Highmark's Weekly Capitol Hill Report

Issues for the week ending February 9, 2024

Federal Issues

Legislative

Senate Committee Examines Artificial Intelligence in Health Care

On Thursday, the Senate Finance Committee (SFC) held a hearing titled "Artificial Intelligence and Health Care: Promise and Pitfalls."

Why this matters: Witnesses and senators expressed optimism that Artificial Intelligence (AI), if used with appropriate guardrails and patient protections, could produce better outcomes while also driving savings for the health care system overall.

However, participants in the hearing generally recommended more transparency, accountability, and privacy protections in legislation and regulations.

Several of the witnesses pointed to the recent court cases where patients claimed specific Medicare Advantage (MA) plans were using AI algorithms to improperly deny care. The Centers for Medicare and Medicaid Services (CMS) has since clarified that MA

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plans cannot use AI algorithms for this purpose.

Nonetheless, senators and witnesses alike agreed that there needs to be a balance between allowing the government to enforce transparency, patient protection and privacy without stifling innovation. There was general agreement that fine-tuning regulations within government programs is a good first step.

State Issues

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Legislative

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- **Medicare Advantage Insurers' Lawsuits Call New Star Ratings Arbitrary**

Committees Hold Hearings on Drug Prices, Shortages

On Thursday, The CEOs of Johnson & Johnson, Merck, and Bristol Myers Squibb testified before the Senate HELP Committee on high-priced drugs. The witnesses acknowledged affordability challenges and asked that discounts negotiated by pharmacy benefit managers be passed on to patients.

Why this matters: Democratic Senators pushed drugmakers to focus more on patients than profits and Republicans spoke in support of the benefits of a market-driven system that promotes competition.

- Chairman Bernie Sanders (I-VT) reviewed highlighting from the recent Democratic committee staff report highlighted profits tallied by the drugmakers in 2022 — $17.9 billion by J&J, $6.3 billion by Bristol Myers Squibb, and $14.5 billion by Merck — which the chairman argued constitutes "ripping off the American people."

- Sanders also stated that he plans to introduce new drug pricing legislation but did not give any details.

Also last week, the House Ways & Means Committee convened a hearing entitled, "Examining Chronic Drug Shortages in the United States" to identify potential policy solutions to drug shortages facing the American health system. Among those testifying included executives from McKesson Pharmaceutical Solutions & Services, nonprofit generic drug firm Civica Rx, and the American Society of Clinical Oncology.

Members raised several concerns exacerbating drug shortages, including reliance on foreign countries for the drug supply chain and exclusive manufacturing contracts. Chairman Jason Smith (R-MO) suggested changes to Medicare reimbursement policy, stating, "Medicare's reimbursement system ensures affordability and access for seniors, but should be reexamined to avoid making the situation worse."

Zoom in: Senate Finance Committee leadership has also floated reforms to Medicare Part A and B payments to maintain a supply of generic sterile injectable drugs. Additionally, they have suggested reforms to Medicare Part D and possible changes to the Medicaid drug rebate program. On the House side, Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-WA) has focused on providing certain drugmakers with exemptions from the Medicaid inflation rebate and 340B safety-net programs.

QALY Ban Passes House

On Wednesday, the U.S. House passed H.R. 485, which would prohibit all federal health care programs from using Quality-Adjusted Life Years (QALYs) to determine relevant thresholds for coverage, reimbursements, or incentive programs. The House also adopted an amendment from Rep. Mark Molinaro (R-NY) that would require a study on how QALYs "negatively impact individuals with intellectual and developmental disabilities and their access to care." The 211-208 vote was split along party lines with Republicans supporting and Democrats opposed. The bill also would prohibit Medicare, Medicaid, and other federal programs from using "similar measures" to QALYs, which could open the door to a broad interpretation. The Congressional Budget Office has scored the bill as increasing federal spending by $1.1 billion.

Next Steps: This is likely the end of the road for this proposal in the current Congress. Senate Majority Leader Chuck Schumer (D-NY) indicated that the Senate will not vote on the bill and the White House opposes the legislation.

House Committee Passes PBM Delinking in FEHBP

The House Committee on Oversight and Accountability (O&A) advanced H.R. 6283, the Delinking Revenue from Unfair Gouging (DRUG) Act, last week by a vote of 29-10-1. The DRUG Act would impose various government mandates on pharmacy benefit managers (PBMs) including applying delinking to the commercial and federal employees markets; banning spread pricing; and prohibiting PBMs from using preferred pharmacies to obtain cost savings (so-called "steering").

Why this matters: The move represents the latest in a wave of anti-PBM legislation that has dominated the health care discussion in this Congress. A variety of PBM reforms are on the table for consideration for a health care package that could be included in expected omnibus government funding legislation next month.

Yes, but: The O&A committee only has jurisdiction over the Federal Employee Health Benefits Program (FEHBP) portion of the bill. To date, the other House committees of jurisdiction have not expressed an interest in advancing H.R. 6283, instead clearing less onerous PBM reforms that have already passed the House.

Federal Issues

Regulatory

Medicare Advantage Insurers Can't Use AI, Algorithms to Deny Care: CMS Issues FAQs on 2024 MA Coverage Criteria and Utilization Management Requirements

On February 6, the Centers for Medicare & Medicaid Services (CMS) issued a memorandum to address frequently asked questions (FAQs) regarding the 2024 Medicare Advantage (MA) coverage criteria and utilization management requirements that were finalized in the 2024 MA & Part D rule.

Medicare Advantage Insurers Can't Use AI, Algorithms to Deny Care: CMS clarified that Medicare Advantage insurers are not allowed to use algorithms or AI-powered tools as basis for denying care or coverage. Algorithms and AI tools can be used only to support coverage decisions, and insurers must ensure that the tools they are using comply with the CMS' coverage decision requirements, the agency said.

"We are concerned that algorithms and many new artificial intelligence technologies can exacerbate discrimination and bias," the agency wrote Feb. 6. "MA organizations should, prior to implementing an algorithm or software tool, ensure that the tool is not perpetuating or exacerbating existing bias, or introducing new biases."

CMS Releases Postpartum Coverage FAQs

The Centers for Medicare and Medicaid Services (CMS) released a set of frequently asked questions (FAQs) as a follow-up to the 2021 State Health Official (SHO) letter "Improving Maternal Health and Extending Postpartum Coverage in Medicaid and the Children's Health Insurance Program (CHIP)."

Key Takeaway: The FAQs provide guidance to state Medicaid programs regarding what are considered “full benefits” during the 12-month extended postpartum eligibility period and clarify whether a state needs to submit a state plan amendment (SPA) to amend its coverage documentation. Read the FAQ document here.

HHS Releases Final Rule on Confidentiality of Substance Use Disorder Patient Records

The Department of Health and Human Services (HHS), through the Office for Civil Rights (OCR) and the Substance Abuse and Mental Health Services Administration (SAMHSA), released the Confidentiality of Substance Use Disorder (SUD) Patient Records final rule. The rule aligns certain regulations for SUD treatment records (“Part 2” rules) with the privacy rules under the Health Insurance Portability and Accountability Act (HIPAA).

Why this matters: As directed by Congress in the 2020 Coronavirus Aid, Relief, and Economic Security Act (CARES Act), HHS made several changes to the Part 2 rules to support improved care coordination and reduce administrative complexity, while maintaining strong protections for confidentiality of sensitive patient information.

Key highlights of the final rule include:

- Permitting use and disclosure of Part 2 SUD records based on a single patient consent given one time for all future treatment, payment, and health care operations uses and disclosures.
- Establishing new rights for patients to obtain an accounting of disclosures and to request restrictions on certain disclosures, aligned with the HIPAA Privacy Rule.
- Expanding prohibitions on the use and disclosure of Part 2 records in civil, criminal, administrative, and legislative proceedings.
- Providing enforcement authority to HHS, including the potential imposition of civil money penalties, for Part 2 violations.

- Defining new breach notification requirements applying to Part 2 records.

Why this matters: Insurers have long supported legislative and regulatory action to update the Part 2 rules. The proposals in this rule will substantially improve hospitals' and health systems' ability to provide safer, better coordinated care to patients with substance use disorder through vital information sharing.

A **fact sheet** is available online. The **final rule** will be published February 16.

ACL Finalizes Rule on OAA Transportation and Nutrition Programs

The Administration for Community Living (ACL) recently released a final rule to update regulations for implementing its Older Americans Act (OAA) programs, including meal delivery, transportation to medical appointments and support for family caregivers.

Role of MCOs: The final rule does not address Medicaid requirements but does specifically acknowledge the role Medicaid managed care plans play in serving older adults in need.

Key Provisions:

- Clarifies requirements for state and area plans on aging and details requirements for coordination among tribal, state, and local programs.
- Clarifies and strengthens provisions for meeting OAA requirements for prioritizing people with the greatest social and economic needs.
- Specifies the broad range of people who can receive services, how funds can be used, fiscal requirements, and other requirements that apply across programs.
- Includes guidance for the National Family Caregiver Support Program and the Native American Caregiver Support Program.
- Addresses emergency preparedness and response, incorporating lessons from the COVID-19 pandemic.

Next Steps: The rule will take effect on March 15, 2024, but regulated entities have until October 1, 2025, to comply.

CMS Shares Guidance on Paxlovid Coverage in Medicaid

CMS shared guidance on ensuring access to Paxlovid for Medicaid enrollees.

Why this matters: As described in the guidance, Pfizer has agreed to pay rebates for the number of units of commercial Paxlovid products invoiced at the 'Medicaid paid amount' submitted on the State's quarterly rebate invoice. For managed care, Pfizer will pay rebates at either the managed care encounter reporting of the 'Medicaid paid amount' on the quarterly invoice or based on the fee-for-service state-specific 'Medicaid paid amount' rate. If the managed care encounter reporting of the 'Medicaid paid amount' is missing or questionable, the fee-for-service calculated 'Medicaid paid amount' rate will be used to determine the appropriate amount to pay for managed care invoice units.

State Issues

New York

Legislative

Biomarker Coverage Bill Amendment Signed

Originally passed last session, the bill **(A8502/S8040)** requires coverage for biomarker testing in certain circumstances in commercial and Medicaid policies. It was signed by the Governor with the agreement that it would be amended before enactment; she signed the amendment on February 7, 2024. Highmark had engaged on the amendments. It will be effective on January 1, 2025.

Bills in Committee This Week

The Senate and Assembly Health Committees will both meet this week, with several bills of interest on their agendas.

- **PAs as PCPs for Medicaid (S.2124/A.7725)** – would allow physician assistants to be primary care practitioners for Medicaid managed care plans. Plan medical directors have expressed concerns about the proposal.
- **Carve-outs from MMC (S.2867/A.7369)** – would permanently carve out individuals served by the nursing home transition diversion and traumatic brain injury waivers from the Medicaid managed care program.
- **Breast ultrasound coverage (S.2917A.2516)** — would require health plans to cover breast ultrasounds based on an individual receiving a "notice of dense breast tissue," which would be deemed a determination of medical necessity. This does not meet United State Preventive Services Task Force "A" or "B" recommendations for breast cancer screening and would create a new mandated benefit.
- **UR and PA restrictions (S.3400/A.7268)** – would impose new standards on health plans' utilization review criteria, imposes standing prior authorization requirements and prohibit health plans from retroactively denying claims to providers for members who are no longer covered by the health plan.
- **Non-timely UR response (S.3402/A.6898)** – would require that a non-timely plan utilization review response be deemed "approved."
- **School based health center services in Medicaid (S.7840/A.8862)** – would allow school based health center services to remain outside the Medicaid managed care benefit package.

Regulatory

New Pharmacy Benefit Manager Regulation Issued

The Department of Financial Services last week issued a proposed new market conduct regulation to govern Pharmacy Benefit Managers operating in New York. This is the follow up to the PBM regulation that was ultimately withdrawn last fall.

Major changes in the new proposal include:

- **Fees:** Removes the prohibition that PBMs shall not charge pharmacy fees related to enrollment or participation in a pharmacy network, including application fees, credentialing fees, change of ownership fees or fees for claim management.
- **Pricing:** The sections related to requiring maximum allowable cost (MAC) lists and appeals; necessitating that "minimum" price for drugs be set at no less than the national average drug acquisition cost (NDAC); imposing a $10.18 dispensing fee; and prohibiting certain dispensing restrictions and network adequacy were all removed.
- **Termination:** DFS deleted some circumstances and added other circumstances to the basis for immediate termination.
- **Pharmacy Disclosures:** New language was added that provides that a PBM shall not directly or indirectly prohibit a pharmacy from:

    - discussing information regarding the cost of the prescription with the individual;
    - disclosing to a covered individual the availability of any therapeutically equivalent alternative medication;
    - selling a more affordable alternative to a covered individual;
    - providing a covered individual with the option of paying the pharmacy's cash price and not filing a claim with the health plan if the cash price is less than the cost-sharing amount; or
    - offering and providing mail or delivery services to a covered individual as an ancillary service of the pharmacy.

This was issued as a pre-proposed regulation, which is subject to a 10-day comment period with comments due later this week. Once the regulation is published in the State Register, there will be a 60-day comment period.

Related to this, DFS also issued a request for comments and data or documented evidence regarding: minimum network adequacy requirements, limits on midyear formulary changes, use of drug manufacturer rebates, and aberrant quantity/product list restrictions in pharmacies.

Essential Plan (EP) Expansion Update

Last week, staff from the New York State of Health (NYSoH) stated that the plan to implement the expansion of EP eligibility for those with incomes up to 250% of the federal poverty level (FPL) is scheduled to move forward on April 1, 2024 – pending final federal approval.

A notification process will begin on March 2 to inform impacted Qualified Health Plan (QHP) enrollees that they are no longer QHP eligible and will be default enrolled into an aligned EP plan or must choose a new plan. Eligible individuals who do not choose a new plan will be auto-assigned after 10 days. Eligible individuals may choose to stay in a QHP, but with no financial assistance. The amended 1332 waiver will also begin moving Deferred Action for Childhood Arrivals (DACA) individuals aged 19-64 from Medicaid to EP beginning in August. Finally, NYSoH staff stated that plans will be required to carry over any accumulators through March 31, 2025. NYSoH will distribute accumulator data to plans.

State Issues

Pennsylvania

Legislative

2024–2025 Governor's Budget Proposal Released

On February 6, 2024, Governor Josh Shapiro presented his proposal for Pennsylvania's fiscal year 2024–2025 budget. This is the governor's second annual proposal and follows closely on the heels of last year's budget process, which extended through the end of last year.

While key themes of this year's address heavily emphasized education and economic development, the governor also renewed his support for raising Pennsylvania's minimum wage. He also referenced several health-related issues, including, but not limited to, mental health programming, the high cost of health insurance, medical debt relief, **pharmacy benefit manager (PBM) reform**, the need to invest in Pennsylvania's direct-support workforce, and legalization of marijuana.

Also included in health-related issues was support for rural hospitals, Governor Shapiro did not offer a funding proposal but noted that rural health care is facing a crisis and his intention to develop a plan to address this crisis and put rural health care on stable footing.

Initial Analysis: The governor's proposal calls for $48.3 billion in general fund spending, an 8.4 percent increase over last year. Initial review notes several budget lines of particular interest to the health care community. **Some highlights include:**

Access to Care

- **$50 million in state funding to continue Pennsylvania's reinsurance program to "create an additional subsidy wrap for low- and middle-income Pennsylvanians that are on the cusp of being able to afford health insurance"**
- $4 million for medical debt relief for low-income Pennsylvanians

Behavioral Health

- $100 million for school-based mental health services

- $20 million to increase counties' base funding for behavioral health services and supports
- $10 million for 988 crisis line operations and capacity building
- $5 million to establish and maintain walk-in mental health crisis stabilization centers, with a focus on geographic areas that may not have any (hospital partnerships encouraged)

Health Care Workforce

- $216 million to leverage additional federal funds with an aim to increase recruitment and retention of home- and community-based service providers
- $30 million for the fire and emergency medical services grant program
- $10 million to increase PENNCARE to help area agencies on aging stabilize the elder care workforce

Population Health

- $37.5 million to support a violence intervention and prevention program at Pennsylvania Commission on Crime and Delinquency
- $2.6 million for continued maternal health programming at the Department of Health
- $1 million for firearm injury prevention programming at the Department of Health

The governor's proposal also maintains a transfer from the cigarette tax to the Tobacco Settlement Fund as well as Medicaid supplemental payments to hospitals, including:

- $14.47 million for critical access hospitals
- $8.657 million for trauma centers
- $4.438 million for burn units
- $3.682 million for obstetric and neonatal services

Senate Republicans responded swiftly, asserting that the governor's proposal is "absolutely fiscally irresponsible and unsustainable." Among their concerns were the governor's substantially higher revenue assumptions as compared to last year.

The General Assembly's appropriations committees will begin budget hearings on February 20. Both chambers will return to session on March 18. Pennsylvania's annual budget deadline is June 30, 2024.

Why this matters: The Hospital & Healthsystem Association of Pennsylvania (HAP) highlighted the hospital community's priorities for rural health, as well as workforce, behavioral health, and maternal health in a December **letter to the governor**.

State Issues

West Virginia

Legislative

Legislative Update: Biomarker Mandate, EMS Ambulance Reimbursement & Dental Expenditure Reporting

HB 4753—Cancer Biomarker Testing
This bill was previously advanced from the House Insurance Committee under an agreement between Highmark, AHIP, The Health Plan and the MCO Association with the American Cancer Society that was brokered by Delegate Steve Westfall, chairman of the committee. However, after the bill was passed in the first committee, ACS representatives have been trying to gain support for modifications to the bill outside of the agreement—and have actually gone over to the Senate trying to undercut the agreement as well.

ACS and the Michael J. Fox Foundation's representatives are proposing to remove the prior authorization rights of plans regarding biomarker testing, to expand testing to include pre-diagnosis circumstances and to remove prohibitions in the bill against paying for non-FDA approved testing and treatment. Chairman Westfall has made it clear that he will only support the version of the bill that was previously agreed to and if ACS persists in pushing for changes, it will imperil the passage of the bill.

HB 5417—NCOIL model bill on dental plan expenditure reporting.
The House Insurance Committee endorsed the NCOIL model dental plan reporting bill last week and will next be considered in the Health Committee. There were no modifications proposed to the model bill and the WV Dental Association did not attempt to gain any modifications. We expect this bill to move through the legislative process unchanged by the end of the session.

EMS-Ambulance Reimbursement
Bills on emergency ambulance services and insurance reimbursement (SB 444 and HB 5255) are key portions of the EMS coalition's efforts to secure stable funding for their operations outside of state appropriations. Insurers were able to negotiate favorable terms in these bills with the EMS coalition by removing emergency air ambulance services from the legislation and any entitlement to receive reimbursement for non-patient treatment/non-transport scenarios. SB 444 has moved in the Senate to the Finance Committee where the Chairman, Senator Eric Tarr, has indicated that he will likely add Medicaid into the provisions of the bill as a way to save money on emergency room visits. HB 5255 will likely move from the Fire and Emergency Services Committee —also with an exclusion of air ambulance from the provisions of the bill.

HB 5379—Fairness in Cost-sharing calculations
This bill is proposed to create technical corrections to the co-pay maximizer legislation originally enacted in 2018. This bill is expected to be endorsed by the House Health Committee and then be passed by the full House by the end of this week.

HB 5310—Broadband providers/Health plan cooperative agreements
This bill proposes to establish a statutory framework for broadband providers and health plans to voluntarily partner in delivering services to plan members for purposes of improving patient access to telemedicine services and remote health monitoring. It was

advanced from one committee and is now in the possession of the House Judiciary Committee.

Other Significant Mandated Coverage Proposals
SB 443, pertaining to oral health and cancer rights, mandates coverage that would fall outside of the EHB under ACA and has remained in the Senate Banking & Insurance Committee without any attention so far in the legislative session. Similarly, the same Senate committee has control of SB 486 mandating breast cancer screening and there are no current indications of this bill moving forward for consideration at this point either. There are no current signs that HB 4174 prohibiting "white bagging," is going to be considered in the House Health Committee.

HB 5338—Data Privacy Protection Act
This is a comprehensive privacy bill that loosely follows the Virginia statute on privacy. There are no current indications on how this bill will be managed in the House Finance Committee.

HB 4809—Health Sharing Ministries Act
This measure will move forward in the House Judiciary Committee over the next two weeks or so and is written in a fashion that does not impact health plans and in a form acceptable to the Office of the Insurance Commissioner.

Industry Trends
Policy / Market Trends

2021 Medicare Current Beneficiary Survey Chartbook
CMS released its annual update to the Medicare Current Beneficiary Survey (MCBS) Chartbook with data for 2021. The Chartbook provides an interactive collection of charts and tables based on estimates from the MCBS, organized into 4 domains:

- **Domain 1: Medicare Population Overview.** Demographic and socioeconomic characteristics of Medicare beneficiaries.
- **Domain 2: Beneficiary Health and Well-Being.** Self-reported health status and health behaviors of Medicare beneficiaries.
- **Domain 3: Health Care Access and Satisfaction**. Access to and satisfaction with health care services.
- **Domain 4: Health Care Use and Expenditures.** Health care use by Medicare beneficiaries across eleven service categories, including: dental services, hearing services, inpatient hospital services, long-term facility care, Medicare home health services, Medicare Hospice Services, outpatient hospital services, physician/supplier services, prescription drugs, skilled nursing facility care, and vision services. Health care expenditures and all sources of payment across service categories.

Medicare Advantage Insurers' Lawsuits Call New Star Ratings Arbitrary

Lawsuits from Medicare Advantage insurers SCAN Health and Elevance Health claim HHS' 2024 star ratings calculations are unlawful and arbitrary, as the payers expect lower ratings from a new methodology will reduce their quality bonus payments. The lawsuits could challenge the ability of HHS and the CMS to lower costs in the Medicare Advantage program amid heightened scrutiny.

Full Story: Bloomberg Law

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/.** .