Highmark's Weekly Capitol Hill Report

Issues for the week ending May 3, 2024

Federal Issues

Legislative

House and Senate Committees Hold Hearings on Change Cyberattack

The Senate Finance Committee held a hearing on Wednesday titled "Hacking America's Health Care: Assessing the Change Healthcare Cyber Attack and What's Next." Later in the day, the House Energy and Commerce Oversight and Investigations Subcommittee held a similar hearing titled, "Examining the Change Healthcare Cyberattack."

Why this matters: The cyberattack has had far reaching implications on our health care system, causing many disruptions and exposing the degree to which our health care system is interconnected and heavily reliant on large entities that are vulnerable to attack.

The only witness in the Hearings, UnitedHealth Group (UHG) CEO Andrew Witty, apologized to both panels, stating, "As a result of this malicious cyberattack, patients and providers have experienced disruptions and people are worried about their private health data. To all those

In this Issue:

impacted, let me be very clear: I am deeply sorry. From the moment I learned of the intrusion, I felt a profound sense of responsibility to do everything we could to preserve access to care and support our customers and clients."

He confirmed that the company had paid a $22M ransom with their priority being protection of patient health and personally identifiable information. He also noted that UHG has entirely rebuilt its systems in new environments and largely shifted these functions to the cloud to minimize risk going forward.

Witty focused his testimony largely on the response to the attack, including the interest free loans offered by United to providers and pharmacies, as well as the volume of advanced, accelerated payments and their swift action to ensure systems were disconnected from Change Healthcare products. He stated that all claims processing has returned to virtually normal, a claim that was disputed by nearly every Committee member who had heard from providers, practices, hospitals and pharmacies in their states that there was a significant backlog.

Chairman Ron Wyden (D-OR) attacked United for its anticompetitive practices that have allowed the insurer to become "to big to fail." Ranking Member Mike Crapo (R-ID) blamed the Administration for a response delay and the impact on providers. Other themes included how purported financial and administrative burdens beyond the Change attack, such as PBMs and prior authorization, were exacerbating the difficulties affected institutions were having following the hack. Several Members also pressed Mr. Witty on when and how United planned to notify Americans on whether, and what data, had been compromised. Mr. Witty acknowledged that this was United's responsibility but could not provide a concrete timeline.

- **CMS Issues Draft Guidance for Second Cycle of Medicare Drug Price Negotiation**
- **CMS Releases Appointment Wait Time Secret Shopper Survey Technical Guidance for QHPS**
- **HHS Finalizes Rule to Extend Eligibility to DACA Recipients for Marketplace and BHP Coverage**
- **CMS: Excise of Enforcement Discretion for Existing Health Care-Related Tax Programs with Hold Harmless Arrangements Involving Redistribution of Medicaid Payments**
- **Extension of the HEDIS Data Submission Deadline**
- **FTC Challenges Over 300 Patent Listings in FDA Registry**
- **CMS Releases January 2024 Medicaid Redetermination Data**
- **HHS Final Rule Strengthens Protections Against Disability Discrimination**
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- **State General Assembly Advances Additional Healthcare Bills**

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- **Shapiro Administration Announces Five State Boards Have Adopted New**

The House hearing also saw overwhelming bipartisan frustration from members on United's continued delay in identifying the full scope of the breach and those impacted. Witty committed to members that United would take full responsibility for notifying consumers impacted by the breach. Mr. Witty also committed to working on improving PBM and prior-authorization practices and reassured that United would not pursue retro-active prior authorization denials.

Next steps: The Committees will likely continue to scrutinize United's lack of security safeguards, influence and consolidation in the healthcare sector, as well as conducting oversight of their breach notification requirements in the coming weeks and months.

Policies Around Conversion Therapy for Minors

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- **CMS Publishes Health Care Guide to Assist Individuals Re-Entering Communities After Incarceration**
- **Update to CMS Quality Strategy**
- **New AHA Maternal Health Resource Focuses on Heart Health for Pregnant Women**
- **ACHI Releases New Community Health Assessment Toolkit Resources**

House Panel Holds Hearing on Role of Medicaid Managed Care and LTSS

On Tuesday, the House Energy and Commerce Subcommittee on Health held a hearing on several legislative proposals aimed at to increasing Medicaid access and improving program integrity. The only witness at the hearing was Daniel Tsai, Deputy Administrator and Director of the Center for Medicaid and CHIP Services, Centers for Medicare & Medicaid Services (CMS).

More than a dozen bills were examined at the hearing. Two of note included:

H.R. 8115, which would allow for the deferral or disallowance of portions of payments for certain managed care violations under Medicaid. Rep. John Sarbanes (D-MD), lead sponsor, stated that CMS lacks effective enforcement mechanisms, calling his bill a "nuclear option" to promote compliance.

- Tsai agreed that an "all or nothing" payment approach is "not an effective option" for smaller compliance issues. He pointed to the Managed Care final rule and the "frequent number of direct audits" as actions CMS has taken on MCO oversight.
- Committee Chair Cathy McMorris Rodgers (R-WA) stated that she is concerned about how H.R. 8115 "would upend the shared state-federal partnership of the Medicaid program."

H.R. 8084, which would require states to disenroll Medicaid enrollees found to be deceased. Sponsor Gus Bilirakis (R-FL) commended Tsai on the recent CMS letter on identifying deceased Medicaid enrollees. Tsai noted that states and MCOs complete data matching to confirm someone is deceased as quickly and efficiently as possible.

Other topics discussed at the hearing included making permanent the Money Follows the Person program, home and community-based services investments, postpartum coverage, and the CMS nursing home staffing final rule.

Federal Issues

Regulatory

Labor Department Rescinds 2018 Association Health Plan Rule

The Department of Labor (DOL) released a final rule rescinding a 2018 rule, "Definition of Employer Under Section 3(5) of ERISA – Association Health Plans." DOL determined that the core provisions of the 2018 AHP Rule were not consistent with ERISA's statutory requirements governing the definition of "employer" for purposes of establishing group health plans.

- **AHPs allow employers** to band together under certain criteria to purchase health coverage.

Why this matters: The regulatory changes made in 2018 expanded the ability for employers to form AHPs, which are treated as large group employers — excluding them from coverage and consumer protection requirements established by the ACA under which individual and small group markets operate.

- The rescission of the 2018 rule, which was finalized but never fully implemented due to legal challenges, results in a return to the longstanding pre-rule guidance for whether a group or association of employers is considered a bona fide employer group or association capable of sponsoring an ERISA plan on behalf of its employer members.
- The rule finalizes rescinding in full the ability to form “Pathway 2” AHPs using the expanded flexibility from the rule. The rule does not make any changes to existing AHPs, also known as “Pathway 1” AHPs.

The details: The 2018 AHP final rule was effectively invalidated by a 2019 court ruling, but the
underlying litigation remained.

- **The final rule issued** resolves that litigation and any lingering uncertainty over the rule.

The rule will become effective on July 1, 2024.

Go Deeper: For more information, see the fact sheet, which also was released with the rule. AHIP commented in support of rescinding the 2018 AHP Rule earlier this year. BCBSA strongly supported the DOL's decision to reverse the 2018 final rule, while leaving in place other long-standing AHP rules, as detailed in their comment letter.

HHS Releases Change Healthcare Cyber Attack FAQ Resource

Recently, the Department of Health and Human Services (HHS) published a new resource compiling frequently asked questions (FAQs) regarding the Change Healthcare cybersecurity incident. The FAQ answers 10 of the most common inquiries HHS has received about the incident, including several resources to help entities protect their record systems and patients from cyberattacks.

UnitedHealth CEO, Andrew Witty, testified on the cyber attack before the Senate Finance Committee and the House Energy and Commerce Subcommittee on Oversight & Investigation on Wednesday, May 1.

Go Deeper: Read the resource here.

AHIP & BCBSA Urge HHS to Issue Clear Cyber Breach Notification Guidance

AHIP and BCBSA joined a health care stakeholder letter to Health and Human Services (HHS) Secretary Xavier Becerra urging the Office of Civil Rights to issue clear guidance that Change Healthcare bears sole responsibility for notifying consumers that their information has been breached.

Why this matters: An approach clearly stating that only Change must perform breach notification would provide clarity and avoids tens of millions of Americans being left confused, frustrated, and inundated by numerous breach notification letters from multiple parties.

Signing Organizations: AHIP, Blue Cross Blue Shield Association, Alliance of Community Health Plans, American Medical Association, American Academy of Family Physicians, Association for Community Affiliated Plans

Go Deeper: Read the full stakeholder letter.

White House Update on AI Executive Order Requirements

On April 29, the White House issued a press release highlighting recent actions federal agencies have taken on artificial intelligence (AI).

Background: On October 30, 2023, President Biden issued an Executive Order (EO) establishing new standards and rules for AI that aims to mitigate risks by proactively addressing consumer protections, data privacy, cybersecurity, and algorithmic discrimination through a whole-of-government approach.

Highlights Include:

- Development of the first AI safety and security guidelines for critical infrastructure owners and operators.
- Launch of the AI Safety and Security Board to advise the Secretary of Homeland Security, the critical infrastructure community, private sector stakeholders, and the public on the safe and secure development and deployment of AI technology in our nation's critical infrastructure.
- A final rule clarifying that nondiscrimination requirements in health programs and activities continue to apply to the use of AI, clinical algorithms, predictive analytics, and other tools.
- Strategy development to ensure the safety and effectiveness of AI deployed in the health care sector.

Go Deeper: The National Institute for Standards and Technology also announced the release of 4 draft publications as part of the EO implementation. Comments are due by June 2, 2024.

USPSTF Publishes Final Recommendation for Breast Cancer Screening

The U.S. Preventive Services Task Force (USPSTF) published a final recommendation and evidence summary on screening for breast cancer. Highlights include:

- All women aged 40 to 74 years of age should be screened every other year for breast cancer.
- More research is needed on the benefits and harms of screening women for breast cancer who are older than age 75.
- More research is needed about whether and how additional screenings might help women with dense breasts stay healthy.

Updates from the 2016 Recommendation:

- USPSTF previously recommended that women in their 40s make a decision with their clinician on when they should start screening (between ages 40 to 50), considering personal health history.
- The new recommendation confirms digital mammography and 3D mammography are both effective screening methods.

Why this matters: Breast cancer is the second most common cancer and the second most common cause of cancer death for women in the United States. Under the Affordable Care Act, health insurance providers are required to cover without cost sharing the screenings addressed in this recommendation beginning in the plan year starting one year following publication -- in this instance, January 1, 2026.

The USPSTF's recommendation has a "B" grade and recommends biennial screening mammography for women aged 40 to 75 years. Following the court decision in the *Braidwood Management, Inc. v. Becerra* case, the Departments of HHS, Labor and Treasury (Departments) issued Frequently Asked Questions (FAQs) Part 59 to address

how the decision impacts coverage requirements for preventive services under the Affordable Care Act (ACA). The FAQs clarify that the Departments will no longer enforce coverage requirements for items and services recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010. The FAQs note that the Departments will be issuing further guidance on how to handle updates to recommendations which precede 2010. The original USPSTF recommendation on breast cancer screening is from 1996.

In addition, the Human Resources and Services Administration (HRSA) Women's Preventive Services also has Guidelines which are not impacted by the *Braidwood* decision. The HRSA guidelines include a recommendation on breast cancer screening that women initiate mammography no earlier than age 40 and no later than age 50, among other specifications. The Departments' FAQs indicate that plans and issuers are required to continue to provide coverage, without cost sharing, for items and services supported by HRSA, even if they are also recommended with an "A" or "B" rating by the USPSTF on or after March 23, 2010.

Departments Release New Process for Resubmitting Certain Surprise Billing IDR Disputes

The Departments of Health and Human Services, Labor, and the Treasury (Departments) announced a new process for resubmitting Independent Dispute Resolution (IDR) disputes that were originally improperly batched or bundled. This new resubmission process is automated in the Federal IDR portal.

Why this matters: Starting on May 1, certified IDR entities will notify parties through an email from the Federal IDR portal that a dispute is eligible for resubmission due to improper batching or bundling. Initiating parties will receive a resubmission email notification that will direct them to a unique web form called the Notice of IDR Initiation – Resubmission to complete the resubmission process. Initiating parties have four business days from the date of the resubmission email notification to resubmit a dispute.

Departments Issue FAQs Extending *TMA III* Enforcement Safe Harbor

The Departments of Health and Human Services (HHS), Treasury and Labor (Departments) issued frequently asked questions (FAQs) Part 67, which **announced an extension of the *Texas Medical Association v. HHS (TMA III)* enforcement safe harbor until Nov. 1, 2024**. The safe harbor was previously issued by the Departments in the FAQs about Consolidated Appropriations Act, 2021 Implementation Part 62 (October 6, 2023) following the *TMA III* decision. The FAQs acknowledge the significant resources and challenges associated with recalculating the qualifying payment amount (QPA) following the court decision as well as that plans and issuers need additional time to come into compliance.

The Departments encourage States that are the primary enforcers of the relevant No Surprises Act provisions to adopt a similar approach to enforcement. HHS will not consider a State to be failing to substantially enforce these provisions because the State

adopts such an approach. The Departments will continue to assess the status of QPA calculations but do not expect to further extend enforcement relief for items and services furnished on or after Nov. 1, 2024.

FDA Issues Final Rule on Laboratory Developed Tests
The FDA issued the pre-publication copy of a final rule, *Medical Devices; Laboratory Developed Tests*, that treats Laboratory Developed Tests (LDTs) as devices, subjecting them to FDA review.

Why this matters: While FDA had previously stated that it considered LDTs as devices, it has used enforcement discretion to exempt them from review. With this rule, FDA will codify LDTs as devices and will implement a four-year gradual withdrawal of its enforcement discretion, citing concern that some of the tests may not provide accurate results or perform as well as FDA-approved in vitro diagnostic products.

Insurer Perspective: AHIP commented in support of the proposed rule in December 2023, agreeing with the FDA on the wide variability in the accuracy and validity of LDTs across therapeutic areas. This rulemaking follows legislative attempts to establish a similar FDA review system for LDTs, notably the VALID (Verifying Accurate Leading-edge IVCT Development) Act, which has been active in Congress since 2018 but has failed to pass.

Next Steps: The FDA will host a webinar on May 14 to provide an overview of the final rule and the phaseout policy. The rule takes effect 60 days after publication in the May 6 *Federal Register*.

Hospital Perspective: The American Hospital Association (AHA) had urged the FDA not to apply the proposed rule to hospital and health system laboratory developed tests. In the final rule, FDA said it intends to exercise limited enforcement discretion for certain categories of IVDs, including LDTs developed and performed by a laboratory integrated within a health care system to meet an unmet need of patients receiving care within the same health care system, currently marketed LDTs that were first marketed prior to the date of issuance of the final rule, and LDTs approved by the New York State's Clinical Laboratory Evaluation Program. In addition, the agency released draft guidance on the rule's enforcement discretion policy during an infectious disease outbreak or public health emergency.

- Hospitals are pleased that the FDA has recognized the unique value and safety of laboratory tests developed by hospitals and health systems for direct use in patient care. The enforcement discretion in this final rule is of particular importance.

- Hospitals also welcome the agency's attention to the gaps in FDA-authorized commercially available tests in meeting certain patient needs, such as for rare diseases or conditions. The FDA's decision to apply limited enforcement discretion for currently marketed laboratory-developed tests rightly recognized that applying

the full scope of its device regulations to these tests would likely prompt many hospital laboratories, particularly small ones, to stop offering safe and effective tests upon which patients and their communities rely.

- **However, hospitals remain concerned** that many vital tests developed in hospitals and health systems may be subjected to unnecessary and costly paperwork, especially as certain FDA device requirements are phased in over the next four years. As a result, this may cause a substantial reduction in patient access to innovative and targeted diagnostic tests.

CMS Updates RxDC Materials

CMS released an Information Collection Request for the Prescription Drug and Health Care Spending reporting requirements (RxDC) for the 2023 reference year for use in reporting by the June 1, 2024, deadline. The updated reporting instructions are available on REGTAP.

Why this matters: BCBSA submitted recommendations to CMS on the previous version of the reporting instructions based on Plan feedback. The agency continues to grant flexibility to reporting entities to use a group health plan identifier other than the Form 5500 Plan Number and adds in this version of the reporting instructions that the reporting entity may leave that field blank. CMS continues to allow entities to exclude group health plans in columns E & F that do not provide employer-paid and member-paid premium amounts to reporting entities. Per BCBSA's recommendation, CMS directs group health plans to report these data directly to CMS ("If the plan does not provide [the reporting entity] this information, then the plan must submit its own P2 and D1 to CMS."). CMS did not accept BCBSA's recommendation to continue non-enforcement of the aggregation restrictions for an additional year.

Comments are due in 30 days (May 30).

CMS Issues Draft Guidance for Second Cycle of Medicare Drug Price Negotiation

CMS issued initial guidance on key elements of the second cycle of negotiations for the Medicare Drug Price Negotiation Program, which begins in 2025 and will result in negotiated prices for 2027. The draft guidance also includes provisions addressing manufacturer effectuation of the maximum fair price (MFP) in 2026 and 2027. CMS will select up to 15 additional drugs covered under Part D for this second cycle of negotiations. In the fact sheet, CMS states that the "draft guidance build on lessons learned from implementing the Negotiation Program to date."

CMS is seeking feedback on the proposals outlined in this guidance, with key elements of particular interest to CMS for input highlighted in the fact sheet. Comments on the draft guidance are due to CMS by July 2. Submission instructions are included in the draft guidance.

CMS Releases Appointment Wait Time Secret Shopper Survey Technical Guidance for QHPs

CMS has released a document that provides QHP issuers and QHP issuers' third-party entities with methodological standards and structured guidelines for administering secret shopper surveys to providers.

Why this matters: In the 2025 Final Letter to Issuers in the FFEs, published April 10, 2024, the Centers for Medicare & Medicaid Services (CMS) stated that, beginning January 1, 2025, Qualified Health Plan (QHP) issuers, including stand-alone dental plan (SADP) issuers, in the Federally-facilitated Exchanges (FFEs) are required to meet appointment wait time standards established by the FFEs.

For the 2025 plan year, QHP issuers, including SADP issuers, will be required to ensure that enrollees seeking an appointment are able to schedule an appointment within specific timeframes at least 90% of the time. CMS is particularly concerned with the ability of new patients to schedule appointments with in-network providers; more than half of enrollees on the FFEs newly enroll in QHPs or change their enrollment to a new QHP each year, and these enrollees may need to seek care as a patient who is new to a provider.

HHS Finalizes Rule to Extend Eligibility to DACA Recipients for Marketplace and BHP Coverage

The Centers for Medicare & Medicaid Services (CMS) published a final rule to modify the definition of "lawfully present" applicable to eligibility for enrollment in a Qualified Health Plan (QHP) through the Health Insurance Marketplace and a Basic Health Program (BHP). The final rule clarifies the definition of "lawfully present" includes DACA recipients, determining that they will be treated the same as other individuals with deferred action for purposes of eligibility for specific CMS programs.

Why this matters: With this modification, DACA recipients will no longer be excluded from that definition, thereby making it possible, effective November 1, 2024, for DACA recipients who meet all other eligibility requirements to enroll in a QHP through the Marketplace with financial assistance like Advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSRs), or a BHP.

HHS finalized its proposal to extend eligibility for coverage through the health insurance Marketplaces and Basic Health Plan (BHP) to Deferred Action for Childhood Arrivals (DACA) recipients. The Centers for Medicare & Medicaid Services (CMS) estimates that this rule could lead to 100,000 previously uninsured DACA recipients enrolling in Marketplace health coverage or a BHP.

No Changes to Medicaid and CHIP: Notably, HHS did not finalize a proposed definition of "lawfully present" for purposes of Medicaid and CHIP, stating the agency is "taking more time to evaluate and carefully consider the comments regarding our proposal with respect to Medicaid and CHIP, and specifically, to continue evaluating the potential

impact of our proposed definition of 'lawfully present' on State Medicaid and CHIP agencies."

Technical Changes: The final rule made technical modifications to the definition of "lawfully present" used to determine eligibility for coverage through a Marketplace or a BHP to promote administrative simplification, clarity, and transparency. The final rule also updates the definition of "qualified noncitizen" for Medicaid and CHIP, which clarifies the categories of noncitizens that states must cover in these programs.

Enrollment Periods: The final rule will go into effect on November 1, 2024. DACA recipients, and other noncitizens newly considered lawfully present, will also qualify for a special enrollment period during the 60 days following the rule's November 1 effective date.

Go Deeper: A prepublication of the final rule is available here. CMS also issued a press release and fact sheet. The final rule will be published in the *Federal Register* on May 8.

CMS: Excise of Enforcement Discretion for Existing Health Care-Related Tax Programs with Hold Harmless Arrangements Involving Redistribution of Medicaid Payments

The Centers for Medicare & Medicaid Services (CMS) issued an informational bulletin indicating that until Jan. 1, 2028, it will not enforce specific federal regulations related to healthcare-related tax programs with hold-harmless arrangements involving the redistribution of Medicaid payments.

Why this matters: This decision allows states time to adjust existing financial structures without facing immediate federal enforcement, aimed at avoiding disruptions in Medicaid services and potential impacts on provider solvency, especially for safety net providers. During this period, CMS will offer technical assistance to help states transition to compliant financing mechanisms and prepare for the enforcement of these policies starting in 2028. Read More

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Extension of the HEDIS Data Submission Deadline

Given the unprecedented cyberattack on Change Healthcare and its widespread impact on health care operations across the country, CMS and National Committee for Quality Assurance (NCQA) announced an extension to the data submission deadline for HEDIS measurement year 2023 audited summary-level and PLD data to 5:00 p.m. Eastern Time on June 28, 2024. NCQA notes that all submissions must be marked final, and attestations must be signed by this time and no additional extensions, late submissions or resubmissions will be considered.

NCQA strongly recommends that organizations maintain their existing HEDIS® MY 2023 operational timeline for submission if no relief is needed. The June 1 plan lock deadline is still encouraged, but it should be applied for all submissions approximately 2 weeks before the final submission deadline to allow auditors time to review the final data.

FTC Challenges Over 300 Patent Listings in FDA Registry

The Federal Trade Commission is challenging more than 300 patents for 20 drug products for weight loss, diabetes, asthma and chronic obstructive pulmonary disease that don't cover actual inventions and were improperly listed in the FDA's Orange Book. Several companies received warning letters from the FTC, and they were given 30 days to amend or withdraw their patent listings or to "certify under penalty of perjury that the listings comply with applicable statutory and regulatory requirements," the agency said.

CMS Releases January 2024 Medicaid Redetermination Data

The Centers for Medicare & Medicaid Services (CMS) reported the latest batch of Medicaid Redeterminations data reported under the Consolidated Appropriations Act, 2023; click here to access. **CMS posted a summary of outcomes for the renewals initiated in January, including:**

- 6.2 million people were due for renewal in January, a number which usually hovers around 7 million.
- Of those due for renewal, 62.8% had their coverage renewed in Medicaid and CHIP. Of those who had their coverage renewed, 72.7% were completed through an *ex parte* review, continuing a positive trend.
- Fewer than one fifth (18.5%) lost their Medicaid and/or CHIP coverage, which also continues a slight downward trend. Within that cohort, 67.0% of terminations in January were for procedural reasons.
- A slightly lower percentage of people are pending final resolution at the end of the month, at 18.7%.

The January 2024 National Summary of Renewal Outcomes (click here to access) includes month-by-month comparisons on the data listed above, among other things. The Medicaid and CHIP Unwinding Operations Snapshot (here) includes state-by-state changes in Medicaid and CHIP enrollment, new applications, and call center data.

CMS also released several new batches of data on the Monthly Data Reports page, under "Most Recently Released Unwinding Data," including:

- February 2023 Preliminary Medicaid and CHIP Renewal Outcomes;
- The Marketplace Medicaid Unwinding Report (Healthcare.gov, Healthcare.gov Transitions, State-based Marketplace);
- November 2023 Separate CHIP Report; and
- Updated August 2023 Medicaid and CHIP renewal outcomes, reflecting the outcomes of previously pending renewals three months after the renewal was due.

HHS Final Rule Strengthens Protections Against Disability Discrimination

The Department of Health and Human Services May 1 released a final rule bolstering discrimination protections for people with disabilities under Section 504 of the Rehabilitation Act.

The rule clarifies and strengthens civil rights protections for people with disabilities, addresses discrimination in medical treatment, adds enforceable standards for accessible medical diagnostic equipment, and ensures accessible web content and mobile apps. It also helps protect individuals with disabilities from experiencing discrimination in any program or activity receiving funding from HHS because of their disability.

Additionally, the final rule updates existing requirements to make them consistent with the Americans with Disabilities Act. The rule takes effect 60 days after publication in the May 9 *Federal Register*.

See the HHS fact sheet for more on the rule.

CMS Opens Comment Period for Medicare Drug Price Negotiation Program
The Centers for Medicare & Medicaid Services (CMS) May 3 announced the opening of the comment period for the Inflation Reduction Act's Medicare Drug Price Negotiation Program, which will negotiate prices with drug makers for certain high-cost, sole-source drugs and apply them beginning in 2026. Comments are due July 2.

State Issues

Delaware
Legislative

Pharmacy Legislation Introduced
SB 272 : Pharmacists in Delaware provide some of the same medical services as physicians, advance practice registered nurses, and physician assistants, including immunizations. This Act would require health insurance providers to provide the same reimbursement to pharmacists that is already provided other providers performing the same services at the same rates as advance practice registered nurses and physician assistants.

HB 383: This Act prohibits discrimination against 340B drug distribution by manufacturers, repackagers, third-party logistics providers, and wholesalers as well as prohibiting discrimination by pharmacy benefits managers against 340B covered entities.

State Issues

New York

Regulatory

2025 NY State of Health Invitation Sent

Last week, the NY State of Health issued its invitation to insurers to participate for the 2025 plan year. Applicants are requested to submit Letters of Interest and Participation Proposals ***electronically*** to the following email address: nyhxpm@health.ny.gov

As outlined in the invitation, Letters of Interest are due by May 10, 2024, and Participation Proposals are due on May 24, 2024. This link will take you directly to the 2025 invitation and related documents.

The Plan Year 2025 invitation requirements are consistent with the 2024 invitation with the following updates, consistent with policies that have been discussed with plans:

QHP

- New for 2025, subject to federal approval, are three cost sharing initiatives for QHPs: Cost Sharing Subsidies to 400% FPL, Diabetes and Maternal Health. Information can be found on pages 9 through 11 and in Attachment “U” of the plan invitation.

Essential Plan

- The Diabetes Cost Sharing Initiative also applies to the Essential Plan. Information can be found on pages 9 and 10 and in Attachment “U” of the plan invitation.

SADP

- Beginning, January 1, 2025, for standalone dental plans offered through NYSOH, waiting periods will not be permitted for any adult dental services, other than up to 12 months for orthodontics for on exchange individual stand-alone dental plans. See page 21.

State Issues

Pennsylvania

Legislative

State General Assembly Advances Additional Healthcare Bills

State lawmakers continue to focus on the healthcare workforce and other health priorities, as they advance work on the 2024–2025 state budget. Both the House and Senate will be in Harrisburg this week.

Workforce legislation:
Senate committees have advanced three bills to support Pennsylvania's health care workforce. They include:

- **Senate Bill 1165** would address long-standing issues associated with federal background checks that have delayed Pennsylvania's participation in the Nurse Licensure Compact and Medical Licensure Compact.
    - The Senate Consumer Protection and Professional Licensure Committee advanced the bill last week.
- **Senate Bill 1102** would expand the Pennsylvania Nurse Aide Training program and allow student and graduate nurses to immediately take the Certified Nurse Aide exam after completing their education programs.
- **Senate Bill 1104** would allow high school juniors and seniors to earn up to two credits toward their graduation requirements if they have worked in a congregate health care setting, including a hospital.

Senate Bill 1102 and 1104 advanced through the Senate Education Committee last week.

Workplace violence legislation:
The House Labor and Industry Committee will consider **House Bill 2247** during a voting meeting Tuesday. The bill mandates workplace violence prevention committees in hospitals and other health care settings and provides expansive oversight by the Department of Labor and Industry.

Nursing workforce legislation:
Following its voting meeting this Tuesday, the House Labor and Industry Committee will hold an informational meeting to consider "the nursing workforce crisis from the nurses' perspective."

"Momnibus" legislation:
The House Insurance Committee will consider **House Bill 2138** during a voting meeting Monday. The bill requires insurance coverage for blood pressure monitors for home use on a per-pregnancy basis.

Also in the House, two other bills that are part of the Pennsylvania "Momnibus" package passed second consideration and are with the appropriations committee.

- **House Bill 2097** would expand coverage of at-home blood pressure monitors for pregnant and postpartum women.
- **House Bill 1608** would extend Medicaid coverage for doula services and create the doula advisory board.

New reinsurance pilot program: The House Insurance Committee will consider **House Bill 2234**. The legislation implements a program proposed in the governor's budget that creates an "affordability assistance program" to help buy health insurance through Pennie.

Regulatory

Shapiro Administration Announces Five State Boards Have Adopted New Policies Around Conversion Therapy for Minors

On May 2, the State Board of Nursing, and Medicine, Social Workers, Marriage and Family Therapists and Professional Counselors, Psychology and Osteopathic Medicine voted to adopt new Statements of Policy that oppose the use of conversion therapy on minors in Pennsylvania.

Why this matters: The new policies make clear to licensees that all five Boards consider the use of conversion therapy to be unprofessional and harmful conduct that may subject any licensee engaging in such activity to administrative discipline.

The Trevor Project, a national organization devoted to ending suicide among LGBTQ+ young people along with the Pennsylvania Chapter of the National Association of Social Workers and the Pennsylvania Association told State boards earlier this year that conversion therapy on minors remains an issue in Pennsylvania despite an Executive Order protecting citizens from this practice, which was issued by Governor Tom Wolf in August of 2022. The new Statements of Policy will become effective upon publication in the Pennsylvania Bulletin.

The Press Release by the Shapiro Administration also reminds citizens that they may file a complaint against any licensed professional who they believe to be engaging in unprofessional or harmful behavior by visiting the Department of State website.

Industry Trends

Policy / Market Trends

CMS Publishes Health Care Guide to Assist Individuals Re-Entering Communities After Incarceration

CMS has released and posted a publication Returning to the Community: Health Care After Incarceration to assist individuals re-entering the community to better understand their health care needs, including physical and behavioral health. Developed in partnership with the Department of Justice, the guide contains information to help individuals connect to health care services pre- and post-release, and to learn about insurance coverage types and how to apply, and tips to get started using health coverage to receive needed services to support a successful reentry and healthy life.

Update to CMS National Quality Strategy

On April 29, CMS released an update on the CMS National Quality Strategy (NQS) including a three-part call to action:

- Adopt the Universal Foundation measure sets across quality and value-based programs, including the newly published hospital, maternity care, and post-acute care/long-term care add-on sets.
- Commit to improving health care safety and reducing harm.
- Advance health equity in all quality and value-based programs.

New AHA Maternal Health Resource Focuses on Heart Health for Pregnant Women

Cardiovascular conditions are one of the most common causes of morbidity and mortality among pregnant women. The American Hospital Association's (AHA) Better Health for Mothers and Babies initiative April 29 released a resource highlighting strategies hospitals are implementing to raise awareness and detect heart health needs early, during and after pregnancy.

ACHI Releases New Community Health Assessment Toolkit Resources

The American Hospital Association's (AHA) Community Health Improvement network has added new resources to its Community Health Assessment Toolkit, including four new supplements focusing on how to involve specific populations in the CHA process: older adults, caregivers, people with disabilities; and refugee, immigrant and migrant communities.

In addition, eight new case studies highlight how health care organizations and community partners have used tactics and strategies from the toolkit to address priority health needs in their communities.

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/.**