Highmark's Weekly Capitol Hill Report

Issues for the week ending July 1, 2022

Federal Issues

Legislative

Rx Deal Reached as Reconciliation Talks Continue

A deal on the drug pricing component of a potential budget reconciliation package was reached last week as discussions on the broader package continue between Senate Majority Leader Chuck Schumer (D-NY) and Sen. Joe Manchin (D-WV).

Why This Matters: With August recess fast approaching, Democrats need to move forward with the reconciliation process in areas of agreement, even though the fate of the overall package remains unclear. With a deal on drug pricing, the Senate Parliamentarian can begin to review the legislation to ensure it complies with the rules of budget reconciliation.

Highlights of the drug deal, which largely tracks with the version passed by the House last year, include:

- Government negotiation of Medicare Part D drug prices starting in 2023
- A $2,000 annual Part D maximum out-of-pocket cap
- Required drug company rebates for price increases higher than inflation

In this Issue:

- Free vaccines in Medicare
- Expanded Rx premium and co-pay assistance for low-income seniors
- Incentives to prevent blocking of generics.

Discussions between Sens. Manchin and Schumer continue other components of the package, including climate/energy, tax reform, deficit reduction, and, potentially, Affordable Care Act tax credits.

- **340B Update Following Positive Supreme Court Decision**
- **CMS Issues Proposed Rule for Critical Access and Rural Emergency Hospitals**
- **CMS Releases FAQs on No Surprises Act**

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Legislative

- **Healthcare Waivers and Flexibilities Extended; Bills Approved Supporting Workforce and Behavioral Healthcare**
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House Oversight Panel Examines Medicare Advantage

Last week, the House Energy and Commerce Oversight and Investigations Subcommittee held a hearing on Medicare Advantage (MA). The hearing featured witnesses from the Department of Health Human Services (HHS) Office of the Inspector General (OIG), the Government Accountability Office, and the Medicare Payment Advisory Commission.

The witnesses primarily focused on issues addressed in recent government reports on plan denials of prior authorization requests, home health risk assessments and coding intensity, and disenrollments from MA during the last year of life.

Why This Matters: The HHS OIG report in particular is bolstering advocacy efforts to pass H.R. 3173, the "Improving Seniors' Timely Access to Care Act," which institutes new requirements surrounding prior authorization on MA plans. Key takeaways from the hearing's exchanges around prior authorization include support for additional guidance from CMS on appropriate criteria for use in evaluating prior authorization requests and support for electronic prior authorization.

In addition to passing H.R. 3173, panelists specifically called on CMS to take additional steps, including:

- Conduct more robust risk adjustment audits
- Require insurers to submit more complete encounter data
- Eliminate in-home assessments as the sole source of risk assessments
- Adjust Medicare benchmarks and revisit health plan bonus payments

Despite framing the hearing around oversight of MA, a repeated theme that subcommittee members on both sides of the aisle mentioned was the popularity of MA in their individual districts, and how the program is an essential avenue of coverage for millions of American seniors. America's Health Insurance Plans provided a statement for the hearing highlighting the positive aspects of the program and providing important context to some of the issues discussed at the hearing.

Senators Release Bipartisan Insulin Bill

Senators Jean Shaheen (D-NH) and Susan Collins (R-ME) have released text for their bipartisan proposal, the INSULIN Act, aimed at making insulin more affordable for consumers. A bill summary and section-by-section summary are also available.

Why This Matters: Legislation capping insulin cost sharing has already passed the House and Majority Leader Chuck Schumer (D-NY) has pledged to bring it up on the Senate floor. It is unclear, however, whether the legislation will have enough GOP support to reach the 60 votes required for passage.

The bill requires insurers to designate selected insulin products with cost sharing that does not exceed the lesser of $35 or 25% of the list price for a 30-day supply, beginning in 2023. The bill also offers manufacturers the option to 'certify' insulin products by pricing products at or below the net 2021 Medicare Part D weighted average price, beginning in 2024. Certified insulin would not be eligible for price concessions, must be included on the plan's formulary would not be subject to any utilization management tools.

Federal Issues

Regulatory

Biden Administration Releases Spring 2022 Updated Unified Agenda of Expected Regulatory Actions

Last week, the White House Office of Management and Budget (OMB) posted the 2022 Spring regulatory agenda that describes major actions impacting the commercial market and exchanges, the No Surprises Act implementation, Interoperability, Privacy, Medicare and Medicaid and several additional topics.

HHS' Office of Civil Rights Issues Guidance on Privacy and Reproductive Health Care

The Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) released new guidance on privacy related to reproductive health care subsequent to the Supreme Court ruling in Dobbs v. Jackson Women's Health Organization. HHS' press release is available here.

Why This Matters: The first document clarifies the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and disclosures of protected health information (PHI). Specifically, the guidance outlines circumstances where covered entities may use or disclose PHI in accordance with the Privacy Rule without an individual's signed authorization or when requested by law enforcement. The document also includes several examples to illustrate the application of these provisions.

The second document outlines information for individuals to protect their own data. The guidance explains that in most cases, individuals' health information is not covered by HIPAA when they access or store information using personal devices. The document also provides tips to decrease collection or sharing of their personal data by turning off location services, outlining best practices for selecting apps, browsers, and search engines, and properly disposing of devices.

CMS Releases 2021 Benefit Year Risk Adjustment Summary Report

CMS released the 2021 Benefit Year Risk Adjustment Summary Report. This report includes summary-level and issuer-level data related to risk adjustment transfers for the 2021 benefit year for all issuers in the individual and small group markets. CMS is required to notify issuers of risk adjustment covered plans of their expected risk adjustment payments or charges by June 30, 2022. The related appendices can be found here:

- Appendix A to 2021 Benefit Year Risk Adjustment Summary Report – HHS Risk Adjustment Program State-Specific Data (XLSX)
- Appendix B to 2021 Benefit Year Risk Adjustment Summary Report – HHS Risk Adjustment Geographic Cost Factor (GCF) (XLSX)
- Appendix C to 2021 Benefit Year Risk Adjustment Summary Report – Table 4: Issuer-Specific Information for Non-Merged Market Issuers (XLSX)
- Appendix D to 2021 Benefit Year Risk Adjustment Summary Report – Table 5: Issuer-Specific Information for Merged Market Issuers (XLSX)
- Appendix E to 2021 Benefit Year Risk Adjustment Summary Report – Table 8: Default Risk Adjustment Charge (XLSX)

- Appendix F to 2021 Benefit Year Risk Adjustment Summary Report – Table 9: Default Risk Adjustment Charge Allocation (XLSX)

Biden Administration Secures 105 Million Doses of Pfizer's COVID-19 Vaccine

HHS, in collaboration with the Department of Defense, announced an agreement to purchase 105 million doses of Pfizer's COIVD-19 vaccine for a fall vaccination campaign. The announcement follows a recommendation by the U.S. Food and Drug Administration (FDA) to include an Omicron component for COVID-19 booster vaccines.

Both adult and pediatric doses are included in the contract, with some of the adult doses provided coming as a single-dose, a first for COVID-19 vaccines. Pending FDA authorization of the vaccine and a recommendation by the Centers for Disease Control and Prevention, HHS could receive the first delivery of the vaccine in early fall.

This contract was purchased with funds that were reallocated from other COVID-19 public health programs.

HHS and DOL Secretaries Underscore Contraceptive Coverage Requirements for Private Insurance

HHS, DOL, and the Department of the Treasury sent a joint letter to group health plan sponsors and issuers and issued a press release outlining several concrete steps health insurance providers should immediately take to ensure they comply with requirements that women have access to contraceptives and related services with no cost-sharing under the Affordable Care Act.

HHS Secretary Xavier Becerra told reporters Tuesday (June 28) that the Administration is also focused on the following:

- Take steps to increase access to medication abortion in limited circumstances;
- Ensure patient privacy and nondiscrimination for patients seeking reproductive health care, as well as for providers who offer reproductive health care;
- Examining its authority under the Emergency Medical Treatment and Labor Act to ensure that clinical judgment of doctors and hospitals is supported in treating pregnant patients, including those experiencing pregnancy loss or complications, and reaffirming that abortion care can be appropriate to stabilize patients;
- Directing all HHS agencies in to work to ensure that all providers, including doctors, pharmacists, and clinics, have appropriate training and resources to handle family planning needs, including administering patient referrals for care;
- Directing CMS to take every legally available step to protect family planning care, including emergency contraceptives and long acting reversable contraceptives, such as IUDs; and
- Ensure all federally funded Title X family planning clinics are full participants in the Medicaid program.

The Secretaries encouraged health insurers to make their members and providers aware of the requirements of the law using the information included in the Administration's new website that includes information for consumers on contraception coverage requirements under ACA.

CMMI Announces New Value-Based Oncology Care Model

CMS announced a new model aimed at improving cancer care for Medicare patients and lowering health care costs.The Biden Administration announced it will pilot test the Enhancing Oncology Model (EOM) under the Center for Medicare and Medicaid Innovation (CMMI). The EOM aims to transform oncology care by preserving or enhancing quality of care while reducing program spending under Medicare fee-for-service. The voluntary model builds off the Oncology Care Model, which was also implemented under CMMI, and will run from July 1, 2023 through June 30, 2028.

Oncology practices who participate in EOM can expect to provide patient-focused Enhanced Services, such as 24/7 access to a clinician, patient navigation services, a detailed care plan, and screenings for health-related social needs. Patients will also have an opportunity to share feedback on their overall cancer care experience and health outcomes.

EOM also includes a focus on improving health equity, including a strategy that includes requiring oncology practices to screen for health-related social needs, introducing data reports on expenditure and utilization patterns of their patient population to help health care
professionals identify and address health disparities. A fact sheet on EOM can be found on the CMS website here.

Why This Matters: EOM is a multi-payer model that aims to promote a consistent approach across payers and their patient population. As such, private payers, Medicare Advantage plans, and state Medicaid agencies are eligible to apply to align with CMS.

Supreme Court Upholds Medicare DSH Formula

The U.S. Supreme Court ruled 5-4 that the Centers for Medicare & Medicaid Services (CMS)'s approach to paying safety net hospitals under the disproportionate share hospital (DSH) payment allotments was not contrary to law. The DSH program provides for payments intended to offset hospitals' uncompensated care costs to improve access for Medicaid and uninsured patients as well as the financial stability of safety-net hospitals. The DSH formula, dating from 2004, includes two statutory fractions, called the Medicare and Medicaid fractions, which together determine whether a hospital will receive a DSH payment and how high that payment will be. Under a 2005 regulation, the formula broadly considers anyone eligible for Medicare Part A to be counted in the Medicare fraction, regardless of whether Medicare is the primary payer for hospital treatment. This results in a larger denominator for the Medicare fraction, which led to lower DSH percentages for most safety-net hospitals. The formula was challenged by Empire Health Foundation, a private health foundation, which argued the formula works to harm the very hospitals the program is presumably designed to help in leading Medicare to make less payments to safety net hospitals. However, the Court sided with HHS, stating its interpretation is consistent with the text, context, and structure of the DSH provisions.

Federal Agency Proposes a Nationwide Initiative to Improve Primary Care

The Biden Administration is seeking requests for information from providers, patients, and other stakeholders as it looks to improve the nation's primary care system.

The Office of the Assistant Secretary for Health is developing a 2022 action plan to strengthen primary health care across federal agencies. The office is seeking input from subject matter experts, patients, families, community advocates, and other health groups to inform the new action plan.

The agency is seeking information about:

- Successful models or innovations that improve primary health care
- Barriers to implementing successful models or innovations
- Successful strategies to engage communities
- Proposed federal actions

Why This Matters: The nation's primary health care foundation is weakening and in need of support: primary health care is under-resourced; the workforce is shrinking; workforce well-being is in peril; and many practices face reimbursement challenges that may result in financial instability.

The goal of the U.S. Department of Health and Human Services initiative to strengthen primary health care is to develop a federal foundation for the provision of primary health care for all that supports improved health outcomes and advanced health equity, the agency said.

The **request for information** period is open for 36 days from June 27 through August 1.
Additional information about the primary care initiative is available **online**.

340B Update Following Positive Supreme Court Decision

The American Hospital Association (AHA) **outlined** the key next steps following the U.S. Supreme Court decision unanimously rejecting significant payment cuts in the 340B Drug Pricing Program.

In its opinion last month, the court sided with the AHA and other leading hospital groups that had sued the U.S. Department of Health and Human Services (HHS) following the agency's changes to the 340B program.

Immediately after the ruling, the AHA sent a letter to **HHS** urging the Department to "ensure prompt repayment of 340B hospitals following the Supreme Court's decision in American Hospital Association v. Becerra, without penalizing the rest of the hospital field."

Additionally, advocacy activities are underway to safeguard the 340B program from actions by drug manufacturers that weaken and undercut the benefits of the program:

- A "**Dear Colleague**" letter urging HHS to ensure 340B benefits reach providers and patients and "impose civil monetary penalties against all drug manufacturers who have unlawfully overcharged safety net health care providers." Representatives have until July 7 to sign onto the letter.
- A **friend-of-the-court brief** asking the Third Circuit U.S. Courts of Appeals to require drug companies to fulfill their 340B discounted drug obligations.

CMS Issues Proposed Rule for Critical Access and Rural Emergency Hospitals

Last week, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule that would update the conditions of participation (CoP) for critical access hospitals (CAH) and establish CoPs for the newly created rural emergency hospitals (REH).

The rule proposes to update the CoPs for CAHs by:

- Adding a definition of primary roads to the location and distance requirements
- Establishing a patient's rights CoP
- Allowing CAHs that are part of a health system with more than one hospital to use participation in the health system's infection control and antibiotic stewardship programs, medical staff, and quality assessment and performance improvement programs to meet the CoP

During December 2020, the Consolidated Appropriations Act of 2021 established the new REH provider type which provides emergency and observation care and other outpatient medical and health services. In addition to updating CoPs for CAHs, the rule seeks comment on the proposed standards including the ability of an REH to provide low-risk labor and delivery services and the minimum qualifications for professionals who will provide on call emergency services.

Additional information regarding REH payments and quality measurements are expected to be forthcoming. Currently, Pennsylvania law does not allow for REHs in the state. Instead, the Pennsylvania Department of Health recently established "outpatient emergency departments," a new innovative model designed to preserve and increase access to high-quality care in areas that may be medically underserved.

Comments on the **proposed rule** will be accepted until August 29.

Why This Matters: Pennsylvania law and agency guidance are in conflict with the new CMS provider type and will need to be modified or amended in order to effectuate the stated goals to preserve and increase access to healthcare, especially in rural regions of the state.

CMS Releases FAQs on No Surprises Act

As part of its effort to implement provisions under the No Surprises Act (NSA), the Centers for Medicare & Medicaid Services (CMS) released a set of FAQs that address the types of providers to which the surprise billing provisions apply and clarify the notice and consent provisions of the law.

State Issues

Delaware

Legislative

Legislative Session Concludes

The 151st Delaware General Assembly finished its work on June 30. While the Speaker of the House and the President Pro Tempore of the Senate can call their respective chambers back to the capitol at any time, it is unlikely they will convene again this year.

Bills of interest that passed both chambers in the final weeks of session that are expected to be signed into law or have already been signed into law are linked below.

- HB 303 w/ HA 2 Relating to Mental Health

- SB 267 w/ HA 1 Coupons applied to Deductibles
- SS 1 for SB 222 w/ HA 2 Relating to Insurance Rates
- HB 455 Relating to Women's Reproductive Health
- SB 316 w/ SA 1 Insurance Coverage for Diabetes Equipment and Supplies
- HB 399 w/ HA 1, HA 2 + SA 1 Relating to the Practice of Pharmacy
- HB 334 w/ HA 2 + SA 1 Relating to Telemedicine

State Issues

Pennsylvania

Legislative

Healthcare Waivers and Flexibilities Extended; Bills Approved Supporting Workforce and Behavioral Healthcare

Emergency regulatory waivers and flexibilities for health care, which have helped hospitals prioritize patient care through the COVID-19 pandemic, will be extended another four months. The General Assembly passed legislation last week extending the waivers until October 31. The waiver extension was amended into **House Bill 2041** (now Act 30 of 2022), which the governor signed on June 30.

Why This Matters: The waivers—which were set to expire on June 30—expand access to telehealth services, increase vaccine access, allow hospitals to quickly adapt to emergencies by altering space as needed for influxes of patients, and ease regulatory barriers to clinician licensing.

Home health care: As part of the waiver extension bill, the General Assembly passed a measure, sponsored by Representative Jeff Wheeland (R-Lycoming), that extends the reach of home health care providers by allowing certified registered nurse practitioners and physician assistants to order and oversee orders, and allowing registered nurses to remotely supervise visits in certain circumstances.

Other key legislation passed: Lawmakers also sent other health care priorities to Governor Wolf's desk, including:

- **Veterans in health care:** **House Bill 1868**, sponsored by Zach Mako (R-Northampton), strengthens the health care workforce by expediting professional licensure for veterans and military spouses, including in health care fields.
- **Whole person care:** House Bills **1561** and **1563**—introduced by Speaker Bryan Cutler (R-Lancaster) and Representatives Frank Farry (R-Bucks) and Michael Schlossberg (D-Lehigh)—supports whole person health care initiatives by allowing better sharing of patient information between physical and behavioral health care providers. The bills modernize state laws so they align with HIPAA and other relevant federal regulations.

Senate Advances Mental Health and Substance Use Disorder Confidentiality Alignment Legislation

On Thursday, June 30, the Senate advanced the following bills:

- House Bill 1561 (Farry, R-Bucks) updates the Mental Health Procedures Act to bring PA into alignment with HIPAA standards to permit providers, facilities, and health plans to share appropriate patient mental health and substance use disorder-related information.

- House Bill 1563 (Cutler, R-Lancaster) updates the Drug and Alcohol Abuse Act to bring PA into alignment with HIPAA standards to permit providers, facilities, and health plans to share appropriate patient mental health and substance use disorder-related information.

House Bill 1561 and House Bill 1563 were presented to the Governor for signature.

Why This Matters: Highmark and AHN support legislation that brings PA into alignment with current HIPAA standards which would permit providers, facilities, and health plans to collaboratively share appropriate patient mental health and substance use disorder-related information, in accordance with HIPAA, to provide more effective care.

Senate Advances Prior Authorization Legislation

On Wednesday, June 29, the Senate advanced Senate Bill 225 (Phillips-Hill, R-York) with amendment A05208, on third consideration. Amendment A05208 seeks to streamline and standardize the process for prior authorization and step therapy considerations for insurers, MCO's and contractors.

Senate Bill 225 was referred to the House Insurance Committee for consideration.

Regulatory

Pennsylvania Insurance Department Proposes Network Adequacy Study

The Pennsylvania Insurance Department has been awarded a total of $698,584 in federal funds as a part of the State Flexibility to Stabilize the Market Grant Program Cycle II. The Department states, "One of the proposed projects includes studying the availability of providers in various specialties and geographic areas. The goal of this study is to understand areas of need based on current availability of providers to accept new patients, the amount of time it takes to get an appointment with these providers and assess network adequacy considerations based on the findings. The development of this proposed list was informed by research on provider accessibility."

The Department is inviting public comment from organizations, consumer advocates, providers and consumers about their experience with getting an appointment or finding available specialists. Insurers have been invited to provide feedback as well. The Department has included a list of proposed targeted providers to be included in the study but other suggestions are welcome. The list includes, but is not limited to, Obstetrics and Gynecology, Neurologists, Oncologists, Dermatologists, etc. The final list for the study will include no more than ten (10) provider types. Those who respond must indicate which providers they believe have accessibility issues and support the assertion with known issues or experiences.

Comments will be accepted until Friday, August 5, 2022.

Industry Trends

Policy / Market Trends

Medical Loss Ratio (MLR) Rebates

According to this Data Note from the Kaiser Family Foundation, **i**nsurers expect to pay $1 billion across all commercial markets in MLR rebates in 2022, down from $2.5 billion in 2020 and $2 billion in 2021, according to this analysis of NAIC financial data. The expected decline in 2022 MLR rebates is primarily due to higher loss ratios in the individual market for 2021. The article notes that "after years of relatively flat premiums in the individual market, the higher loss ratios seen in 2021 may foretell steeper premium increases in 2023." KFF examined NAIC insurer-reported financial data from Health Coverage Portal TM, a market database maintained by Mark Farrah Associates for this analysis. These data do not include data from California HMOs regulated by California's Department of Managed Health Care.

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/.**