Issues for the week ending May 12, 2023

Federal Issues

Legislative

Senate Panel Clears PBM, Drug Pricing Legislation

On Thursday, the Senate Health, Education, Labor and Pensions (HELP) Committee resumed a markup to advance legislation on generic drug approvals and pharmacy benefit managers (PBMs). The markup began on May 2, but was initially postponed over disagreements on amendments.

Why it matters: The markup came on the heels of a much-anticipated hearing on PBM practices and insulin affordability, featuring the CEOs of several drug manufacturers and PBMs -- Eli Lilly, Nordisk, Sanofi, CVS Health, Express Scripts, and OptumRx. Multiple committees on both sides of the Capitol have shown bipartisan interest in PBM reform legislation.

In the markup, the Committee advanced 4 bills aimed at lowering prescription drug costs. Legislation on copay accumulators was raised during the markup but was not voted on.

The bills advanced included:

- S.1339 – Pharmacy Benefit Management Reform Act [Advanced 18-3]

In this Issue:

- S.1067 – Ensuring Timely Access to Generics Act [Advanced 21-0]
- S.1114 – Expanding Access to Low-Cost Generics [Advanced 20-1]
- S.1214 – RARE Act [Advanced 21-0]

There was significant discussion over S.1339, which, among other things, mandates greater PBM transparency to issuers and plan sponsors, bans spread pricing, and requires that 100 percent of rebates and other remuneration to plan sponsors. Several amendments were ultimately adopted during the markup, requiring greater transparency from drug manufacturers around price increases, exemptions to step therapy protocol, PBM reporting requirements, and a U.S. Department of Labor study on PBMs.

Next steps: HELP is one of several Senate committees working on PBM legislation. Some senators are hopeful to see floor activity on a drug pricing bill soon. However, the Senate Finance Committee – which held a hearing last week on international tax strategies employed by pharmaceutical manufacturers – is still working on its anticipated PBM bill, which may delay the process.

- **DFS Issues Guidance on COVID Testing, Vaccine Coverage Post-PHE**

Industry Trends

Policy / Market Trends

- **New Study Shows Site-Neutral Payment Policies Create Medicare Savings**
- **MACPAC Examines Access to Midwives and Birth Centers**

Federal Issues

Regulatory

COVID-19 Public Health Emergency Ends; HHS Provides Guidance

After more than 3 years, the federal COVID-19 public health emergency (PHE) declaration expired at midnight on May 11, 2023.

Why this matters: Federal waivers, flexibilities, and requirements contingent on the PHE end with it unless specifically extended by another authority. Major telehealth flexibilities, for example, were extended by Congress through December 2024. AHIP developed a resource detailing information on which pandemic-era relief measures are tied to each emergency declaration.

- The termination of the PHE does not directly impact the transition of COVID-19 medical countermeasures, including vaccines, treatments, and test kits previously purchased by the government to established pathways of procurement, distribution, and payment by both public and private payers – a process known as "commercialization."

- **Importantly, coverage for COVID-19 testing is impacted by the expiration of the PHE**.
    - For example, the requirement for private health insurance companies to cover COVID-19 tests without cost sharing (OTC and laboratory) ended with the PHE.
    - HHS released a fact sheet conveying it is maintaining a "strong stockpile" and distribution channels for tests and that it will make tests available through COVIDtests.gov through the end of May.
    - HHS may also continue to distribute free COVID-19 tests from the Strategic National Stockpile through states and other community partners. Pending resource availability, the CDC Increasing Community Access to Testing (ICATT) program will continue to focus on no-cost testing for uninsured individuals and areas of high social vulnerability through pharmacies and community-based sites.
- Also of note, **the expiration of the PHE will impact COVID-19 vaccine and treatment coverage**.

On Tuesday and Wednesday, the Department of Health and Human Services released two fact sheets intended to clarify how the flexibilities enabled by the COVID-19 public health emergency (PHE) authority will be affected by the end of the PHE. The first fact sheet, released Tuesday, addresses a broad range of flexibilities, while the second fact sheet, released Wednesday, is focused on the telehealth-specific flexibilities.

HHS developed several materials to assist stakeholders with the transition out of the PHE:

- White House Fact Sheet: Actions Taken by the Biden-Harris Administration to Ensure Continued COVID-19 Protections and Surge Preparedness After Public Health Emergency Transition
- HHS COVID-19 Public Health Emergency Landing Page
- HHS Fact Sheet: End of the COVID-19 Public Health Emergency
- HHS Fact Sheet: HHS Announces Intent to Amend the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19
- HHS Fact Sheet: HHS Announces 'HHS Bridge Access Program For COVID-19 Vaccines and Treatments' to Maintain Access to COVID-19 Care for the Uninsured
- ASPR PREP Act Question and Answers
- CMS FAQ: CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency

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HHS Commercialization of COVID-19 Products

On May 9, HHS hosted another webinar on the transition of COVID-19 Medical Countermeasures (MCM) to the commercial marketplace.

Why this matters: HHS continues to estimate COVID-19 vaccine commercialization will occur in the fall with the presumed new vaccine recommendations from the CDC. Commercialization of COVID-19 treatments may occur by the end of 2023. There were a few updates from the HHS presenters on extending PREP Act amendments providing liability protections for pharmacists administering COVID-19 vaccines and for certain medical devices.

Therapeutics

The Department shared updated tentative transition dates for COVID-19 therapeutics including:

- Lagevrio (Merck and Ridgeback's oral COVID-19 antiviral medicine): Commercialization is targeted for Q4 2023.
- Paxlovid Pfizer's oral COVID-19 antiviral medicine: HHS is no longer providing a transition date. Officials indicated there is currently "sufficient" USG supply.
- Under changes adopted under the Consolidated Appropriations Act, Medicare Part D is able to cover oral drugs for COVID-19 available under an Emergency Use Authorization (EUA) through December 31, 2024.

Vaccines

- HHS reiterated previous statements that the transition to commercialization of vaccines will likely occur in Fall 2023 as part of the adoption of a new strain of the vaccine.

HHS Bridge Access Program For COVID-19 Vaccines and Treatments

- HHS highlighted an April 18 announcement establishing a "bridge" program to maintain access to COVID-19 vaccines for uninsured Americans. The bridge program will work with local health departments and pharmacy chains, where vaccines and treatments will be provided free of charge to certain individuals. HHS stated that the vaccines may be provided to these partner locations through either USG procurement or by manufacturers.

See the HHS Administration for Strategic Preparedness & Response (ASPR) landing webpage that serves as a one-stop-shop for resources related to the transition of COVID-19 countermeasures to standard channels.

CMS Releases Frequently Asked Questions Document on End of Medicaid Continuous Enrollment Condition

CMS released a frequently asked questions (FAQs) document regarding changes made to the Medicaid continuous enrollment condition under the Families First Coronavirus Response Act (FFCRA) by the Consolidated Appropriations Act 2023 (CAA, 2023).

Why this matters: Topics include conditions states must meet while performing Medicaid eligibility redeterminations in order to claim enhanced FMAP, reestablishment of premiums in Medicaid and CHIP, renewal requirements for individuals who receive Social Security Income, and state agency capacity to share beneficiary data with enrolled providers to support renewals.

FDA Votes to Recommend Approval of Over-the-Counter Contraception Pill

Two panels of expert advisers to the Food and Drug Administration (FDA) voted unanimously (17-0) to recommend the agency approve an over-the-counter (OTC) contraception pill. The FDA Nonprescription Drugs Advisory Committee and Obstetrics, Reproductive, and Urologic Drugs Advisory Committee determined that the benefits and safety profile of the pill outweighed the potential health risks to the public.

Why this matters: The conclusions from the advisory committees are not binding, in that FDA is not required to approve the medication following this vote. However, FDA generally follows these recommendations, and is expected to decide on over-the-counter approval in the coming months.

Telehealth Prescribing of Controlled Substances COVID-19 Flexibilities Continued through November 2023

The U.S. Drug Enforcement Administration (DEA), in concert with the Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA), issued a temporary rule to extend certain flexibilities regarding the use of telemedicine during the COVID-19 pandemic.

Why this matters: The goal of this temporary rule is to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine, as well as allowing adequate time for providers to come into compliance with any new standards or safeguards that DEA and/or SAMHSA promulgate in final rules.

The extensions include:

- The full set of telemedicine flexibilities regarding prescription of controlled medications in place during the COVID-19 public health emergency (PHE) will remain in place through November 11, 2023.
- For any practitioner-patient telemedicine relationships established on or before November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID-19 PHE will continue to be permitted through November 11, 2024.

This rule extension applies to the prescribing of certain controlled substances without the need for an in-person evaluation, including buprenorphine for the treatment of opioid use disorder.

- **Background:** This announcement is in response to comments regarding the Telemedicine Buprenorphine Proposed Rule and the Telemedicine Controlled Substance Proposed Rule. These Proposed Rules would have implemented limits for telemedicine prescribing of controlled substances without a prior in-person exam.

- **Insurer perspective:** AHIP submitted comments in response to the proposed rules on prescribing controlled substances and prescribing buprenorphine, stating support for the tremendous value of telemedicine as a treatment modality in providing a cost-effective, convenient means of delivering high quality care, particularly to traditionally underserved areas, and the critical role it has played during the pandemic.
- **Hospital perspective**: Hospitals strongly urged the government to extend these flexibilities, citing the harm to patients receiving treatment for substance use disorders that would occur if a reversion back to pre-pandemic requirements occurred at this time.

  State regulations that could potentially impact the ability of providers in Pennsylvania to take full advantage of the federal flexibilities also have been waived. **February 3 guidance** posted to the Department of Drug and Alcohol Programs website indicates that "Act 30 aligned the timing for DDAP's regulatory suspensions with the deadline for flexibilities granted by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA)—not with the deadline of the PHE itself".

Next steps: DEA is continuing to evaluate comments on the proposed rule. As such the timeline for issuing a final rule is not yet clear. The full text of the temporary rule may be found **online**.

CMS Issues Updated Social Security Income and Spousal Impoverishment Standards

The Centers for Medicare & Medicaid Services (CMS) issued a bulletin outlining updated Social Security Income (SSI) and Spousal Impoverishment standards for 2023.

Why this matters: While some of the spousal impoverishment standards are adjusted each January, section 1924 of the Social Security Act directs requires the community spouse's minimum monthly maintenance needs allowance (MMMNA) and housing allowance be adjusted effective July 1 of each year. Effective July 1, for all states except Alaska and Hawaii the MMMNA will be $2,465.00 and the community spouse monthly housing allowance will be $739.50.

State Issues

New York

Legislative

Bills in Committee this Week

Legislative committees will consider several bills of interest this week:

- **Step therapy override notice (A.463/S.2677)** —requires written notice of an adverse determination made by a utilization review agent in relation to a step therapy protocol override determination.
- **Biomarker testing coverage (A.1673/S.1196)** — requires health insurance policies and Medicaid to cover biomarker testing.

- **UR program standards (S.3400)** -- would impose new standards on health plans' utilization review criteria, impose standing prior authorization requirements, and prohibit health plans from retroactively denying claims to providers for members who are no longer covered by the health plan.

- **Non-timely UR (S.3402/A.6898**) -- would require that a non-timely plan utilization review (UR) response be deemed "approved."

- **Home care claims forms (A.5750/S.6123)** -- would require home care providers to use forms approved by the federal Centers for Medicare and Medicaid Services (CMS) to submit claims, and would allow providers to submit claims directly to Medicaid managed care plans

- **FQHC telehealth parity (S.6733)** -- would require telehealth payment parity for Federally Qualified Health Centers (FQHCs) for care delivered where neither the provider nor the patient were located in a clinic

- **Payment parity for "supportive stabilization services"(S.5367)** -- would mandate the same reimbursement level for "supportive stabilization services" that are substantially equivalent to crisis stabilization services as for those services

- **Medicaid managed care quality pool (A.6021/S.3146)** — would codify the quality incentive program for Medicaid managed care and the managed long-term care program to ensure guaranteed funding for the program.

- **Home care provider reports (A.1928/S.1683)** – would require the Department of Health to issue quarterly reports related to the providers of home care services, including managed care plans

- **Breast reconstruction tattooing coverage (A.5729/S.6146)** —requires insurance coverage for tattooing performed by a physician as part of breast reconstruction surgery.

Regulatory

DFS Issues Guidance on COVID Testing, Vaccine Coverage Post-PHE

With the end of the COVID Public Health Emergency, various emergency policies, including the waiving of cost-sharing for COVID-19 testing and vaccinations come to an end. The Department of Financial Services last week issued a circular letter providing guidance on the rules changes related to coverage of COVID-19 testing and immunizations following the end of the PHE.

Industry Trends

Policy / Market Trends

New Study Shows Site-Neutral Payment Policies Create Medicare Savings

Following a recent Energy and Commerce (E&C) Subcommittee on Health hearing, the American Action Forum released a new study highlighting how site-neutral payments work to create savings for Medicare. The study found that over 10 years, site-neutral payment policies could save Medicare up to $153 billion, beneficiaries up to $94 billion, and the greater U.S. health care system up to $672 billion while reducing the national deficit by a potential $279 billion, and potentially reducing the Part A trust fund's shortfall.

Why this matters: The study acknowledges legislation is required to make changes to current Part B payments and enact site-neutral payment policies. The study's authors recommend thoughtful consideration when deciding which services are best suited for site-neutral payments and how to protect certain safety-net hospitals that may see a decrease in revenue.

AHIP has been following these discussions and submitted a response to the E&C Committee's hearing sharing policy suggestions to improve health care competition through site-neutral payments.

MACPAC Examines Access to Midwives and Birth Centers

The Medicaid and Children's Health Insurance Program (CHIP) Access Commission (MACPAC) published an issue brief on access to midwives and birth centers for Medicaid beneficiaries.

Why this matters: Medicaid finances a significant portion of births, particularly for women who are more likely to have disparities in maternal health outcomes. This issue brief highlights evidence that midwives and the midwifery-led model of care provided in birth centers can improve maternal and child health outcomes at a lower overall cost to Medicaid.

Certified nurse-midwife services and coverage for care at licensed birth centers are mandatory Medicaid benefits under federal law. However, there are barriers to expanding access. These include variation in payment policies, challenges contracting with managed care organizations, requirements related to licensure, certification, and accreditation, scope of practice for midwives, and the limited supply of these providers, especially in rural and traditionally marginalized communities. Read More

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/.**