



H&K Health Dose: June 14, 2022

A weekly dose of healthcare policy news

Legislative Updates

House Passes User Fee Legislation; Senate Moves Next

Last week, the [House of Representatives passed its version](#) of the U.S. Food and Drug Administration (FDA) user fee legislation. The bill includes reforms to the accelerated approval process and incorporates the [Pre-approval Information Exchange \(PIE\) Act of 2022](#). The PIE Act would authorize pharmaceutical manufacturers to exchange certain clinical or economic information with payers regarding new drugs prior to approval by the FDA. Overall, the House legislation differs from the Senate version, which may require changes to the House bill during reconciliation.

The Health, Education, Labor and Pensions (HELP) Committee is scheduled to markup the Senate's bipartisan bill today. The Committee released the [latest version](#) on June 12, along with an updated [section-by-section summary](#). Sen. Bernie Sanders (I-Vt.) has stated that he plans to offer an amendment to allow for the importation of prescription drugs during the markup. The current user fee authorization will expire at the end of the fiscal year on Sept. 30, 2022.

Senate Reaches Bipartisan Agreement on Gun Violence Framework

Senate negotiators have reached a bipartisan framework on a narrow set of gun safety measures. The framework was announced on June 12 by Sens. John Cornyn (R-Texas), Chris Murphy (D-Conn.), Thom Tillis (R-N.C.), Kyrsten Sinema (D-Ariz.), Richard Blumenthal (D-Conn.), Roy Blunt (R-Mo.), Cory Booker (D-N.J.), Richard Burr (R-N.C.), Bill Cassidy (R-La.), Susan Collins (R-Maine), Chris Coons (D-Del.), Lindsey Graham (R-S.C.), Martin Heinrich (D-N.M.), Mark Kelly (D-Ariz.), Angus King (I-Maine), Joe Manchin (D-W.Va.), Rob Portman (R-Ohio), Mitt Romney (R-Utah), Debbie Stabenow (D-Mich.) and Pat Toomey (R-Pa.). A number of these senators are working on the Senate Finance Committee's mental health legislation. The framework is expected to also include a national expansion of community behavioral health centers, school mental health expansions and telemental health policies, as well as grants to states to enact red flag laws. It would also expand the nation's background check system to include juvenile records for any prospective gun buyer under age 21. Senate Majority Leader Chuck Schumer (D-N.Y.) has pledged to put the legislation up for a vote once the agreement is finalized.

The House passed its package of gun control measures in a 223-204 vote last week. Only five Republicans voted in support of the legislation, which would raise the minimum age to purchase semiautomatic rifles from 18 to 21, restrict the sale of large-capacity ammunition magazines and set federal standards for the safe storage of firearms. The House also passed a bill to allow federal courts to temporarily confiscate guns from individuals deemed by a judge to pose a threat to themselves or others.

Quick Bites:

- House Appropriations Chair Rosa DeLauro (D-Conn.) [announced](#) the committee's schedule for Fiscal Year (FY) 2023 spending bills. Subcommittee reviews are set to begin June 15, followed by full committee markups of each of the 12 annual appropriations bills. The committee is expected to conclude its FY 2023 review by June 30, with potential floor votes in July.
- Rep. David Kustoff (R-Tenn.) will replace former Rep. Tom Reed (R-N.Y.) on the House Ways and Means Committee. Reed's spot as ranking member of the Social Security Subcommittee will be filled by Rep. David Schweikert (R-Ariz.).



- The Senate confirmed Samuel Bagenstos to serve as general counsel for the U.S. Department of Health and Human Services (HHS) last week. Bagenstos will inherit approximately 4,500 active lawsuits involving HHS, including litigation over vaccine mandates, surprise medical billing and the 340B drug pricing program.
- The Congressional Budget Office (CBO) released scores for three major drug pricing reform bills, as well as the budgetary effects of the House user fee legislation for 2023 through 2027: [S. 1435 \(cbo.gov\)](#), [S. 1428 \(cbo.gov\)](#), [S. 1425 \(cbo.gov\)](#) and [H.R. 7667 \(cbo.gov\)](#). The three drug pricing bills would reduce the federal deficit by a combined \$1.9 billion over 10 years.

Regulatory Updates

FTC Launches Multi-Pronged Deep Dive into Pharmaceutical Drug Prices

Last week, the Federal Trade Commission (FTC) [voted unanimously](#) to order the six largest pharmacy benefit managers (PBMs) to provide documents and information regarding their business practices. The FTC listed several PBM practices that will be the focus of the inquiry:

- impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients
- prevalence of prior authorizations and other administrative restrictions
- complicated and opaque methods to determine pharmacy reimbursement
- use of specialty drug lists and surrounding specialty drug policies
- methods to steer patients toward PBM-owned pharmacies
- fees and clawbacks charged to unaffiliated pharmacies
- whether vertical integration impacts non-affiliated pharmacies
- potentially unfair audits of independent pharmacies

Next, the FTC and U.S. Department of Justice (DOJ) will hold a joint two-day session on how pharmaceutical mergers affect competition. On June 16, the FTC will host an open meeting on drug rebates and costs. The Commission is also starting a formal inquiry into pharmacy benefit manufacturers, which FTC Chair Lina Khan said have "enormous influence" over the prescription drug system. As part of this effort, the Commission will collect data and aim to shed more light into pricing practices.

First Price Transparency Fines Issued

Last week, two Georgia hospitals became the first to be penalized for failing to disclose prices under the new price transparency rules that have been in effect since 2021, but more fines could soon be coming. The Centers for Medicare & Medicaid Services (CMS) has issued more than 350 warning letters, and a CMS spokesperson says nearly half of those healthcare facilities are still non-compliant. According to a [recently published analysis](#) by the *Journal of the American Medical Association (JAMA)* based on data from more than 5,200 hospitals from July to September 2021, only 6 percent of hospitals surveyed displayed a comprehensive list of prices for all hospital services and a list of shoppable prices for common services, both of which are required. The maximum potential fine [was raised](#) to \$2 million last year. The penalties for the two Georgia hospitals totaled just over \$1 million.



HHS Announces National Competition to Boost Primary Care Access

HHS [has announced](#) the launch of the [Building Bridges to Better Health: A Primary Health Care Challenge](#), a national competition with a total of \$1 million in cash prizes to encourage innovation through technical assistance to health centers. Competition participants will accelerate the development of low-cost, scalable solutions to help Health Resources and Services Administration (HRSA)-supported community health centers improve patient access to primary care and strengthen the link between health care and social services.