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Senate HELP Committee Reschedules Markup of FDA User Fee Legislation

The Senate Committee on Health, Education, Labor and Pensions (HELP) has rescheduled its markup of the Food and Drug Administration (FDA) Safety and Landmark Advancements Act for Tuesday, June 14 at 10 AM EDT. The delay has been partly attributed to disputes in the chamber over the infant formula shortage, prescription drug importation and lab oversight. HELP Committee Ranking Member Senator Richard Burr (R-NC) has pushed for additional accountability measures to address the formula shortage while Senator Bernie Sanders (I-VT) is pushing for the inclusion of drug importation. The FDA Safety and Landmark Advancements Act of 2022 would reauthorize and update the user fee drug programs for the Prescription Drug User Fee Act, Generic Drug User Fee Amendments, Biosimilar User Fee Act, and the Medical Device User Fee Amendments. The bill outlines a sizable increase in estimated fees for fiscal year (FY) 2023 in comparison to the first year of the most recent UFA reauthorization in 2018. The House of Representatives passed the Food and Drug Amendments of 2022 (FDA22) reauthorizing the user fee programs by a vote of 392-28 on Wednesday.

The bill also includes several provisions aimed at amending the Federal Food, Drug, and Cosmetic (FD&C) Act to include new provisions for cosmetic and dietary supplement product oversight and to create a new risk-based framework for lab-developed testing regulation. Provisions addressing competition in the prescription drug market; the safe disposal of opioids; medical product development data; FDA hiring authorities authorized by the 21st Century Cures Act (Cures); and FDA transparency and accountability for the collection of user fees are also included.

Medicare Solvency Projections Improve in Medicare Board of Trustees' Report

The Medicare Board of Trustees released their annual report for Medicare's Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) Trust Funds. The report found that the HI Trust Fund will be depleted two years later than last year's projections, in the year 2028. Afterward, Medicare Part A is projected to only have the ability to pay 90 percent of estimated expenditures. Last year's Trustees Report estimated that the SMI Trust Fund was expected to be adequately financed for the next 10 years, while the 2022 report now finds that the SMI Trust Fund is "adequately financed into the indefinite future." This upward projection is attributed to current law that would provide a steady flow of general revenue to cover costs, as well as increases to beneficiary premiums to meet expected SMI program costs.

The Trustees note that there is no consensus regarding the impact of COVID-19 on the Trust Fund, but they are working under the assumption that it will have little long-term effects. The Trustees Report did state that HI expenditures will be lower than 2021 estimates on a short-term basis due to the pandemic. The report points to steadily rising health care costs as one of the reasons for the Fund's depletion, as well as the retirement of the baby boomer generation. The Trustees project that expenditure rates will surpass either the rate of average workers' earnings or the economy overall, and that the percentage of Medicare spending will rise from 3.9 percent of gross domestic product (GDP) in 2021 to 6.5 percent by 2096. Part B outlays were 1.9 percent of GDP in 2021 and the Trustees project that rate will grow to about 3.6 percent by 2096. Part D outlays are also anticipated to increase from 0.5 percent of GDP in 2021 to 0.8 percent in 2096. SMI revenues are expected to increase from 1.8 percent in 2021 to approximately 3.1 percent in 2096, which could place a larger strain on the Federal budget, the report notes.

The Trustees reissued a determination of projected excess general revenue Medicare funding for the fifth year in a row, triggering a Medicare funding warning. This requires the President to submit proposed legislation in response to the warning within 15 days of the Fiscal year (FY) 2024 budget and requires that Congress consider the legislation on an expedited basis.

CBO Scores $2.5 Billion Deficit Reduction from Multiple Drug Pricing Bills

The Congressional Budget Office (CBO) has released the estimated budget impact of three Senate drug pricing bills. S.1428, the Preserve Access to Affordable Generics and Biosimilars Act; S.1425, the Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act; and S.1435, the Affordable Prescriptions for Patients Act of 2021 would reform antitrust and patent enforcement laws, resulting in a combined deficit reduction of $1.9 billion over ten years. CBO also estimates that the House FDA user fee legislation would cut the deficit by $598 million due to measures promoting increased competition among generic drug production.