April 2018

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Spotlight on AMCP Annual Meeting Sessions

Keep Up with Legislative and Regulatory Matters Relevant to Managed Care Pharmacy

We hope to see you at the AMCP Annual Meeting in Boston next week! Here's a synopsis of the exciting sessions we have planned with a legislative and regulatory focus:

- MTM symposium – [M2] Innovations in Medication Therapy Management (MTM)-Improving Patient Outcomes Across the Health Care Continuum with faculty from The Center for Medicare and Medicaid Innovation (CMMI) – Tuesday April 24, 12:45-3:45pm in Room 157AB
- [L3] Federal and State Legislative and Regulatory Update with faculty from AMCP – Tuesday April 24, 2:30-3:45pm in Room 156ABC
- PIE Session-[L4] Best Practices to Implementing Proactive Communications Between Manufacturers and Payers with Faculty from the FDA – Wednesday April 25, 8:30am-9:45am in Room 258ABC
- PIE Roundtable-[RT4] Implementing Proactive Communications Between Manufacturers and Payers with faculty from QualChoice - Wednesday April 25, 4:30pm-5:30pm in Room 108
- Call Letter session- [L6] Medicare Part D Call Letter Update with faculty from Applied Policy – Thursday April 26, 8:00am-9:15am in Room 156AMC
- [L7] A Biosimilars Update: Regulation and Legislation with faculty from University of New England College of Pharmacy and AMCP – Thursday April 26, 11:15am-12:30pm in Room 156ABC

For more information on these and other sessions at the Annual Meeting, please visit www.amcpmeetings.org.

Federal Legislative Update

Congress Set to Recess Soon for Memorial Day

Congress is scheduled to go on recess near the end of May. House members are set to return to their districts on May 24th and return to DC on June 5th, while the Senate will recess from May 25th until June 4th. Both chambers are planning to "move" the opioid package of legislation by the end of May. At this point, there are 17 working days scheduled on the House Calendar and 22 on the Senate calendar.

Action on Opioids

The Senate has developed a document titled The Opioid Crisis Response Act of 2018. Senators have held 6 bipartisan hearings that included testimony from FDA, NIH, CDC, SAMHSA, DEA, governors, industry experts and families. Their proposals include increasing research, requiring opioid packaging specifications and safe disposal systems, clarifying the development and regulatory pathways for new non-addictive and non-opioid pain products and opioid prescription limits. controlled substance data collection and increasing public and provider education.

Meanwhile, the House Energy and Commerce Committee continued to hold a series of hearings on opioid legislation. The House currently is considering nearly 40 bills, designed to address different aspects of the crisis: helping communities balance enforcement and public safety; public health and prevention efforts; and insurance coverage and payment issues, all intended to promote treatment and recovery.

Two of the bills in the "package" are H.R. 3545 – the Overdose Prevention and Patient Safety Act and S. 1850, the Protecting Jessica Grubb's Legacy Act. AMCP supports both bills as a member of the Partnership to Amend Part 2. The Partnership continues to grow, just added 3 new members: National Association of ACOs, National Association of Counties and OCHIN (Oregon based health information and innovation networks) There are 42 organizations now in the Partnership.

Medicare Part D Beneficiaries Will Have Access to Biosimilars at Lower Costs Beginning in 2019

Beginning in 2019, Medicare Part D beneficiaries will have the opportunity to access biosimilars at lower costs. Under a provision approved in the "Bipartisan Budget Act of 2018" (Public Law 115-119), in 2019, biosimilars will be eligible for beneficiary cost sharing reductions in the Medicare coverage gap, also known as the donut hole. The Bipartisan Budget Act, approved in March 2018, closed the donut hole for all eligible products by 2109. Beneficiaries will now pay 25% of costs of biosimilars and other products in the donut hole; manufacturers will provide a 70% rebate, and plans will be responsible for 5% of costs. The Medicare Part D 2019 final rule also included a provision to reduce cost-sharing of biosimilars for beneficiaries eligible for low-income subsidies. *(More information on the 2019 Medicare Part D and Medicare Advantage Final Rule can be found in the Regulatory Update sections listed below.)*

Regulatory Update

CMS Releases Final CY2019 Call Letter

On April 2, CMS released the Final CY 2019 Call Letter for Medicare Advantage (MA) and Medicare Part D Plans. The Final Call Letter contained no substantial changes to proposals in the Draft Call Letter, and these were finalized generally as proposed. CMS did, however, update the Standard Benefit Parameters to reflect changes to the coverage gap that were included in the Bipartisan Budget Act of 2018. CMS says the updates will continue to create more choices for Medicare beneficiaries that choose MA

Advocacy Tip

Social media and technology have become a part of daily life. Use this to your advantage to stay on top of what your state and congressional representatives are posting. Social media can also be a great tool to gain traction toward your advocacy goal by tweeting and posting articles or statistics which back up your position as well.

and Part D plans in 2019. The provisions finalized in the Call Letter will apply to plans in the 2019 plan year. AMCP released a summary of the Final CY 2019 Call Letter and the major provisions impacting managed care pharmacy that is available here.

CMS Releases Final Rule for Medicare Parts C and D

On April 2, CMS released a final rule titled *"Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program."* The rule finalizes proposals originally set forth in November 2017 and amends regulations for Medicare Part C and Part D to implement provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act. The rule also makes changes to improve program quality, accessibility, and affordability, as well as adopts the updated NCPDP script standard for electronic prescribing. AMCP provided detailed comments to CMS on the proposed rule. For a summary of the comments visit here.

AHRQ Requests Information on Patient-Reported Outcomes Measures

AMCP submitted comments to the Agency for Healthcare Research and Quality (AHRQ) in response to a request for information on patient reported outcomes measures. AHRQ plans to conduct a Challenge Competition in late 2018 to develop user-friendly technical tools to collect and integrate patient-reported outcome (PRO) data in electronic health records (EHRs) or other health information technology products. AMCP is supportive of the initiative and has encouraged the Agency to ensure that PRO data is also available outside of traditional settings of care so managed care professionals and health care decision makers will have access to PRO data necessary to design and deliver patient care. AMCP will continue to monitor the Agency's activities on PROs. Additionally, AMCP will be hosting a second Partnership Forum on PROs titled "Building the Foundation for Patient Reported Outcomes: Infrastructure and Methodologies." The Forum, scheduled for October 25, 2018, will focus on an action plan to implement key recommendations received from our members and stakeholders including developing a health IT strategy for PRO collection and use that is streamlined and efficient. The full comment letter to AHRQ may be viewed here.

CMS Requirements for 2019-2020 Prescription Plan Offerings in Marketplace Exchanges Plans

In April, CMS released the 2019 final requirements for health insurance benefit offerings for marketplace exchanges and outlined requirements for offering essential health benefits (EHBs), including prescription drug plans, beginning in 2020. While prescription drug coverage requirements for 2019 remain virtually the same as in 2018, formulary reviews conducted by states or CMS will consider whether plans offer appropriate coverage for opioids and addiction treatment. Open enrollment for beneficiaries will begin on November 1, 2018.

Beginning in 2020, states will have more flexibility in how they select their EHB-benchmark plan to provide states with additional choices with respect to benefits and affordable coverage. However, each plan must continue to offer all 10 EHBs and are subject to additional requirements. The specific options for flexibility include:

- Use of the EHB benchmark used in another state in the 2017 plan year;
- Replace one or more categories of EHBs used in the 2017 plan year by a different state;
- Select another set of benefits to become the state EHB's benchmark plan.

The 2020 EHB selection is due to CMS on July 2, 2018. More information on the requirements for health insurance marketplaces is available here.

Focus on States

State Legislative and Advocacy Activity

By the end of April, only 23 of the 46 state legislatures and Washington D.C will still be in session. This session the overarching themes in health care were drug pricing transparency, as well as legislation limiting the impact of the opioid epidemic.

Biosimilars: Michigan, South Dakota, Wisconsin, West Virginia and Wyoming all passed biosimilar legislation leaving Alaska, Connecticut, and Vermont still in the committee process for 2018. Each of the remaining states has had at least 1 hearing on their respective biosimilar legislation in April. AMCP continues to advocate for allowing pharmacists to dispense interchangeable biosimilar products without additional administrative reporting requirements and that the FDA Purple Book be recognized as the authority for information on this drug category and not the FDA Orange Book. You can follow biosimilar legislative activity here.

This month AMCP also submitted letters to New York and New Hampshire recommending amendments to their legislation proposing to mandate medication synchronization coverage. Medication synchronization programs are a great tool in managed care, but coverage determinations should not be determined solely by a prescriber or pharmacist, without consideration of contract coverage requirements. AMCP continues to advocate for those in managed care pharmacy to be part of the process of developing and implementing these best practices.

Grassroots Activity: AMCP initiated a grassroots advocacy campaign in Illinois urging members to contact their state representative to vote no on House Bill 4146. This legislation prevents formulary changes during an enrollee's plan year such as prohibiting increasing cost sharing and moving medications to a more restrictive formulary tiers. Formulary management is one tool managed care organizations can implement to encourage the use of safe, efficacious medications for a specific patient population while moderating health care costs. Members in Illinois can still submit a letter by following the link here.

AMCP members engage student chapters: Earlier this month, Brian Lehman, MHA, MBA, RPh presented at The Ohio State University AMCP Student Chapter. Brian is the Vice Chair of AMCP's Public Policy Committee and the Ohio State Advocacy Coordinator. In spite of a tornado warning requiring part of the presentation to be given in a hallway, Brian spoke to 25 students about the importance of advocacy and the legislative process as well as pending legislation in Ohio which could impact the profession.

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