Highmark's Weekly Capitol Hill Report

Issues for the week ending April 19, 2024

Federal Issues

Legislative

House Subcommittee Holds Hearing on Change Healthcare Cyberattack

On Tuesday, the Energy and Commerce Health Subcommittee held a hearing titled "Examining Health Sector Cybersecurity in the Wake of the Change Healthcare Attack."

In general, the hearing saw bipartisan criticism of UnitedHealth and its response to the Change cyber incident from Committee Members and witnesses alike. The hearing highlighted how the cyberattack impacted claims processing, payment and billing, and eligibility verifications. Members expressed concerns about the recent increase in data breaches with Full Committee Ranking Member Cathy McMorris Rodgers (R-WA-5) and Subcommittee Ranking Member Anna Eshoo (D-CA-16) both noting that vertical integration and consolidation posed risks to cybersecurity in health care. Subcommittee Chairman Brett Guthrie (R-KY) also called on the Administration to proactively partner with industry stakeholders to prevent future attacks.

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Next Steps: McMorris Rodgers indicated there will be additional Committee hearings. Also, Senate Finance Chairman Ron Wyden (D-OR) is planning a hearing on the Change cyberattack and cybersecurity infrastructure for later this month.

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- **CMS Finalizes Rules to Improve Medicaid, CHIP Access and Payment**
- **CMS Finalizes Minimum Staffing Standards for Nursing Homes**
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House Panel Examines Improper Medicare & Medicaid Payments

On Tuesday, the Energy and Commerce Oversight and Investigations Subcommittee held a hearing titled, "Examining How Improper Payments Cost Taxpayers Billions and Weaken Medicare and Medicaid." Witnesses included officials from the Government Accountability Office (GAO), Medicare Payment Advisory Commission (MedPAC), Medicaid and CHIP Payment and Access Commission (MACPAC), and the Department of Health and Human Services.

Why this matters: During the hearing, subcommittee members raised concerns about programmatic oversight, overpayments, and efficient use of taxpayer dollars in the Medicare and Medicaid programs. Several Democratic Members, including full-Committee Ranking Member Frank Pallone (D-NJ-06), Subcommittee Ranking Member Kathy Castor (D-FL-14) and Rep. Jan Schakowsky (D-IL-09), expressed concerns with increasing costs and what they term overpayments to Medicare Advantage (MA) plans.

Go Deeper: Subcommittee Chairman Morgan Griffith (R-VA) submitted for the record the America's Health Insurance Plans (AHIP) commissioned Wakely report. The report refutes MedPAC's recent analysis regarding the difference between MA and traditional Medicare costs, finding that MA saves nearly 9% when compared to original Medicare. AHIP's resource on how MedPAC's recent report on MA spending is fundamentally flawed is available here.

Griffith also highlighted the need to leverage technology and foster collaboration between federal and state agencies to ensure Medicare and Medicaid integrity. He cited GAO's 2023 report that found approximately $51.1 billion in improper payments occurred in the Medicare program and $50.3 billion in improper payments occurred in the Medicaid program. The panel answered questions on strategies to improve accountability of the Medicare and Medicaid programs and discussed how to protect essential health care services.

Congressional Committee Announces Oversight Subcommittee Hearing On Change Cyberattack

The House Energy and Commerce Subcommittee on Oversight and Investigations announced it will hold a hearing on the Change cyberattack May 1. UnitedHealth Group CEO Andrew Witty will testify.

Why this matters: This will be the second hearing the Energy and Commerce Committee has held on the cyberattack, following an April 16 Health Subcommittee hearing featuring several health care stakeholders. UnitedHealth is the parent company of Change Healthcare, one of the nation's largest providers of health care payment management systems, which experienced a cyberattack on its platforms on February 21, 2024. The aftermath of this event is still impacting patients and providers.

Go Deeper: Read more about what health insurance plans are doing to support patients and providers after the cyberattack.

Federal Issues

Regulatory

CMS Releases Prescription Drug Event Reporting Instructions

On April 15, CMS released an HPMS memo, "Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2025." CMS referenced the release of this guidance in Final CY 2025 Part D Redesign Program Instructions.

Why this matters: The reporting instructions outline changes to the IRA necessitating updates to PDE reporting and examples using the CY 2025 benefit parameters. The document is organized into five sections that contain PDE examples for calculating and reporting the Basic Benefit (Section 1), the Enhanced Alternative (EA) Benefit (Section 2), Employer Group Waiver Plans (EGWP) (Section 3), ACIP-Recommended Vaccines and Covered Insulin Products (Section 4), and Miscellaneous Scenarios (Section 5).

Fact Sheet on PrEP

CMS issued a fact sheet in preparation for a potential National Coverage Determination (NCD) for Preexposure Prophylaxis (PrEP) using antiretroviral drugs to prevent HIV infection.

Why this matters: CMS is not announcing any coverage changes at this time. However, CMS is sharing this information before issuing an NCD to avoid any possible disruptions for people with Medicare and encourage pharmacies and other interested parties to review Medicare enrollment instructions and other important information.

White House Revokes Prior Executive Orders on COVID-19 Responsibilities

The White House issued a new Executive Order (EO) on COVID-19 and Public Health Preparedness and Response.

Why this matters: The EO revokes several previous orders relating to COVID-19 resources and federal mandates on mask-wearing. Additionally, it transfers responsibilities and duties specified in previous EOs to the Director of the Office of Pandemic Preparedness and Response Policy (OPPR).

Context: The Office of Pandemic Preparedness and Response Policy (OPPR) was established by Congress in December 2022. According to the White House, OPPR is providing advice and supporting the Administration's continued work to address COVID-19 and other public health threats, facilitating coordination and communication among executive departments and agencies to ensure that the United States can quickly detect,

identify, and respond to such threats as necessary. With the transfer of responsibilities, the EO terminates the positions of COVID-19 Response Coordinator & Deputy Coordinator.

Go Deeper: Read the EO here.

Former HHS Secretaries Urge Congress to Adopt Site-Neutral Payments

Former Health and Human Services Secretaries **Alex Azar** (Trump Administration) and **Kathleen Sebelius** (Obama Administration) recently wrote a joint op-ed for *STAT News* urging Congress to pass legislation expanding site-neutral payments. Azar and Sebelius write passing site neutral payment policies is a "no-brainer" and "commonsense policy that will reduce costs for patients and taxpayers," as well as "diminish perverse incentives for consolidation, and incentivize care delivery in the right place for the right price."

Key Quote: "*Even though we served under presidents for different parties, we both recommended that Congress adopt policies advancing site-neutral payments to save patients and taxpayers money. People should pay for the care they receive, not for the sign on the door.*"

Legislative State of Play: The House-passed *Lower Costs, More Transparency Act* contained site-neutral provisions for Medicare for drug administration. Further, several bicameral, bipartisan bills have been introduced this session, offering a range of site-neutral payment solutions. Site-neutral reform could also be included as a policy in a larger legislative package or end-of-year bill.

Go Deeper: Read the Alliance to Fight for Health Care's press release spotlighting the op-ed.

CMS Releases Final Rate Review Bulletin

The Centers for Medicare & Medicaid Services (CMS) released additional guidance and technical resources for health insurance issuers for the Plan Year 2025 QHP certification cycle. This guidance includes the final Rate Review Bulletin, the Calendar Year 2024 Key Dates Calendar, and the 2025 QHP Data Submission and Certification Timeline Bulletin. Links to these guidance documents follow below.

Links:

- **Final Rate Review Bulletin: Final Rate Review Bulletin**
- **Calendar Year 2024 Key Dates Calendar: Calendar Year 2024 Key Dates Calendar**

- **Plan Year 2025 QHP Data Submission and Certification Bulletin: Plan Year 2025 QHP Data Submission and Certification Bulletin**

CMS Announces Initiative to Address Climate Change in Health Care Industry

CMS proposed the Decarbonization and Resilience Initiative, a voluntary element of the proposed Transforming Episode Accountability Model (TEAM), to assist selected hospitals by collecting, monitoring, assessing and addressing the threats of climate change.

Why this matters: The health care industry is a significant source of harmful greenhouse gases, some of which come from building energy emissions, vehicles used for transportation, and anesthetic gas used in surgeries that escapes into the atmosphere. This initiative is the first time HHS proposes to collect data on health care greenhouse gas emissions and its effects on health outcomes, costs, and quality. Read More

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Federal Agencies Launch Website for Reporting Anticompetitive Health Care Practices

The Federal Trade Commission, Justice Department and Department of Health and Human Services April 18 launched HealthyCompetition.gov, an online portal for the public to report potentially unfair and anticompetitive health care practices.

The FTC and the Justice Department's Antitrust Division plan to review complaints for the appropriate agency to investigate if it raises sufficient concern under antitrust laws or HHS authorities.

The goal for this initiative is to bolster agency work to check illegal business practices that harm consumers and workers, and to stop monopolistic, anti-competitive practices that undermine the delivery of health care to Americans. Specifically, these submissions, the agencies said, can help them ensure healthcare organizations provide quality care and pay their employees a fair wage.

The government said it will protect submitter confidentiality "to the fullest extent possible under the law," and will support other relevant whistleblower protections. Submitters are instructed not to include sensitive personal information in their comments but may choose to leave contact information in case the agencies opt to seek more information.

Additional information about the portal is available **online**.

Why this matters: This initiative is consistent with ongoing enforcement trends and agency statements regarding the healthcare sector. In a February 2024 speech before the American Medical Association, FTC Chair Lina Khan described collaborative enforcement efforts with the DOJ and HHS in the healthcare industry following President Biden's Executive Order. She set forth five specific enforcement priorities for the healthcare industry, including: (1) inquiries into intermediaries in healthcare supply

chains, including group purchasing organizations and drug wholesalers that may contribute to generic drug shortages; (2) scrutiny into allegedly unlawful consolidation and "roll-ups" in health care by private equity firms that may lead to increased healthcare costs, lower quality, and less access; (3) potential antitrust harm in labor markets, including through mergers and non-compete clauses in employment contracts; (4) challenges to allegedly unlawful practices in the pharmaceutical industry that may be driving higher drug costs; and (5) a focus on protecting privacy in health care by emphasizing companies' need to secure sensitive health data.

HHS finalizes Rule on 340B Administrative Dispute Resolution Process
The Department of Health and Human Services published in the April 19 *Federal Register* its rule to establish a 340B Administrative Dispute Resolution process as required under the Affordable Care Act.

The rule establishes an ADR process that allows all 340B covered entities, regardless of the size of the organization or monetary value of the claim, to avail themselves of this important process to address claims at dispute with drug companies.

The rule is effective June 18, 2024. The Health Resources and Services Administration (HRSA) will provide additional details and a webinar soon on filing a claim.

Specifically, the new finalized ADR process would:

- Create a more conventional administrative process that is less trial-like consisting of 340B program subject matter experts from the Health Resources and Services Administration's Office of Pharmacy Affairs.
- Allow covered entities to bring forth claims where they have been overcharged by a drug company including where the drug company or its wholesaler denies access to 340B pricing.
- Allow claims for ADR panel review even if the particular issue at stake is subject to concurrent federal court review.
- Require decisions be reached by the ADR process within one year of submission of claims for ADR review.
- Include a reconsideration process for parties dissatisfied with the 340B ADR panel decision.

Why this matters: The final rule for the 340B drug pricing program administrative dispute resolution (ADR) process is an important step in ensuring the integrity of the 340B program. The final rule contains several important process improvements, including a clear timeline for when ADR decisions must be made and an opportunity for reconsideration when parties are dissatisfied with the initial ADR decision.

Of particular importance is that the final rule makes clear that an overcharge claim includes instances where a drug company has limited a hospital's ability to purchase 340B drugs at or below the 340B ceiling price. This rule will help hold drug companies accountable for their rampant abuses of the 340B program and the patients it serves.

CMS Finalizes Rules to Improve Medicaid, CHIP Access and Payment

The Centers for Medicare & Medicaid Services finalized rules intended to improve access in both the Medicaid fee-for-service and managed care programs. The rules also align requirements in the Children's Health Insurance Program with the Medicaid program and finalize several changes to state directed payments, including codifying state flexibility for directed payments to match the average commercial rate. The final rules are scheduled to be published in the *Federal Register* on May 10.

Specifically, hospitals support the following provisions in the final rules:

- CMS' formal adoption of the average commercial rate as the upper payment limit.
- Efforts to streamline the approval of certain existing arrangements, which will cut down on bureaucracy and burden and allow hospitals to focus on their patients.
- Delaying enforcement of the attestation provision as the various courts evaluate this issue.
- CMS' efforts to strengthen network adequacy requirements and oversight.

Why this matters: The final rule acknowledges the critical role hospitals play in state Medicaid financing and the importance of supplemental payments to sustain beneficiary access to care in light of low Medicaid base payment rates, including rates paid through managed care organizations.

CMS Finalizes Minimum Staffing Standards for Nursing Homes

The Centers for Medicare & Medicaid Services finalized minimum staffing requirements for nursing homes that participate in Medicare and Medicaid. The final rule is scheduled to be published in the May 10 *Federal Register*.

As proposed in September, the final rule will require nursing homes to provide a minimum of 3.48 hours of nursing care per resident day, including 0.55 hours of care from a registered nurse per resident day and at least 2.45 hours of care from a nurse aide per resident day, as well as 24/7 onsite RN services. CMS slightly expanded the opportunity for facilities to seek exemptions from the requirements from its original proposal.

Why this matters: The American Hospital Association (AHA) had urged CMS not to finalize the proposal but instead develop more patient- and workforce-centered approaches focused on ensuring a continual process of safe staffing in nursing facilities.

The process of safely staffing any health care facility is about much more than achieving an arbitrary number set by regulation. It requires clinical judgment and flexibility to account for patient needs, facility characteristics and the expertise and experience of the care team. CMS' one-size-fits-all minimum staffing rule for nursing homes creates more problems than it solves and could jeopardize access to all types of care across the continuum, especially in rural and underserved communities that may not have the workforce levels to support these requirements.

This final rule could lead nursing homes to reduce capacity or close outright, including those that are otherwise high performers on quality and safety metrics. The loss of these nursing home beds could adversely impact patients who have completed their hospital treatment and need continuing care in nursing facilities.

The AHA has already documented rising lengths of stay for hospital patients in need of skilled post-acute care, with patients waiting days, weeks or even months for post-acute care placements. As those patients continue to occupy hospital beds, other patients awaiting elective surgeries or other scheduled procedures may find their care disrupted because there is no bed for them in the hospital.

Even more troubling, this final rule could lead to delays in urgent medical care as patients coming into hospital emergency departments may experience longer waits as EDs and inpatient beds are occupied by patients awaiting nursing home placements.

Lastly, this final rule could exacerbate the already serious shortages of nurses and skilled health care workers across the care continuum. Strengthening the health care workforce requires investment and innovation, not inflexible mandates.

OCR Finalizes Rule Prohibiting Certain Reproductive Health Care Disclosures

The Department of Health & Human Services' Office for Civil Rights announced a final rule prohibiting entities regulated by the HIPAA Privacy Rule from using or disclosing protected health information to investigate or prosecute patients, providers or others involved in providing legal reproductive health services.

The rule requires covered entities to obtain a signed attestation that certain requests for PHI potentially related to reproductive health care are not for these prohibited purposes.

The final rule makes clear that hospitals can rely on the attestation and are not required to investigate the validity of an attestation provided by a person requesting a use or disclosure of PHI.

The final rule is scheduled to be published in the April 26 *Federal Register* and will take effect 60 days after publication. Covered entities are required to comply within 240 days.

As requested by the American Hospital Association, OCR plans to issue a model attestation form before the compliance date.

Why this matters: The new rule will protect the privacy of information on abortion, contraception and fertility treatments provided to women in states where the services are legal. It will also protect healthcare providers in abortion-restrictive states whose patients seek healthcare services out of state.

Under the former HIPAA Privacy Rule, healthcare providers were allowed, but not required, to provide reproductive health information to law enforcement.

The rule does not offer protection of reproductive health information in instances where the services were not legal. It also does not cover information outside of HIPAA such as a patient's location data or health information stored on their phone.

ONC Requires Health Information Exchange Networks to Support FHIR Standard

The Department of Health and Human Services' Office of the National Coordinator for Health Information Technology released Common Agreement Version 2.0, which requires health information networks participating in the Trusted Exchange Framework and Common Agreement to support the Health Level Seven Fast Healthcare Interoperability Resources standard.

This will make it easier for participating health care organizations to securely exchange information directly with each other and patients to access their health care information through digital health apps. Among other enhancements, they said the release includes simplified onboarding for clinicians and other end users.

In February, ONC designated CommonWell Health Alliance and Kno2 as Qualified Health Information Networks, meaning seven QHINs can now electronically exchange health information nationwide under TEFCA, a set of common rules for secure exchange of treatment and other health information required by the 21st Century Cures Act of 2016.

Why this matters: TEFCA's common agreement sets up the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other – all under commonly agreed-to rules-of-the-road.

The new enhancements and updates mark a huge step forward for TEFCA as it meets the promise of seamless nationwide exchange at scale.

State Issues

New York

Legislative

Legislature Approves Budget

Lawmakers gave final approval of the FY2025 state budget Saturday afternoon, almost three weeks late and totaling more than $237 billion budget – up from $233 billion originally proposed by Governor Hochul in January.

The final spending plan included partial restoration of the Medicaid Quality Improvement Program. The Governor's proposal had eliminated funding for the program entirely, and since January, Highmark has been working with the Health Plan Association, the NY Black, Puerto Rican, Hispanic and Asian Legislative Caucus, other plans and many of the community groups plans partner with, fighting to restore the funding. The QI program funds innovative initiatives that target the factors contributing to health disparities and improve the quality of care.

Other significant health care provisions in the final budget include:

- **MCO Tax** – The budget includes a provision to create a new managed care organization tax, which is designed to generate new revenue for the Medicaid program. The proposal authorizes the Commissioner of Health to apply for a waiver for the tax, with the waiver subject to approval from the Centers for Medicare and Medicaid Services. Details on the MCO tax will be developed in the weeks ahead.

- **$0 insulin cost share** – As expected, the Governor's proposal for no cost sharing for insulin was included in the final budget, effective 1/1/25.

- **Medicaid Managed Care Procurement** – The final budget rejected the Governor's proposal to subject the Medicaid managed care program to a procurement process.

Next Steps: With the budget finally approved, lawmakers left Albany for a two week break. They are scheduled to return on May 6, at which point they will begin their push to wrap up the 2024 session, scheduled to end on June 6.

Regulatory

2025 Rate Setting Update

At its meeting with plan actuaries last week, the Department of Financial Services (DFS) to provided updates on the 2025 rate setting process for individual and small group policies. DFS staff reported that due to the recent Change Healthcare cyberattack, CMS has delayed finalizing the 2023 Risk Adjustment results. As a result of the delay, DFS is shifting the dates for the 2025 rate submissions slightly.

- May 15 –2025 rate applications due to DFS (previously May 9)

- May 24 – ACA form Filing Submissions due (unchanged)

- August 5 – Rate decisions must be rendered (previously July 29)

State Issues

Pennsylvania

Legislative

State House Advances Health Bills

Last week, lawmakers in the state House took action on several notable health bills related to maternal health, the interstate nurse and physician licensure compacts, and non-compete clauses, among others.

The action from last week included:

- **Licensure compacts:** On Monday, the House Professional Licensure Committee **advanced House Bill 2200**, which addresses administrative issues associated with federal background checks. The legislation is a key step to allow the state to participate in the multistate Nurse Licensure Compact and Medical Licensure Compact.

- **Maternal health:** On Wednesday, the state House Health committee advanced **House Bill 2097** to expand coverage of home blood pressure monitors for pregnant and postpartum women and **House Bill 1608** to extend Medicaid coverage for doula services.

- **State oversight over health mergers:** The House Judiciary Wednesday advanced **House Bill 2012**, which establishes a state antitrust law in Pennsylvania and mandates notice of health care mergers and acquisitions to the Pennsylvania Office of Attorney General and defines enforcement authority. During discussion, several lawmakers requested a hearing with stakeholders to better understand the implications of the bill before a full House vote.

- **Non-compete:** On Wednesday, the House passed **House Bill 1633**. The legislation would ban new and void upon license renewal existing restrictive covenants between health care practitioners and health care facilities.

Industry Trends

Policy / Market Trends

New Research Highlights Premium Impact of Provider Markups on Specialty Drugs

The findings of a new AHIP-commissioned study from Oliver Wyman released found provider markups on specialty drugs increased commercial health insurance premiums by **$13.1 billion in 2024**.

Background: When a health care provider purchases a specialty drug directly and stores the drug until it is required for patient care, they typically include a significant markup on the patient's bill when the drug could have been supplied by a specialty pharmacy at a lower cost.

Impact of Markups: The research found that on average, **providers charge 42% more than a specialty pharmacy** for the same drug.

Other Takeaways:

- Consumers and employers will pay on average $50 more for single coverage and $175 more for family coverage in premiums in 2024 due to the markups charged by providers.
- The total value of health insurance premiums and premium equivalents that could have been saved if providers charged the same price as those from specialty pharmacies would be as much as $13.1 billion in 2024.
- The cost of markups charged by providers on specialty drugs represents about 0.7% of total health expenditures.

Go Deeper: Read the full report here

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/.**