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Senate HELP Committee Marks Up User Fee Bills

On Tuesday, the Senate Committee on Health, Education, Labor, and Pensions (HELP) conducted a markup of five bills, most notably S. 4348, the Food and Drug Administration (FDA) Safety and Landmark Advancements (FDASLA) Act. All five bills were approved by the Committee, with FDASLA adding several amendments. The included amendments covered lowering drug prices and improving innovation, expediting access to generic and biosimilar drugs, improving access to infant formula, requiring conflict of interest disclosures when consulting with the FDA, and including patient perspectives in the rare disease therapy approval process.

Democrats on the Committee were supportive of measures that would further reduce drug prices, but were unsuccessful in attaching them to the bill due to concerns that adding them would jeopardize the bill. The user fee package now heads to the full Senate for consideration.

MedPAC Releases Annual June Report to Congress

On Wednesday, the Medicare Payment Advisory Commission (MedPAC) released its annual June 2022 Report to Congress. This year's report did not

include any formal recommendations to Congress and instead opted to provide the legislative branch with a slew of suggestions, many tied to several of their June 2021 recommendations.

In its report, the Commission (MedPAC) advocated for the streamlining of alternative payment models (APM) within the Medicare program, keeping in line with previous recommendations that the Centers for Medicare & Medicaid Services (CMS) decrease the number of Medicare alternative payment models, and design the remaining models to work together more harmoniously.

The Commission stated that while APMs give healthcare organizations financial incentive to furnish a more efficient mix of services and improve the care they deliver, "the presence of multiple [APMs] operating concurrently can create unnecessary complexity and may dilute incentives when Medicare beneficiaries are attributed to more than one model simultaneously and/or when providers participate in more than one [alternative payment model] at the same time." They suggest reducing the number of population-based payment model tracks available to providers, where a smaller number of tracks could each be geared toward provider organizations of different sizes and involve different degrees of financial risk."

Their suggestions also called for updating ACOs' benchmarks using external administrative growth factors that would be known to ACOs in advance so that incentives may be increased, as well as a national Medicare-run, episode-based payment model that would be mandatory for certain providers, as well as proven clinical episodes, such as hip and knee replacements.

The Commission also fulfilled a request from Congress to study access to care within the vulnerable Medicare population and found that using medically underserved areas (MUA) as an indicator of where to direct supplemental Medicare funding is inefficient, as the research identified similar service rates in full, partial, and non-MUAs. MedPAC researchers also concluded that dually-eligible beneficiaries and those with chronic conditions have greater health needs than non-duals and those with fewer conditions.

In its chapter on evaluating drug prices covered under Part B, the Commission noted that high launch prices of first-in-class drugs with uncertain clinical benefits must be addressed, pointing to the importance of promoting price competition for drugs with therapeutic alternatives. The Commission's report also explored the costs associated with Medicare Advantage (MA), concluding that limiting the impact of outliers in CMS' risk-adjustment model would assist in driving down costs. The Commission explained that outlier costs undercut payment accuracy and suggested that by leveraging reinsurance principles and repayments, plans can limit the impact of outlier prediction errors, and would subsequently improve the models' predictive power.

Supreme Court Rules on Hospital-Medicare Drug Payment Case

Earlier this week, the U.S. Supreme Court ruled in favor of hospitals in American Hospital Association vs. Xavier Beccera in a 9-0 decision authored by Justice Brett Kavanaugh. The case covered the 340B drug program and was brought against the Department of Health and Human Services (HHS) after the agency reduced the government's yearly Medicare payments for discounted outpatient drugs by $1.6 billion beginning in 2018, payments whose savings had helped subsidize the operations of a group of nonprofit hospitals that cater to poor and

uninsured people. The Court ruled that HHS exceeded its authority when it made the cuts, arguing that HHS can't lower its payment rates only for a certain subset of hospitals without conducting a survey first. "The question is whether the statute affords HHS discretion to vary the reimbursement rates for that one group of hospitals when, as here, HHS has not conducted the required survey of hospitals' acquisition costs. The answer is no," wrote Justice Kavanaugh. The justices also held that courts have the right to review HHS decisions on Medicare pay rates. It declined the Biden administration's call to apply the legal doctrine known as the "Chevron deference" where courts defer to federal agencies on the meaning of ambiguous statutes.

HHS Sends Guidance for Telehealth Providers to Prepare for HIPAA Compliance

On Monday, the Department of Health and Human Services (HHS) released guidance on how telehealth providers should prepare to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) health privacy law once the federal public health emergency (PHE) ends. Healthcare providers, health plans, and healthcare clearinghouses that transmit electronic health records were previously exempt from complying with HIPAA "in connection with the good faith provision of telehealth using non-public facing audio or video remote communication technologies" during the PHE. The guidance includes FAQs to help covered entities understand how they can use remote communication technologies for audio-only telehealth in compliance with HIPAA Rules post-PHE to help ensure that individuals can continue to benefit from audio-only telehealth and improving public confidence that covered entities are protecting the privacy and security of their health information.