

EDITION: May 13, 2022



COVID-19 Resources

[HLB COVID-19 Resource Center](#)

Congressional

FDA User Fee Package Released

On May 4, bipartisan leaders from the House Energy and Commerce Committee released its initial U.S. Food and Drug Administration (FDA) User Fee [legislative package](#). The [legislative package](#) reauthorizes the Prescription Drug User Fee Act (PDUFA), the Generic Drug User Fee Act (GDUFA), the Biosimilar User Fee Act (BsUFA), and the Medical Device User Fee Act (MDUFA). In addition, the agreement includes provisions on accelerated approvals, clinical trial diversity, generic drug competition and strengthening of supply chains through the FDA's inspection programs. The Committee will continue to work through this legislation into the summer, combining with the Senates efforts to pass a final package.

Administration

MA & Part D Final Rule Released

On April 29, the Center for Medicare & Medicaid Services (CMS) released the CY 2023 Medicare Advantage and Part D [Final Rule](#). The rule details marketing and communications oversight, updates to network adequacy, and greater transparency in Medical Loss Ratio (MLR) reporting among other provisions.

UPCOMING HEALTH CARE ACTIVITIES ON THE HILL

Senate HELP Committee

5/18 at 10:00am: Full Committee [hearing](#) on Cybersecurity in the Health and Education Sectors

Senate Aging Committee

5/19 at 10:00am: Full Committee [hearing](#) on Mental Health Care for Older Adults: Raising Awareness, Addressing Stigma, and Providing Support

Final NBPP Published

On April 28, CMS released its 2023 [Notice of Benefit and Payment Parameters](#) for Qualified Health Plans (QHPs) in the federally-facilitated exchange. The [rule](#) includes updates to requirements for network adequacy, risk adjustment, and special enrollment period (SEP) verification. It also includes provisions related to health equity. The rule goes into effect July 1.

CAA Implementation Proposed Rule Released

On April 22, CMS issued a [proposed rule](#) Implementing Certain Provisions of the Consolidated Appropriations Act (CAA) and updating some Medicare eligibility and enrollment rules. In addition the proposed rule implements CAA provisions extending coverage of immunosuppressive drugs for kidney transplant patients. Comments are due June 27.

IPPS Proposed Rule Released

On April 18, CMS released the FY 2023 Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospitals (LTCH PPS) [Proposed Rule](#). The [proposal](#) reflects an estimated 3.2% increase in payments as well as proposed updates related to MS-DRGs, graduate medical education (GME) proposals, uncompensated care payments, among other provisions. CMS is also soliciting comments on social determinants of health (SDOHs) and payment adjustment for domestic N95s. The proposal also includes provisions and an Request for Information (RFI) on advancing [maternal health](#) equity. Comments are due June 17.

CMS Cross-Cutting Initiatives Announced

On April 15, CMS announced new [Cross-Cutting Initiatives](#) (CCIs) intended to drive activities of the agency moving forward. The seven Strategic Pillars of this initiative include:

- [Advance Equity](#)
- Expand Access
- Engage Partners
- Drive Innovation
- Protect Programs
- Foster Excellence

Advancing health equity has been announced as the agency's first strategic pillar and CMS has detailed information on working with stakeholders to collect information and ideas moving forward. In addition to the specific pillars, CMS has indicated its CCIs aim to improve behavioral and maternal health coverage, drug price affordability, and rural health care delivery along with strengthening quality improvement strategies and ensuring coverage for eligible individuals post-

pandemic.

CMS Publishes SNF PPS Proposed Rule

On April 11, CMS released its FY 2023 Skilled Nursing Facility Prospective Payment System [Proposed Rule](#). The [proposal](#) includes payment updates, a recalibration of the Patient Driven Payment Model (PDPM) parity adjustment, and a permanent cap on wage index decreases. The proposed rule also includes requests for information (RFIs) on coding infection isolation and revising staffing requirements for Long Term Care (LTC) Facilities. Comments are due June 10.

No Surprises Act FAQ Released

On April 6, CMS released a frequently asked questions (FAQ) [document](#) for health care providers on the No Surprises Act. The document walks through requirements, exceptions, and details on the Federal Independent Dispute Resolution (IDR) process.

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