AMCP Legislative/Regulatory Briefing - June 2019

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Eye on Washington

Senate Drug Pricing Bill Unveiled; House Passes CREATES Act

Lower Health Care Costs Act: The Senate Health, Education, Labor and Pension (HELP) Committee recently unveiled the Lower Health Care Costs Act of 2019, which would promote access to lower-cost generic drugs and biosimilars, and encourage manufacturers to speed development of these products.

In general, AMCP supports the bill, but has expressed concern with one provision that would exclude all biological products from requirements to follow the U.S. Pharmacopeia compendial standards. Although the proposal is framed as one that will lower drug costs by accelerating the development of biologic medicines, including biosimilars, we are not aware of any evidence that USP standards delay or hinder the development or approval of biologics or biosimilars.

Far from promoting innovation or cost-savings, the provision would undo decades of public and transparent quality standards that help ensure the quality and safety of biologic medicines. Lawmakers aim to move the bill to the Senate floor by the end of July and send it to the House before Congress' August recess.

Update on CREATES Act: The House recently passed HR 965, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act), as well as two other bills addressing drug prices: HR 1499, the Protecting Consumer Access to Generic Drugs Act of 2019, and HR 938, the Bringing Low-cost Options and Competition While Keeping Incentives for New Generics (BLOCKING) Act of 2019.

The CREATES Act, which was reintroduced with bipartisan support earlier this year, provides a market-based approach to ensuring the timely entry of generic and biosimilar products, and increase competition in the pharmaceutical marketplace. Specifically, the bill would stop the use of Risk Evaluation and Mitigation Strategy (REMS) requirements to block generic drug and biosimilar manufacturers from acquiring samples of branded products. AMCP previously communicated its support of bill to sponsors in both the Senate and House.

The Senate companion legislation has been placed on the Senate calendar for consideration when the Majority Leader calls it up for a vote. Whether the bills, which generally have bipartisan support, progress through the Senate and onto

the President's desk remains to be seen. The bills were packaged into the larger HR 987, the Strengthening Health Care and Lowering Prescription Drug Costs Act, which includes provisions targeting the Trump Administration's actions towards the Affordable Care Act.

Regulatory Update

AMCP Comments on Biosimilar and Interchangeable Insulin Products

On May 31, AMCP submitted comments in response to the FDA's May 13 hearing on the Future of Biosimilar Insulin. AMCP expressed its concern with the agency's proposed updates to the naming convention for these products, which could negatively impact patients as well as impede biosimilar adoption. AMCP cautioned FDA that utilizing a different naming approach for a biosimilar or interchangeable product — including insulin products — is likely to lead to confusion among prescribers and pharmacists. AMCP also urged support for training efforts and development of educational resources, including the adoption and dissemination of existing education resources, such as AMCP's Biosimilars Resource Center (BRC). Such resources can provide neutral, unbiased education information to pharmacists, physicians, nurses and other health care providers. The FDA's public hearing received input from stakeholders in preparation for the submission and review of applications for biosimilar and interchangeable insulin products. Biological products are certain to play an increasingly important role in the country's health care system for many chronic conditions, in addition to diabetes, and have resulted in scientific improvements in the treatment of disease.

AMCP Comments on Proposed Rule on Information Blocking

AMCP submitted comments on June 3 to the Office of the National Coordinator for Health Information Technology (ONC) in response to its proposed rule on "21st Century Cures Act: Interoperability, Information Blocking, and the Health IT Certification Program." In addition to supporting the comment submission from the Pharmacy Health IT Collaborative, of which AMCP is a member, AMCP commented on points relevant to managed care pharmacy. AMCP requested that as often as is possible, ONC explicitly state what organizations are intended by the term "health care providers." Health plans and managed care organizations may be subject to information blocking by relevant actors who misinterpret the term to apply only to individuals and entities providing direct patient care. A level of specificity should be used to clarify the term "health care provider." AMCP also noted that as the country moves forward with combating the opioid epidemic, a focus should remain on integrating substance use disorder, mental health, and primary care services to improve patient outcomes and support care coordination. We highlighted that lack of clarity around the application of HIPAA and Part 2 that places a significant burden on clinicians to interpret compliance with existing regulations.

Advocacy Tip

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

CMS Issues RFI on Reducing Administrative Burden to 'Put Patients Over Paperwork'

On June 11, CMS published a Request for Information (RIF) 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 prior authorization. You may provide feedback on the RFI by Aug. 1 to Afton Wagner, Director, Regulatory Affairs, at awagner@amcp.org.

AMCP's PA and UM Concepts in Managed Care Pharmacy Is Available in *JMCP*

AMCP has long advocated for effective and efficient prior authorization (PA) programs that support appropriate medication use. With recent calls to reform the PA process, 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 Prior Authorization, please contact Tricia Lee Wilkins, Director of Pharmacy Affairs at tlwilkins@amcp.org.

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