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### **Congress Takes Steps Toward Passage of User Fee, Mental Health Packages**

This week, both the Senate and House chambers of the United States Congress made progress on passing bills that will reauthorize user fee agreements (UFA) and programs administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). The UFAs are reauthorized every five years and represent an agreement between lawmakers, manufacturers, patients, and industry stakeholders to strike a balance between efficient product approval processes and garnering fees that advance the goals which the FDA relies on to supplement their appropriated funds. The current five-year authorization for the UFAs ends on September 30.

On Wednesday, the House Committee on Energy and Commerce held a full committee [markup](#) of six bills, with all passing out of committee and heading the House chamber for a vote. Some amendments included in the package were a

remanufacturing guidance requirement from the Food and Drug Administration (FDA), oversight of medical device shortages, patient-focused drug development, and lifting the inmate limitation on benefits under the Medicaid program. Two of the bills passed renew several mental health programs and establish an agency geared toward accelerating biomedical innovations.

Senate Committee on Health, Education, Labor, and Pension's (HELP) Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) also introduced a discussion draft this week that would reauthorize several UFAs, including 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 2023 compared to the first year of the last UFA reauthorization in 2018. The Senate HELP Committee is soliciting feedback on their discussion draft from stakeholders, due by May 22, 2022.

### **HHS Urges States to Prepare for Eventual End of PHE, Start of Medicaid/CHIP Redetermination Process**

Last week, the Department of Health and Human Services (HHS) sent a [letter](#) to state governors advising them to prepare their states for the end of the COVID-19 public health emergency (PHE), which is currently slated to last through July 15. The PHE is expected to be extended through October since federal health officials did not announce an expiration date on Monday within the 60-days' notice deadline the agency has committed to recognizing. An end to the PHE would require states to commence a Medicaid redetermination process. In 2020, Congress passed a maintenance-of-effort requirement to prevent beneficiaries from losing coverage during COVID-19. Despite this, some stakeholder groups are concerned that over 16 million Medicaid and CHIP beneficiaries could lose coverage once HHS terminates the PHE. State Medicaid agencies will have 14 months to complete the determination process, though HHS's letter notes that states can maintain certain PHE flexibilities to ease the potential coverage losses. Specifically, HHS outlined that suspending premiums, limiting cost-sharing, increasing provider payments, and altering provider enrollment requirements can mitigate the impact of redetermination on beneficiaries.

CMS will hold the first of a monthly series of webinars with stakeholders on May 25 to prepare for the restart of the Medicaid/CHIP redetermination process once the public health emergency (PHE) ends and states are no longer required to maintain continuous coverage. The [webinar](#) will provide background information on the Medicaid continuous enrollment requirements, efforts underway to connect people to coverage, discuss strategies to engage people with Medicaid & CHIP, and review resources currently available for partners to begin sharing information on preparing for the Medicaid and CHIP redetermination process.

### **Medicare Makes Changes to Website to Improve Usability**

The Centers for Medicare & Medicaid Services (CMS) made updates to its Medicare.gov website on Wednesday to improve transparency for consumers. The site's new features include more detailed information on Medigap policies and plan costs and improved tools for comparing and selecting drug coverage. New messages on the homepage highlight the information most requested by Medicare beneficiaries, people nearing eligibility, or their family members. The agency has

stated that more improvements are planned for the next few months that will streamline the Medicare Plan Finder and Medicare Account landing pages.



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