# Highmark's Weekly Capitol Hill Report

**Issues for the week ending June 10, 2022**

## Federal Issues

Regulatory

### Fixing the "Family Glitch"

AHIP & BCBSA submitted comments in response to the U.S. Department of the Treasury and the Internal Revenue Service's (IRS) proposed rule to fix the Affordable Care Act's (ACA) "family glitch." The proposal would allow the cost of family coverage to be considered when determining whether an employee's spouse and dependents qualify for premium tax credits.

**Why this matters: The Biden administration estimated that under this proposed rule 200,000 would gain health insurance coverage and 1 million Americans would have reduced premiums.** A Kaiser Family Foundation analysis found that most of the people impacted by the "family glitch" are enrolled in employer-based coverage but could pay lower premiums if allowed to buy subsidized marketplace coverage.

- The new interpretation would base the affordability of employer coverage for an employee's family members on the cost of covering the employee and their family members but would continue to bar employees with affordable self-only employer coverage

## In this Issue:

from tax credit eligibility. Additionally, both AHIP and BCBSA recommended changes related to the calculation of minimum value, and offered suggestions for a smooth implementation of the proposed changes.

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### Departments Release Checklist of Requirements for Federal IDR Process

The Departments of the Treasury, Labor, and Health and Human Services (Departments) released a checklist to help group health plans and group and individual health insurance issuers comply with requirements of the No Surprises Act (NSA). This checklist was released in response to questions and complaints the Departments received regarding plan and issuer requirements. The checklist is not an exhaustive list of NSA requirements and focuses on the requirement to process claims within 30-calendar-day timeframe, the requirement to provide certain information in writing with each initial payment or notice of denial of payment, open negotiation period and Federal IDR Initiation.

CMS is holding a training for plans and issuers on the No Surprises Act Qualifying Payment Amount (QPA) calculation methodology and QPA audits on Monday, June 13, from 1-3 pm Eastern time. Visit the REGTAP registration page by Friday, June 10, at 1:00 pm Eastern time to register for the training.

- **Regulatory Update: COVID-19 Emergency Regulations Extended; Maternity Report & Pharmacy Regulations**

**Pennsylvania**

***Legislative***

- **House and Senate Advance CHIP Choice Legislation**
- **Senate Health and Human Services Committee Advance Pasteurized Donor Human Milk Legislation**
- **House Insurance Committee Holds Meeting on Insurance Data Security Legislation**
- **Senate Committee Passes Childhood Lead Testing Legislation**
- **Supreme Court Committee Signaling It Will Move Forward with Proposal to Change Venue Rules in Medical Malpractice Cases**

## Industry Trends

**Policy / Market Trends**

- **FTC Launces Inquiry into Pharmacy Benefit Managers**
- **MACPAC Releases Issue Brief on LGBT Medicaid Beneficiaries Accessing Care**
- **HHS Resources on Infant Formula Shortage**

## CMS Releases Behavioral Health Strategy

The Centers for Medicare & Medicaid Services (CMS) released a behavioral health strategy that focuses on ensuring that access, equity, quality and data integration are used in the prevention and treatment of mental health and substance use disorders (SUD). The Behavioral Health Strategy consists of five interrelated goals: strengthening equity and quality in care; improving access to SUD care; ensuring effective pain treatment; improving access and quality of mental health care; and utilizing data to inform effective actions and impact on behavioral health. The strategy supports the Administration's efforts to address the national mental health crisis.

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## CMS National Quality Strategy

Leaders from the Centers for Medicare & Medicaid Services (CMS), Center for Clinical Standards and Quality published a blog post on the CMS National Quality Strategy and next steps for the first phase of this multi-part approach. CMS will begin listening sessions in early summer 2022 to further collaboration with stakeholders to develop and operationalize short- and long-term actions. To ensure a unified approach the agency will also look to federal affiliates, external stakeholders, Quality Improvement Organizations, private payers, states and territories, and others to implement the goals outlined in the CMS National Quality Strategy. The success of this strategy relies on coordination, innovative thinking, and collaboration across all entities.

In April CMS launched their eight goal National Quality Strategy to help create a more equitable, safe, and outcome-based health care system for all individuals. **The core goals of the strategy include:**

- Embed Quality into the Care Journey
- Advance Health Equity
- Promote Safety
- Foster Engagement
- Strengthen Resiliency
- Embrace the Digital Age
- Incentivize Innovation and Technology Adoption to Drive Care Improvements
- Increasing Alignment

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## AHIP Comments on HIPAA Civil Monetary Penalties RFI

AHIP submitted comments on the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) request for information (RFI) on security practices and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

**Why this matters:** The RFI focuses on situations when OCR makes determinations regarding fines, audits, and remedies to resolve potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Security Rule and the potential distribution of a percentage of civil money penalties (CMPs) or monetary settlements to harmed individuals.

The comment letter highlights support for the goals of recent cybersecurity laws designed to address threats to electronic systems. AHIP also emphasized how health insurance providers implement physical, technical, and administrative safeguards to protect members' personal information.

As OCR considers potential regulation of security practices, AHIP's comments focus on the following key themes:

- How "recognized security practices" is defined.
- Public and private entities working together to share information on cyber threats.
- Exploring ways public and private entities can measure the effectiveness of security practices.
- Any OCR investigation or review should deem compliance when an entity uses good faith practices.
- Determining compensable harm with respect to HIPAA security violations should closely follow the statutory language of the HITECH Act.

AHIP's full comment letter can be found here.

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## CMS Releases Frequently Asked Questions (FAQs) on Agent and Broker Compensation

These FAQs address compensation paid by issuers to agents and brokers who assist consumers with enrollment during a Special Enrollment Period (SEP) or during Open Enrollment Periods (OEPs). The document notes paying differential compensation to agents and brokers for coverage in the same benefit year based on whether the enrollment is completed during an SEP or during the OEP is prohibited under federal law.

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## CMS Released the 2021 Part C and D Program Audit and Enforcement Report via a HPMS Memo

This report provides information on the program audit process, a current snapshot of the program audit landscape, a summary of the 2021 program audits, as well as CMS' enforcement actions. *The report was shared as an attachment to the HPMS memo but will eventually be uploaded here.*

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## COVID-19 Updates

- The Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended that the FDA grant emergency use authorization (EUA) for the Novavax COVID-19 vaccine in adults by a vote of 21-0. The FDA is expected to make a decision on granting Novavax an EUA soon. If approved the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) will meet to determine when and how the vaccine should be administered.

- During a press briefing regarding the impending release of COVID-19 vaccines for children under five, Dr. Ashish Jha, White House Coronavirus Response Coordinator, spoke publicly to the news that the Biden Administration will divert funds from public health programs to ensure the next generation of vaccines are available for Americans in the fall and winter and to continue to acquire

therapeutics approved to fight COVID-19. Dr. Jha emphasized that, in addition, the White House COVID Response Team is discussing the urgency of getting the necessary resources to continue to protect the American people directly with Congress.

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### Medicare Trustees Project Part A Trust Fund Insolvency in 2028, Two Years Later than Previous Report

Medicare trustees issued their annual report, including a projection that the Hospital Insurance (Part A) Trust Fund, which helps pay for services such as inpatient hospital care, would become insolvent in 2028, two years later than predicted in last year's report. The report credited a stronger-than expected economy and increased tax revenue for extending the life of the trust fund. According to the trustees, the share of Medicare Advantage payments coming from the Part A trust fund has declined from 52.3% in 2011 to 42.1% in 2021 and is projected to continue falling to 37.9% by 2031. The trustees also issued a Medicare funding warning, which is required when, for two years in a row, the trustees project the difference between Medicare's total outlays and its dedicated financing sources to exceed 45 percent of outlays within 7 years. This is the fifth consecutive year such a warning has been triggered in the report.

## State Issues

### Delaware

Legislative

### Senate Introduces Diabetes Supply Cap Legislation

Senate Bill 316 caps the amount that an individual, group, or State employee plan may charge for diabetes equipment and supplies, other than insulin, at $35 per month. This cap does not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, disability income, or other limited benefit health insurance policies.

## State Issues

### New York

Regulatory

### COVID-19 Emergency Regulations Extended

The Department of Financial Services (DFS) has once again extended the two emergency regulations related to cost sharing for COVID-19 services: waving cost sharing for coronavirus testing and waiving cost sharing for COVID-19 vaccines.

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### Maternity Report

As required by a law signed last year, DFS, in consultation with DOH, must issue a report to the NYS legislature by the end of the year on coverage for maternity care, including the scope of review of benefits related to childbirth under commercial and Medicaid plans. DFS last week provided a draft 308 letter and spreadsheets that will be used to collect plan data on claims for calendar years 2019 and 2020 that will be used in the report.

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### Pharmacy Regulations

Two DFS proposed regulations were published in the June 8 State Register. The first, Registration of Pharmacy Benefit Managers, establishes regulations for the registration and first annual report of pharmacy benefit managers. The second relates to the Pharmacy Benefits Bureau within DFS, changing the name the Office of Pharmacy Benefits to the Pharmacy Benefits Bureau and expanding its authority. Previously charged with conducting investigations with respect to prescription drugs, the Bureau's responsibilities now also include the regulation of PBMs.

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## State Issues

### Pennsylvania

Legislative

### House and Senate Advance CHIP Choice Legislation

Last week, the House unanimously advanced House Bill 2585 (Pickett, R-Bradford) and the Senate unanimously advanced Senate Bill 1235 (DiSanto, R-Dauphin).

This legislation would prohibit the Pennsylvania Department of Human Services from developing or utilizing bidding or service zones that limit a health service corporation or hospital plan corporation contractor from submitting a bid for CHIP.

House Bill 2585 was referred to the Senate Banking and Insurance Committee and Senate Bill 1235 was referred to the House Insurance committee, for consideration.

**Why this matters:** Highmark expressed support for advancing this legislation, which would provide a path for certain CHIP families to maintain CHIP coverage without disruption.

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### Senate Health and Human Services Committee Advance Pasteurized Donor Human Milk Legislation

On Tuesday, the Senate Health and Human Services Committee Advanced Senate Bill 1202 (Brooks, R-Mercer). Senate Bill 1202 would require health insurers to cover the use of medically prescribed pasteurized donor human milk (PDHM) in inpatient and outpatient settings for children under the age of 12 months if the child's mother is medically or physically unable to produce maternal breast milk in an amount needed to meet the child's needs.

Amendment A04462 (Brooks, R – Mercer) was offered to Senate Bill 1202 and unanimously adopted by the committee which specifies that inpatient reimbursement for human donor milk would be paid separately from a bundled payment.

Highmark currently covers this service in an inpatient setting as part of a bundled payment for maternity care. Highmark expressed concerns with mandating coverage for specific conditions in an outpatient setting and that PDHM should be prioritized for high-risk, low birthweight inpatient infants.

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## House Insurance Committee Holds Meeting on Insurance Data Security Legislation

The House Insurance committee held an informational meeting on House Bill 2499.

**Why this matters:** The legislation would amend Title 40 (Insurance), to propose the adoption of the National Association of Insurance Commissioners (NAIC) model law requiring licensees to conduct an annual risk assessment.

- Further, this legislation would require each insurer domiciled in Pennsylvania to submit an annual written statement to the Pennsylvania Insurance Department certifying that the insurer is in compliance with the risk assessment, information security program, and oversight portions of the Act, and this legislation would require a licensee or an outside vendor and/or service provider to conduct a prompt investigation and notify the Commissioner of the Pennsylvania Insurance Department within three (3) business days from a determination that a cybersecurity event involving nonpublic information in the possession of the licensee has occurred.

David Buono, deputy insurance commissioner, Office of Market Regulation, Pennsylvania Insurance Department (PID), described cybercrime as one of the "greatest threats" consumers and businesses work to prevent. He expressed support for establishing "uniformity" for the country's cyber security laws by utilizing a model law. He delineated how insurance providers must provide notification of cyber attacks or data breaches to the proper authorities.

Laura Rieben, deputy privacy officer, Internal Audit and Compliance Department, Independence Blue Cross, testified that IBC supports House Bill 2499. She explained the bill requires notification based on the determination one individual may likely be impacted, in contrast to federal Health Insurance Portability and Accountability Act (HIPAA) standards that set a threshold based on the size of an impacted population. She added HIPAA standards allows 60 days following the discovery of a breach to notify a federal regulator for populations with more than 500 individuals, and 60 days following the end of the calendar year for cases with fewer than 500 individuals.

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## Senate Committee Passes Childhood Lead Testing Legislation

The Senate Appropriations Committee unanimously passed SB 522, which provides for blood lead testing of certain children and pregnant women by health care providers; imposes duties on the Department of Health; and requires certain health insurance policies to cover blood lead tests.

Sen. Lisa Baker (R-Luzerne), the bill's prime sponsor, thanked the committee for advancing Senate Bill 522 and noted the bipartisan legislation will "increase awareness, assessment and testing to detect lead poisoning in our children." She noted a floor amendment is anticipated.

### Pennsylvania Supreme Court Committee Signaling It Will Move Forward with Proposal to Change Venue Rules in Medical Malpractice Cases

The Civil Procedural Rules Committee is planning to propose to the Supreme Court of Pennsylvania changes to the procedural rules regarding venue in medical malpractice actions. The proposed change, detailed in a notice published in the December 22, 2018 *Pennsylvania Bulletin*, would revive the venue rules that largely created PA's severe medical malpractice insurance crisis.

**Background:** Prior to 2003, Pennsylvania's loose venue rules allowed medical malpractice plaintiffs to sue defendants almost anywhere they did business, even if the alleged malpractice occurred elsewhere. The result was that the vast majority of PA malpractice cases were filed in Philadelphia, Allegheny County, and a couple other pro-plaintiff counties.

In 2003, with insurance options limited and premiums soaring, the PA Supreme Court amended the venue rules to require the filing of medical malpractice cases only in the county where the alleged malpractice occurred (Pa.R.Civ.P 1006(a.1)). This amendment, which was the most important of the reform efforts that addressed the insurance crisis, reduced medical malpractice filings in PA by 40%, from about 2,500 cases per year to 1,500 cases per year.

Now, the Civil Procedural Rules Committee is proposing to ask the Supreme Court to consider a proposal to rescind the venue reform and restore the prior venue rules. This change is being proposed on the theory that the insurance crisis is over and medical malpractice defendants are no longer entitled to special treatment.

**Legislative action:** In 2002, Pennsylvania's governor, General Assembly and Supreme Court worked together to end venue shopping. That same approach is not present so a bid to amend Pennsylvania's constitution to stop the return of venue shopping in medical malpractice liability cases is underway in the General Assembly.

State Representative Rob Kauffman (R-Franklin) has introduced **House Bill 2660**, which would begin the process of amending the state constitution to allow the General Assembly to establish the venue of civil lawsuits and prevent venue shopping. To amend the state constitution, lawmakers must pass identical resolutions in back-to-back legislative sessions. The amendment is then put to a public vote as a statewide ballot question.

## Industry Trends

Policy / Market Trends

### FTC Launches Inquiry into Pharmacy Benefit Managers

The Federal Trade Commission announced it will launch an investigation into Pharmacy Benefits Managers (PBMs).

**Why this matters:** As part of the investigation the six largest PBMs will be required to provide information to the FTC on their business practices. The aim of the investigation is to analyze the impact of vertically integrated PBMs on access and affordability of prescription drugs.
The FTC voted 5-0 to issue the investigation under Section 6(b) of the FTC Act, which allows the FTC to conduct studies without a specific law enforcement purpose. CVS Caremark, Express Scripts, OptumRx., Humana, Prime Therapeutics, and MedImpact Healthcare Systems were identified in the press release and will have 90 days from the date they are contacted to respond.

**Specifically, the inquiry will aim to shed light on several practices:**

- fees and clawbacks charged to unaffiliated pharmacies
- methods to steer patients towards pharmacy benefit manager-owned pharmacies
- potentially unfair audits of independent pharmacies
- methods to determine pharmacy reimbursement
- the prevalence of prior authorizations
- the use of specialty drug lists and surrounding specialty drug policies
- the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients

Last month, AHIP submitted comments to the FTC on PBM business practices, highlighting insurers' shared commitment to more affordable prescription drugs, and detailing how health insurance providers and PBMs use their bargaining power to negotiate savings for millions of Americans.

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## MACPAC Releases Issue Brief on LGBT Medicaid Beneficiaries Accessing Care

The Medicaid and CHIP Payment and Access Commission (MACPAC) published an issue brief which found that the majority of lesbian, gay, and bisexual adults on Medicaid had a usual source of care and similar rates of physical health care service use as heterosexual adults on Medicaid. However, these adults were significantly more likely to report not having received necessary behavioral health or alcohol and drug treatment in the past 12 months. Medicaid-covered transgender and gender-diverse adults reported similar rates of access to providers for both routine and most gender-affirming health care as those covered by private insurance, but those covered by Medicaid were more likely to report not being able to find in-network providers for gender affirming surgery. Read More

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## HHS Resources on Infant Formula Shortage

The Department of Health and Human Services (HHS) has created a resource for families on how to manage their needs during the ongoing infant formula shortage, including finding substitutes and safe feeding practices. Most recently, they released an infographic with a conversion chart for converting milliliters to fluid ounces among other common conversions. Last week, the Food and Drug Administration (FDA) also provided an update on incoming formula supplies. New formula from Nestlé (Mexico) is expected beginning in July.

**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/.**