mental Health Services Administration (SAMSHA) on Aug. 26 issued a notice of proposed rulemaking (NPRM) that aims to facilitate better coordination of care for substance-use disorders, as a means to enhance care for opioid-use disorders (OUD).

The NPRM, titled "[Coordinating Care and Information Sharing in the Treatment of Substance Use Disorders](#)", would modify several sections of 42 CFR Part 2, but would not change the basic framework for substance-use disorder patient record confidentiality protection in federally funded treatment programs. A [fact sheet](#) on the NPRM can be found on the HHS website. The NPRM is part of HHS's 2018 regulatory review initiative to re-examine rules in the Stark Law, Anti-Kickback Statute, and HIPAA, which could impede coordinated care.

In a statement, HHS Secretary Alex Azar said, "President Trump has promised Americans a health care system that provides affordable, high-quality, patient-centric health care—a system that treats you like a person, not a number. But outdated regulations have often stood in the way of delivering that kind of care, and our proposed reforms to 42 CFR Part 2 aim to change that. These changes also reflect the high priority that the Trump administration places on improving the quality and availability of behavioral health care, especially as we combat our nation's crisis of opioid addiction and substance abuse."

AMCP appreciates the efforts that the administration is taking to address the current barriers to accessing a patient's entire medical record. These barriers could lead to potentially dangerous medical situations such as harmful drug-drug interactions and lack of integrated care. As the country moves forward with combating the opioid epidemic, a focus should remain on integrating substance use disorder, mental health, and primary care services to improve patient outcomes.

Advocacy Tip

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

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Since 2016, AMCP has been working with a coalition of nearly 50 health care stakeholders created by the Association for Behavioral Health and Wellness. The coalition, called the Partnership to Amend 42 CFR Part 2, is committed to aligning Part 2 with HIPAA to allow appropriate access to patient information that is essential for providing comprehensive patient care. The Partnership appreciates SAMHSA's efforts to take on the task of modernizing 42 CFR Part 2.

Comments on the NPRM can be submitted to SAMHSA through Oct. 25. AMCP plans to review the NPRM and submit comments. You may provide feedback on the NPRM by Oct. 16 to Afton Wagner, AMCP director of regulatory affairs, at awagner@amcp.org.

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