Health Policy Update - June 2, 2020

COVID-19 Update: HHS Extends Compliance Deadline for Provider Relief Funds & House Passes Revisions to Paycheck Protection Program

The U.S. Department of Health and Human Services announced May 22 that it was extending the deadline for recipients of provider relief funds to accept payment terms and conditions by an additional 45 days. Providers will now have 90 days from the date of receipt to accept these terms in order to keep the funds they received from the Provider Relief Fund which was established by the bipartisan Coronavirus Aid, Relief, and Economic Security (CARES) Act and Paycheck Protection Program and Health Care Enhancement Act.

Additionally, on May 28, the House of Representatives passed H.R. 7010, the Paycheck Protection Program Flexibility Act. The bill makes several revisions to the Paycheck Protection Program, including extending the timeline for businesses to spend loan money and still qualify for loan forgiveness from 8 weeks to 24 weeks, extending the June 30 rehiring deadline to December 31, and reducing the requirement that 75 percent of the loan dollars be spent on payroll expenses to 60 percent. H.R. 7010 passed the House by a vote of 417-1, but consideration in the Senate is uncertain at this time.

Separately, the House Committee on Oversight & Government Reform held a video briefing with HHS Principal Deputy Inspector General Christi Grimm to discuss the OIG's April report that showed hospitals across the country were facing significant resource challenges related to the pandemic including shortages of testing supplies, PPE, and other critical medical supplies. The briefing also covered the agency's other efforts to review and report on the Administration's coronavirus response, including testing, the Strategic National Stockpile, the health and safety of HHS employees, and the Department's emergency preparedness plans.

To view HHS' announcement of the PRF deadline extension, **CLICK HERE**.

To read a press release on H.R. 7010 from the bill sponsor's office, CLICK HERE.

To view the House Oversight Committee Briefing, **CLICK HERE**.

To view a complete list of HHS OIG's planned oversight work, CLICK HERE.

CMS Finalizes MA and Part D Final Rule, Delays Changes to Drug Program

On May 22, the Centers for Medicare & Medicaid Services (CMS) released the Contract Year 2021 Medicare Advantage (MA) and Part D Final Rule. Among other provisions in the final rule, CMS aims to strengthen network adequacy rules for MA plans by codifying the existing network adequacy methodology and finalizing new policies to provide support for more plan options in rural areas. CMS is also encouraging MA plans to increase their telehealth benefits by giving them more flexibility to count telehealth providers in certain specialty areas (Dermatology, Psychiatry, Cardiology, Ophthalmology, Nephrology, Primary Care, Gynecology, Endocrinology, and Infectious Diseases) towards meeting CMS network adequacy standards.

CMS noted that it was finalizing the above policies before the MA and Part D plan bids for the 2021 plan year were due on June 1, 2020, and would address remaining proposals not included in the final rule in subsequent rulemaking due to the demands created in response to the ongoing COVID-19 pandemic. This includes proposals to create a new Part D

specialty tier with lower cost-sharing, pharmacy performance measurement reporting, and electronic real-time benefit tools. CMS plans to address the remaining proposals later in 2020 for the 2022 plan year.

To read a CMS press release on the new rule, CLICK HERE.

To read a CMS fact sheet on the new rule, **CLICK HERE**.

CMS Announces Plan to Lower Medicare Out-of-Pocket Costs for Insulin

On May 26, the Centers for Medicare & Medicaid Services (CMS) announced that more than 1,750 standalone Medicare Part D prescription drug plans and Medicare Advantage plans with prescription drug coverage have applied to offer lower insulin costs through the Part D Senior Savings Model for the 2021 plan year. Through the voluntary model, which was unveiled by the Trump Administration in March, Medicare beneficiaries will be able to access insulin this year with a maximum monthly copay of \$35.

According to CMS, approximately one-third of Medicare beneficiaries live with diabetes, with more than 3.3 million using at least one form of insulin. Rising costs of insulin have been a major concern for Americans with diabetes in recent years. Instead of leaving seniors to pay 25 percent of the drug's cost in the coverage gap out of pocket—as required by previous policy—the new policy announced by CMS would incentivize plans to offer fixed, predictable copays for Medicare beneficiaries. According to CMS estimates, the new policy would lower seniors' out of pocket costs by an average of 66 percent or \$446 throughout the year.

To read the CMS press release on the out of pocket maximum for insulin, CLICK HERE.

To read more about the Part D Senior Savings Model, CLICK HERE.

Report Finds Insurers Rarely Favor Biosimilars over Reference Biologics

On May 19, the Journal of the American Medical Association (JAMA) published a research letter that analyzed how commercial health plans cover biosimilars relative to reference products. Out of 535 coverage decisions made by 17 of the largest commercial health plans in the United States, insurers required patients to first try biosimilars just 14 percent of the time before trying brand name biologics. The results of the study underscore the slow growth in utilization—and difficulties in gaining access to insurance coverage—for biosimilars, which have the potential to reduce healthcare costs and spending.

In one-third of all coverage decisions examined, the researchers found that the country's largest health plans favored brand-name medicines only, while they extended preferred coverage to both biologics and biosimilars in 53 percent of decisions. Yet, 10 of the United States' biggest insurers did not offer preferred coverage to a single biosimilar, while only 2 plans made biosimilars a preferred choice at least half of the time. The 17 plans examined by the researchers represent 60 percent of Americans covered by commercial health plans.

Despite the abbreviated licensure pathway for biosimilars that Congress created in 2010, the study suggests that there are still lingering barriers that disincentivize or prevent commercial insurers from covering biosimilars. While more research is needed to identify those barriers, one of the study's authors suggests that rebate traps—a practice in which brand name manufacturers try to maintain preferred coverage by extending aggressive rebates—could be one possible factor.

To read the study in JAMA, CLICK HERE.