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CAPITOL HILL UPDATE: Opioid Legislation

House Moves Forward on Passage of Opiod-Related Bills, Senate to Take up Legislation Next Month

The House this month is set to approve and send a myriad of opioid related bills to the Senate for consideration. AMCP has been actively supporting several of the bills at the Committee level, and will continue advocating passage of the legislation that reaches the House floor for final votes expected this week. Meanwhile, the Senate is expected to pass one comprehensive opioid bill next month. As such, a Conference Committee likely will be needed to resolve differences between the House and Senate approaches on this important issue.

AMCP has sent letters of support for several bills under consideration: H.R. 4841 (Standardizing Electronic Prior Authorization for Safe Prescribing Act); H.R. 3528 (Every Prescription Conveyed Securely Act); and H.R. 4275 (Empowering Pharmacists in the Fight Against Opioid Abuse). In addition, AMCP and the Partnership to Amend 42 CFR Part 2 has strongly supported H.R. 6082 (the Overdose Prevention and Patient Safety Act), which would allow substance use disorder records to be covered under HIPAA consent provisions. This legislation has had two other bill numbers, H.R. 3545 and H.R. 5795, which contain nearly identical language.

All of the legislation supported by AMCP has received bipartisan support. However, H.R. 6082 continues to face opposition by some members, and its floor vote will be watched closely by AMCP and the other members of the Partnership to Amend 42 CFR Part 2.

Finally, the House decided late last week to combine many of the opioid bills passed in Committee into H.R. 6 (the “Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act," or SUPPORT for Patients and Communities Act"). That bill includes the language in H.R. 3528. The House is expected to vote on H.R. 6 on Thursday, June 21st.

Grassroots Activity

AMCP Action Alerts

AMCP has been actively engaging at the federal level this month with a series of action alerts:

Senate Judiciary Committee Alerts: AMCP supports S. 974 – the "Creating and Restoring Equal Access to Equivalent Samples" or CREATES ACT. Leading up to the Senate Judiciary Committee's June 14 vote on the bill, AMCP sent an Action Alert to encourage members with Senators on the Committee (AZ, CA, CT, DE, HI, ID, IL, IA, LA, MN, NE, NJ, NC, RI, SC, TX, UT and VT) to support the legislation. The Committee voted 15 in favor and 6 against, sending the legislation to the Senate floor. AMCP thanks its members, who contacted 16 of the 21 Senators on the Committee. AMCP will continue to advocate for passage when the bill is scheduled for a full Senate floor vote.

House Floor Vote Action Alerts: AMCP sent Action Alerts calling for support of several bills up for votes on the House floor last week and later this week, including H.R. 3528, which requires e-prescribing of controlled substances; H.R. 4841, which requires e-PA in Medicare Part D; H.R. 4275*, which provides for training and education for pharmacists on detecting fraudulent prescriptions/refusing to dispense; and H.R. 6082, would align 42 CFR Part 2 with HIPAA for substance use disorder record consent requirements (formerly H.R. 5795). **H.R. 4275 was favorably voted out of the House during the first week of opioid votes.*

Opioid Legislation Alerts: More than 100 AMCP members responded to the Grassroots advocacy alerts tailored to encourage continued bipartisan support of the opioid legislation up for vote later this week (see story above).

THANK YOU! Kudos to AMCP Members, Affiliates, State Advocacy Coordinators and the California Pharmacists Association for your participation in these alerts. Your engagement is making a difference. Your elected officials need to hear from you and AMCP appreciates your voices of support.

Federal Regulatory Activity

AMCP Applauds FDA Final Guidance on Payer and Manufacturer Communications

The U.S. Food and Drug Administration (FDA) this month issued final guidance to clarify how biopharmaceutical manufacturers can communicate truthful and non-misleading information with payers across a product's lifecycle. The Academy is pleased the guidance largely aligns with consensus recommendations developed at an earlier AMCP Partnership Forum, and has been expanded to include unapproved uses of approved or cleared products.

The final guidance, released June 11, provides assurances that manufacturers can share with payers certain health care economic information (HCEI) on unapproved products and unapproved uses of cleared drugs, as long as certain conditions are met. Conditions include providing a clear statement in the communication that the product or use is not approved/cleared, and that the safety or effectiveness of the product or use has not been established.

Advocacy Tip

Be aware of the timing of any visits and calls you may do as an advocate. Your legislator may be preoccupied with a disruptor issue or news story, which may push other initiatives timelines further back. Be sure to follow up after the visit, to ensure your efforts do not go unnoticed.

30 YEARS
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AMCP has been leading efforts to clarify and modernize payer and manufacturer communications, both in the pre-FDA approval and post-FDA approval space, to help address the rising cost of pharmaceuticals, enable the shift towards value-based payment models, and improve patient access to emerging therapies.

AMCP CEO Susan A. Cantrell, RPh, CAE, said, the "FDA's action is an important step toward greater value for our pharmaceutical dollar and greater access for patients to emerging and breakthrough drug therapies. The FDA's guidance also represents significant progress in the move toward adopting value-based health care models, which require payer access to better and timelier information during the decision making process."

With the FDA guidance finalized, AMCP looks forward to continuing its work with Congress, the FDA, and stakeholders to advance H.R. 2026 – The Pharmaceutical Information Exchange (PIE) Act to provide additional clarity to manufacturers and payers regarding truthful and non-misleading communications pre-FDA approval.

The FDA's final guidance, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities--Questions and Answers" is available at http://bit.ly/2t8deQ3.

AMCP Seeks Member Feedback on White House Blueprint to Lower Drug Prices

The White House last month issued a request for information (RFI) on ways to lower prescription drug costs for Americans. The RFI, called the "Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Out-of-Pocket Spending Costs," includes dozens of ideas for lowering prescription drug spending.

[AMCP will provide comments on the blueprint, and is inviting members to offer feedback by June 27.]

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 oversea. Also absent are calls specifically assessing the quality of prescription medications in improving patient outcomes, an important issue to AMCP. In addition, the RFI did not include specific information on payer and biopharmaceutical manufacturer communications, but these were addressed in final guidance released by FDA (see story above).

Comments on the RFI are due on July 16, 2018, but the docket will remain open for additional comment submissions after the deadline. AMCP's comments will focus on the following Blueprint policy areas:

- Value-based arrangements and value-based contracting;
- Utilization management in Medicare Part B and the impact of shifting coverage and payment form Medicare Part B to Part D;
- Additional flexibility for plans to manage Medicare Part D formularies; and

- Promoting a competitive marketplace to spur greater adoption of generic and biosimilar medications.

As AMCP develops its comments, we want to hear from you! We created a form linked here to make your submissions easier. Your comments will be considered anonymously. However, you can also submit your comments directly to mcarden@amcp.org by June 27.

On a related topic, the RFI requests feedback on development of long-term financing models for high cost treatments. AMCP will be hosting a multi-stakeholder Partnership Forum called 'Designing Benefits and Payment Models for High Investment Medications" on July 24-25. AMCP will provide comments to the docket once the recommendations of this partnership forum are finalized.

Read comments by AMCP CEO Susan A. Cantrell, RPh, CAE, following the release of the White House blueprint. AMCP also reviewed the blueprint at a May 21 webinar. A recording of the webinar is available at http://amcp.org/webinars/.

State Legislative Activity

State Legislatures Wrap up Sessions

State legislatures are wrapping up their sessions, with New Hampshire and North Carolina set to adjourn by the middle of July. States remaining in session are California, Illinois, Massachusetts, Michigan, New Jersey, New York, Pennsylvania, Wisconsin, and the District of Columbia. The overarching health care legislation themes this year included drug pricing transparency, and limiting the impact of the opioid epidemic, which garnered a wide range of proposals from across the country.

Biosimilars: An Alaska bill requiring pharmacies to notify prescribers prior to substituting a biosimilar for its reference product is now awaiting the governor's signature. Similar biosimilar substitution language recently was signed into law in New Hampshire, Connecticut and Vermont, as provisions included in drug pricing transparency bills. Currently, only Oklahoma, Arkansas, Mississippi, Alabama, and Maine do not have biosimilar substitution laws on the books, and these states are most likely targets for legislation in the 2019 sessions. You can follow biosimilar legislative activity here.

AMCP is Accepting Applications for State Advocacy Coordinators (S.A.C.)

AMCP is looking for members in several states to volunteer to be a State Advocacy Coordinator (S.A.C). These volunteers are AMCP's go-to individuals to help educate legislators, stakeholder organizations, and other AMCP members on our advocacy efforts both in their state and federally. If you are interested in becoming an S.A.C., please follow the link here for more information on which states need a S.A.C., as well as the role of a S.A.C. and the application form.

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