Highmark's Weekly Capitol Hill Report

Issues for the week ending June 17, 2022

Federal Issues

Legislative

House Panel to Examine Prior Authorization in Medicare Advantage

The House Energy and Commerce Subcommittee on Oversight and Investigations is expected to hold a hearing June 28 examining prior authorization in the Medicare Advantage (MA) program. The hearing is likely to focus on the April HHS Office of Inspector General report that was critical of some MA plans' prior authorization practices.

The hearing is also like to highlight legislation that has been introduced to reform prior authorization in MA, including promoting electronic prior authorization and increasing transparency around the process.

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Federal Issues

Regulatory

Supreme Court Saves Hospitals from $1.6B Cut to 340B Program

On June 15, 2022, the Supreme Court issued its opinion in *American Hospital Association et. al. v. Becerra*, overturning massive reimbursement reductions in the 340B drug pricing program.

The 340B Program, in which some 40% of U.S. hospitals participate, requires drug manufacturers to provide outpatient drugs to participating providers at discounted rates. Participating hospitals rely on profits from the differential between the reimbursement they receive for these drugs and the discounted rates they pay to fund patient care services.

Background: *Becerra* reversed a D.C. Circuit ruling that upheld the U.S. Department of Health and Human Services' (HHS) $1.6 billion annual cut to reimbursement in the 340B Program. The court concluded that, absent a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals. As a result, HHS's 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful.

HHS' move to reduce 340B drug reimbursement originated in 2017, when it issued a final rule reducing hospital reimbursement under the 340B Program for 2018 from 6% over each drug's average sales price to 22.5% below the average sales price, resulting in a total reimbursement reduction of $1.6 billion. Several hospital groups sued to challenge this reduction in the U.S. District Court for the District of Columbia, claiming that the change was in violation of federal law and exceeded HHS' statutory authority. The District Court ruled in favor of the hospitals in December 2018, and ordered additional briefing to determine an appropriate remedy. Nevertheless, on January 1, 2019, HHS effectuated its 2019 Outpatient Prospective Payment System rule, which continued the 340B Program cuts first implemented in the prior year, and expanded them to additional hospital locations.

In May 2019, the District Court also found the 2019 rule unlawful, but did not vacate either rule, choosing instead to remand the rules to HHS for the agency to figure out how to "unscramble the egg," given the complexities of Medicare reimbursement.

HHS did not revert to its prior payment methodology for 340B Program drugs, nor did it make retroactive payment adjustments to providers. Instead, HHS appealed the District Court decisions to the U.S. Court of Appeals for the District of Columbia Circuit. In July 2020, a three-judge panel of the Court of Appeals reversed the District Court, ruling in favor of HHS and cleared the way for HHS to continue and build up their cuts to 340B Program drug reimbursement.

In August 2020, HHS proposed further cuts to 340B reimbursement, with drugs to be reimbursed at average sales price minus 34.7%, plus an add-on of 6% of the products average sales price, for a net payment rate of average sales price minus 28.7%.

Why this matters: Based on the ruling, HHS will have to conduct a full survey of actual acquisition costs before making changes to Medicare Part B reimbursement for 340B drugs.

The decision remands the case back to the lower court, which will likely have to work through potential remedies for the unlawful cuts to Medicare Part B reimbursement for 340B drugs.

Guidance on HIPAA and Audio-Only Telehealth Beyond PHE

The HHS Office for Civil Rights (OCR) issued guidance on how covered health care providers and health plans can use remote communication technologies to provide audio-only telehealth services in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules. The guidance will help ensure that individuals can continue to benefit from audio-only telehealth by clarifying how covered entities can provide telehealth services and improving public confidence that covered entities are protecting the privacy and security of their health information.

The guidance says the HIPAA security rule applies to audio-only telehealth when it is conducted electronically, but not over landlines. It also requires that providers have to enter a business associate agreement with apps that store protected health information. OCR also stated that it would not impose penalties against telehealth providers attempting to comply with HIPAA in “good faith.”

The COVID-19 PHE is currently set to expire on July 15 but is expected to be renewed.

Postpartum Coverage Through Medicaid and CHIP Extensions

On Thursday, the Centers for Medicare & Medicaid Services (CMS) announced that 253,000 parents have gained access to 12 months of postpartum coverage through Medicaid and Children’s Health Insurance Program (CHIP) extensions. Extensions were made possible by a new state plan opportunity established by the American Rescue Plan. Last week Maine, Minnesota, New Mexico, and Washington, D.C., join California, Florida, Kentucky, Oregon, South Carolina, Tennessee, Michigan, Louisiana, Virginia, New Jersey, and Illinois in extending Medicaid and CHIP coverage from 60 days to 12 months after pregnancy.

From the press release the agency is working to extend coverage in other states that have submitted proposals, including Connecticut, Indiana, Kansas, Maryland, Massachusetts, North Carolina, Pennsylvania, Washington, and West Virginia. If all states adopted this option, as many as 720,000 pregnant and postpartum individuals annually could be guaranteed Medicaid and CHIP coverage for 12 months after pregnancy.

MedPAC Releases June Report to Congress

On Wednesday, the Medicare Payment Advisory Commission (MedPAC) released its June Report to Congress: Medicare and the Health Care Delivery System. The report includes seven chapters with recommendations. A high-level overview is below.

1. An approach to streamline and harmonize Medicare's portfolio of alternative payment models (APMS).
    a. This chapter follows up from last year's report recommending the CMS reduce the number APMs with five specific suggestions.

2. Congressional request: Vulnerable Medicare beneficiaries' access to care (final report).
    a. This final report responds to the July 2020 request from the House Ways & Means Committee for an update on rural beneficiaries' access to care and information on access to care for beneficiaries who reside in a medical underserved area, are dually eligible for Medicare and Medicaid, or have multiple chronic conditions.

3. Supporting safety-net providers.
    a. MedPAC presents a two-part framework first identifying safety-net providers and then determining the need for new Medicare safety-net funding.

4. Addressing high prices of drugs covered under Medicare Part B.
    a. The Commission examines three approaches to improve price competition and payment for Part B drugs. These approaches could also apply to Part D and other services such as medical devices.

5. Improving the accuracy of Medicare Advantage payment by limiting the influence of outliers in CMS's risk-adjustment model.
    a. This chapter evaluates a modification to the CMS-HCC risk adjustment model that incorporates the principles of reinsurance and repayment by redistributing a share of annual beneficiary costs in the FFS data which is used to estimate the risk adjustment model coefficients.

6. Aligning fee-for-service payment rates across ambulatory settings.
    a. MedPAC discusses payment alignment for ambulatory surgery centers (ASCs), hospital-based outpatient departments (HOPDs) and free-standing physician offices as these settings have the highest payment rates.

7. Segmentation in the stand-alone Part D plan market.

a. The Commission recommends policymakers consider three possible reforms that would either reduce the level of segmentation in the market or address undesirable consequences of segmentation.

MACPAC June Report to Congress on Medicaid and CHIP

Also, on Wednesday, MACPAC shared their June 2022 Report to Congress on Medicaid and CHIP. The report contains six chapters of interest to Congress, five of which include recommendations to Congress and the Secretary of the U.S. Department of Health and Human Services (HHS):

1. Monitoring access to care
    a. MACPAC offers recommendations to CMS to develop an ongoing and robust access monitoring system consisting of a core set of measures for a broad range of services that are comparable across states and delivery systems.

2. Improving the oversight and transparency of directed payments
    a. The Commission recommends that HHS make directed payment information publicly available on the Medicaid.gov website, make provider-level data on directed payment amounts publicly available in a standard format that enables analysis, require states to quantify how directed payment amounts compare to prior supplemental payments, and clarify whether these payments are necessary for health plans to meet network adequacy requirements and other existing access standards.

3. Improving access to vaccines for adults enrolled in Medicaid
    a. The Commission recommends making coverage of recommended vaccines a mandatory benefit for all adult Medicaid beneficiaries, for CMS to implement regulations for vaccine payment and encourage broad use of Medicare providers in administering vaccines.

4. Encouraging the use of health information technology (IT) among behavioral health providers
    a. It is recommended that CMS, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Office of the National Coordinator for Health Information Technology (ONC) develop and issue joint guidance on how states can use Medicaid authorities and other federal resources to promote behavioral health IT adoption and interoperability.

5. Requiring states to integrate care for people who are dually eligible for Medicaid and Medicare
    a. The Commission recommends requiring all states to develop a strategy to integrate care for beneficiaries dually enrolled in Medicaid and Medicare within two years. This state strategy should include how the state will approach integration, eligibility, benefits, enrollment strategy, beneficiary protections, data analytics, and quality measurement and be structured to promote health equity.

6. Advancing health equity in Medicaid.
    a. This chapter begins the foundation for MACPAC to address key areas in Medicaid policy to advance health equity. The Commission will continue working on health equity over the next year and monitor federal and state efforts that promote equity to understand their impact.

COVID-19 Updates

- The Federal Drug Administration (FDA) authorized the Pfizer and Moderna vaccines for children under 5 and 6 years of age, respectively. The FDA's independent advisory panel reviewed and recommended the vaccines earlier this week. The Centers for Disease Control and Prevention (CDC) is scheduled to vote on recommendations Saturday. Pending approval, vaccines could be available in the coming weeks for children under 5.

- The FDA's Vaccines and Related Biological Products Advisory Committee also voted unanimously to recommend authorizing Moderna's COVID-19 vaccine for kids ages 6-17 year. The FDA will need to issue an official emergency use authorization and the CDC's expert panel will also need to review the Moderna vaccine. Children 5 to 11 are already eligible for the vaccination with Pfizer-BioNTech's vaccine.

- The CDC has also announced that air passengers traveling from foreign countries to the United States will no longer need to show a negative COVID-19 viral test or documentation of recovery from COVID-19 before they board their flight. More information can be found here.

President Biden Signs Executive Order on Advancing Equality for LGBTQI+ Individuals

The Biden Administration signed an executive order (EO) on advancing equality for LGBTQI+ individuals. The EO includes a variety of initiatives directing several federal agencies to evaluate existing programs and identify additional opportunities to combat discrimination and eliminate disparities particularly for LGBTQI+ youth.

With regards to health care, the EO includes the following directives:

- **Access to Health Care**
    - Directs HHS to protect LGBTQI+ individuals' access to medically necessary care from state and local laws and practices, promote adoption of policies to support health equity including mental health care, and develop and release sample policies for States to safeguard and expand access to health care for LGBTQI+ individuals and their families
    - Promote expanded access to comprehensive health care for LGBTQI+ individuals, including working with states on expanding access to gender-affirming care

- **Federal Data Collection Practices**

- Directs the Co-Chairs of the Interagency Working Group on Equitable Data to establish a subcommittee on sexual orientation, gender identity, and sex characteristics (SOGI) data
- Directs the SOGI Data Subcommittee to develop and release a Federal Evidence Agenda on LGBTQI+ Equity to describe and measure disparities and identify practices to safeguard privacy, security, and civil rights
- Directs relevant Agency Heads to submit plans to use SOGI data to advance equity and implement recommendations

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CMS Releases 2020 Medicaid Data Tables

The Center for Medicare & Medicaid Services (CMS) released the 2020 Medicaid Managed Care Enrollment and Program Characteristics and Data Tables. This national data is broken down by program and population, as well as by individual state. The enrollment data provides an accurate snapshot of Medicaid managed care enrollment as of July 1, 2020.

Learn more here:

- Medicaid Managed Care National Program Data by Program and Population
- Medicaid Managed Care State Data

State Issues

Pennsylvania

Legislative

Senate Advances Childhood Lead Testing Legislation

On Monday, June 13, the Senate unanimously advanced Senate Bill 522 (Baker, R-Luzerne). Senate Bill 522 seeks to ensure pregnant women and children receive blood testing to detect lead poisoning and requires applicable insurance policies cover blood lead tests.

Senate Bill 522 was referred to the House Children and Youth Committee for consideration.

House Committee Advances CHIP Choice Legislation

On Tuesday, June 14 the House Insurance Committee advanced Senate Bill 1235 (DiSanto, R-Dauphin). Senate Bill 1235 would prohibit the Pennsylvania Department of Human Services from developing or utilizing bidding or service zones that limit a health service corporation or hospital plan corporation contractor from submitting a bid for CHIP.

Senate Committee Advances Early Eye Drop Refill Legislation

On Wednesday, June 15, the Senate Banking and Insurance Committee advanced Senate Bill 1201 (Pittman, R-Indiana). Senate Bill 1201 would provide coverage of prescription eye drops refills if the refill is requested:

- Between 21 and 30 days after the original date for 30 day supplies or after the insured received the most recent refill;
- Between 42 and 60 days after the original date for 60 day supplies or after the insured received the most recent refill; and
- Between 63 and 90 days after the original date for 90 day supplies or after the insured received the most recent refill.

Amendment A04400 (DiSanto, R-Dauphin) was offered to Senate Bill 1201 and was unanimously adopted by the committee. This amendment makes technical changes and revisions to allow for filings made after the effective date of the bill.

Industry Trends

Policy / Market Trends

AHIP Advocates for Extending Pandemic-Driven Subsidies

President and CEO of AHIP, Matt Eyles, sent a letter to the editor expressing concerns over an editorial in the *Wall Street Journal* over the extension of pandemic-driven subsidies "jacking up" premiums. AHIP's response explains that subsides reduce consumer premiums, helping people access affordable coverage. The subsidies don't affect how premium rates are set.

AHIP agreed with the editorial's concerns about affordability, while suggesting that making it harder for consumers to buy affordable coverage doesn't provide a solution.

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/.**