Health Policy Update – February 25, 2020

New Rule Would Enable Medicare Part D Plans to Create Preferred Specialty Drug Tiers to Help Lower Out-of-Pocket Costs

On February 5, the Centers for Medicare & Medicaid Services (CMS) released the CY 2021/ 2022 Medicare Advantage and Part D proposed rule, which would enable Part D plans to create a new "preferred" specialty drug tier with lower cost-sharing than the current specialty tier. The current maximum cost-sharing threshold (25 percent or 33 percent depending on whether the plan has a deductible) would still apply to the plan's highest, non-preferred specialty tier. The move is meant to incentivize drug manufacturers, who typically prefer lower patient cost-sharing for their drugs, to offer higher rebates in order to have their drugs included in the new tier.

The rule also proposes requiring Part D plans to disclose to CMS the measures they use to evaluate pharmacy performance in their network agreements. CMS is accepting comments on the proposed rule through April 6, 2020.

To read the proposed rule, **CLICK HERE**.

To read CMS' factsheet on the proposed rule, **CLICK HERE**.

Secretary Azar Defends Administration Budget Request Before Senate Finance Committee

On February 13, Department of Health and Human Services (HHS) Secretary Alex Azar testified before the Senate Committee on Finance on the Administration's fiscal year 2021 budget.

Prescription drug pricing was one of the most highly discussed topics and Secretary Azar was specifically asked if the Administration supports the bipartisan Prescription Drug Pricing Reduction Act of 2019 (S.2543). In response to that question Secretary Azar responded, "We've been very deeply engaged with the Democrats and Republicans on this committee to advance the Grassley-Wyden legislation."

Though the President called on Congress during the State of the Union Address to pass a bipartisan bill to lower drug costs, the Administration's budget request was ambiguous as to whether it specifically supported the Grassley-Wyden bill. The bill passed the Senate Finance Committee last year but has yet to gain enough support to pass the full Senate. A number of Republicans have expressed concern over the inclusion of a provision requiring drug manufacturers to pay rebates if their drug costs raise faster than the rate of inflation.

Secretary Azar will also appear before the House Appropriations Labor-HHS-Education Subcommittee and the House Energy and Commerce Health Subcommittee on Wednesday, February 26 and House Ways and Means Committee on February 27 to testify on the HHS budget request.

To view the Senate Finance Committee hearing, **CLICK HERE**.

CMS Leader Hints at Reforming Prior Authorization Requirements

On February 11, the Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma announced that the agency plans to make changes to prior authorization requirements this year during a speech at the American Medical Association's National Advocacy Conference in Washington D.C.

Though Administrator Verma highlighted the frustration many patients and providers feel towards prior authorization policies, she offered few details of the policies CMS is looking to change. One idea she mentioned, but did not elaborate on, was the potential for automation to improve efficiencies in the process. While she said prior authorization is an important tool for utilization management, the current prior authorization process has become “indefensible” in practice because it creates needless delays that negatively impact patient care, while increasing administrative burdens for physicians.

"The Trump administration is once again ready to take action to support doctors and patients and we will reduce administrative waste, increase patient safety and free physicians to spend time caring for their patients," Verma said during the speech.

To read the full remarks made by Administrator Verma, **CLICK HERE**.

CMS Releases Proposed Three-Year Extension of Comprehensive Care for Joint Replacement Model

On February 20, CMS issued a proposed rule that would extend the Comprehensive Care for Joint Replacement (CJR) demonstration for three years for certain hospitals. The CJR model has been in operation since April 2016 and is currently scheduled to end on December 31, 2020. According to CMS, the model “aims to reduce expenditures while preserving or enhancing quality of care by supporting better and more efficient care for beneficiaries undergoing the most common inpatient surgeries for Medicare beneficiaries: hip and knee replacements (also called lower extremity joint replacements or LEJR).” Each LEJR episode is defined as the surgical hospitalization through 90-days post hospital discharge and includes all Medicare-covered items and services. The model is mandatory for hospitals in 34 randomly selected metropolitan statistical areas (MSAs) and voluntary for hospitals in 33 MSAs.

Under the proposed rule, CMS would make changes to the following aspects of the CJR Model: incorporating outpatient hip and knee replacements into the episode of care definition, the target price calculation, the reconciliation process, the beneficiary notice requirements, gainsharing caps, and the appeals process. The three-year extension would only apply to hospitals required to participate in the demo. The proposed changes would be effective beginning with CJR episodes that end on or after January 1, 2021. CMS is accepting comments on the proposed rule through April 24, 2020.

To read the proposed rule, **CLICK HERE**.

To read CMS’ factsheet on the proposed rule, **CLICK HERE**.

Report Shows Americans with Employer Coverage Saw Growth in Drug Spending That Outpaced Other Medical Costs

On February 13, the Health Care Cost Institute (HCCI) released a report on spending, price and utilization trends for commercially insured Americans in 2018.

In examining more than 2.5 billion medical and prescription drug claims for 40 million people with employer health coverage under the age of 65, HCCI found Americans with private employer health insurance experienced a sharp increase in prescription drug spending (nearly 26%) between 2014 and 2018. Overall, HCCI found that spending per person, utilization and average price all rose substantially faster for prescription drugs than any other service category including inpatient care, outpatient care and professional services. During the same period, the average price of a medicine purchased by each employee rose by almost 21 percent and their usage rose more than 4 percent, according to the researchers.

Total expenditures for healthcare have also increased, according to the report. In 2018, per-person spending increased to $5,892 (including amounts paid for medical and pharmacy claims but excluding manufacturer rebates for prescription drugs), while average out-of-pocket spending increased to $907 per person. Compared to 2014, prices in 2018 were a full 15 percent higher due to years of annual healthcare spending growth—even though spending per person has slowed.

To read the complete report, **CLICK HERE**.

Commentary Highlights Forthcoming Expansion of Biosimilars

A commentary published in Oncology Letters earlier this month by Sofia Konstantinidou, Angeliki Papaspiliou and Eleni Kokkotou of the National and Kapodistrian University of Athens in Greece argues that the number of oncology biosimilars entering the market will expand significantly in the coming years.

The authors highlight that by 2023, the patents on 20 oncology biologics will expire which will open the door for dozens of new biosimilars to enter the global market over the next several years and could therefore substantially reduce costs.

Further, the authors note that since the FDA and European Medicines Agency (EMA) launched their biosimilar regulatory and approval process, enough data has accumulated to demonstrate that biosimilars have no clinically meaningful differences in purity, safety, and efficacy compared to their respective reference products. However, they also note that because biosimilars are not identical to their reference products physicians and practices have been generally slow to adopt their use in the oncology field. The authors call for more education about the safety and efficacy of biosimilars as well as the collection of long-term safety data to improve their acceptance and use in cancer treatment.

To read the commentary, **CLICK HERE**.