

Health Policy Update - July 24, 2019

Senate Finance Committee Releases Drug Pricing Package

On July 23, Senate Finance Committee Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) introduced their long-awaited drug pricing package, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Among other provisions, the bill would establish a maximum add-on payment for Part B drugs, cap price hikes beyond the rate of inflation in both Medicare Part B and Part D, and make significant changes to the Part D benefit structure. It would also temporarily boost payments for biosimilars and advance site neutral payments for drug administration. According to the Congressional Budget Office (CBO), the bill is estimated to save beneficiaries \$27 billion in out-of-pocket costs and \$5 billion in premiums. The Senate Finance Committee will hold a markup of the package on Thursday, July 25.

To read a summary of the package and the press statement, [CLICK HERE](#).

CMS Proposes Mandatory Radiation Oncology Bundled Payment Model as Head of CMMI Announces Departure

On July 10, the Centers for Medicare & Medicaid Services (CMS) released a mandatory bundled payment model for radiation oncology that would replace Medicare's fee-for-service payments in certain geographic areas. The proposed Radiation Oncology (RO) model would base prospective payments to providers on a 90-day episode of care model.

According to CMS, the bundled pay model is designed to test whether prospective, site neutral, episode-based payments for radiotherapy episodes of care would reduce Medicare expenditures while preserving or enhancing care for Medicare beneficiaries. The proposed model, which is slated to begin on either January 1 or April 1, 2020, would last for five years and be implemented by the Center for Medicare & Medicaid Innovation (CMMI).

The radiation oncology model was announced alongside several other models pertaining to kidney care and end-stage renal disease. On the day CMS unveiled the new proposals, Adam Boehler, director of CMMI, announced he would be stepping down from the agency. On July 10, it was announced that President Donald Trump selected Boehler to be CEO of the U.S. International Development Finance Corp, a federal nomination that requires Senate confirmation.

To read a CMS fact sheet about the proposed Radiation Oncology model, [CLICK HERE](#).

To visit CMMI's dedicated site for the model, [CLICK HERE](#).

Judge Blocks HHS Rule Requiring Drug Companies to List Prices in TV Ads

On July 8, the United States District Court in the District of Columbia ruled the Department of Health and Human Services (HHS) exceeded its regulatory authority by seeking to require all pharmaceutical companies to include the list price of any drug that costs more than \$35 a month in their television commercials to consumers. The rule, which was slated to go into effect in early July, was one of President Trump's priority policies for making the drug pricing process more transparent and prescription drugs more affordable. The lawsuit was brought by a group of pharmaceutical companies who argued the proposed rule would violate the companies' First Amendment rights, though the Court did not rule on this issue. Instead, it concluded HHS overstepped its authority in seeking to implement this rule.

To read the United States District Court of the District of Columbia's ruling, [CLICK HERE](#).

Administration Abandons Proposal to Eliminate Certain Drug Rebates

On July 10, the Trump Administration's drug-pricing plans saw another change in policy when the Administration withdrew a proposed rule to ban many of the rebates drug companies pay to pharmacy benefit managers under Medicare. The rule, which was announced in January and designed with the goal of encouraging pharmaceutical companies to lower their list prices, was originally touted as one of the Administration's highest priority proposals. However, Congressional Budget Office (CBO) projections showed the rule could cost the federal government roughly \$177 billion in the next decade, and other policy experts worried the rule would lead to higher premiums for Medicare beneficiaries.

To read the CBO's report on the proposed rebate rule, [CLICK HERE](#).

HHS Secretary Azar Shifts Position on Drug Importation

On July 11, Department of Health and Human Services Secretary Alex Azar announced he believes it is possible to safely import prescription drugs, marking a significant shift from earlier statements. Noting that technological changes have "opened the door to safe approaches" to importation, Azar suggested importation could be done safely, which could help lower the cost of prescription drugs. Four states (Florida, Vermont, Colorado, and Maine) have passed drug importation laws, but the HHS Secretary must certify that importation is safe and saves money before it can occur. Meanwhile, an FDA study group tasked with studying the issue has yet to issue its report on importation.

CMS Releases Quality Payment Program Results

On July 11, the Centers for Medicare & Medicaid Services released data on participation and bonuses for the Quality Payment Program in 2018. According to the agency, the number of participants in Advanced Alternative Payment Models grew significantly last year compared to 2017, increasing to more than 183,000 from just below 100,000.

However, total participation in the in the Merit-Based Incentive Payment System (MIPS) fell between 2017 and 2018 even as the number of eligible clinicians participating grew to 98% last year, up from 95% in 2017. This is likely due to the fact CMS excluded more clinicians from MIPS in 2018, raising the threshold for participation to \$90,000 or higher in annual Medicare revenue plus 200 or more Medicare patients, up from \$30,000 and fewer than 100 Medicare patients in year one. CMS estimated the change would leave out about 134,000 clinicians. Meanwhile, the number of practices receiving positive payment adjustments grew 11 percentage points over that same time period.

Both MIPS and Advanced APMs were introduced in 2015 as a part of the Medicare Access and CHIP Reauthorization Act (MACRA) and are intended to incentivize cost reductions and increases in quality among providers participating in the Medicare program. However, the program has come under criticism from providers – especially small and rural ones – who argue participation in the programs creates a significant time and paperwork burden and requires expensive investments in administrative tools such as EHRs.

To view a blogpost from CMS on the results, [CLICK HERE](#).

Federal Appeals Court Hears Arguments on the Constitutionality of the Affordable Care Act

On July 9, the U.S. Fifth Circuit Court of Appeals heard oral arguments on the Constitutionality of the Affordable Care Act (ACA) in the case of Texas v. Azar, a suit brought by 18 state attorneys general against the law. The Fifth Circuit court is hearing the case after U.S. District Court Judge Reed O'Connor ruled last year the entire ACA is now unconstitutional after Congress repealed the individual insurance mandate in 2017.

The ACA's defenders include a coalition of Democratic state attorneys general led by California and the Democrat-controlled House of Representatives which has been granted intervenor status in the case. The Trump Administration also weighed in against the law, filing a brief earlier this year on the behalf of the plaintiffs.

While the judges have yet to make a decision, it is possible that case will make it to the Supreme Court after the Fifth Circuit ruling.