

Health Policy Update – August 20, 2019

CMS Issues National Coverage Determination for CAR-T Therapy

On August 7, CMS finalized a new rule to provide Medicare coverage of Chimeric Antigen Receptor T-cell (CAR-T) therapy.

According to agency's final National Coverage Determination (NCD), Medicare will pay for CAR-T in all facilities that follow the FDA's risk evaluation and mitigation strategies (REMS) safety rules rather than just hospitals, as had been indicated in the draft rule. Medicare will cover CAR-T for all FDA-labeled indications and off-label uses recommended by CMS-approved compendia, and the proposed coverage with evidence development requirement was eliminated in the final rule.

There are currently two CAR-T therapies on the market, Yescarta (Gilead) and Kymriah (Novartis), which are approved to treat non-Hodgkin lymphoma and acute lymphoblastic leukemia, respectively. Prior to the NCD, coverage for CAR-T therapy was determined by regional Medicare administrators.

To read the NCD, [CLICK HERE](#).

To read CMS' statement on the NCD, [CLICK HERE](#).

ASP Coalition Commends Senate Finance Committee Members for Opposing IPI

On August 7, the Part B Access for Seniors and Physicians (ASP) Coalition sent letters to 14 members of the Senate Finance Committee who voted in favor of a measure to block the International Pricing Index model. The vote came during the Committee's consideration of drug pricing legislation, and the amendment ultimately failed on a tie vote of 14-14. The letters encourage the Senators to continue fighting to protect critical access to Medicare Part B drugs.

"Thank you for standing up to defend patients, physicians and hospitals from this wide-scale demonstration that could fundamentally alter the Part B program," the groups wrote. "We look forward to continuing work with you to halt implementation of this model and find actionable solutions that put patients first."

Lawmakers commended by the coalition include Sens. Thomas Carper (D-DE), Bill Cassidy (R-LA), John Cornyn (R-TX), Mike Crapo (R-ID), Steve Daines (R-MT), Michael Enzi (R-WY), Johnny Isakson (R-GA), James Lankford (R-OK), Rob Portman (R-OH), Pat Roberts (R-KS), Tim Scott (R-SC), John Thune (R-SD), Patrick Toomey (R-PA), and Todd Young (R-IN).

To learn more about the ASP Coalition, [CLICK HERE](#).

To view the ASP Coalition letters, [CLICK HERE](#).

John O'Brien, Senior Advisory to the Secretary on Drug Pricing Reform, to Leave HHS

On August 12, John O'Brien, one of the leading policymakers involved with drafting the Administration's blueprint to lower prescription drug costs, announced he will be leaving the Department of Health and Human Services (HHS); his last day is August 22. HHS Secretary Alex Azar announced that John Brooks, principal deputy director of the Center for Medicare, will take over for O'Brien.

"John O'Brien's time at HHS will leave a legacy of lasting improvements to American healthcare, including the way that Americans pay for prescription drugs," Azar said in a statement. "From the beginning of President Trump's administration, John led policy research, analysis and development on a number of important issues, including strengthening the Medicare program for our seniors and addressing the effects of the Affordable Care Act. Later, he turned his attention and deep expertise to prescription drug pricing. Prices and out-of-pocket costs are lower, and will go lower still, because of the work we did to execute on President Trump's American Patients First blueprint."

To read Secretary Azar's statement, [CLICK HERE](#).

GAO Report Finds Part D Drug Rebates Growing Fast; PBMs Give Nearly All Rebates To Plan Sponsors

On August 13, the Government Accountability Office (GAO) released a new report that found rebates and other types of price concessions grew faster than Part D expenditures between 2014 and 2016. The report, titled "Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization," showed gross expenditures - the amount paid to pharmacies by plan sponsors, or by the pharmacy benefit managers (PBMs) on their behalf, and by the beneficiary - grew by 20 percent during this time period, while rebates and other price concessions increased 66 percent, to \$29 billion – 20 percent of 2016 gross expenditures.

Price concessions and retroactive fees that PBMs charge pharmacies grew by more than 300 percent from 2014 through 2016, accounting for 7 percent of the \$29 billion total. While rebates have grown significantly, the GAO report found that PBMs retained less than 1 percent of these rebates, passing the rest to plan sponsors. Ultimately, the bulk of PBMs' revenues generated under Medicare Part D came from volume-based fees paid by plan sponsors on PBM-focused claims.

To read the GAO report, [CLICK HERE](#).

UnitedHealth Group Analysis on Rising Cost of Hospital Care

On August 12, UnitedHealth Group released a new analysis finding consumers and employers are paying significantly more for hospital-based inpatient services largely because of rising hospital prices, adding to the growing body of literature that suggest hospital prices are the largest driver of healthcare spending in the U.S. The researchers found that between 2013 and 2017, hospital prices for inpatient services increased by 19 percent (roughly 4.5% per year), while physician prices for the same category of inpatient services increased by just 10 percent (roughly 2.5% per year) during the period. During that same time frame, patients' utilization of inpatient services actually decreased by 5 percent. The report noted that the U.S. could save \$250 billion over the next decade by moderating hospital price increases for all inpatient services by 2 percent per year between 2020 and 2029.

To read the new UnitedHealth Group analysis, [CLICK HERE](#).