AMCP Legislative/Regulatory Briefing - March 2019

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In This Issue

AMCP Holds Successful Annual Legislative Days in March

Volunteers, Staff Explained Prior Authorization, Urged Reintroduction of PIE Act

AMCP volunteer leaders and staff hit Capitol Hill earlier this month to advocate on crucial issues affecting managed care pharmacy.

Six teams of 35 volunteers from AMCP's Board of Directors, the Legislative and Regulatory Action Committee and the Public Policy Committee participated in the annual Legislative Days, March 5th and 6th. The teams completed over 60 visits to Senate and House offices, as well as the office of the HHS Secretary, and emphasized AMCP's message on:

- Reintroduction and passage of the Pharmaceutical Information Exchange (PIE) Act, which would allow biopharmaceutical manufacturers to proactively share truthful and non-misleading clinical and economic information about pipeline medications with population health decision makers. AMCP led advocacy efforts on the previous PIE Act (H.R. 2026) in the 115th Congress. That bill would have allowed decision makers to expedite coverage decisions as soon as new medications hit the market.
- Initiatives to educate officials on the importance of prior authorization as an evidence-based process to ensure that plan members receive medication therapies that are safe and effective for their condition, and provide the greatest value.

For more information on these positions and more, visit Federal/State Legislative-Regulatory Issues.

Regulatory Update

AMCP Comments on CMS' Draft CY2020 Part D Call Letter

AMCP this month submitted comments on CMS's Advance Summary of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Call Letter. In the March 1 letter, AMCP said it appreciates CMS's intent to improve generic utilization, lower out-of-pocket costs, and avoid beneficiary confusion. However, AMCP expressed concerns with several of the areas regarding tier composition for generic and biosimilar medications where CMS sought feedback for future consideration. Specifically, AMCP did not recommend that CMS consider requiring or recommending an alternative tiering policy that would require generic drugs to be placed only on generic tiers and brand drugs to be placed only on brand tiers. Additionally, AMCP did not support automatic inclusion of newly available generics on generic tiers or treating biosimilars the same as generic medications in terms of specialty tier placement.

In its draft Part D Call Letter, CMS is encouraging the co-prescribing of naloxone with opioid prescriptions to beneficiaries who are at increased risk for opioid overdose consistent with guidance from the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS). AMCP shared recommendations specific to naloxone co-prescribing with CMS from the AMCP Addiction Treatment Advisory Group (ATAG) to improve access to addiction treatment. AMCP also offered to share future findings from the AMCP Addiction Advisory Group (AAG) to promote best practices that improve addiction prevention and treatment services such as naloxone co-prescribing.

CMS will propose revisions in a separate proposal for public comment for the Medication Therapy Management (MTM) standardized format with the goal of optimizing the utility of the CMR summary for beneficiaries. AMCP shared recent research that focused on the utilization of the standardized format among beneficiaries has brought to light several areas for improvement in the standardized format document. AMCP was able to share the research that was published in the *Journal of Managed Care and Specialty Pharmacy (JMCP)* in March, 2019.

FDA Releases Updated Draft Guidance on the Nonproprietary Naming of Biologics

The FDA released updated draft guidance this month on the

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

Eye on the States

Update on State Legislative Activities

Five states (NM, UT, VA, WV, WY) have concluded regular sessions for 2019 with Louisiana the only state left to convene on April 8th. Key health care related issues in states this session include drug price transparency, bills supporting electronic prescribing or electronic prior authorization, and bills impacting opioid misuse, abuse, and diversion. Meanwhile, 13 states have proposed importing or studying importation of drugs from Canada to combat rising drug prices (CO, CT, FL, IN, ME, MA, MO, OK, OR, UT, VT, WV, WY). These proposals would require the approval of the Administration to create such programs and are not likely to advance. AMCP does not support drug importation as a way to combat drug costs and more information can be found in our Where We Stand statement. AMCP will continue to monitor and work with state legislators on proposals which impact the roll of managed care pharmacists.

Coming to AMCP Annual Meeting 2019 in San Diego Next Week?

Check out these sessions for up-to-the-minute updates on hot legislative and regulatory issues:

- **L1 –** Federal and State Legislative and Regulatory Update – Tuesday, March 26th at 10am
- **L4** – Drug Pricing Reform Efforts: The Blueprint Turns 1 Year Old – Wednesday, March 27th at 8:30am
- **F4** – The Road to Pre-Approval Information Exchange: Where Are We Today? – Wednesday March 27th at 8:30am
- **L6** – The Current Status of Safe Harbor Protection for Rebates: Is the End Near? – Wednesday, March 27th at 4:30pm **Note this session does not have CPE credit**

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