Health Policy Update – August 24, 2021

President Biden Delivers Prescription Drug Pricing Speech, Urges Congress to Pursue Medicare Negotiation in Reconciliation Bill

In an August 12th speech from the East Room of the White House, President Biden outlined a series of proposals for addressing the high cost of prescription drugs and called on Congress to include these reforms in the upcoming budget reconciliation bill.

In addition to calling for a cap on beneficiary out-of-pocket costs, penalties for drug companies that raise prices faster than inflation, and allowing states to import lower-cost drugs from Canada, President Biden also publicly backed a plan to allow Medicare to negotiate prices for drugs that currently don't face generic competition and endorsed a policy that would impose a 95% excise tax on drug manufacturers that refuse to partake in price negotiations or offer their products at a Medicare-acceptable price. This provision is currently part of the Elijah E. Cumming's Lower Drug Costs Now Act – more commonly known as H.R. 3 – which passed the House of Representatives in 2019 and is one of the components Democratic lawmakers may include in the reconciliation bill.

Notably, Biden's speech stopped short of supporting the use of "march-in rights," in which the government aims to leverage drug company patents in price negotiations, and excluded any mention of using international reference pricing as a benchmark for negotiations. A Trump Administration rule that would have implemented international reference pricing was withdrawn by the Biden Administration earlier this month.

To view President Biden's speech, CLICK HERE.

To view the latest White House talking points on drug pricing, CLICK HERE.

CMS Leaders Outline the Future of Value-Based Care

In a blog post published by *Health Affairs* on August 12, top officials at the Centers for Medicare and Medicaid Services (CMS) outlined a vision for the future of value-based healthcare that relies on fewer, but more impactful, payment models and a greater focus on equity.

Authored by CMS Administrator Chiquita Brooks-LaSure, Centers for Medicare and Medicaid Innovation (CMMI) Director Elizabeth Fowler, Center for Medicare Director Meena Seshamani and Center for Medicaid & CHIP Services Director Daniel Tsai, the blog post presents a 10-year retrospective on CMS' payment model programs.

The authors state that, according to CMS' own strategic review, of all the payment models that have

been launched in the 10 years since CMMI was established, only 6 have generated statistically significant savings for Medicare while 4 have met the requirements to be expanded in duration and scope. From this experience, CMS identified the following key takeaways to guide the development and implementation of future payment models:

1. The Innovation Center should make equity a centerpiece of every model.
2. Offering too many models is overly complex, particularly when models overlap.
3. The Innovation Center needs to re-evaluate how it designs financial incentives in its models to ensure meaningful provider participation.
4. Providers find it challenging to accept downside risk if they do not have tools to enable and empower changes in care delivery.
5. Challenges in setting financial benchmarks have undermined our models' effectiveness.
6. Innovation Center models can define success as encouraging lasting transformation and a broader array of quality investments, rather than focusing solely on each individual model's cost and quality improvements.

These strategies build on remarks agency leaders have made in recent months. In June, CMMI Director Fowler said in an interview that her agency was looking to streamline payment models, require more mandatory participation and hasten Medicare's transition away from fee-for-service. The Medicare Payments Advisory Commission (MedPAC) has also come out in favor of fewer models and advocated for a smaller and more targeted suite of models in its June 2021 report.

To view the *Health Affairs* blog post, CLICK HERE.

Biden Administration Recommends COVID-19 Vaccine Booster Shots

On August 18, the Biden Administration announced plans to provide COVID-19 booster shots to Americans who have already received two full doses of mRNA vaccines in order to help address the challenges posed by the highly infectious Delta variant. The joint statement, issued by public health and medical experts at the Department of Health and Human Services, said the department will be prepared to offer booster shots for all Americans beginning the week of September 20. The plan is still subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer/BioNTech and Moderna mRNA vaccines and CDC's Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence.

Speaking at a White House briefing, Dr. Vivek Murthy, the U.S. Surgeon General, said that vaccines become less effective over time and that American adults who have already received a two-dose regimen, including seniors and healthcare providers, should consider receiving a third dose about eight months after their second dose. The announcement - which was echoed by Dr. Rochelle Walensky, Director of the Centers for Disease Control and Prevention, Jeffrey Zients, the White House Coronavirus Response Coordinator, and Dr. Anthony Fauci, the Chief Medical Adviser to President Biden - comes as COVID-19 infections are again surging nationwide.

In making the new recommendations, federal health officials pointed to three new studies that were

published in CDC's Morbidity and Mortality Weekly Report on August 18 that suggest COVID-19 vaccines produce less protection from infection over time, including in nursing homes and against the Delta variant. That said, they noted that vaccines' effectiveness against severe disease, hospitalization and death from COVID-19 remains relatively high.

The Biden Administration also announced it would require nursing home staff to be vaccinated against COVID-19 as a condition for Medicare and Medicaid reimbursement. This federal mandate follows an announcement requiring federal employees and contractors to be vaccinated, including the U.S. military. Medical and religious exemptions are available under these policies, though weekly mandatory testing may be required for the unvaccinated or those who decline to disclose vaccination status.

On August 23, the FDA granted full approval to the Pfizer/BioNTech vaccine – the first to reach the milestone. Previously, the vaccine was conditionally approved under an emergency use authorization.

To read the Joint Statement from HHS, CLICK HERE.

To read the CDC's Morbidity and Mortality Weekly Report studies that helped inform the booster shot decision, CLICK HERE, HERE, and HERE.

HHS Yet to Issue Hospital Fines for Price Transparency Rule Noncompliance as PCMA, Chamber, Sue

Last week a CMS spokesperson confirm the agency has yet to issue fines for noncompliance with the price transparency rule finalized in January. Though the Biden Administration recently proposed increasing penalties for hospitals who fail to comply with the price transparency provision, to date, CMS has only issued warning letters, roughly 165 as of last month. Several analyses have suggested hospital noncompliance exceeds 90%.

On the same day, researchers released a new study that examines the hospital price transparency rule in practice to better understand its impact on hospital behavior and prices. Examining colonoscopy pricing disclosures, researchers found that just 28% of all general acute care hospitals disclosed their commercial negotiated prices, though the price transparency rule had been in effect for 7 months at the time of the analysis. Moreover, median prices that were disclosed had high variation. Approximately 60% of hospitals reported median prices for colonoscopies that were below $1,500, while the top 10% of the disclosing hospitals reported median prices of at least $3,677, roughly 5 times the national average Medicare reimbursement for the procedure. Half of the top 10% high-price hospitals were concentrated in just 7 states: Illinois, California, Ohio, Kentucky, Virginia, Indiana, and South Dakota.

In related news, the Pharmaceutical Care Management Association (PCMA) and the U.S. Chamber of Commerce filed separate lawsuits against the HHS to block implementation of a new insurance price transparency rule.

The complaint lodged by the PCMA alleges that the price transparency rule must not be

implemented because it would prevent pharmacy benefit managers (PBMs) from negotiating drug prices directly with manufacturers, thereby increasing the price of certain drugs. By allowing drug manufacturers and their competitors to publicly view information about the size of PBM rebates, concessions, and discounts, the trade association for the PBM industry argued that pharmaceutical companies would begin to cut back on concessions. Meanwhile, the U.S. Chamber of Commerce suit argues that HHS went well beyond its statutory authority in adopting the rule and that would require payers to post internal, proprietary data on a website in a "machine-readable" format, describing it as arbitrary, capricious, and difficult for consumers to understand.

To read the PCMA complaint, CLICK HERE.

To read the U.S. Chamber of Commerce complaint, CLICK HERE.

Merck Requires Hospitals to Share Claims Data to Receive 340B Discounts
Access

Merck announced last week that it will now require hospitals to report claims data from contract pharmacies in order to receive discounts through the 340B Drug Discount Program, a move the company said is needed to prevent hospitals from claiming duplicate discounts. Previously, Merck – along with other pharmaceutical companies including Novartis and Sanofi – had a voluntary "program integrity" initiative. Starting September 1, 2021, unless the hospital lacks its own in-house pharmacy and designates a single contract pharmacy of its choice, Merck will not honor 340B program discounts.

Merck's new policy exempts federal grantees who participate in the 340B program, such as Ryan White clinics and federal qualified health centers, from having to report claims data as a condition of receiving the discounts.

340B hospitals and their advocates criticized the decision. "Drug companies should not impose conditions on hospitals eligible for 340B discounts, including demanding access to patients' drug claims," Maureen Testoni, CEO and president of the advocacy group 340B Health told Fierce Healthcare. "Merck's leaders should withdraw their threat and continue to abide by the law." Merck argues that participation in the 340B program does not require discounts to be provided to contract pharmacies.

In May, the Health Resources and Services Administration (HRSA) warned six drug makers - Eli Lilly, AstraZeneca, Novartis, Novo Nordisk, Sanofi and United Therapeutics - that their attempts to cut off discounts to contract pharmacies violated federal law. The HHS general counsel issued an advisory opinion near the end of the Trump Administration stating drug manufacturers must provide the discounts, regardless of how many pharmacies hospitals have contracts with. In response the drug manufacturers sued.

This summer, a federal court in Delaware allowed a lawsuit brought against the policy by AstraZeneca to move forward, rejecting the Biden Administration's request to have the case

dismissed. HRSA later withdrew the advisory opinion but announced that it still plans to enforce fines on drug manufacturers who fail to provide discounts through contract pharmacies, claiming the opinion was unnecessary for enforcement.