

# McDermottPlus Check-Up

*McDermott+Consulting is pleased to introduce the McDermottPlus Check-Up, your regular update on health care policy from Washington, DC.*



**THIS WEEK'S DIAGNOSIS:** Welcome back – sort of. The partial federal government shutdown drags on. We are on day 21 with no end in sight, which has shifted the focus of the new Congress away from overarching health priorities and toward continued efforts to reopen the government.

## CONGRESS

- + **HOUSE PASSES COMBINED PAHPA AND OTC BILL, AGAIN.** The House overwhelmingly passed the bipartisan Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPA, [H.R. 269](#)), legislation that would reauthorize and update public health emergency response programs at the US Department of Health and Human Services. The bill also includes reforms of the Food and Drug Administration's (FDA) regulation of over-the-counter (OTC) drugs, creating a new user fee program. An identical version passed late last year, but was held up in the Senate due to procedural challenges between two Senators: Senator Richard Burr (R-NC), who is lead sponsor of the Senate's version of PAHPA, is standing in the way of the OTC bill due to concerns related to the user fee program; in response, Senator Johnny Isakson (R-GA), who is the lead sponsor of the OTC bill, has been holding up PAHPA in retaliation. It is unclear if these issues are resolved, but look for pressure to continue to drive action.
- + **DRUG PRICING BILLS PILE UP.** The new Congress is off and running. Returning and new Members introduced a handful of bills, some bipartisan, to tackle the rising cost of prescription drugs.
  - o Representatives Peter Welch (D-VT) and Francis Rooney (R-FL) [introduced a bill](#) that would require the federal government to negotiate lower drug prices under the Medicare Part D program. This has been a priority for Democrats for years, and President Trump signaled his support on the campaign trail in 2016. As President, however, his administration has not pushed this policy. Rep. Rooney is the only Republican supporting the measure in the House. Expect this policy change to be pushed by House Democrats as they begin to implement their priorities.
  - o Senator Bernie Sanders (I-VT) [introduced three bills](#) tackling drug importation, the government's ability to negotiate drug prices in the Medicare program and linking US drug prices with other developing countries. These bills have companion bills in the House led by Representatives Elijah Cummings (D-MD) and Ro Khanna (D-CA). These policy topics are likely to be among those considered by the House Democratic majority, and the Administration is

somewhat supportive of international pricing and may consider the others. Some Republican senators have expressed interest in importation (see below).

- Senators Chuck Grassley (R-IA), the chairman of the Senate Finance Committee, and Senator Amy Klobuchar (D-MN) introduced the [Safe and Affordable Drugs from Canada Act of 2019](#). This bill directs the FDA to allow importation of a limited individual supply of prescription drugs from certain Canadian pharmacies. Chairman Grassley has the power and ability to move this bill through his committee. Given the interest from the House, this bill (or something similar) could garner more bipartisan support and see Committee action soon.
- + **HOUSE VOTES TO JOIN ACA LAWSUIT.** House Democrats approved a measure on a largely party-line vote allowing the body to join the federal lawsuit challenging the constitutionality of the Affordable Care Act (ACA). The lawsuit, [Texas v Azar](#), was recently decided by a federal district judge in Texas, and is currently making its way through the appeals process. A group of Republican attorneys general argue that the zeroing out of the individual mandate rendered the law unconstitutional and therefore, the entire ACA must fall. The case is expected to be tied up in appeals courts for at least another year.
- + **HOUSE WAYS AND MEANS BIPARTISAN LETTER ON CMMI.** New House Ways and Means Committee Chairman Richard Neal (D-MA) and Ranking Member Kevin Brady (R-TX) sent a [letter](#) to the Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma urging greater transparency for the Centers for Medicare and Medicaid Innovation (CMMI). The letter requests specific information about the models under consideration and the timelines, and requests a response by January 23, 2019. Senator Hatch sent a [letter](#) December 19, 2018, expressing similar concerns about the International Pricing Index model and CMMI's "excessive authority." Expect additional scrutiny of the CMMI as its funding is slated to renew in 2020 and as new models potentially push toward new frontiers in traditional Medicare.
- + **NEW COMMITTEE MEMBERS.** The Senate and House are continuing to finalize Committee rosters.

In the Senate, seven Senators were added to the Health, Education, Labor and Pensions (HELP) and Finance Committees.

- New to the HELP Committee: Mitt Romney (R-UT), Mike Braun (R-IN) and Jacky Rosen (D-NV).
- New to the Finance Committee: Steve Daines (R-MT), James Lankford (R-OK), Todd Young (R-IN), Maggie Hassan (D-NH) and Catherine Cortez Masto (D-NV).

The House is expected to wrap up its appointments next week, but new Democratic Members were announced for the Ways and Means and Energy and Commerce Committees.

- New to the Ways and Means Committee: Jimmy Panetta (D-CA), Gwen Moore (D-WI), Dan Kildee (D-MI), Brad Schneider (D-IL), Steven Horsford (D-NV),

Stephanie Murphy (D-FL), Don Beyer (D-VA), Brendan Boyle (D-PA), Dwight Evans (D-PA) and Tom Suozzi (D-NY).

- New to the Energy and Commerce Committee: Nanette Barragan (D-CA), Robin Kelly (D-IL), Marc Veasey (D-TX), Tom O'Halleran (D-AZ), Darren Soto (D-FL), Don McEachin (D-VA), Lisa Blunt Rochester (D-DE) and Annie Kuster (D-NH).

## ADMINISTRATION

- + **OPEN ENROLLMENT ENDS SLIGHTLY DOWN FOR 2019.** CMS released final enrollment numbers from the 2019 federal exchange open enrollment period. According to HHS, 8.4 million people enrolled in insurance through the exchanges this year, compared to 8.7 million last year. The agency pointed to the improved economy as a factor in this year's open enrollment, with more people having access to employer-based coverage, reducing demand for exchange-based coverage. Other observers have also credited Medicaid expansion in Virginia, which moved some people off of the exchanges and into Medicaid. Exchange enrollment was remarkably steady given administrative changes made by the Administration, which some ACA supporters thought would weaken enrollment, and the decision in the Texas case, which invalidated the ACA just days before open enrollment closed. Enrollment numbers from state-based exchanges are not yet in, as many of those state exchanges, including large states like California, are still enrolling individuals.
- + **FDA NEW DRUG EVALUATION OFFICE.** FDA Commissioner Scott Gottlieb announced that the Office of Drug Evaluation Science will have 52 members to assess drug efficacy and safety, explore how to use information technology and monitor how biomarkers are researched. The Office, which is under the current Center for Drug Evaluation and Research, will examine data related to the safety of new drugs. Biomarkers, bioinformatics and patient-reported outcomes are also high on the priority list.
- + **HOSPITALS PREVAIL OVER CMS IN INITIAL RULING ON 340B LAW SUIT.** A federal District Court in the District of Columbia recently held that CMS exceeded its authority by reducing Medicare payment rates for 340B drugs, but because of the budget-neutral nature of the cuts, the court left implementation details of its order temporarily unresolved to avoid disrupting administration of the Medicare Hospital Outpatient Prospective Payment System. At this time, it is unclear what remedies the court will ultimately order and whether CMS will appeal the decision. Noting that neither party thoroughly addressed the question of remedies in their briefs, the court ordered supplemental briefings on the issue of remedies from both parties. The briefings are due to the court within 30 days of the December 27 ruling, after which the parties will each have two weeks to respond to one another's briefs. The court will then make a ruling on the issue of remedies. Depending on how this shakes out in the next few months, Congress may decide to intervene through legislation.

## NEXT WEEK'S DOSE

As the shutdown drags on, anticipated regulatory action may be delayed, as many Office of Management and Budget staff remain furloughed.

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