

# 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:** The 2019 legislative session has come to an end. Lawmakers reached a deal to fund the government through fiscal year (FY) 2020, the House of Representatives impeached President Trump, and a federal appeals court issued a highly anticipated ruling with implications for the Affordable Care Act (ACA).

## CONGRESS

- + **CONGRESS PASSED FY 2020 SPENDING DEAL.** The \$1.4 trillion spending package includes two bills that fund the government through the remainder of FY 2020. [H.R. 1158](#) funds the departments of Defense, Homeland Security, Commerce, Treasury and Justice, as well as the Internal Revenue Service and the National Science Foundation. It passed the House by a vote of 280-138 and the Senate by a vote of 81 to 11. [H.R. 1865](#) passed the House by a vote of 297-120 and the Senate by a vote of 71-23. It funds the departments of Education, Health and Human Services (HHS), Interior, Labor, State, Agriculture, Transportation, Veterans Affairs, Energy and Housing and Urban Development, as well as water projects, the Food and Drug Administration (FDA), congressional operations and military construction projects. It also includes a handful of healthcare policies, including an extension of many expiring healthcare programs, a permanent repeal of certain ACA taxes, and raises the tobacco purchasing age to 21. Additionally, the spending package also includes the CREATES Act, which that allows a biosimilar or generic-drug manufacturer to sue in federal court for an injunction to obtain samples it needs from the product's manufacturer to create generic alternatives. Read our complete summary of the spending package and what's next for 2020 [here](#).
- + **INVESTIGATION ON SURPRISE BILLING PRACTICES.** On Thursday, Energy and Commerce Committee Republican Leader Greg Walden (R-OR), Chairman Frank Pallone, Jr. (D-NJ), and Senate Health Education Labor and Pensions (HELP) Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) announced [a bipartisan investigation](#) into surprise billing practices of physician staffing companies and top insurers. Letters were sent to several organizations requesting information on in-network and out-of-network reimbursement rates, practices to protect beneficiaries from surprise medical bills, and network adequacy information. Surprise billing will remain a hotly debated health policy topic as we enter 2020.

## ADMINISTRATION

- + **ADMINISTRATION ISSUED DRUG IMPORTATION RULE.** The [proposed rule](#) would allow states to import certain prescription drugs from Canada and includes draft guidance to let pharmaceutical companies import their own drugs intended for distribution abroad. The proposed rule for states only applies to drugs that meet FDA labeling standards and safety requirements, and excludes controlled substances, biologics and intravenous drugs. The guidance allowing drug companies to import their own products, on the other hand, applies to any brand-name drug approved in the US. Several states have expressed support for the importation policy, and Florida, Maine, Colorado, Vermont and New Hampshire already have importation plans in place, pending implementation of the rule. However, some patient safety groups have raised concerns about the government's ability to guarantee the safety of imported drugs, and the rule is almost certain to face legal challenges from some pharmaceutical companies that oppose it.
- + **ADMINISTRATION PROPOSED TWO RULES TO INCREASE ORGAN TRANSPLANTS.** In response to President Trump's July [Executive Order on Advancing American Kidney Health](#), HHS issued two proposed rules aimed at increasing the availability of organs for transplant. The [Removing Financial Disincentives to Living Organ Donation](#) proposed rule would add lost wages, childcare and elder care expenses to the list of reimbursable expenses for living organ donors. The [Organ Procurement Organization \(OPO\) Conditions for Coverage](#) proposed rule would implement new performance standards for OPOs, organizations that procure organs from hospitals and deliver them to transplant centers, and establish more frequent oversight by the Centers for Medicare and Medicaid Services (CMS). OPOs would be required to disclose the number of organs transplanted, not just procured, which HHS says will incentivize them to ensure all viable organs are transplanted. Both proposed rules will undergo a 60-day comment period.

## COURTS

- + **COURT ISSUED RULING IN *TEXAS V. AZAR*.** In a highly anticipated verdict, a federal appeals court ruled that the ACA's individual mandate is unconstitutional, but did not invalidate the entire law, as some had feared. Last year, a federal district judge in Texas held that because Congress eliminated the individual mandate penalty as part of the Tax Cuts and Jobs Act of 2017, the individual mandate was unconstitutional and not severable from the rest of the law, rendering the entire ACA unconstitutional. The ruling this week affirmed the district court's decision that the individual mandate was unconstitutional, with little practical effect given that Congress already zeroed out the penalty, but did not address the question of the ACA's validity without the mandate. The appeals court remanded the case back to the district court with instructions for the lower court to reconsider its prior decision as to which parts of the ACA can still stand. The partial ruling changes the trajectory of the case, which was expected to come before the Supreme Court early next year had the appeals court ruled the entire law was unconstitutional. However, the California Attorney General Xavier Becerra, who is leading the group of Democratic-led states defending the ACA, has said they plan to appeal directly to the Supreme Court. Currently, it is unclear if the Supreme Court will take up the appeal or the timing of a Supreme Court ruling on the matter before the 2020 election. As a result, there is still uncertainty regarding the ACA's future, particularly its

protections for people with preexisting conditions. The ACA remains in effect while the legal battle continues.

- + **HOSPITALS AND CMS CONTINUED BATTLE OVER SITE-NEUTRAL CUTS.** A federal district court has denied a request from hospitals to block CMS from enacting so-called site-neutral payment cuts next year. In September, the district court ruled that CMS overstepped its authority when it implemented a payment cut for certain off-campus hospital facilities as part of its 2019 Medicare Hospital Outpatient Prospective Payment System (OPPS) [final rule](#). Following the ruling, CMS announced that it will reimburse hospitals for the 2019 payment cut beginning in January of next year, but will continue with the second year of the site-neutral policy in 2020. CMS has appealed the court ruling regarding the 2019 cut and simultaneously argues that the ruling has no bearing on the 2020 policy, which was included in the [2020 OPPS rule](#). Hospitals asked the district court to apply the ruling to the 2020 cut as well, but the judge this week responded that the court does not have jurisdiction over the 2020 rule since it has not yet taken effect. However, the judge noted that CMS is relying on the same argument to defend the 2020 cuts that it did to defend the 2019 policy, and the hospitals will likely prevail in their legal challenge once they have standing.

## QUICK HITS

- The Senate Judiciary Committee [examined](#) the government's response to the opioid crisis. Read our summary of the hearing [here](#).
- CMS extended the 2019 open enrollment period on [healthcare.gov](#) through December 18, following reports that technical issues prevented some consumers from enrolling in coverage by the original December 15 deadline.
- CMS updated its [Drug Spending Dashboards](#) with new features and 2018 data. The dashboards offer researchers information on average spending for prescription drugs under Medicare Parts B and D and Medicaid, and track spending trends over time.
- CMS announced states selected to receive funding under the [Maternal Opioid Misuse Model](#) and issued cooperative agreements for the [Integrated Care for Kids Model](#). The models aim to combat opioid misuse among expectant mothers and improve care for children impacted by the crisis.
- Kentucky's newly elected Democratic governor will roll back the state's Medicaid work requirement, the first ever approved by the Trump Administration. A case concerning the legality of the Kentucky work requirement and similar requirements in Arkansas is currently pending before a federal appeals court, but Kentucky submitted paperwork asking the court to dismiss the case as moot.

## M+ RESOURCES

- + The latest episode of the [Health Policy Breakroom](#) breaks down what you need to know about CMS's Direct Contracting payment model.

## NEXT WEEK'S DOSE

Congress adjourns for the holiday recess. We'll be back in the New Year

For more information, contact [Mara McDermott](#) or [Rachel Stauffer](#).

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