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AMCP Comments to HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Comments focus on AMCP's engagement to solve issues such as medication management and ways to consider innovative, high cost medications

AMCP submitted comments on July 16 to the Department of Health and Human Services on HHS's Blueprint to Lower Drug Price and Reduce Out-of-Pocket Costs released in May 2018. Many of the suggestions have been offered in other ways throughout the past decade, and AMCP has advocated for several of the ideas, including initiatives to spur generic and biosimilar market competition, allowing plans more flexibility in managing Medicare Part D and shifting Part B drugs to Part D. The blueprint also includes provisions to change some pharmacy benefit management and health plan practices of negotiating and obtaining rebates. The blueprint does not contain provisions for HHS to negotiate pharmaceutical prices or import drugs from Canada or overseas. Also absent are calls specifically assessing the quality of prescription medications in improving patient outcomes, an important issue to AMCP.

Comments focused on AMCP's proactive engagement with HHS to solve some of the more difficult issues associated to medication management, patient care services, and patient care services for Part B medications and ways to consider innovative and high cost medications. Many of the recommendations focused on AMCP's Partnership Forums as a way to solve some of the most pressing issues related to medication management today. AMCP's comments also focused on pharmacists' as key stakeholders in improving patient outcomes and controlling medication costs.

Other key provisions in AMCP's comments are:

- CMS should carefully consider ways to effectively manage medications in Part B, transition coverage of select medications from Part B to Part D and carefully evaluate the impact of beneficiary out-of-pocket costs, access to care, and Medicare Advantage;
- Part D plans should have full formulary flexibility to manage high-cost medications, including the classes of clinical concern;
- CMS should adopt the Medicare Part D formulary coverage policy as proposed in the President's FY2019 budget;
- AMCP supports efforts to curb the inappropriate use of shared system Risk Evaluation and Mitigation Strategy program (REMS) to deter generic entry;
- Food and Drug Administration (FDA) policies should promote biosimilar development and adoption;
- Stakeholder collaboration and a reexamination of current policies are needed to encourage value-based contracts (VBC), including the need for a common definition of VBC, best practices, and legal and regulatory infrastructure to support VBC; and,
- AMCP's Peer-Reviewed Journal of Managed Care and Specialty Pharmacy should be considered a resource for research in managed care pharmacy.

Capitol Hill Update

Wrap Up of Relevant Legislation

The House is scheduled to begin its recess on Aug. 1st and return Sept. 4th. The Senate is not scheduled to recess in August. The opioid-related bills passed by the House at the end of June have not been addressed yet in the Senate. Other bills before lawmakers include:

H.R. 2026 – The Pharmaceutical Information Exchange (PIE) Act of 2017: Earlier this year, the House Energy and Commerce Health Subcommittee voted in support of H.R. 2026 and now the bill is ready to be heard and approved by the entire House Energy and Commerce Committee before it goes to the House floor. AMCP has an active alert on the Grassroots Advocacy page so you can encourage your Representative on the full Committee to vote in favor of H.R. 2026.

H.R. 6478 – the Biosimilar Competition Act of 2018: The Biosimilar Competition Act of 2018 was introduced July 23rd by Reps. John Sarbanes (D-MD) and Bill Johnson (R-OH). Current law requires brand and generic manufacturers to file patent settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DOJ). The intent of the filings is twofold: 1) to allow the agencies to take enforcement action on anticompetitive agreements and 2) to deter manufacturers from entering into anticompetitive settlements. The FTC uses this information to 1) publish an annual tally of anticompetitive reverse payment settlements and 2) sue in federal court to prevent anticompetitive settlements from going into effect. This notification requirement, however, does not extend to biologic and biosimilar manufacturers, since the statutory requirement predates enactment of the biosimilars pathway under BPCIA by seven years. The purpose of the Biosimilar Competition Act is to apply the existing filing requirements to biologic and biosimilar products.

Advocacy Tip

When speaking to a legislator or a staff member, they may have questions regarding particular legislation or pharmacy practices which may be impacted. If you don't know the answer, it's okay to say so. This sets the tone that you are being truthful with an office, and also allows you to follow up as a credible source after the meeting by providing the answer to their question. Remember AMCP government affairs staff are available to provide you with information and resources.

S. 974 – Creating and Restoring Equal Access to Equivalent Samples Act (CREATES ACT): Late last month the Senate Judiciary Committee voted in favor of the S. 974 by a vote of 15-6. It is now on the Senate Legislative Calendar awaiting a vote by the full Senate. AMCP has sent a letter in support to each member of the Senate and will activate grassroots in advance of a scheduled Floor vote. In advance of the scheduled vote by the Judiciary Committee, AMCP activated its grassroots and members contacted their Senator on the Judiciary Committee (16 were contacted). Responses to grassroots efforts have been positive.

AMCP Continues its Support for Increased FDA Funding

AMCP is a member of the Alliance for a stronger FDA and joined 60 other organizations in a letter to House and Senate Appropriations Committees in support of increased funding for the FDA. In this appropriations cycle, House appropriators have recommended $150 million more than the Senate. We support the higher levels of the House version, as well as the Senate's proposals for certain accounts -- including larger increases in monies for generic drugs and combating opioid abuse. Letter of support is here.

Federal Regulatory Activity

CMS Releases Memo on Indication-based Utilization Management

The Medicare Drug Benefit and C& D Data Group within the Centers for Medicare & Medicaid Services (CMS) issued a memorandum on July 25th to all Part D sponsors concerning indication-based utilization management. In this memorandum, CMS clarifies that Part D sponsors may employ indication-based utilization management in Part D via prior authorization requirements by requiring beneficiaries to use a preferred formulary agent before authorizing coverage of a non-preferred agent, with requirements differing across indications. CMS noted that, if a plan chooses to apply this strategy, its Health Plan Management System formulary submission and prior authorization criteria must clearly define the requirements. CMS will allow Part D sponsors the opportunity to modify their formulary submissions during the formulary update window on Aug. 6-8 and will provide additional instructions regarding how to modify submissions in a subsequent memorandum to be released in August.

FDA Releases Biosimilar Action Plan

FDA Commissioner Scott Gottlieb on July 18 released the FDA's Biosimilars Action Plan (BAP): Balancing Innovation and Competition at an event hosted by The Brookings Institute. He highlighted the four key focus areas of BAP: (1) improving efficiency in product development and approval process, (2) maximizing scientific and regulatory clarity, (3) creating and disseminating effective communications to patients and providers, and (4) supporting market competition by decreasing unfair practices in the system. While Commissioner Gottlieb focused his discussion around unfair practices in intellectual property law and the REMS program which lead to decreased access to samples for approval testing, the BAP focuses more on streamlining the regulatory and approval processes, which FDA has direct jurisdiction over. Another point in his remarks and in the BAP was support for moving some biologics and biosimilars from Medicare Part B to Part D, a move AMCP supports and touted as part of a solution in our comments to the HHS Drug Pricing Blueprint RFI. You can read Gottlieb's prepared remarks for the event here.

FDA Draft Guidance to Allow Expanded Access to Medications Without a Prescription

In a draft guidance document released on July 17, FDA suggests that patients may soon be able to access certain medications without a prescription. The draft guidance is vague on specific details but could impact the way that patients potentially access certain classes of prescription medications without a prescription provided certain requirements are met. Some categories of medications included as examples are cholesterol lowering agents, certain antibiotics, naloxone, and products such as EpiPen®.

Under the provisions of the draft guidance, entitled, Innovative Approaches for Nonprescription Drugs, company sponsors would have to submit studies showing that patients could use the product safely without a prescription. Patients could use mobile apps or other technology to help determine whether the use of the product without a prescription is appropriate.

The draft guidance indicates that the product would have to be used "under the supervision of a health care professional" but does not indicate specifically whether pharamcists would be included in this definition. The draft guidance does not specifically include a reference to a "behind-the-counter" designation where pharmacies would be allowed to dispense medications without a prescription.

Comments are due to FDA by Sept. 17. AMCP will be commenting that pharmacists should be included in the list of professionals who may supervise the use of these products. AMCP will also provide comments on other potential positive and negative implications on patient safety and cost associated with this potential change. If you would like to provide input for AMCP's comments, please email mcarden@amcp.org by Sept. 10.

Trump Administration Announces Potential Next Steps on Ways to Lower Drug Prices

The Trump Administration last week announced two additional steps that it may consider in an attempt to lower drug prices through potentially restructuring the rebate safe harbor and studying importation under limited circumstances. The Office of Management and Budget (OMB) is reviewing a proposed HHS rule to potentially change safe harbor protections for rebates to health plans or pharmacy benefit management companies. Details on the proposal are not clear and the proposal will not be released until and unless OMB approves its publication in the Federal Register. The Administration also announced plans through FDA to create a working group on importation of medications in the limited circumstance of when a single manufacturer dramatically raises prices for an off-patent product. AMCP will continue to oppose legislation to allow importation of prescription drugs in the United States until more conclusive data are available as to its likely impact. AMCP will provide updates as more details emerge.

AMCP Comments to FDA on Final Payor-Manufacturer Communications Guidance

AMCP submitted comments July 13 to FDA in support of provisions contained in the Final Guidance, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities - Questions and Answers.* AMCP is particularly pleased that the final guidance expands the scope of preapproval communications to include new indications of approved molecules, and not solely new

molecular entities. AMCP will continue efforts to advocate for the passage of H.R. 2026, The Pharmaceutical Information Exchange Act of 2018 to legally codify provisions to allow for payor-manufacturer communications.

State Legislative Activity

Most States Wrap Up Regular 2018 Sessions

Although many states have adjourned their regular sessions for 2018, Maine and New Hampshire are convening special sessions to wrap up remaining legislative matters. Massachusetts, Illinois, Ohio, Pennsylvania, New York, New Jersey, Michigan, Wisconsin and the District of Columbia meet throughout the year and California is set to adjourn in August.

Biosimilars: Alaska Governor Bill Walker signed biosimilar legislation into law, making it the 9th state of 2018 to pass legislation surrounding dispensing of interchangeable biological products. Alabama, Arkansas, Maine, Mississippi, and Oklahoma are the only states left without legislation on biosimilars and interchangeable biological products. AMCP anticipates that those states will be potential targets for legislation in the 2019 sessions. You can follow state biosimilar legislative activity here.

Opioid Summary of State Legislation

Since the majority of states have adjourned, AMCP prepared a summary report of opioid management legislation as of July. You can access that report here.

AMCP Continues to Accept Applications for State Advocacy Coordinators

AMCP is looking for members in several states to volunteer to be a State Advocacy Coordinator (S.A.C). These volunteers are our go to individuals to educate legislators, stakeholder organizations, and other AMCP members on our advocacy efforts both in their state, and on the federal level. Thank you to our members who recently volunteered in CA, OH, KY, VA, DE, IL, and FL! States can have more than one S.A.C. so if you are interested, but there is already an S.A.C. listed for your state, please contact us. If you would like more information on becoming an S.A.C, please follow the link to see which states need volunteers, the role of an S.A.C. and application.

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