Holland & Knight

H&K Health Dose May 3, 2022

A weekly dose of healthcare policy news

COVID-19 Relief Funding

Lawmakers continue to negotiate a $43 billion package that includes $33 billion in relief to Ukraine and $10 billion for COVID testing, treatment, and vaccines. Senate Democrats want to combine both funding packages to streamline the process. Given disagreements over tying Title 42 restrictions to the package, how leadership will proceed remains unclear. The Biden administration recently announced that it would rescind the policy, which allows the White House to restrict immigration based on public health concerns, by May 23. That decision has been challenged in court, with a federal judge in Louisiana issuing a temporary restraining order against the phasing out of Title 42. Notably, only the Senate is in session this week. However, with a few Democratic Senators out with COVID-19 a vote likely won't take place this week in the Senate, and the House is on a one-week district work period.

User Fee Agreements & Other Health Priorities in the House

The current legislative authority for the user fee programs expires at the end of FY 2022 on September 30, 2022; Congress often seeks to pass reauthorization legislation well before the September 30 deadline to avoid disruptions to agency operations. Accordingly, the Energy and Commerce Committee will release the text tomorrow morning. The bipartisan bill will be officially introduced on Friday during a pro forma session. A subcomittee markup will take place next Wednesday (May 11), with full committee action the following Wednesday (May 18). The goal is to be on the House floor by June. Next week's markup will include a separate Advanced Research Projects Agency for Health (ARPA-H) bill, a mental health package, the Gabriella Miller cancer bill, and Salvation Heart Health Awareness.

Healthy Future Task Force Releases Set of Treatment Recommendations

The Treatment Subcommittee of the GOP's Healthy Future Task Force released its key findings and policy solutions to promote new life-saving cures and lower drug costs. Treatment Subcommittee's plan recommends:

- Passage of H.R. 19, the *Lower Costs, More Cures Act;*
- Building off bipartisan proposals that allow for innovations in paying for curative therapies;
- Offering incentives for health plans to share drug discounts with patients directly at the pharmacy counter;
- Speeding up the Food and Drug Administration approval process to bring more treatments to patients quickly;
- Expanding and speeding up Medicare coverage for breakthrough drugs and devices;
- Giving seniors access to new, innovative blood tests to diagnose cancers earlier;
- Banning the use of quality-adjusted life years from all coverage and payment decisions;
- Making clinical trials more widely available;
- Incentivizing domestic medical manufacturing of therapies and therapeutics to prepare for the next pandemic;
- Promoting sufficient supply of testing and personal protective equipment; and
- Ensuring secure access to critical ingredients for medicine.

CMS Releases Final 2023 Medicare Advantage (MA)/Part D Rule

On Friday, April 29, CMS issued the contract year 2023 MA and Part D final rule. The rule takes effect June 28, 2022. Highlights are listed below. More information can be found in the CMS press release and fact sheet.

- **Pharmacy discounts-** Part D plans will now be required to pass on pharmacy discounts at the point of sale starting Jan. 1, 2024, which is expected to reduce out-of-pocket expenses for beneficiaries.

- **Health disparities-** CMS announced several new requirements to address health disparities, including requiring MA special needs plans to annually assess social risk factors and reaffirming existing requirements for plans to inform enrollees about free interpreter services.

- **Dual eligibles-** CMS specifies that out-of-pocket limits for dual eligibles will be based on Medicare cost-sharing regardless of whether another payer such as Medicaid paid and whether the cost-sharing remains unpaid. The agency also created a slate of integrated materials for dual eligibles to understand their benefits under both programs better.

- **Transparency and oversight-** CMS will enhance oversight by considering additional criteria when determining whether allowing plans to renew or expand, including poor past quality performance, enhancing oversight of MA provider networks, requiring reporting of underlying data to verify medical loss ratio calculations, and expanding this requirement to MA supplemental benefits plans, and increasing oversight of third party marketing of MA plans.

- **Preparing for future health crises-** CMS finalized several new policies to preserve consistent access to health services for MA beneficiaries during future disasters and public health emergencies.

- **Quality reporting-** CMS finalized several changes, including metric-level changes to accommodate COVID-19 related data disruptions and separate D-SNP star ratings from MA star ratings to enhance transparency.

CMS Finalizes 2023 Benefit and Payment Parameters for Marketplace Plans

CMS also finalized its Notice of Benefit and Payment Parameters for 2023. Overall, the rule aims to strengthen coverage requirements and help consumers more easily navigate and compare plan options. Specific highlights are included below. More information can be found in this CMS fact sheet.

- **Standardized plan options-** If a marketplace issuer offers a non-standardized plan, it must now submit a standardized option within the same service area.
- **Network adequacy-** CMS will conduct reviews to ensure all states are meeting federal network adequacy requirements. Starting in 2023, plans will be required to contract with at least 35% of essential community providers in a given region (up from 20%). Starting in 2024, HHS will monitor wait times and may consider specialty-specific time and distance standards.
- **Actuarial Value (AV) Ranges-** CMS tightened AV requirements, including for individual market silver plans, which will likely increase premium tax credits.
- **Health equity-** CMS refined its nondiscrimination policy to ensure all benefit designs are grounded in clinical evidence and is requiring plan issuers to address disparities within their quality improvement strategies. The agency is developing a separate proposed rule to address health coverage discrimination based on sex.
- **Special enrollment verification-** CMS rolled back eligibility verification requirements for special enrollment periods to avoid deterring enrollment.
- **Quality and risk adjustment-** CMS will require five new data elements, including zip code, race, and ethnicity, and clarified that indirect quality improvement expenses might not count towards medical loss ratios.
- **Transparency of third-party websites-** Independent websites must prominently display their rationale for recommending specific health plans and may not offer plan's preferred placement in exchange for compensation.

FDA Sets June Dates to Review COVID-19 Vaccines

On Friday, the FDA announced three tentative dates in June (8, 21, and 22) to review Pfizer and Moderna COVID-19 vaccines for children under 5. Moderna applied on Thursday for its vaccine to be authorized in children as young as six months old but must follow up with additional data from real-world clinical trials. Pfizer is awaiting final data that proves its new three-dose regimen for that age group is sufficiently effective.

GAO Calls on Federal Agencies to Have More Specific COVID-19 Recovery Goals

In a new report, the U.S. Government Accountability Office (GAO) made 15 recommendations to improve COVID-19 payment oversight, public health data collection, manufacturing of critical health supplies, and other critical pandemic response categories. Among other cross-agency recommendations included in the more than 400-page report, GAO recommends that the Office of Management and Budget (OMB) require federal agencies to certify the reliability of submitted improper payment data, and recommends the CDC Director detail more specific goals for COVID-19 surveillance and data modernization efforts along with detailed action steps, time frames, and assessment metrics.

FDA Revamps Office of Product Evaluation and Quality as Path Forward for Reimbursing FDA-Approved Breakthrough Devices Remains Unclear

On May 2, the FDA announced a new organizational structure within its Office of Product Evaluation and Quality, including two new offices and two new divisions. The two new offices will focus on in vitro diagnostics and radiological products. The first new division will focus on total lifecycle analysis and policy development for devices and products plus industry forecasting; the second will focus on real-world and post-market studies.

Meanwhile, CMS officials remained guarded about a specific timeline for an expedited coverage pathway for FDA-approved breakthrough technologies after the Agency nixed such a plan approved under former President Trump that would have provided immediate coverage. The agency did offer insights into potential strategies, including an overhaul of benefit categories, a public dashboard for determination updates, streamlined data collection, and more transparent standards around "medically necessary and reasonable" and real-world evidence requirements. However, the agency acknowledged that some or all of these changes might require support from Congress.

MIPS 2022 Extreme and Uncontrollable Circumstances Portal Now Open

CMS is now accepting applications for MIPS extreme and uncontrollable circumstances for the 2022 performance year. Applications will be accepted through Dec. 31. More information can be found here.