

Health Policy Update – November 5, 2019

Michigan State Legislature Rejects Proposed CAR-T Regulation

Last week, the Michigan state legislature voted to overturn a proposal from the Michigan Certificate of Need (CON) Commission that would have required any site of care to receive CON Commission approval before providing CAR-T cell therapy to patients. This is a victory for cancer patients and community-based practices, as this was the first proposal to require CON approval for a pharmaceutical therapy and had the potential to delay, limit, or prevent sites from providing cellular therapies across the state.

A variety of stakeholders opposed the regulation of cellular therapy under the CON Commission, including The US Oncology Network, the American Cancer Society Cancer Action Network, Cancer Support Community, International Myeloma Foundation, Lymphoma Research Foundation, American Red Cross, Community Oncology Alliance, as well as the biopharmaceutical community and many national and local conservative groups.

CMMI Extends Oncology Care First Model Comment Deadline to December 13

On Friday, November 1, the CMS Center for Medicare and Medicaid Innovation (CMMI) released an informal request-for-information (RFI) on a potential Oncology Care First (OCF) model, largely expected to be the successor to the Oncology Care Model (OCM). CMS is seeking feedback on the potential new OCF model which would be voluntary and build on lessons learned from the OCM. The potential OCF model would test whether holding model participants accountable for total cost of care and offering them predictable revenue streams through an alternative payment mechanism improves care while reducing Medicare expenditures. The potential OCF model would have three risk tracks, including a one-sided risk track and two tracks with two-sided risk; both of the OCF two-sided risk tracks would qualify as Advanced APMs. The agency anticipates the OCF model would start in January 2021, when no new episodes would be initiating in the OCM.

CMS held a public listening session on the model on November 4, and the submission deadline for written feedback is November 25, 2019.

To learn more about the proposed OCF model, [CLICK HERE](#).

House Passes Two PBM Transparency Bills

Last week, the U.S. House of Representatives unanimously passed two bills to improve pharmacy benefit manager (PBM) transparency. The first bill, the Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act (H.R. 2115) sponsored by Representative Abigail Spanberger (D-VA) would require the Department of Health and Human Services make public aggregate rebate data from Medicare and Affordable Care Act (ACA) exchange plans on a drug-class level. It would also require Medicare Part D plans to incorporate real-time benefit tools to inform patients about drugs costs and their cost-sharing responsibility by 2021.

The Payment Commission Data Act of 2019 (H.R. 1781), sponsored by Rep. Buddy Carter (R-GA), would give the Medicare Payment Advisory Commission (MedPAC) and Medicaid and CHIP Payment and Access Commission (MACPAC) access to drug pricing and rebate data to help policymakers better understand how the drug market works.

To view the Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act (H.R. 2115), [CLICK HERE](#).

To view the Payment Commission Data Act of 2019 (H.R. 1781), [CLICK HERE](#).

Floor Vote on House Drug Pricing Bill Postponed

While the full House was initially expected to vote on Speaker Pelosi's drug pricing bill in late October, House leadership has delayed the vote as they work to appease both moderate and progressive Democrats. The bill, also known as H.R. 3, would allow the federal government to negotiate the prices of certain drugs, among other provisions. It went through an extensive mark-up period in the House Energy & Commerce, Education & Labor, and Ways & Means Committees last month which exposed divisions within the House Democratic caucus over how far the bill should go.

Additionally, the Congressional Research Service (CRS) issued a memo last week suggesting certain provisions of H.R. 3 could be unconstitutional. The memo, which did not reach a definitive conclusion on the constitutionality of the bill, questioned whether the bill's excise taxes on drug manufacturers who do not reach an agreement with the government qualify as "excessive" fines under the Eighth Amendment. The memo also notes that the portion of the bill that empowers the Department of Health and Human Services to negotiate drug prices, could run afoul of the "Takings Clause" of the Fifth Amendment, which prevents the government from taking private property – in this case lost revenue from drug manufacturers – without "just compensation."

On October 30, it was reported that the White House is withholding its support for Speaker Pelosi's drug pricing proposal in favor of a bipartisan reform package that passed the Senate Finance Committee last month.

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

HHS Delays Primary Care First Model to 2021

On October 24, the Department of Health and Human Services announced that it will delay the start of the Primary Care First payment model until January 2021, pushing it back a full year from its proposed start date of January 2020. The new payment model, which aims to reward physicians in small practices for delivering value-based care, was delayed giving stakeholders more time to consider whether they want to participate as well as to allow providers additional time to move away from the fee-for-service model.

Under Primary Care First, participating physicians will receive a set fee per patient that will be adjusted based on whether the practice can meet certain quality outcomes. Physicians could see their Medicare payments increase as much as 50 percent each quarter or decrease by up to 10 percent. The model would also increase payments to physicians that care for a high portion of complex, chronically ill or seriously ill patients.

For more information about Primary Care First, [CLICK HERE](#).

Representative Greg Walden, Ranking Member of House E&C Committee, Announces Retirement

On October 28, Representative Greg Walden (R-OR), the Ranking Member on the House Energy & Commerce Committee, announced he will retire from Congress at the end of his term. Congressman Walden has served in Congress since 1999 and as the leading Republican on the Committee since 2017. As Chairman, Rep. Walden played a significant role in Republicans' efforts to roll back the Affordable Care Act (ACA) and pass the Right To Try Act.

According to media reports, the Republicans vying to replace Rep. Walden on the Energy & Commerce Committee include Reps. Bob Latta (R-OH), Michael C. Burgess, MD (R-TX), Cathy McMorris Rodgers (R-WA) and Brett Guthrie (R-KY).

New Report Finds Hospital Consolidation Raises Prices; UnitedHealthcare Implements Site of Service Medical Necessity Reviews for HOPDs

On October 24, the Georgetown Center on Health Insurance Reforms released a new report that analyzed strategies private insurers and employer-purchasers use to limit healthcare costs and how these strategies are affected by increased provider consolidation.

The report, which examined six mid-sized healthcare markets that recently experienced provider consolidation, found that hospital systems are "empire-building" and used their larger size following mergers to seek higher reimbursement rates, including through "all-or-none" contracting. In addition, out of fear of backlash from employees, limited evidence of savings, and potentially negative news stories, employers have refused to support insurance companies' approaches to exclude high-priced providers from their plan networks, roll out narrow networks, or use tiered benefit designs. While the researchers argue that anti-trust policies have had limited impact to slow or stop the negative effects of consolidation, some state-level efforts to limit provider prices are showing promise.

In related news, UnitedHealthcare recently expanded prior authorization requirements and site of service medical necessity reviews for certain surgeries in an effort to shift surgical procedures to less expensive locations. The policy, which will take effect in November, will empower UnitedHealthcare to only pay for surgeries in hospital outpatient departments (HOPDs) if it determines that the site of service is medically appropriate.

To read the Georgetown Center on Health Insurance Reforms report, [CLICK HERE](#).

To read the UnitedHealthcare health bulletin on the site of service policy change, [CLICK HERE](#).

FDA Releases New Report on Drug Shortages

On October 29, the U.S. Food and Drug Administration (FDA) released a new report that analyzed the underlying factors behind drug shortages and recommended solutions for addressing the issue.

The report identified three root causes for drug shortages:

- a lack of incentives for manufacturers to produce less profitable drugs;
- a failure of the market to recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues; and
- logistical and regulatory challenges that make it difficult for the market to recover from a disruption.

The report also recommended several solutions to address drug shortages, including:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (e.g., with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

To read *Drug Shortages: Root Causes and Potential Solutions*, [CLICK HERE](#).