Issues for the week ending July 14, 2023

Federal Issues

Legislative

House Panel Advances PBM, Issuer, & Hospital Transparency Bills

On Wednesday, the House Committee on Education & the Workforce (E&W) advanced bipartisan legislation on a number of health care topics, including pharmacy benefit managers (PBM), hospital billing practices, and transparency requirements.

Why this matters: Nearly all House and Senate Committees with jurisdiction have now taken up some form of bipartisan transparency/PBM reform legislation, moving the issue closer to floor activity in both chambers.

Legislation passed by the E&W Committee included:

- H.R. 4507, the Transparency in Coverage Act of 2023: The bill would codify the commercial market Transparency in Coverage regulations, impose additional reporting requirements for PBMs and issuers, and require plain language public disclosures on claims denial rates and other plan policies and procedures. The bill's

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PBM and issuer reporting requirements are similar to the Senate HELP Committee-passed Pharmacy Benefit Manager Reform Act and the House Energy & Commerce Committee-passed PATIENT Act.

- H.R. 4508, the Hidden Fee Disclosure Act: Expands existing ERISA reporting requirements to fiduciaries to include specific PBM and TPA reporting requirements.

- H.R. 4509, the Transparency in Billing Act: Prohibits ERISA plans from paying claims by hospitals that do not use a unique identifier for off-campus hospital outpatient departments.

- H.R. 4527, the Health DATA Act: Establishes greater audit rights for plan fiduciaries, including the ability to audit all claims and encounters.

- **CMS Releases Expanded Report to Congress on Non-Emergency Medical Transportation**
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Federal Issues

Regulatory

Updates on COVID-19 Vaccine & Therapeutics Commercialization

The U.S. Department of Health and Human Services (HHS) held a meeting to discuss COVID-19 Medical Countermeasures Commercialization to hear from the U.S. government (USG) on the transition plans for the commercialization of COVID-19 vaccines and therapeutics, which is expected to begin in mid-to late September 2023.

The Department indicated tentative transition dates for COVID-19 therapeutics remain as previously reported:

- Lagevrio (Merck and Ridgeback's oral COVID-19 antiviral medicine): Commercialization is targeted for Q4 2023. Officials indicated there is currently "sufficient" USG supply.
- Paxlovid (Pfizer's oral COVID-19 antiviral medicine): Transition date remains TBD. Officials indicated there is currently "sufficient" USG supply, including 9.2 million doses that remain available.

Additionally, CDC issued a new HHS Commercialization Transition Guide. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted to update the COVID-19 vaccine composition, and FDA subsequently advised manufacturers they should develop updated vaccines with a monovalent XBB.1.5 composition. These vaccines will be the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market, rather than through the USG.

Uninsured Individuals: The CDC will continue to provide access to COVID-19 vaccines for uninsured individuals once commercialization takes place. Uninsured children will be able to receive COVID-19 vaccines through the existing Vaccines for Children (VFC) program implemented in 1994. Uninsured adults will also be able to receive COVID-19 vaccines through a new temporary program called the Bridge Access Program for COVID-19 Vaccines and Treatments.

Letters to Payers & to Vaccine Manufacturers: In a letter to payers, the Secretary of HHS highlighted requirements for Medicare Part B and Medicare Advantage to cover COVID-19 vaccines, noting plans should begin preparing now to ensure their systems are ready by mid- to late September to support administration of the updated COVID-19 vaccines.

- Additionally, after the government ceases to supply COVID-19 vaccines from its current stock for most children enrolled in Medicaid, the cost of COVID-19 vaccine doses is expected to be borne by the VFC program. For other Medicaid populations, and for children enrolled in CHIP, states would have to pay for COVID-19 vaccine doses after the government ceases to supply doses, but states' payments on those doses will be federally matched at 100% until September 30, 2024.

- Finally, most private health insurance products that are subject to the Affordable Care Act (ACA) market reforms are required to cover vaccines for COVID-19 that are authorized for emergency use or approved by the FDA and recommended by the ACIP, as well as and their administration, without patient cost-sharing.

In a separate letter to vaccine manufacturers, HHS urged manufactures with updated COVID-19 vaccines entering the market this fall to price them at a reasonable rate, reflective of the value that manufacturers have obtained through USG investment. They noted that price gouging behavior takes advantage of the trust the American people have placed in manufacturers through the COVID-19 response.

HHS Announces Proposed Rule to Preserve LGBTQI+ Non-Discrimination Protections

The Department of Health and Human Services (HHS) announced a Notice of Proposed Rulemaking (NPRM) that seeks to preserve non-discrimination protections for LGBTQI+ people in HHS programs.

Why this matters: Specifically, the proposed rule ("HHS Grants Rule") would clarify and reaffirm the prohibition on discrimination on the basis of sexual orientation and gender identity in federal programs and services funded and administered by HHS. The proposed rule would confirm non-discrimination protections in HHS programs, substance abuse treatment and prevention services, community mental health services, maternal and child health services, and community services.

The proposed HHS Grants Rule also includes a provision that ensures those with religious objections may seek an exemption from or modification of program requirements, as appropriate.

Comments on the new HHS Grants Rule are due 60 days after publication in the Federal Register.

CMS Releases Outpatient Prospective Payment System Proposed Rule

The Centers for Medicare & Medicaid Services (CMS) released the Calendar Year (CY) 2024 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule outlining proposed changes to the Medicare payment rates, quality reporting requirements, and other policies.

Why this matters: CMS proposes to make updates to the OPPS and ASC payment rates for hospitals that meet applicable quality reporting requirements by 2.8%. CMS also proposes to establish payment for intensive outpatient programs (IOPs) under Medicare. For CY 2024, CMS proposes to continue to apply the default rate, generally average sales price (ASP) plus 6 percent, to 340B acquired drugs and biologicals.

CMS is amending its hospital price transparency requirements to improve the agency's monitoring and enforcement capabilities, improve the usability of the provided information, and align with the Transparency in Coverage (TIC) initiative. These changes include requiring hospitals to affirm the accuracy and completeness of data in their machine-readable file (MRF), expanding the required data elements that must be included in their MRFs, requiring conformance with a specific format for the file, and revising enforcement policies.

CMS is also seeking comments on ways to improve compliance and align policies and requirements with other federal price transparency initiatives, such as the requirements on commercial market plans and issuers and the No Surprises Act (NSA).

The proposed rule is available here. Comments are due September 11.

CMS Releases Medicare Physician Fee Schedule Proposed Rule

CMS released a proposed rule that updates Medicare payment policies, reimbursement rates, and quality reporting for professional services furnished under the CY 2024 Medicare Physician Fee Schedule (PFS). See a fact sheet here. The rule will be published in the *Federal Register* on August 7. Just like the OPPS, comments are due on September 11.

Among other items, the agency proposes to:

- Implement provisions of the Consolidated Appropriations Act of 2023 that extend certain Medicare telehealth flexibilities and expand access to behavioral health services;
- Establish an add-on payment for complex office/outpatient evaluation and management (E/M) visits; and
- Codify previously finalized payment for dental services prior to, or during, head and neck cancer treatments, whether primary or metastatic; and permit payment for certain dental services inextricably linked to other covered services to treat cancer.

CMS Issues Proposed NCD for PrEP Therapy to Prevent HIV

On July 12, the Centers for Medicare & Medicaid Services (CMS) issued a proposed National Coverage Determination (NCD) that would provide Medicare coverage for Pre-Exposure Prophylaxis (PrEP) with effective antiretroviral therapy (ART) to persons at high risk of Human Immunodeficiency Virus (HIV).

Why this matters: Under the proposed NCD, Medicare would cover both oral and injectable PrEP therapies, and would pay for administration of injectable PrEP medication. CMS also proposed to cover up to 7 individual counseling visits every 12 months, including HIV risk assessment and HIV risk reduction and medication adherence.

PrEP medications are currently covered under Medicare Part D but may have cost-sharing and deductibles. Under the proposal, both oral and injectable forms of the medication would be covered for certain individuals under Part B as an "additional preventive service," and without requiring payment of Part B coinsurance or meeting the deductible.

Comments on the proposed NCD are due to CMS by August 11.

CMS Releases Request for Information on Episode-Based Models

On July 14, the CMS Innovation Center released a request for information (RFI) on episode-based payment models.

Why this matters: The Innovation Center intends to test a payment model that aims to improve care transitions for beneficiaries and increase the engagement of specialists in value-based models.

- It expects this model would be mandatory for Medicare providers in certain regions and would be implemented no earlier than 2026, after a notice and comment period is issued.
- The new model would include design features that consider a shorter, 30-day episode compared to previous demonstrations to support coordination.

The RFI notes the Innovation Center is focused on including multi-payer alignment approaches where feasible and seeks information on how to support multi-payer alignment. In particular, the Innovation Center seeks feedback on selection criteria of interest to other payers and how to best align quality measurement between new and established models and across payers, how other payers have approached quality measurement in episode-based models, and potential areas of alignment for a future episode-based payment model.

The RFI is available here. Comments are due August 17.

Mental Health Parity and Addiction Equity Act Proposed Rule Pending Regulatory Review

The Office of Information and Regulatory Affairs (OIRA) is now reviewing the upcoming Proposed Rule from the Department of Labor regarding the Mental Health Parity and Addiction Equity Act (MHPAEA), a key step towards release of the proposed rule.

Why this matters: This rule will propose amendments to the final rules implementing MHPAEA.

FDA Approves First Over-the-Counter Contraceptive Pill

The Food and Drug Administration (FDA) approved Opill (norgestrel) tablet, the first daily hormonal (progestin-only) contraceptive pill for sale over the counter (OTC) without a prescription.

The timeline for availability and price of this nonprescription product will be determined by the manufacturer, Perrigo. FDA-approved formulations and dosages of other oral contraceptives will remain available by prescription only.

The approval of Opill comes following a unanimous vote by a panel of FDA experts in May. Perrigo, formerly HRA Pharma, submitted data to the panel that demonstrated most individuals took the pill correctly at the same time every day -- or used an alternative form of birth control if they did not.

The President recently signed an Executive Order on Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services. In the EO, the Administration directed the Secretaries of the Treasury, Labor, and HHS to consider new actions to improve access to affordable OTC contraception.

Industry Trends

Policy / Market Trends

CMS Releases Expanded Report to Congress on Non-Emergency Medical Transportation

The Centers for Medicare & Medicaid Services (CMS) released an expanded report to Congress on non-emergency medical transportation (NEMT) in Medicaid. The report adds T-MSIS data for 2021 to CMS's previous NEMT report, which included data from 2018-2020. The report also adds extensive analysis of Medicaid NEMT coverage, including types of services accessed using NEMT broken out by beneficiary subgroup and trends in the use of NEMT versus telehealth services. According to the report, 4-5% of all Medicaid beneficiaries used NEMT each year between 2018 and 2021. NEMT usage was greatest among individuals enrolled in the Money Follows the Person demonstration, participants receiving home- and community-based services and dually eligible beneficiaries.

CCIO Posts Summary Report on Permanent Risk Adjustment Transfers

CCIO posted the summary report on permanent risk adjustment transfers for the 2022 Benefit Year (BY). The report found the HHS-operated risk adjustment program saw a slight increase in issuer participation nationally in the 2022 benefit year, compared to the 2021 benefit year. Additionally, risk scores decreased slightly between the 2021 and 2022 benefit years and average risk scores

and premiums varied by on-Exchange and off-Exchange enrollment in the individual non-catastrophic market risk pool. The report and associated appendices can be found here.

CMS Innovation Center Releases White Paper Reviewing Health Equity Aspects of Models

On Monday, the Centers for Medicare & Medicaid Innovation (CMMI), within the Centers for Medicare & Medicaid Services (CMS) released a white paper detailing the findings of its review of all model evaluation reports as of June 2022 that included analyses related to health equity. The review is part of CMMI's 2021 strategic refresh, which has sought to embed health equity in every aspect of its models and increase the focus on underserved populations. CMMI notes that most models designed prior to 2021 did not have an explicit equity focus, however, they still offer valuable lessons for program design, implementation, and evaluation. **The review found a number of challenges that have, to date, prevented CMMI from gathering data to assess whether the models are improving health equity. Notably:**

- The variable quality of race/ethnicity data in Medicare and Medicaid claims data presents a challenge for understanding whether models reach and enroll underserved beneficiaries.
- Model designs have not always considered needs specific to underserved beneficiaries and have not prioritized closing gaps in care.
- Model designs that do not prioritize enrolling substantial numbers of underserved beneficiaries result in small sample sizes and limit the ability to draw conclusions from analyses related to equity.

The findings from this review will be used to guide future model development at CMMI for the purpose of developing more equitable models, with the goal that no underserved group is excluded from a model's benefits.

Connecting to Coverage Coalition Highlights Developments in Medicaid Unwinding

The Connecting to Coverage Coalition (CCC) spotlighted recent national and state-specific articles that highlight efforts underway to minimize Medicaid coverage disruptions as a result of redeterminations.

- The articles detail some of the challenges Medicaid enrollees have obtaining accurate information about their health care coverage. For example, some families have received conflicting information about when their coverage may end or pre-populated applications to renew coverage that have incorrect information with no room for updates.

- As the articles demonstrates, it is imperative that leaders coordinate across a comprehensive set of stakeholders, including Medicaid Managed Care organizations, Qualified Health Plans, hospitals, doctors, Federally Qualified Health Centers, consumer advocacy groups, patient groups, community leaders, and navigators. The CCC is working to increase collaboration among stakeholders to ensure that Medicaid enrollees either stay covered or have other easily accessible coverage options.

The CCC seeks to be a source of trusted information about the Medicaid redetermination process. The Coalition is working to convene stakeholders to support information sharing, build on best practices, and develop solutions to ensure Americans can enroll in coverage that is right for themselves and their families.

Alliance to Fight for Health Care Urges Congress to Pass Site Neutral Reform

The Alliance to Fight for Health Care ("The Alliance") issued a press statement following the release of the Medicare Payment Advisory Commission (MedPAC) June 2023 Report to Congress, which includes a unanimous recommendation to stop overpaying hospitals for care safely provided in a physician's office.

The statement details how Medicare currently pays hospitals more than doctors for the same outpatient care: by providing incentive for hospitals to purchase independent physician practices to get the higher hospital reimbursement and calling the doctors' offices hospital outpatient departments (HOPDs).

MedPAC's report urges Congress to expand site neutral payments to outpatient services that are safely provided in physician's office settings. MedPAC identified 66 services for site neutral payment alignment and estimates these changes could have generated $4.9 billion in Medicare savings and $1.2 billion in savings for seniors.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: **http://legis.delaware.gov/.**
New York Legislation: **https://nyassembly.gov/leg/**
Pennsylvania Legislation: **www.legis.state.pa.us.**
West Virginia Legislation: **http://www.legis.state.wv.us/**
For copies of congressional bills, access the Thomas website – **http://thomas.loc.gov/.**

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