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Recap of Midterm Elections: Federal and State Results

Federal Election Results: two weeks post-elections, most races have officially been called. In the Senate, we are waiting for results of the runoff in Mississippi between incumbent Sen. Cindy Hyde-Smith (R), and former U.S. Agriculture Secretary Mike Espy (D), scheduled for Nov. 27th. The current party split sits at 52 Republicans, 45 Democrats, and 2 Independents who caucus with the democrats. In terms of leadership, Mitch McConnell (R-KY) will remain at the helm of the Republican party, as will Chuck Schumer for the Democratic Party (D-NY). Democrats Bill Nelson (D-FL), Claire McCaskill (D-MO), Joe Donnelly (D-IN), and Heidi Heitkamp (D-ND) all lost their re-election bids as well as republican Dean Heller (R-NV).

On the House side, five races remain undecided. Democrats have gained 37 seats thus far for a total of 232 seats and control of the House. Republicans stand at 198 seats. Most notably, democrats in California flipped 6 seats and their delegation total stands at 45 democrats and 8 republicans. Pennsylvania and New Jersey had 4 seats flip Democrat, leaving their delegations at 9 Democrats, 9 Republicans and 11 Democrats, 1 Republican respectively. Florida, Illinois, lowa, Michigan, New York, and Texas all flipped 2 seats Democrat, while Minnesota had 2 seats flip to Republican and 2 seats flip to Democrat leaving their delegation the same at 5 Democrats and 3 Republicans. In the House, Republicans have voted Kevin McCarthy (R-CA) as their new Minority Leader, replacing the retiring Paul Ryan (R-WI) and Democrats will vote on their leadership for the next Congress after the Thanksgiving recess.

State Election Results: with 36 governorships up for election in 2018, the states also saw changes to party control. Eight states have flipped governors' parties, with Illinois, Kansas, Maine, Michigan, Nevada, New Mexico, and Wisconsin flipping to Democrat, and Alaska changing from Independent to Republican. Several contentious races were finalized after recounts with Ron DeSantis (R) beating out Andrew Gillum (D) in Florida and Brian Kemp (R) eking out the vote against Stacey Abrams (D) in two of the most closely watched state races this year. Both republicans Scott Walker, Governor of Wisconsin, and Bruce Rauner, Governor of Illinois, lost their re-election bids at the state level.

In state legislatures, more than 350 seats flipped from Republican to Democrat across the country. Colorado, Illinois, Maine, New Mexico, New York, and Nevada will have a "trifecta" of both chambers of their state house and governors' mansions Democrat next year. Democrats now have "trifectas" in 14 states, and republicans have 22 state "trifectas." Kansas, Michigan, and Wisconsin will have Democratic governors with both chambers held by Republicans and New Hampshire's chambers both flipped to Democrat, while Republican incumbent Chris Sununu won re-election for governor. Minnesota is now the only state with a split legislature with Democrats controlling the state House and Republicans holding a one-seat majority in the state Senate.

If you're interested in more election details and what this will mean for the coming years, sign up for our "2018 Midterm Elections and Implications for Health Care" webinar Monday, Dec. 3 at 3pm EST.



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LON-PM-US-0670

Regulatory Update

AMCP Seeks Feedback on Recent CMS Proposed Rules

The Centers for Medicare and Medicaid Services (CMS) recently released several new proposed rules that may be of interest to AMCP members.

New Proposed Rule on Disclosing Drug Prices in Direct-to-Consumer Advertisements

On Oct. 15th, CMS released a new proposed rule that would require prescription drug manufacturers to disclose the list prices for U.S. prescription drugs in direct-to-consumer television ads in an effort to provide greater transparency to list prices set by drug manufacturers. The proposed rule would require direct-to-consumer television advertisements for prescription drug and biological products paid for by Medicare or Medicaid to include the Wholesale Acquisition Cost if it is greater than \$35 for a month's supply or the usual course of therapy. Prices will be updated quarterly.

AMCP has not taken a position in pricing in DTC ads, but has a policy that supports DTC ads that increases public awareness about disease symptoms, informs consumers about available treatments and diagnostics procedures and encourages a healthy lifestyle. Furthermore, AMCP supports DTC that promotes patient engagement and information that increases knowledge about a disease state or the importance of adherence and good outcomes. AMCP discourages advertising that promotes the use of a specific product.

Comments on the proposed rule can be submitted to CMS through Dec. 17th. AMCP plans to submit comments consistent with our policy. You may provide feedback on the provisions in the proposed rule by Dec. 5 to Afton Wagner, Director, Regulatory Affairs, at awagner@amcp.org.

Advanced Notice of Proposed Rulemaking for an International Pricing Index (IPI) Model

On Oct. 30, CMS published an <u>Advanced Notice of Proposed</u> <u>Rulemaking (ANPRM)</u> for a new potential International Pricing Index (IPI) Model for Medicare Part B Drugs. The IPI model is intended to lower expenditures for Part B drugs by implementing an international reference price to shift payments to a level that is comparable with prices in other countries. It also seeks to reform the current "buy and bill" system for Part B drugs and proposes alternatives to the current add-ons to the Average Sales Price (ASP)-based payments for physicians.

Advocacy Tip

Learn about AMCP's policy and advocacy focus areas <u>here</u>. The webpage includes a <u>Policy Digest</u> with short statements that document AMCP's position on professional practice issues. You can also access AMCP's <u>Where We Stand Position</u> <u>Statements</u>, which provide detailed descriptions of our position on a wide range of managed care pharmacy topics. AMCP shares the Administration's concern about the rising costs of medications and the impact on patients, payers, and providers. In July, AMCP <u>submitted comments</u> to HHS on its Request for Information (RFI) on the Blueprint to lower drug prices and reduce out of pocket costs. In that letter, AMCP shared three key areas that were identified in 2017 where AMCP members help to improve health outcomes and lower costs. These include enhancing value for outcomes; enhanced approaches to medication coverage determinations; and market competition for generics and biosimilars to lower costs. Implementation of effective, outcomes-driven value-based contracting (VBC) strategies also remains a key focus area for AMCP.

Comments on the proposed rule can be submitted to CMS through Dec. 31. AMCP plans to submit comments that align with our identified focus areas. You may provide feedback on the provisions in the proposed rule by Dec. 7 to Afton Wagner, Director, Regulatory Affairs, at awagner@amcp.org.

New Proposed Rule on Changes to Medicare Advantage (MA or Part C) and Medicare Prescription Drug Benefit (Part D)

On Nov. 1, CMS issued a <u>new proposed rule</u> that updates Medicare Advantage (MA or Part C) and the Medicare Prescription Drug Benefit (Part D) Programs. The proposed rule in intended to implement several provisions in the <u>Bipartisan Budget Act of 2018</u>, improve program quality and accessibility, and propose policies that strengthen program integrity. Proposed provisions are intended to reduce provider burden and promote flexibility and innovation that will provide MA and Part D sponsors with tools to improve quality of care and increase choice for MA and Part D enrollees. As part of its effort to improve program quality and accessibility, CMS is proposing several enhancements to measure-level star ratings to include a proposed cut point methodology for data collected and proposed quality measure updates.

AMCP has offered <u>comments</u> to CMS in the past on how the Medicare Part C and D programs can be transformed through innovation to best meet the individual health needs of Medicare beneficiaries. AMCP plans to comment on the new proposed rule and is seeking feedback from its members to inform the comments that will be submitted to CMS. Comments on this proposal can be submitted to CMS through Dec. 31. You may provide feedback via email to Afton Wagner, Director of Regulatory Affairs, at <u>awagner@amcp.org</u> by Dec. 7 on any of the provisions included in the proposed rule.

Webinar Recordings for new CMS Rulemaking Now Available

On Nov. 9, AMCP hosted a webinar that reviewed managed care pharmacy implications from the Centers for Medicare and Medicaid Services (CMS) Advanced Notice of Proposed Rulemaking (ANPRM) on a potential International Pricing Index (IPI) Model for Medicare Part B Drugs and proposed rule on changes to the Medicare Advantage (MA or Part C) and Medicare Part D Programs. A <u>recording of the</u> <u>webinar</u> is available for AMCP members. A detailed summary on each of the key issues contained in the ANPRM and proposed rule, as well as specific areas where AMCP is seeking stakeholder feedback, is located on the <u>AMCP website</u>.

CMS Finalizes Physician Fee Schedule Changes for Calendar Year 2019



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LON-PM-US-0671



On Nov. 1, CMS published a <u>final rule</u> on the 2019 Physician Fee Schedule (PFS) and Quality Payment Program (QPP). AMCP <u>submitted comments</u> to the proposed rule in September, 2018 that specifically focused on opioid management in the PFS. In its letter, AMCP provided feedback regarding the use of a bundled episode of care payment to ensure patients with SUDs have access to care. AMCP supported the use of bundled episode of care payment for SUDs but encouraged CMS to consider increasing access to SUD treatment, recognition of certain services to be provided, and variabilities that could affect payment. In its final rule, CMS recognized the variability in patient needs for treatment of SUDs from all comments received and will take the information into consideration for future rulemaking.

Additionally, CMS issued an Interim Final Rule within the Final Rule to establish a new Medicare benefit category for opioid use disorder treatment services provided by opioid treatment programs (OTPs) as directed by the <u>SUPPORT for Patients and Communities Act</u>. CMS is seeking input though the interim final rule on services furnished by OTPs beginning on January 1st, 2020.

The final rule also addresses drug pricing in Medicare Part B by reducing wholesale acquisition cost (WAC)-based payment for newly-launched physician-administered drugs to 103% of WAC (from 106% of WAC). This policy change will only impact drugs that do not have an average sales price (ASP). Once a drug has an ASP, payment will revert to 106% of ASP.

A summary of the final rule can be found on the AMPC website.

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