AMCP Legislative/Regulatory Briefing - April 2019

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In This Issue

Eye on Washington

House Committee Advances CREATES Act; Drug Pricing Hearing in the Senate; Actions on Biosimilars and Biologics

Update on CREATES Act: On April 3, the House Energy and Commerce Committee advanced the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019" (H.R. 965) and "Protecting Consumer Access to Generic Drugs Act of 2019" (H.R. 1499). The bills will next be considered by the full House of Representatives. The CREATES Act was reintroduced with bipartisan support earlier this year and is a market-based way for generic drug and biosimilar manufacturers to address the current tactics which delay market entry of generics and biosimilars. It would promote the timely entry of generic and biosimilar products and increase competition in the prescription drug market by stopping the use of Risk Evaluation and Mitigation Strategy requirements to block access to samples of branded products by sponsors who seek to offer competition. AMCP previously communicated our support to sponsors in both the Senate and House. The Senate companion legislation has been placed on the legislative calendar for floor vote consideration at a future date to be announced. Read updates on drug pricing, biosimilars, ACA.

Eye on the States

Update on State Legislative Activities

Advocacy Tip

Stay up-to-date: Read AMCP's

Eight states (ID, KY, MD, MS, NM, SD, UT, WV, WY) have concluded regular sessions for 2019 with Georgia, Arkansas, and Kansas set to adjourn shortly. This session AMCP has seen several states propose legislation which imposes regulations on formulary management, such as MD HB 435 which sets an exemptions process requirement when drugs are removed or change tiers on a formulary. AMCP submitted a letter to Governor Hogan asking him to veto the legislation, as this process is already in place for most organizations. One of AMCP's priority areas for 2019 is Advancing Managed Care Pharmacy Strategies, and legislation like the aforementioned challenges this. You can find AMCP's 2019 priorities here. AMCP continues to monitor and work with state legislatures on legislation which helps it's member optimize medicine and improve lives.

Regulatory Update

HHS-OIG Proposed Rule on Removal of Safe Harbor for Rebates

On April 8, AMCP submitted comments to the Department of Health and Human Services Office of Inspector General (HHS-OIG) on its proposed rule titled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees". In the April 8 letter, AMCP expressed its concerns with the proposed rule to eliminate the safe harbor protections for rebates that currently exist in the federal Anti-Kickback Statute (AKS) and replace these protections with proposed new safe harbors allowing for point-of-sale discounts to beneficiaries and for manufacturer-paid service fees to PBMs. Read more.

Memorandum on Guidance & Compliance with Congressional Review Act

On Thursday, April 11, the Office of Management and Budget (OMB) released a Memorandum titled "Guidance on Compliance with the Congressional Review Act (CRA)". The memo becomes effective on May 11, 2019. It addresses review of regulations by the Office of Information and Regulatory Affair (OIRA) and updates OIRA's current process for reviewing rules under the CRA. The memorandum clarifies that the CRA applies not only to regulations, but also guidance documents (such as FDA guidance documents), general statements of policy, and interpretive rules. Additionally, the memorandum clarifies that the review will apply to all agencies covered by the centralized review process of Executive Order 12866 as well as to Independent Regulatory Agencies.

Seeking Feedback on Updated Guidance on Nonproprietary Naming of Biologics

The FDA released updated draft guidance last month on the nonproprietary naming of biologics, biosimilars, and interchangeable biosimilar products. In the document, the FDA says it will no longer retroactively modify the legacy names of biological products that have already been licensed or approved without an FDA-designated suffix. The agency will continue to assign suffixes to newly approved innovator biologics, biosimilars, or interchangeable biosimilar products. FDA is also reconsidering whether vaccines should remain within the scope of the naming convention in the naming guidance. Comments on the draft guidance may be submitted to FDA by May 7.

Letters, Statements and Analysis on all legislation and regulation impacting managed care pharmacy.

To submit suggestions, please email Afton Wagner, Director of Regulatory Affairs at awagner@amcp.org by Monday, April 22.

AMCP Publishes Paper on Prior Authorization Concepts in *JMCP*

AMCP is committed to advocating for and advancing effective and efficient prior authorization (PA) programs that support appropriate medication use. With recent attention to PA and calls for reforming the process, AMCP, with the leadership of its Professional Practice Committee, has developed nine specific concepts for effective PA practices focusing on: (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. Read AMCP's "Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy" here: http://bit.ly/2IdCkXz. For questions or additional information on AMCP's work on prior authorization, please contact Tricia Lee Wilkins, Director of Pharmacy Affairs at tlwilkins@amcp.org.

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