In This Issue

House Places CREATES Act on the Calendar; House Subcommittee Holds Drug Pricing Hearing

Lawmakers Eye Measures to Improve Generic Drug Market, Lower Costs

Federal lawmakers are continuing their efforts to address the high costs of pharmaceuticals. AMCP has been closely monitoring developments on Capitol Hill that are relevant to managed care pharmacy. Recent activities include:

Movement on the CREATES Act: The "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019" has been placed on the House calendar, which means House Speaker Nancy Pelosi (D-Calif.) can bring it up for a full vote at a time she deems appropriate.

The CREATES Act, which was reintroduced with bipartisan support earlier this year, 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. As previously noted, the Senate companion legislation has been placed on the Senate calendar for consideration when the Majority Leader calls it up for a vote.

Hearing on the Drug Supply Chain by the House Energy and Commerce Health Subcommittee: The pharmaceutical supply chain is an intricate and complicated network made up of drug manufacturers, wholesalers, providers, insurers, pharmacy benefit managers, pharmacists and patients.

On May 9, the Health Subcommittee of the House Energy and Commerce Committee held a hearing to better understand how these entities operate, how they work in relation to one another, and what impact they have on the drug prices consumers ultimately pay. Chairman Frank Pallone, Jr. (D-NJ), of the full committee, expressed interest in knowing how manufacturers set prices for newly launched drugs, and why some drugs that are already on the market have continually increased in price.

Further, Chairman Pallone asked witnesses to explain how pharmacy benefit managers work with health insurance plans to decide how to cover these medications and under what conditions. The ultimate goal of these hearings is to discuss specific policy solutions that Congress should keep in mind as they move forward with legislative proposals to bring down costs. Witnesses included senior leadership from Amgen, Pfizer, Exelixis, Express Scripts, BCBS of North Carolina, the Chair of the AMA, AARP, and two Chief Pharmacy Officers from Ascension and Navitus Health Solutions.

Eye on the States

State Lawmakers Introduce Hundreds of Bills Addressing Drug Costs

In the 2019 legislative session so far, 44 states have filed more than 240 bills that aim to control some aspect of prescription drug costs. The bills include allowing wholesale importation; licensing, regulating or studying pharmacy benefit manager's impact on the supply chain; and requiring health plans or manufacturers to report on expensive prescriptions or when there is an increase on the wholesale acquisition cost above a pre-determined threshold.

Several states have also looked at the **impact of manufacturer coupon programs** in enrollee's costs including Arizona, Kentucky, New Hampshire, New Jersey, Rhode Island, Virginia and West Virginia. This legislation either prohibits manufacturers from offering coupons or discounts to enrollees if a lower-cost generic is listed on a formulary, or requires an amount paid on an enrollee's behalf through a coupon or discounts counts toward the out of pocket maximum paid.

Another continuing proposal seen among several states is the wholesale **importation of prescriptions from Canada**. Connecticut, Colorado, Florida, Illinois, Indiana, Massachusetts, Maine, Minnesota, Missouri, New Hampshire, and West Virginia all have proposed legislation for the wholesale importation, or to study the importation, of medications. Vermont also has legislation designating a state agency responsible for developing their wholesale importation program. Importation programs must be approved by the federal government, which has sent mixed signals. President Trump met with Florida Gov. Ron DeSantis, a Republican, on May 6, to discuss the state's proposal, but HHS Secretary Alex Azar has called the idea a "gimmick."

AMCP continues to monitor state activity and work with legislatures on proposals which impact managed care pharmacy to optimize medicine and improve lives.

Fourteen states have ended the 2019 session with Alabama, Arizona, Kansas, Missouri, Oregon, and Texas set to adjourn by June 1st.

Regulatory Update

Updated Draft Guidance Nonproprietary

Advocacy Tip

Knowledge is power. Learn about AMCP's latest advocacy efforts at Letters, Statements and Analysis.

Naming of Biological Products

On May 7, AMCP submitted comments to the FDA on its updated draft guidance regarding the nonproprietary naming of biologics, biosimilars, and interchangeable biosimilar products. The FDA document states that it will no longer retroactively modify the legacy names of biological products that have already been licensed or approved without an FDA-designated suffix. However, the agency will continue to assign suffixes to newly approved innovator biologics, biosimilars, or interchangeable biosimilar products. AMCP expressed concern that the establishment of a suffix will create confusion among health care practitioners and patients, and will have negative effects on the ability to ensure safe dispensing and tracking, resulting in lower market adoption and cost-savings. Additionally, should the FDA continue to utilize a suffix in its naming convention, AMCP strongly encourages the FDA to maintain the same suffix for an interchangeable product and its biologic reference product. AMCP's comments can be found on the AMCP website.

FDA Final Guidance on Demonstrating Interchangeability with Reference Product

On May 10, the FDA issued highly anticipated final guidance for the industry on the interchangeability of biologics to help promote competition in the biologic market. This final guidance is intended to provide clarity to applicants seeking to demonstrate interchangeability of a biosimilar product with a reference product per a statement released by acting FDA Commissioner Ned Sharpless, MD.

In May 2017, AMCP provided comments to FDA on its draft interchangeability guidance and encouraged FDA to take action on finalizing interchangeability guidance, and reiterated this point in a Sept. 4, 2018, FDA Public Hearing on, "Facilitating Price Competition and Innovation in the Biologics Marketplace."

Overall, AMCP was pleased to see the FDA outlined a flexible, stepwise, and totality-of-evidence approach to demonstrating interchangeability without being too prescriptive. AMCP did provide recommendations to offer additional clarity to implement the biosimilar pathway prior to finalizing the guidance document. Generally, most of what FDA proposed in its draft guidance was carried over into the final guidance.

AMCP is reviewing the final guidance and a summary will be posted on the AMCP website.

CMS Issues Final Rule to Require Drug Price Transparency in Medicare & Medicaid

On May 10, CMS issued a final rule that will require direct-to-consumer television advertisements of prescription drugs and biological products that are paid for by Medicare and Medicaid to include the Wholesale Acquisition Cost (WAC or list price) of that drug or biological product. The rule is effective beginning July 9, 2019.

Specifically, the final rule requires any advertisement for any prescription drug or biological product on television (including broadcast, cable, streaming, or satellite) to contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: *"The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If*

you have health insurance that covers drugs, your cost may be different." The HHS Secretary will maintain a public list that will include the prescription drugs and biological products identified by the Secretary to be advertised in violation of this final rule.

AMCP submitted comments to CMS on the proposed rule in December 2018 and did not support the use of "list price" as it would not accurately address all the various components that are included in a patient's actual out-of-pocket cost and could cause further confusion for patients. AMCP advocates for the appropriate use of prescription drug products and encourages providers to select products based on the needs of the patient in conjunction with prescription drug benefit designs.

PA and UM Concepts in Managed Care Pharmacy Paper is Available in JMCP

AMCP's concept paper "Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy" is available online through the Journal of Managed Care & Specialty Pharmacy. AMCP is committed to advocate for and advance effective and efficient PA programs that support appropriate medication use. With recent attention to prior authorization (PA) and calls for reforming the process, AMCP along with the leadership of its Professional Practice Committee 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. The full document may be read 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.

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