



H&K Health Dose: July 11, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: Busy July Ahead of August Recess

The U.S. House of Representatives and U.S. Senate are both coming off a two-week recess and are facing lengthy to-do lists. Congress has less than 12 legislative days until the August district period commences, and lawmakers are racing to consider must-pass legislation, including appropriations bills, the National Defense Authorization Act (NDAA) reauthorization, the Federal Aviation Administration (FAA) reauthorization and the farm bill, among a slew of other reauthorizations with Sept. 30, 2023, due dates.

PAHPA Reauthorization Inches Closer

As Sept. 30, 2023, quickly approaches, both chambers of Congress continue to work toward reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA). The House Committee on Energy and Commerce's Subcommittee on Health is expected to mark up its version of the reauthorization bill on July 13, 2023, despite lingering disagreement regarding whether provisions addressing drug and medical device shortages should be considered as a part of the reauthorization. Recently, Rep. Richard Hudson (R-N.C.), introduced three separate bills (H.R. 4419, H.R. 4420 and H.R. 4421), which seek to reauthorize PAHPA-related programs. Democrats on the panel continue to push for the inclusion of drug shortage measures as a part of the reauthorization bill. Ranking Member Frank Pallone (D-N.J.) supports giving the U.S. Food and Drug Administration (FDA) new authorities to combat the shortages. Republicans support a narrower reauthorization package, saying it will ease the chances of passing a reauthorization bill before the current all-hazards and public health security programs expire. Over the next few weeks, PAHPA language will be fine-tuned, and members of Congress are likely also trying to attach additional provisions on items of importance.

Meanwhile the Senate Committee on Health, Education, Labor and Pensions (HELP) released a bipartisan [discussion draft](#) last week. Chair Bernie Sanders (I-Vt.) and Ranking Member Bill Cassidy (R-La.) were able to come to an agreement on major provisions of the discussion draft, but their version is similarly running into partisan hurdles that must be overcome. Differences remain on several prescription drug pricing and drug development voucher provisions. Democrats are pushing to cap the cost of any product developed with the support of the Centers for Disease Control and Prevention (CDC) or the Biomedical Advanced Research and Development Authority (BARDA) at the lowest price among G7 countries – U.S., U.K., Canada, France, Germany, Italy and Japan. Republicans are seeking the reauthorization and expansion of the priority review voucher program at the FDA. The GOP proposal aims to incentivize the development of more medical countermeasures (MCMs) by providing a new, nontransferable priority review voucher to companies that develop new MCMs on top of the transferable voucher they currently receive and by including threats to the Armed Forces within the program. The committee sought feedback on certain partisan policies that are still undergoing negotiations. The HELP Committee hopes to mark up the bill this month.

Schumer Lays Out Priorities for the Senate

Marking the end of the July Fourth recess, Senate Majority Leader Chuck Schumer (D-N.Y.) outlining his priorities for the work period in a [Dear Colleague](#) letter. Among others listed were the goals of making progress on bipartisan legislation that would lower the costs of prescription drugs and insulin and promote community health. The Community Health Center Fund must be reauthorized by Sept. 30, 2023. The House Committee on Energy and Commerce passed a package that included the reauthorization back in May 2023. Passage in the Senate has turned into more of a sticking point; Chair Sanders has proposed a major expansion of community health centers and is pushing for a massive increase in funding.



REGULATORY UPDATES

MPFS/OPPS Proposed Rules Forthcoming

We anticipate that the 2024 Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rules will be released this week. As always, Holland & Knight will publish summaries of these proposed rules and answer any questions you may have regarding their impact on your organizations.

HHS OIG Releases Long-Awaited Information Blocking Penalty Final Rule

On June 27, 2023, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) posted its [final rule](#) implementing information blocking penalties. The rule comes three years after the HHS' Office of the National Coordinator for Health Information Technology (ONC) issued a [final rule](#) that defined and clarified the scope of the information blocking provisions of the 21st Century Cures Act (the [Information Blocking Rule](#)). The OIG Final Rule is effective Aug. 2, 2023; however, enforcement of the information blocking penalties will begin on Sept. 1, 2023. Importantly, OIG will not impose information blocking CMPs for conduct occurring prior to Sept. 1, 2023.

Per the statutory penalties created by the 21st Century Cures Act, if OIG determines that an individual or entity has committed information blocking, that individual or entity may be subject to a penalty of up to \$1 million per violation. The OIG press release can be found [online](#). The rule applies to health IT developers of certified health IT, entities offering certified health IT, health information exchanges and health information networks.

Stakeholders are still awaiting a proposed rule outlining "disincentives" for providers that engage in information blocking.

Inflation Reduction Act Revised Guidance

The Centers for Medicare and Medicaid Services (CMS) released its revised [guidance](#) on implementing the Inflation Reduction Act's "Medicare Drug Price Negotiation Program" on June 30, 2023. CMS also issued the text of the [agreement](#) and an updated proposed Information Collection Request (ICR) for data to be submitted by manufacturers and other stakeholders as part of the negotiation process. The ICR is not yet final, with comments due by Aug. 2, 2023. The final guidance creates the blueprint for how CMS will run the price negotiation process for its first year, which will begin when CMS announces by Sept. 1, 2023, the first 10 drugs selected for negotiation. The revised guidance includes some key changes to assuage stakeholders' concerns about how negotiation-eligible drugs will be selected or accepted from the process and clarify what factors the agency will consider to determine final negotiated prices, among other updates. Notably, the final guidance relaxes the proposed requirement that pharmaceutical manufacturers not disclose information about price negotiations. It also removes the confidentiality policy's data destruction requirements. These changes will result in the government no longer considering such materials confidential.

CMS Proposes 2024 Home Health Payment Updates

CMS recently issued its proposed rule for the Calendar Year (CY) 2024 Home Health Prospective Payment System (PPS) on June 30, 2023. The Home Health PPS provides a standardized case-mix and area-wage adjusted payment to home health agencies over 30-day periods. For CY 2024, CMS is proposing a 2.2 percent decrease in home health payments, relative to CY 2023. CMS estimates that Medicare payments will decrease by \$375 million in CY 2024. CMS also is proposing changes to provider and supplier enrollment policies. The rule will establish a provisional period of enhanced oversight for new providers and suppliers, shorten the Medicare billing privilege deactivation period and expand the definition of "managing employees" for Medicare enrollment applications. Additionally, the rule would allow CMS to resume criminal background checks for certain providers and suppliers who were exempted during the COVID-19 public health emergency.



Stakeholders have until Aug. 29, 2023, to submit their comments on the proposal. Additional details are available on the CMS [website](#).

Labor, HHS and Treasury Release New No Surprises Act and Transparency in Coverage FAQs

The U.S. Department of Labor (DOL), U.S. Department of the Treasury and HHS released a set of [frequently asked questions \(FAQs\)](#) on July 7, 2023, related to surprise billing under the No Surprises Act (NSA). The new FAQs are fairly technical in nature and try to address issues with facility fees and potentially conflicting requirements under the NSA and previous limitations on cost-sharing under the Affordable Care Act (ACA). The departments state they are monitoring the potential implications of facility fees and that facility fees must be included as part of the good faith estimate to uninsured/self-pay individuals as well as the price comparisons required by the Transparency in Coverage (TiC) Final Rule that require plans and issuers to make information available to participants, beneficiaries and enrollees. The remaining FAQs cover the definition of "participating" and "nonparticipating" providers from the NSA as it relates to the maximum out-of-pocket (MOOP) limit defined by the ACA. The departments clarify that services provided by nonparticipating providers are considered out-of-network in terms of the MOOP limit. Moreover, providers that have a contractual relationship with a health plan but are not considered in-network for the MOOP limit cannot be deemed participating providers under the NSA.

RFI on Medical Financing Products

The Consumer Financial Protection Bureau (CFPB), HHS and the Treasury Department issued a [request for information \(RFI\)](#) on July 7, 2023, related to medical credit cards, loans and other financial products used to pay for healthcare. In addition to questions in the RFI around the potential for consumer harm, potential distortion of provider incentives and more, HHS included its own set of questions related to how medical payment products have intersected with federal health programs (like Medicare and Medicaid), federal laws against healthcare fraud and abuse, and ACA and NSA protections. This RFI has a 60-day comment period.

HHS Proposed Rule Distinguishing STLDI from Comprehensive Plans

CMS, the Treasury Department and DOL released a [notice of proposed rulemaking](#) on July 7, 2023, on short-term limited-duration insurance (STLDI) and fixed indemnity insurance. As described in the [fact sheet](#), the proposed rule would change the definition of STLDI. The agencies said the proposed definition amendments would limit STLDI plans to a coverage term of no more than three months and a maximum duration of no more than four months, cutting back sharply on the up-to-36-month maximum duration allowed for these insurance policies under the Trump Administration rule finalized in 2018.

CMS Proposes Returning \$9 Billion to More than 1,600 Hospitals; All OPDS Hospitals Face 16 Years of 0.5 Percent Cuts

On July 7, 2023, CMS released the [Hospital OPDS: Remedy for 340B-Acquired Drugs Purchased in Cost Years 2018-2022](#) to address how the agency will restore payments to hospitals affected by a 2017 rulemaking to cut reimbursement amounts on 340B drugs to certain hospitals paid under the OPDS. For a detailed look at the proposal, see Holland & Knight's alert, "[CMS Proposes Returning \\$9 Billion to More Than 1,600 Hospitals](#)," July 11, 2023. This proposed rule is responsive to a U.S. Supreme Court opinion finding that the 2018 payment cuts were inconsistent with CMS' authority to set Medicare payments to hospitals for outpatient drugs. Notably, the Supreme Court left open the question of the appropriate remedy. Accordingly, the Proposed Rule outlines a potential remedy for cuts to 340B payments from 2018, when the cuts began, to 2022, when the cuts were blocked. The rule provides \$9 billion for hospitals that received a cut in 340B payment from 2018 through 2022. However, to maintain budget neutrality, CMS proposes reducing future nondrug item and service payments by adjusting the OPDS conversion factor by minus 0.5 percent starting in CY 2025 until the full amount is offset, which CMS estimates will take 16 years. Comments are due Sept. 5, 2023.