

Health Policy Update – November 8, 2018

Stay up to date on public policy initiatives and legislation impacting your community specialty clinic. The Health Policy Update is a bi-weekly newsletter for McKesson Specialty Health customers with curated content, and resources to help you advocate for your practice and patients.

2018 Midterm Election Results

Tuesday's elections saw Democrats gain control of the U.S. House of Representatives, winning at least 28 seats as of Wednesday. In the Senate, Republicans further increased their majority by at least 2 seats, defeating Democratic incumbents in Indiana, Missouri and North Dakota. In Nevada, Democrat Jacky Rosen defeated incumbent Republican Senator Dean Heller. Races in Florida and Arizona were still too close to call.

Democrats also picked up 7 Governorships, winning Illinois, Kansas, Maine, Michigan, Nevada, New Mexico and Wisconsin while also flipping nearly a dozen state legislative chambers. The Governor's race in Georgia is still too close to call and may result in a runoff if no candidate receives more than 50 percent of the vote.

Voters listed healthcare as a major issue in this election and the Democrats taking control of the House likely means there will be a renewed focus on healthcare issues. Items likely to be on the agenda include:

- Legislation protecting Americans with pre-existing conditions in the event a court ruling strikes down that portion of the ACA.
- A renewed focus on drug pricing issues, including allowing Medicare to negotiate drug prices.
- New regulations on short-term health plans, which many Democrats claim undermines the stability of the ACA marketplaces.

A Democratic-controlled House may also explore additional healthcare issues that have become popular in some policy circles, including expansion of the Medicare program or giving states additional flexibility to implement Medicaid buy-ins. However, Republican control in the Senate ensures any legislation would have to have bipartisan support before it reaches the President's desk.

The US Oncology Network Responds to International Pricing Index Model for Medicare Part B Drugs

The US Oncology Network issued a statement expressing its concerns with the Centers for Medicare & Medicaid Services' International Pricing Index (IPI) model demonstration project that would allow private-sector vendors to negotiate Part B drug prices to more closely align Medicare payments for these drugs with the prices paid by other countries' national health systems. Through the advance notice of proposed rulemaking (ANPRM), CMS is seeking feedback on the potential parameters of the IPI Model, announced on October 25.

The Network expressed concern the proposal would jeopardize patient access to care and upend ongoing efforts to transition to value-based care models.

"We support the administration's focus on bringing down the high costs of prescription drugs. However, we believe this goal should be accomplished through collaborative, transparent and voluntary models that are also aimed at protecting patient safety and access to care," said Marcus Neubauer, MD, chief medical officer for The Network in a statement. "Rather than easing patient out-of-pocket costs associated with drug prices, we fear this proposal to dramatically restructure Medicare reimbursements for specialty drugs could actually expose patients to unnecessary barriers to care."

The Network also warned the proposal could make it more difficult for community oncology practices to offer personalized cancer treatment to Medicare patients, as many cancer therapies consist of complex drug regimens that must be frequently adjusted by a patient's physician.

To read the Network's statement, [CLICK HERE](#).

To read the CMS Policy Brief outlining the IPI model, [CLICK HERE](#).

Site Neutral Provisions Included in Final OPPS Rule

On November 2, the Centers for Medicare & Medicaid Services (CMS) released the 2019 Outpatient Prospective Payment System (OPPS) Final Rule, which expands site neutral payment policy by reimbursing hospital outpatient departments at a rate equivalent to the Physician Fee Schedule (PFS) for clinic visits.

In a statement released on November 2, CMS Administrator Seema Verma said, "Today's rule advances competition by creating a level playing field for providers so they can compete for patients on the basis of quality and care. The final policies remove unnecessary and inefficient payment differences so patients can have more affordable choices and options."

However, there may be legal challenges on the horizon as the American Hospital Association (AHA) announced last week it and the Association of American Medical Colleges intend to challenge the site neutral provisions in court.

In early October, the Alliance for Site Neutral Payment Reform submitted a letter to CMS praising the proposed rule as a step in the right direction and asking for more changes to advance payment parity across sites of service.

To read the Alliance for Site Neutral Payment Reform press statement, [CLICK HERE](#).

To read the full text of the letter submitted by the Alliance for Site Neutral Payment Reform, [CLICK HERE](#).

To read the full text of the OPPS Final Rule, [CLICK HERE](#).

CMS Releases Physician Fee Schedule Final Rule; Delays Payment Changes to E/M Visits

On November 1, the Centers for Medicare & Medicaid Services (CMS) released the 2019 Physician Fee Schedule and Quality Payment Program Final Rule, which did not include a previous proposal to pay a single rate for most doctors' office visits regardless of their level of complexity after the agency received more than 15,000 comments on the proposal. In July, CMS sought to revise the evaluation and management (E/M) codes doctors use to bill Medicare for office visits by collapsing code levels 2 through 5 into a single code; however, the proposal sparked strong opposition from hundreds of doctors' groups, who said it would underpay doctors who care for Medicare's sickest patients.

In the Final Rule, the agency now says it will collapse code levels 2 through 4 into a single code but retain a separate billing code for level 5, which is used for the most complex patients. But even that more modest change is not set in stone, because it is not scheduled to take effect until 2021 — a delay that will allow the agency to continue working with stakeholders on the issue.

To read the text of the 2019 Physician Fee Schedule and Quality Payment Program Final Rule, [CLICK HERE](#).

In Letter to CMS, Congressman Holding Expresses Concern about Step Therapy in MA Plans

On November 1, Congressman George Holding (R-NC) submitted a letter to the Centers for Medicare & Medicaid Services (CMS) expressing concern about a notification to Medicare Advantage (MA) plans reversing the prohibition on utilizing step therapy protocols for Part B drugs. Congressman Holding urged CMS to suspend the policy in 2019 in order to address concerns about the potential impacts on patient access and care.

While the Congressman acknowledged MA must have the management tools to control cost and drug utilization rates, he noted the proper balance has not been struck as evidenced by the Office of Inspector General's (OIG) report that found MA organizations overturned 75 percent of their own service and payment denials. Due to the serious nature of the illnesses treated by Part B medicines, Congressman Holding urged CMS to not move forward with the step therapy proposal without adopting measures to ensure patient access and non-interference with the physician-patient decision-making process.

To read the full text of Congressman Holding's letter, [CLICK HERE](#).

After Legal Challenge, HHS Accelerates Implementation of 340B Rule

On October 31, the Department of Health and Human Services (HHS) released a notice of proposed rulemaking in the Federal Register which shows its intention to move the effective date for implementing changes to the 340B Drug Pricing Program up from July 1, 2019, to January 1, 2019. The move comes in response to a lawsuit brought by the American Hospitals Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, Rutland Regional Medical Center in Vermont, Genesis HealthCare System in Ohio and Kearny County Hospital in Kansas.

Rather than defend its decision to delay regulatory changes to the 340B Drug Pricing Program that were finalized in the final weeks of the Obama administration, the Trump administration proposed to no longer delay implementation of the changes, which would set forth the calculation of the 340B ceiling price and application of civil monetary penalties.

To read the Notice of Proposed Rulemaking (NPRM), [CLICK HERE](#).