In This Issue

Eye on Washington

White House Withdraws 'Rebate Rule'; AMCP Warned the Rule Could Have Unintended Consequences

The Trump Administration on July 11 abruptly pulled its proposed rule to eliminate safe harbor protections for rebates paid by pharmaceutical manufacturers to pharmacy benefit management (PBM) companies and health plans in Medicare and Medicaid programs. AMCP warned HHS in an April letter that the proposal could have unintended consequences of increasing costs for some patients instead of reducing them.

"There is no question that addressing the rising cost of drugs should be a priority," said AMCP CEO Susan A. Cantrell, RPh, CAE. "However, changing the model currently in place for negotiating drug costs to shift from rebates to chargebacks is not the solution and could increase Medicare Part D premiums without lowering out-of-pocket drug costs."

"The proposed rule would have eliminated one of the few levers available to lower prescription drug costs," Cantrell continued. "AMCP looks forward to working with the administration and Congress to find viable solutions that address the rising costs of medications. AMCP and its 8,000 members remain committed to ensuring that needed medications are both accessible and affordable for patients."

To read AMCP's advocacy positions, visit www.amcp.org/letters-statements-analysis.

Eye on Capitol Hill

House Holds Hearings and Markups on Bills Addressing Drug Pricing Transparency

The House Energy and Commerce Subcommittee on Health held a July 11 hearing on 10 bipartisan health bills, including the FAIR Drug Pricing Act, which aims to increase drug pricing transparency by requiring manufacturers to provide more information on how prescription drugs are priced and why drug prices are increasing.

In addition, the Energy and Commerce Committee on July 17 marked up more than 25 health bills, including H.R. 2296, the More Efficient Tools to Realize Information for Consumers Act (the METRIC Act), which would require drug manufacturers to submit a report to HHS for each increase in the price of a qualifying drug that results in an increase in the wholesale acquisition cost equal to: 10 percent or more within a single calendar year beginning on or after Jan. 1, 2019; or 25 percent or more within three consecutive calendar years for which the first such calendar year begins on or after Jan. 1, 2019. The METRIC Act included transparency provisions from the following bills: H.R. 2115, the Public Disclosures of Drug Discounts Act; H.R. 2376, the Prescription Pricing for the People Act; H.R. 2064, the Sunshine for Samples Act; H.R. 2087, the Drug Price Transparency Act.

AMCP continues to engage with members of the Committee and their staff to ensure that legislative language is in the best interest of our members and the patients they serve.

Senate Crafts Legislation to Lower Health Care and Pharmaceutical Costs

The Senate HELP Committee and Finance Committee continue to work on legislative packages aimed at lowering the cost of health care, including the Lowering Health Care Costs Act of 2019. Among its provisions, the bill would end surprise billing; create more transparency; eliminate gag clauses and anti-competitive terms in insurance contracts; and ban PBMs from charging more for a drug than the PBM paid for the drug. As the Finance Committee develops its package, AMCP expects a measure on pharmaceutical information exchange (PIE) to be considered for inclusion. AMCP is engaging with Senate staff to ensure that the language is in line with our efforts on PIE to date, and we expect that Senate staff on both committees will work on a combined legislative package during the August Congressional recess.

Regulatory Update

CMS Issues New Proposed Rule on ePA

CMS issued a June 19 proposed rule on Secure Electronic Prior Authorization (ePA) for the Medicare Part D program. The proposal would require Part D Plan Sponsors to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard version 2017071 for use in ePA transactions with prescribers by Jan. 1, 2021. The proposal was issued in preparation of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or the SUPPORT for Patients and Communities Act. This law requires the adoption of transaction standards for the Part D e-prescribing program to ensure secure ePA request and response transactions between prescribers and Part D

Advocacy Tip

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

Plan Sponsors by Jan. 1, 2021. Comments on the proposal can be submitted to CMS through Aug. 16. AMCP plans to submit comments and is seeking feedback from AMCP members on the proposal to include members' ability to comply with the proposed effective date of Jan. 1, 2021. You may provide feedback on the proposal by Aug. 1 to Afton Wagner, AMCP Director of Regulatory Affairs, at awagner@amcp.org.

CMS Seeks Comments on Reducing Administrative Burdens in Health Care

On June 11, CMS published a Request for Information (RFI) to seek new ideas on how to continue the progress of its Patients over Paperwork initiative that launched in fall 2017. CMS is specifically seeking potential solutions to relieve clinician burden and ways to improve the following:

- Prior authorization procedures
- Reporting and documentation requirements
- Coding and documentation requirements for Medicare or Medicaid payment
- Policies and requirements for rural providers, clinicians, and beneficiaries
- Policies and requirements for dually enrolled (i.e., Medicare and Medicaid) beneficiaries
- Beneficiary enrollment and eligibility determination
- CMS processes for issuing regulations and policies

Comments on the RFI can be submitted to CMS through Aug. 12. AMCP plans to submit comments consistent with our policy and will primarily focus on PA. You may provide feedback on the RFI by Aug. 1 to Afton Wagner, Director, Regulatory Affairs, at awagner@amcp.org.

AMCP Works to Improve PA Processes

AMCP and its Professional Practice Committee, developed nine specific concepts for effective PA practices: (1) patient safety and appropriate medication use, (2) clinical decision making, (3) evidence-based review criteria, (4) automated decision support, (5) transparency and advanced notice, (6) emergency access, (7) provider collaboration, (8) need for timeliness and avoiding disruptions in therapy, and (9) cost-effectiveness and value. The full document may be read here: http://bit.ly/2IdCkXz. For questions or additional information on AMCP's work on PA, please contact Tricia Lee Wilkins, AMCP Director of Pharmacy Affairs at tlwilkins@amcp.org. AMCP also recently held a Partnership Forum to examine ways of improving the PA process, with recommendations to: ease administrative burdens; increase visibility of the clinical and economic value of PAs; and improve communications between managed care, providers and patients to minimize care delays and improve clarity of coverage requirements.

Academy of Managed Care Pharmacy
675 North Washington Street, Suite 220, Alexandria, VA 22314
703.684.2600 | www.amcp.org