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In This Issue

House and Senate Take First Steps to Repeal and Replace Affordable Care Act

House Replacement Legislation Expected to Be Introduced Early Next Month

The House and Senate are moving forward with plans to repeal and replace the Affordable Care Act. On Feb. 18, House Speaker Paul Ryan (R-Wis.) said legislation would be introduced after the House returns from a 10-day recess on Feb. 27. Lawmakers received a 19-page “policy brief” with details on an ACA replacement plan that includes restructuring Medicaid, eliminating penalties for uninsured and employers that do not offer coverage, incentives for health savings accounts, and an age-based monthly tax credit that does not vary with income for those who purchase coverage.

Also last week, the House Ways and Means Committee Chairman Kevin Brady (R-Texas) said the committee will focus on repealing taxes, mandate penalties, and subsidies under the ACA. The committee also will identify key replacement parts, which Brady says, will “restore” state control of health care, free market choices and more affordable care. The legislation will include increasing the amount of money an individual or family can put into their Health Savings Account and allows the HSA to cover “over-the-counter” health care items.

For its part, the Senate last month voted 51-48 to approve a budget that would repeal parts of the ACA through the budget reconciliation process. Sen. Bill Cassidy (R-La.) has introduced S. 91, The Patient Freedom Act of 2017, which is designed to replace the ACA by creating a state-centric plan that allows states that want to continue to offer the ACA to do so. The bill also would urge price transparency on medical procedures, keep existing subsidies and tax credits and extended coverage.

House Republicans could pass legislation to replace the ACA on a party-line vote. However, at this time, the Senate cannot pass a replacement plan without support from Senate Democrats.

FEDERAL LEGISLATIVE UPDATE

HHS Secretary Confirmed, CMS Head Nominee Moves Forward, But FDA Head Still Vacant

By a 52 to 47 party-line vote, the Senate on Feb. 9 confirmed Rep. Tom Price (R-Ga.) as Secretary of the Department of Health and Human Services (HHS). Republicans view Price, an orthopedic surgeon, as a champion of free market principles who will guide the implementation process of Congressional efforts to repeal and replace the ACA, the top legislative priority for President Donald Trump and Congressional Republicans. A link to Price's confirmation hearing on Jan. 18 can be found here.

The Trump Administration has nominated Seema Verma, president and founder of health consulting company SVC, Inc., to be Administrator of the Centers for Medicare and Medicaid Services (CMS). Verma is credited with developing the Healthy Indiana Plan, which was used by the state of Indiana as the vehicle for Medicaid expansion under the ACA. She had her first confirmation hearing on Feb 16 before the Senate Finance Committee. At the hearing, Verma said she does not support giving vouchers for Medicare beneficiaries to buy insurance. She also supports extending funding for the Children's Health Insurance Plan for eight years, and she'll help Congress investigate EpiPen Medicaid rebates, as well as make innovation center demonstrations voluntary. However, she was reluctant to answer many other questions from Senate Finance Committee members, including how she thinks drug prices should be contained and whether to cap federal funding of Medicaid.

Meanwhile, the Trump Administration has yet to name a nominee for Commissioner of the FDA. At the same time, concerns are rising about how the Trump Administration's government-wide hiring freeze would affect the FDA, which has nearly 1,000 vacancies, as well as its plans to decrease new regulations.

New CREATES Legislation Is Expected Soon

Lawmakers are expected soon to introduce The Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act/Fair Access for Safe and Timely ("FAST") Generics Act. Similar legislation was introduced in the 114th Congress. The legislation is designed to address common abuses of both Risk Evaluation and Mitigation Strategies (REMS) and non-REMS restricted access programs, while maintaining necessary safety protections for patient safety and public health.

Federal Regulatory Updates

CMS Releases 2018 Draft Call Letter, AMCP Will Seek Member Input on Relevant Issues

The Centers for Medicare and Medicaid Services' 2018 Draft Call Letter, released Feb. 1, does not contain any major overall changes that are of serious concern to managed care pharmacy. There are, however, some issues on which AMCP is seeking additional feedback from members. AMCP also is preparing a detailed summary of key issues and other payment methodology and policy provisions of interest to managed care pharmacy. To receive a copy of AMCP's summary of the Draft Call Letter, please sign-up for the Medicare Part D Policy Issue Email List by visiting www.amcp.org/List/.

Advocacy Tip

Not every advocacy effort is aimed at producing legislation. In some cases, the goal may be to get a hearing where diverse views can be aired and the legislators can become better educated. Some are intended to support new legislation, oppose existing legislation, or offer an amendment to a larger bill. Some advocacy is targeted to achieve changes to regulation, which are sometimes simpler to attain. Each of these goals will have a distinct strategy associated with them. You will need to start with the goal clearly in mind.

Comments on this proposal must be submitted to CMS by March 3, 2017 at 6pm ET. AMCP will work with stakeholders to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced as changes to payment policies and the Star Ratings are considered. You may provide feedback via email to Soumi Saha, Assistant Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Tuesday, Feb. 28. AMCP's final comments to CMS will be available on the AMCP website and also included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

In addition, AMCP will host a webinar on Feb. 22 (2-3pm EST) to review the proposed policy provisions and changes to Star Ratings that are applicable to AMCP members in the 2018 Draft Call Letter. This webinar is free for members and $69 for non-members. To register, please visit AMCP's Calendar of Events at www.amcp.org/calendar/.

CMS will release the 2018 Final Call Letter on April 3, 2017.

CMS Releases Proposed Rule on Market Stabilization for the Exchanges

CMS's Feb. 15 proposed rule, "Patient Protection and Affordable Care Act; Market Stabilization," aims to help stabilize the ACA's individual and small group markets. Among other things, it would amend standards relating to special enrollment periods, guaranteed availability, and the timing of the annual open enrollment period in the individual market for the 2018 plan year. The proposed rule also would amend standards related to network adequacy and essential community providers for qualified health plans, as well as rules around actuarial value requirements. The proposed rule does not specifically mention pharmacy benefits and AMCP is verifying if the network adequacy proposals would also be applicable to pharmacy. Comments on the proposed rule are due March 7.

42 CFR Part 2 Stakeholder Group Work Continues

AMCP continues to work with a 29-member stakeholder group to garner Congressional support for amending the underlying statute that is the basis for 42 CFR Part 2 in order to allow appropriate access to patient addiction treatment information consistent with HIPAA. Although the SAMHSA final rule was released last month, the stakeholder group agrees that some steps to modernize Part 2 were taken; however, legislation is necessary to bring Part 2 into compliance with HIPAA. Access to a patient's entire medical record, including addiction records, ensures that providers and organizations have all the information necessary for safe, effective, high quality treatment and care coordination that addresses all of a patient's health needs. To read the partnership one pager, please visit here.

Upcoming Regulatory Comment Periods

Topics	Feedback to AMCP Due	Comments Due
CMS: 2018 Draft Call Letter	Feb. 28	March 3
CMS: Market Stabilization	March 1	March 7
FDA: Biosimilars Interchangeability	March 10	March 19
FDA: Medical Product Communications That Are Consistent With the FDA-Required Labeling — Q&A	April 10	April 19
FDA: Drug and Device Manufacturer		

Communications With Payors, Formulary Committees, and Similar Entities – Q&A	April 10	April 19
FDA: Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products	April 10	April 19

Upcoming Webinars

To register for upcoming webinars, please visit www.amcp.org/calendar/

Implications for Managed Care Pharmacy from the 2018 Medicare Part D Call Letter and Star Ratings Release
Wednesday, Feb. 22, 2-3pm, ET

Driving Value and Outcomes in Oncology - Proceedings from the AMCP Partnership Forum
Wednesday, March 22, 2-3pm, ET

State Legislative Update

Eye on State Legislatures

State legislatures are all in session except for Florida and Louisiana, which will begin their sessions later in the year. AMCP is seeing a flurry of legislation pertaining to biosimilars/interchangeables, medication synchronization, limits on step therapy, and PBM regulation (specifically, legislation that restricts PBM operations, mandates audit policies, and contract provisions). AMCP is closely monitoring these issues and other issues that impact managed care pharmacy.

Biosimilar and Interchangeable Biologic Products: To date, Alabama, Alaska, Arkansas, Iowa, Kansas, Maryland, Minnesota, Montana, Nebraska, New Mexico, South Carolina, and Wyoming have introduced biosimilar and interchangeable biologic product legislation. Generally, these bills have similar language. One positive development to note is that many of these bills generally acknowledge that pharmacists have the authority to substitute an interchangeable biological product; this is consistent with the Biologics Price Competition Innovation Act (BPCIA). However, the burdensome provisions contained in the 2016 legislative proposals persist, e.g, additional notice and record keeping requirements not required for any other class of FDA approved drugs, no requirement that prescribers maintain records, and defining drugs that are not approved as interchangeable but are considered "therapeutically equivalent" as substitutable for a biologic. Other states where AMCP expects to see biosimilar legislation introduced in 2017 include: Connecticut, Nevada, New York, and Vermont.

Map of State Biosimilars Bills

Step Therapy: Hawaii, Kansas, Oregon, Utah, Virginia, Washington, and West Virginia have introduced legislation that would limit or prohibit a step therapy protocol. Generally, these bills mandate that health insurance plans follow a government mandated step therapy exceptions process.

ADF/Opioid Prescribing Guidelines: Connecticut, Idaho, Illinois, Indiana, Pennsylvania, and Texas have introduced bills that would either mandate coverage for ADF opioids in a way that is no less favorable than coverage for non-ADF opioids or mandate government created guidelines for prescribing opioids in certain patient settings (or to certain patient classes, like minors).

State Legislative Tracking

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