
**Issues for the week ending June 9, 2023**

## Federal Issues

Legislative

### House Committees Advances Health Care Bills

On Wednesday, the House Ways & Means Committee advanced legislation in a number of health care areas, including telehealth, health savings accounts (HSA), and health reimbursement arrangements.

**The bills passed by the committee include:**

- H.R. 1843, the Telehealth Expansion Act of 2023: This bill would make permanent the CARES Act provision providing employers with flexibility to offer telehealth services below the deductible to employees with an HSA paired with a consumer directed health plan (CDHP). The provision is currently set to expire on December 31, 2024.
- H.R. 3800, the Chronic Disease Flexible Coverage Act: This bill would codify existing flexibilities for employers to offer coverage of chronic care management services pre-deductible in HDHPs (e.g. beta blockers, blood pressure monitors).
- H.R. 3797, the Paperwork Burden Reduction Act: This bill would eliminate the requirement for employers to mail 1095 tax forms on health

## In this Issue:

coverage to employees and gives them the option to supply the information online.
- H.R. 3801, the Employer Reporting Improvement Act: This bill simplifies certain Affordable Care Act reporting requirements for employers and creates a 6-year statute of limitations on reporting errors.
- H.R. 3798, the Small Business Flexibility Act: This bill requires the Treasury Department to notify small businesses of the flexible coverage options available to them.
- H.R. 3799, the Custom Health Option and Individual Care Expense (CHOICE) Arrangement Act: This bill codifies a Trump-era rule on individual coverage health reimbursement arrangements (ICHRAs), renaming them "CHOICE Accounts."

**Next steps?** While next steps are unclear, the bills could be combined into a larger health care package for the House to consider later in the summer.

- **Senate Advances Cyber Security Legislation**
- **House Approves $100M for PA Mental Health Needs**

**New York**

***Legislative***

- **2023 Legislative Session Concludes**

***Regulatory***

- **Medicaid Waiver Deemed Complete**

## Federal Issues

Regulatory

### CMS Issues Final Rule on Medicare Disproportionate Share Hospital Payments: Treatment of Medicare Advantage Patient Days

On June 9, the Centers for Medicare & Medicaid Services (CMS) issued a final rule concerning the treatment of patient days associated with persons enrolled in a Medicare Advantage plan for purposes of calculating a hospital's disproportionate patient percentage.

**Why this matters:** The disproportionate patient percentage is a key factor in determining a hospital's Medicare disproportionate share hospital (DSH) payment. The final rule establishes that MA patient days will be counted in the Medicare fraction of the disproportionate patient percentage and applies this policy retroactively to any cost reports that remain open for cost reporting periods starting before October 1, 2013.

## HHS Publishes National Model Standards for Substance Use, Mental Health, & Family Peer Worker Certifications

The U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), published the National Model Standards for Peer Support Certification. The model standards were created to support universal adoption, recognition, and integration of the peer workforce across all elements of the health care system. For the purposes of this work, a peer worker is someone who, through their own lived experience of addressing a substance use or mental health issue, can work to help others.

SAMHSA collaborated with federal, state, tribal, territorial, and local partners to develop the national model standards.

**Why this matters:** The national model standards are not intended as a substitute for any state certifications, but instead have been developed as guidance for states, territories, tribes, and others to promote quality and encourage alignment and reciprocity across state peer support certifications.

- In 2015, SAMHSA published Core Competencies for Peer Workers in Behavioral Health Services, which enabled the implementation of state-endorsed or state-run peer certification programs in 49 out of 50 states.
- The new model standards could help augment work force shortage issues. Read the new National Model Standards for Peer Support Certification here.

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## CMS Announces Multi-State Value-Based Payment Model to Strengthen Primary Care

The Centers for Medicare & Medicaid Services (CMS) announced a new primary care payment model – the **Making Care Primary (MCP) Model** – that will be tested under the Center for Medicare and Medicaid Innovation (CMMI) in 8 states: Colorado, Massachusetts, Minnesota, New Mexico, New Jersey, New York, North Carolina, and Washington.

**Why this matters:** Building on previous primary care models tested by CMMI, the model's design progresses from straight fee-for-service (FFS) payments to fully prospective, risk-adjusted population-based payments.

As CMS notes in its statement, this is a multi-payer model. CMS indicated they will engage private payers in the coming months and is working with State Medicaid Agencies in the listed MCP states. MCP will run from July 1, 2024, to December 31, 2034. CMS plans to release a Request for Applications (RFA) and commence the application period for this model "in late summer 2023."

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## Latest IRA Inflationary Rebate Drug List Totals 43 Part B Therapies & ASPE Issues Report on Medicare Part B Drug Spending

On Friday, June 9, CMS released its latest quarterly update revealing which drugs are subject to rebates based on price increases that will outpace inflation for the third quarter of 2023.

There are 43 Part B drugs that made the list in what is the second round of quarterly updates required by the Inflation Reduction Act.

**Why this matters:** Starting April 1, 2023, Medicare beneficiaries taking drugs on the list may pay a lower coinsurance amount for these drugs. In this round, CMS estimates that enrollees taking one of the 43 drugs will save between $1 to $449 per average dose between July 1-September 30. The number of drugs on the rebate list jumped over 200% from the initial list, demonstrating the dynamic nature of Part B drug pricing, specifically, average sales price information.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the Department of Health and Human Services (HHS) also issued a new report highlighting key drivers of growth in Medicare Part B drug spending between 2008-2021.

**Why this matters:** The report shows Medicare Part B drugs had the fastest rate of spending growth among drugs in the Medicare program over the past few decades. **Part B drug spending per enrollee in original Medicare grew on average at 9.2% annually over the 2008-2021 period. This spending growth was more than triple the rate in Part D (2.6%)** and nearly 4 times as high as the rate of per capita annual prescription drug spending across all payers (2.4%).

**Other key findings in the report include:**

- Medicare spending on biologics has grown much more rapidly than spending on non-biologics over the past 13 years. Spending growth on biologics accounted for nearly all (89%) of drug spending growth from 2008-2021.
- Part B drug spending is concentrated among a small number of drugs: the top 20 drugs account for more than 50 percent of Part B drug spending, while the top 10 account for 40% of Part B drug spending in 2021.
- Part B drug spending is largely driven by three medical specialties: ophthalmology, oncology, and rheumatology.

Read the ASPE report here.

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## CMS & FDA Updates

- **Sunset of MHPAEA Opt-out:** On June 7 CMS posted a Bulletin describing when self-funded, non-Federal governmental group health plans that currently opt out of compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) are required to come into compliance with these requirements. The Consolidated Appropriations Act, 2023 had included a sunset provision for the self-funded, non-Federal governmental group health plan election to opt out of compliance with MHPAEA.

- **CMS Publishes 30-day Notice for Proposed Applicable Integrated Plan Coverage Decision Letter:** CMS announced an opportunity for dual eligible special needs plans (D-SNPs) that are applicable integrated plans (AIPs) and other partners to comment on the updated Applicable Integrated Plan Coverage Decision Letter. The Coverage Decision Letter is issued by AIPs as a result of an integrated organization determination under 42 CFR 422.631, when the plan reduces, stops, suspends, or denies, in whole or in part, a request for a service/item or payment (including a Part B drug). Comments are due by July 6, 2023.

- **FDA revokes Emergency Use Authorization (EUA) for Janssen COVID-19 Vaccine:** On June 1, the Food and Drug Administration (FDA) granted a withdrawal of the EUA for the Johnson & Johnson COVID-19 vaccine developed by Janssen Pharmaceutical Companies. Janssen requested the EUA be revoked due to lack of demand, expired lots, and its lack of intention to update the strain composition of the vaccine to address emerging variants.

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## State Issues

### Pennsylvania

Legislative

### Bill Imposing Government-Mandated Nurse Staffing Ratios Advances in General Assembly

On June 6, the state House Health Committee advanced legislation that would mandate one-size-fits-all nurse-to-patient ratios across Pennsylvania hospitals, a move hospitals and nursing leaders have warned would force facilities to close beds and reduce services amid a historic health care workforce shortage.

In a 12–9 vote, the committee sent **House Bill 106** to the full chamber for consideration.

**Background:** During a **hearing** last month, hospitals and nurse leaders emphasized that Pennsylvania hospitals are aggressively working to fill existing vacancies and actively deploying strategies to reduce strain on current bedside nurses.

- **In a letter to the committee last week, HAP President and CEO Andy Carter voiced hospitals' opposition** to the bill and raised concerns that mandating staffing ratios would hurt Pennsylvanians' access to health care. "Given the well-documented, nationwide shortage of bedside nurses, this bill

will put Pennsylvania hospitals in the impossible position of having to choose between turning patients away or breaking the law at the risk of losing their licenses," Carter wrote.

- The committee voted to amend the legislation before reporting it out to the full House. The changes removed a requirement for hospital staffing plans to be developed by staffing committees and added a provision prohibiting hospitals from reducing ancillary and support staff to accommodate mandated ratios for registered nurses.

**Why this matters:** Despite extraordinary efforts to hire and support nurses—including signing and referral bonuses, pay increases, schedule flexibility, retention incentives, loan forgiveness, wellness initiatives, investments in staff who want to advance their careers, and investments that prioritize staff safety—Pennsylvania hospitals reported a nearly 31 percent vacancy rate for bedside registered nurses late last year.

- Hospitals continue to urge the General Assembly to focus on solutions that grow the health care workforce, not mandating staffing ratios that will hurt access to care.

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## Senate Advances Cyber Security Legislation

On Wednesday, June 7, the Senate unanimously advanced House Bill 739 (Boyle, D – Philadelphia). House Bill 739 would require licensed insurance entities to develop cybersecurity policies and report cybersecurity events to the Insurance Commissioner.

House Bill 739 now awaits signature or veto consideration from the Governor.

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## House Approves $100M for PA Mental Health Needs

The state House of Representatives approved legislation last week that would allocate $100 million in federal funding to address Pennsylvania's mental health needs. The legislation passed with bipartisan support by a 173-30 vote.

**Background**: As part of the 2022-23 state budget, the General Assembly established the Behavioral Health Commission on Adult Mental Health, a 24-person group tasked with providing recommendations to the General Assembly on how to appropriate $100 million in one-time federal American Rescue Plan funding to address behavioral health needs in Pennsylvania. The commission, composed of experts in the behavioral health field, advocates and providers, as well as Schlossberg and other legislators, created a set of recommendations.

**The legislation would take the following recommendations from the commission and expand the efforts to address the needs of struggling youth:**

- $34 million toward behavioral health workforce improvements.
- $25.5 million for criminal justice and public safety initiatives.
- $40 million to expand access to mental health services and supports.

- $500,000 to evaluate the overall impact of these initiatives.

**Next steps:** House Bill 849 moves to the Senate for consideration.

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**New York**
Legislative

## 2023 Legislative Session Concludes

The Legislature adjourned on Saturday, with the Assembly expected to return to Albany in the “near future” to complete unfinished work. A date has not been announced, but many are speculating it will be June 20.

**In the closing days of the session the legislature passed a number of bills affecting health plans, including:**

- **Drug price increase notice (A.1707-A/S.599-A)** — requires pharmaceutical manufacturers to provide advance notice of prescription drug price increases of 16% or more. The bill would require 60-days’ notice in advance of the proposed price increase, including the date of the increase, the current price and proposed increase, and an explanation on the need for the increase.

- **Medicaid rate data (A.5381/S.6075)** — expands the level of detail the Department of Health provides to Medicaid managed care plans as part of the rate development process, which will provide greater transparency, allowing plans to better analyze the adequacy of the rates set by the Department and understand the state’s assumptions.

- **Medicaid quality incentive program (A.6021/S.3146)** — codifies in statute the quality incentive program for Medicaid managed care plans. The bill represents an important step to ensure funding would continue to be available for initiatives aimed at addressing the core causes of health disparities and improving health outcomes for underserved populations that health plans support.

- **Biomarker testing coverage (A.1673/S.1196)** — Lawmakers struck a compromise on this proposal that mandates coverage of biomarker testing, addressing concerns Highmark and other plans had raised with the broadness of the bill, with the final version ensuring individuals are able to access biomarker testing while emphasizing the importance of tests that are evidence-based.

- **Step therapy notices (A.463/S.2677)** — Requires written procedures for step therapy adverse determination notices.

- **Medicaid reserve sunset extension (S.7477/A.7393)** – extends the sunset on nonprofit reserve limits in Medicaid for an additional two years.

- **Direct ambulance reimbursement (A.250/S.1466-A)** —requires health plans to directly reimburse ambulance service providers regardless of whether they are in-network or out-of-network providers. The bill gained traction in the final days of session.

**Several other bills did not receive final approval, including:**

- **Step therapy (A.901/S.1267)** – would severely restrict health plans' ability to require step therapy programs for prescription drugs.
- **Transfer tax (S.3122/A.3885)** — Imposing a 9.63% tax on any out-of-state transfers health plans may make, including dividends, payments or loans.
- **"Gold carding" (S.2680/A.859)** — Requiring plans to institute "Gold Card" processes for providers meeting prior authorization thresholds.
- **Coverage expansion for undocumented residents (S.2237-A/A.3020-A)** — Directing the Commissioner of Health to amend the state's recent 1332 waiver request to allow undocumented New Yorkers who are currently excluded to enroll in the Essential Plan.

The Legislature also confirmed Dr. James McDonald as New York's Commissioner of Health. A native of the Albany area, Dr. McDonald served in the Rhode Island Department of Health before being appointed Acting Commissioner by Gov. Hochul in January, 2023.

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Regulatory

## Medicaid Waiver Deemed Complete

The NY State of Health last week announced that the Centers for Medicare & Medicaid Services (CMS) determined that New York's 1332 waiver application is "complete." The application proposes expanding the Essential Plan to New Yorkers with incomes up to 250% of the Federal Poverty Level, which NYSOH says "would allow New York to extend significantly more affordable coverage to additional low-income New Yorkers and reach uninsured individuals and families who may otherwise fall through the cracks." CMS's notice of completeness opens the federal public comment period, which runs until July 5, 2023. Individuals and organizations can provide comment via email at stateinnovationwaivers@cms.hhs.gov.

**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/.**