Join AMCP for the 2021 Legislative and Regulatory Priority Issues & Strategies Webinar

On March 4, AMCP will host a webinar to identify our 2021 federal and state legislative and regulatory priority issues, provide background on how these issues were identified, and present an overview of AMCP's strategy to address these priorities. We will share our approach to federal and state legislative outreach and discuss opportunities for members to drive AMCP's federal and state priorities forward. We will also review federal regulatory actions and AMCP's strategy to promote managed care pharmacy within the Biden administration.

Register for the webinar.

Eye On Washington

The 117th Congress and Biden Administration's 2021 Policy Outlook Webinar Recording Now Available

On Feb. 2, AMCP hosted a members-only webinar on the health care policy landscape under the 117th Congress and Biden administration. The webinar was paneled by health care policy experts Alix Burns and Andrew McKechnie of Tiber Creek Group. Alix and Andrew examined the Biden administration's health care policy priorities, health appointees, and potential regulatory actions. The presentation also reviewed some of the key members of the 117th Congress and key legislation.

AMCP members can now view the recording.

Rebate Rule Delayed

On Jan. 30, the Biden administration agreed to postpone the effective date of the elimination of the safe harbor for manufacturer rebates until Jan. 1, 2023 in response to a lawsuit filed by the Pharmaceutical Care Management Association (PCMA). The Biden administration and the U.S. District Court

Advocacy Tip

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

judge entered into this agreement to give the new administration an opportunity to review the impact the entire rebate rule will have on the Medicare program and its beneficiaries. PCMA retains the ability to reactivate its lawsuit if the Biden administration does not retract the rule or propose changes that would satisfy PCMA's legal claims.

Read the agreement.

AMCP Submits Comments on the Most Favored Nation Rule

On Jan. 26, AMCP submitted comments on the Most Favored Nation (MFN) interim final rule, which would have created a mandatory nationwide drug payment model tying the cost of certain drugs in the Medicare program to an index of prices paid in other countries. In response to a lawsuit brought by pharmaceutical manufacturers, courts in Maryland and California have issued a nationwide restraining order and nationwide preliminary injunction, respectively, preventing the MFN model from going into effect. The courts found that the MFN rule — issued as an interim final rule — was promulgated without adequate notice and issued without adequate comment procedures. The courts also found that the government's rationale for dispensing with such procedures was insufficient under the Administrative Procedures Act. Given the presidential transition and the preliminary court rulings stating that the manufacturers are "virtually certain" to prevail on their claim, the path forward for this model is unclear.

Read AMCP's comments.

CMS Issues Part D Policy and Technical Final Rule

On Jan. 15, CMS issued the final CY 2022 Medicare Part D policy and technical rule. This rule is part two of the finalization of Medicare program policy changes that were proposed by the agency in February 2020. In this final rule, CMS establishes that Part D plan sponsors can include a second, preferred specialty tier with lower cost-sharing, and also finalizes the requirement for Part D plans to offer a beneficiary real-time benefit tool. Additionally, CMS will begin requiring plan sponsors to report the pharmacy performance measures used in pharmacy network agreements to the agency in order to facilitate CMS' understanding of how such measures are applied.

Read AMCP's comments on the proposed rule.

CMS Finalizes Innovative Treatment Coverage Pathway

On Jan. 14, CMS issued the Medicare Coverage of Innovative Technologies (MCIT) final rule. This rule establishes a national coverage pathway for new, innovative medical devices approved by the FDA to allow Medicare beneficiaries faster access to these

breakthrough technologies. The MCIT pathway will apply to devices that receive market authorization by the FDA through the agency's Breakthrough Devices Program, which has been used for market authorization of digital therapeutics.

Read AMCP's comments on the MCIT proposed rule.

AMCP
675 North Washington Street, Suite 220, Alexandria, VA 22314
703.684.2600 | www.amcp.org