Highmark's Weekly Capitol Hill Report

Issues for the week ending May 10, 2024

Federal Issues

Legislative

House Committee Advances Legislation on Telehealth, PBMs

On Wednesday, the House Ways and Means Committee advanced several health care bills, touching on telehealth, pharmacy benefits managers (PBMs), and rural health.

Why this matters: Existing Medicare telehealth flexibilities are set to expire at the end of the year and Congress must take action to avoid a lapse. However, the cost of the extension must be offset, with savings generated from PBM reform legislation a possibility.

Specifically, the Committee advanced H.R. 8261, the Preserving Telehealth, Hospital, and Ambulance Access Act, by a 41-0 vote. The proposal includes a 2-year extension of eased Medicare telehealth rules and other provisions to:

- Remove geographic restrictions on telehealth services and expand originating sites to include the home.
- Allow health centers and rural health clinics to provide telehealth.

In this Issue:

- Establish a modifier for recertifications of hospice care eligibility conducted through telehealth.
- Extend acute hospital care at home waiver flexibilities.
- Enhance certain program integrity requirements for DME under Medicare.

The package also incorporates the Medicare Part D PBM de-linking, PBM reporting to Part D sponsor, and audit and enforcement rights for Part D sponsor provisions of the Senate Finance Committee's Modernizing and Ensuring PBM Accountability Act (MEPA), with some modifications. Specifically:

- The de-linking and reporting provisions include new explicit references to PBM affiliates.
- PBMs would be required to have written agreements with affiliates, under which affiliates identify and disgorge certain remuneration to the PBM.
- PBMs would be required to report the amount of compensation provided to brokers and consultants for referrals, consulting, auditing, or other services offered to Part D sponsors related to PBM services, as well as the methodology for calculating such compensation.
- One of the MEPA PBM reporting requirements, relating to manufacturer rebate or other agreements that are tied to coverage or restrictions placed on other drugs, would be modified to include drugs covered as supplemental benefits or "paid outside of this part." This may include manufacturer agreements tied to Part B drugs covered by Medicare Advantage plans.
- A new confidential reporting mechanism would be established for alleged violations, with anti-retaliation and anti-coercion provisions for reporting of alleged violations.
- The provisions would be effective January 1, 2027.

During the hearing several Members expressed concerns over the pay-fors, including Ranking Member

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- **AHIP Spotlights Mental Health Coverage**
- **New Research Shows Rural FFS Beneficiaries Spend More on Healthcare than MA Enrollees**

Richard Neal (D-MA), who indicated he will continue to work with the Committee on improving the legislation for a year-end package. John Larson (D-CT) in particular expressed reservations over including the PBM policies, suggesting that the provisions were not yet ripe for this package.

Next Steps: The House Energy and Commerce Committee is also expected to announce a markup on telehealth policies in the coming days.

Senate Committee Holds Hearing on Health Care Administrative Burdens

The Senate Budget Committee held a hearing on Wednesday entitled "Reducing Paperwork, Cutting Costs: Alleviating Administrative Burdens in Health Care."

Why this matters: Witnesses, who largely represented providers, testified that transparency of denials and rethinking prior authorization codes are areas for improvement. Several senators specifically called for improving prior authorization in Medicare Advantage (MA) to ease administrative burdens:

- Chairman Sheldon Whitehouse (D-RI) pointed to his draft legislation that would:
  - Require the Centers for Medicare & Medicaid Services (CMS) to identify specific prior authorization practices in MA.
  - Require CMS to set common standards for common prior authorization requirements across insurance plans.
  - Lift prior authorization requirements among accountable care organizations that meet a standard of efficient patient care.
- Ranking Member Chuck Grassley (R-IA) also called for increased oversight of prior authorization in MA, stating that CMS should be "aggressively auditing" plans.
- Finance Committee Chair Ron Wyden (D-OR) criticized prior authorization practices for inhalers.
- Roger Marshall, M.D. (R-KS) also indicated that he would re-introduce his prior auth legislation, the Improving Seniors' Timely Access to Care Act, this June.

Beyond prior authorization, Sen. Whitehouse also emphasized the need for greater standardization, establishing value-based care payments, and provider burnout. Sen. Grassley called for solutions that promote competition and reduce the volume of federal regulations.

Federal Issues

Regulatory

DOJ Announces Task Force on Health Care Monopolies and Collusion

The Department of Justice May 9 announced the formation of a task force focusing on competition concerns in health care. The unit, the Task Force on Health Care Monopolies and Collusion, will enforce strategy and policy guidance, in addition to investigations, and civil and criminal enforcement.

The unit will consist of civil and criminal prosecutors, economists, health care industry experts, technologists, data scientists, investigators and policy advisors from the department.

Why this matters: The task force will consider widespread competition concerns shared by patients, health care professionals, businesses and entrepreneurs, including issues regarding payer-provider consolidation, serial acquisitions, labor and quality of care, medical billing, health care IT services, access to and misuse of health care data and more.

Members of the public can share their experiences with the Task Force by visiting HealthyCompetition.gov.

CMS Issues Proposed Rule for Mandatory Organ Transplant Payment Model

The Centers for Medicare & Medicaid Services May 8 released a proposed rule for the Increasing Organ Transplant Access Model, a new payment model that would test whether performance-based incentives or penalties for participating transplant hospitals would increase access to kidney transplants for patients with end-stage renal disease. The proposed rule is scheduled to be published on May 17 in the *Federal Register*.

The model would run for six years, beginning Jan. 1, 2025. Hospitals eligible for participation would include non-pediatric transplant facilities conducting at least 11 kidney transplants during a three-year baseline period. It is anticipated that 90 hospitals would be required to participate.

The proposed rule also includes standard provisions that would be applicable across all new Center for Medicare and Medicaid Innovation models beginning Jan. 1, 2025, and after. CMS indicated that these provisions would be intended to address beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review, provisions on bankruptcy and other notifications, and the reconsideration review process.

CMS will accept comments on the proposed rule through July 8.

Why this matters: The agency states that the model would align with the Department of Health and Human Services' efforts under the Organ Transplant Affinity Group, as well as the Health Resources and Services Administration's organ procurement modernization initiative to improve equitable access to organ transplants, improve accountability in the U.S. organ transplant system, and increase the availability and use of donated organs.

CMS Releases New Draft Guidance on Medicare Drug Price Negotiation Program

The Centers for Medicare & Medicaid Services (CMS) released draft guidance on the second cycle of negotiations under the Medicare Drug Price Negotiation Program

Why this matters: The second cycle of negotiations will include up to 15 additional drugs covered under Part D for potential negotiation, to be published by CMS by February 1, 2025. This second round of negotiations will occur during 2025, and any negotiated prices will be effective starting January 1, 2027. The negotiation period for the 10 prescription drugs selected for negotiation for 2026 is underway.

The draft guidance proposes new requirements for the second cycle of negotiations, building upon lessons learned from implementing the Negotiation Program to date. The guidance also outlines how drug manufacturers must ensure eligible people in Medicare will have access to the negotiated maximum fair prices for 2026 and 2027, including the procedures that may apply to drug companies, Part D sponsors, pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D.

The comment period is open until July 2, 2024. Read the draft guidance, fact sheet, and CMS press release.

CMS Releases Updated Medicaid Renewal Guidance

The Centers for Medicare & Medicaid Services (CMS) released guidance extending section (e)(14) waiver strategies through June 30, 2025.

Why this matters: CMS stated these waivers, originally granted as part of the continuous eligibility unwinding, help people stay covered and continue to be needed as states update their income and eligibility determination systems.

- The Center for Medicaid & CHIP Services (CMCS) Informational Bulletin (CIB) clarifies states do not need to take any action to benefit from the extension, so long as they continue to meet the conditions and assurances of the approved authority. However, states may opt to end the waivers earlier.

- CMS encourages states to adopt new waiver strategies and indicates it is reviewing all (e)(14) waiver strategies to determine which can be implemented on a longstanding basis under other authorities.

The CIB also summarizes available (e)(14) waivers, including (1) allowing managed care plans to support enrollees with renewal form submission or completion; (2) the ability of states to renew income eligibility based on financial findings from SNAP programs; and (3) the ability to retroactively reenroll a member back to the date of coverage termination, if they were procedurally terminated and then found eligible during a reconsideration period.

CMS Statement on Agent and Broker Marketplace Activity

CMS released a statement reiterating their commitment to resolving and preventing unauthorized enrollments on the HealthCare.gov platform.

Why this matters: CMS reports having received approximately 40,000 complaints of unauthorized plan switches in the first three months of 2024, 97% of which have been resolved, and 50,000 complaints of

unauthorized enrollments, 88% of which have been resolved. CMS states they are accelerating review and resolution of consumer complaints, issuing suspensions and terminations barring bad agents and brokers from being able to enroll consumers in HealthCare.gov coverage, and are adding new technological protections to prevent fraudulent enrollments up front. CMS notes they continue to work with state and insurer partners to stop bad actors.

CMS Releases Guidance for Public Display of Quality Ratings

The Centers for Medicare and Medicaid Services (CMS) released the Quality Rating Information Bulletin to announce guidance for the public display of quality rating information by all Exchanges, including the Federally-facilitated Exchange (FFEs), State-based Exchanges on the Federal Platform (SBE-FPs), and State-based Exchanges (SBEs) that operate their own eligibility and enrollment platform, during the individual market Open Enrollment Period (OEP) for the 2025 Plan Year. This bulletin also details marketing guidance for QHP quality rating information.

USPSTF Comment Opportunity on Draft Research Plan on Counseling to Prevent Food Allergies in Infants

The U.S. Preventive Services Task Force (USPSTF) released a draft research plan on counseling for early introduction of allergens to prevent food allergies in infants. The USPSTF is accepting public comments on the draft research plan until June 5.

CMS Releases Surprise Billing QPA Audit Report to Congress

CMS released a report to Congress on the 2022 and 2023 Qualifying Payment Amount (QPA) audits.

Why this matters: The report describes the audit requirement and annual report requirement, audit methodology and the status of current audits. Following the *TMA III* court decision and its impact on QPA calculations, CMS is in the process of reassessing audit findings for audits initiated prior to the court decision. The report notes, due to the time and resource-intensive nature of audits as well as the ongoing litigation related to the QPA calculation methodology, none of the audits initiated for 2022 and 2023 have concluded as of Dec. 31, 2023.

State Issues

New York

Legislative

Legislative Update

There are four weeks – and just 15 scheduled session days – until the planned end of the 2024 Legislative Session. Bills addressing step therapy, UR determinations, health plan incentive and rewards programs, and coverage of interchangeable biologics and biosimilars are a few of the items that are on committee agendas for end of session.

- Restrictions on the use of step therapy (S.1267 (Breslin)/A.901 (McDonald))
- Limits on UR determinations (S.3400 (Breslin)/A.7268 (Weprin))
- Increasing flexibility in health plan incentive and reward programs (S.2684 Breslin)/A.791 (Hunter))
- Changing the effective date for plan compliance with including Donate Life Registry information on enrollment forms (A.9564 (Gunther)/S8749 (Breslin))
- Requiring coverage of interchangeable biologics and biosimilars (A.9055 (McDonald)/S.7768 (Hinchey))
- Expanding EP coverage for undocumented immigrants, AKA Cove rage 4 All (S.2237-B (Rivera)/A.3020-B (Gonzalez-Rojas))

Regulatory

2025 NY State of Health

The NY State of Health issued its invitation to insurers to participate on the state's official marketplace for the 2025 plan year.

The following summarizes changes of note to the on exchange individual policies (except catastrophic).

- **Qualified Health Plans** — There are three cost sharing initiatives for QHPs, subject to federal approval: cost sharing subsidies will be available for those applicants up to 400% FPL; and cost sharing for diabetes and maternal health services is waived.

- **Essential Plan** — The waiver of cost sharing for diabetes services also applies to the Essential Plan.

- **Stand Alone Dental Plans** — Beginning, January 1, 2025, 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.

Letters of Interest were due last week (May 10th), and Participation Proposals are due on May 24th. Both should be submitted electronically to the following email address: nyhxpm@health.ny.gov.

State Issues

Pennsylvania

Legislative

State Lawmakers Tackle Key Health Bills

Last week, the General Assembly advanced several bills related to telehealth, maternal health, and workplace violence, among other initiatives.

- **Reinsurance Pilot Program:** The House Insurance Committee advanced **HB 2234** to the full floor for consideration. The bill implements a program proposed in the Governor's budget that would create an "affordability assistance program" to help individuals purchase health insurance through Pennie. Second consideration is expected with referral to the House Appropriations Committee.

- **Telehealth:** The Pennsylvania Senate passed a bill that will support access to telehealth. On Wednesday, the chamber passed **Senate Bill 739** by a 47–1 vote. The bill, sponsored by Senator Elder Vogel (R-Beaver, Butler, Lawrence), defines reimbursement requirements for telehealth services and clarifies coverage for virtual care. It also helps ensure that payment cannot be denied simply because care is provided via telehealth. The bill moves to the House for consideration.

- **Workplace violence:** On Tuesday, the House Labor and Industry Committee advanced a bill that would place new requirements for hospitals related to workplace violence. **House Bill 2247** advanced by a 14–11 vote. 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. The bill, sponsored by Leanne Krueger (D-Delaware), advanced following a lengthy back and forth between party leaders about the process to put the bill forward.

  Following the voting meeting, the committee hosted an informational meeting with a panel of nurses about the ways working conditions contribute to the nursing crisis. A second panel discussed the role of health care consolidation.

- **Maternal health:** In the House, lawmakers passed **House Bill 2097**, which would expand Medicaid coverage of at-home blood pressure monitors for pregnant and postpartum women. The bill passed the chamber 164–37. Additionally, House lawmakers unanimously approved **House Bill 1608**, which would extend Medicaid coverage for doula services and create the doula advisory board.

  Both bills are part of the Pennsylvania Momnibus package to address disparities in maternal health.

  In a related action, the House Insurance Committee also advanced **House Bill 2138**, which requires private insurance coverage for blood pressure monitors for home use on a per-pregnancy basis. The bill passed out of committee 24–1.

Regulatory

Insurance Department Proposes Changes in Order to Formally Implement Act 147 of 2002, The Producer Licensing Modernization Act

Act 147-2002 adopted provisions from the Producer Licensing Model Act and brought the Commonwealth into compliance with the Federal Financial Services Modernization Act of 1999 (known as the Gramm-Leach-Bliley Act) (Pub.L. No. 106-102, 113 Stat. 1338), which required states to modernize and provide uniformity in their insurance licensing procedures. Prior to this, insurance producers were subject to varying rules in each state where they transacted business.

Act 147-2002 provided the Commonwealth with the statutory framework to modernize and provide uniformity, thus increasing efficiency in these processes. Act 147-2002 provided for licensing and regulation of insurance producers, managers and exclusive general agents; conferred powers and imposed duties on the Insurance Commissioner and the Department; permitted the payment of referral fees and commissions; imposed penalties; and made related repeals. Until now, however, no regulations were promulgated.

According to the Department, adopting this regulation will not create any new costs for the Department or regulated community, but will modernize and streamline the administrative procedure and provide transparency to the public, licensees and other stakeholders. This proposed rulemaking will become effective 60 days after publication of the final-form rulemaking in the *Pennsylvania Bulletin*. The Department believes that the changes will provide necessary clarity for many constituencies.

The Proposed Rulemaking is available here.

Industry Trends

Policy / Market Trends

Administration Releases 2024 Medicare Trustees Report

The Department of the Treasury released the annual Social Security and Medicare Trustees Reports. The Medicare Trustees Report details information on the past and estimated future financial operations of the Hospital Insurance and Supplementary Medical Insurance Trust Funds.

Why this matters: The Board of Trustees projects that as of 2024, the Hospital Insurance (HI) Trust Fund will be able to pay **100% of total scheduled benefits until 2036, 5 years later than reported last year**. At that point, that fund's reserves will become depleted and continuing program income will be sufficient to pay 89% of total scheduled benefits.

Go Deeper: An AHIP-commissioned study by Avalere found that if original Medicare Part A utilization was the same as Medicare Advantage utilization, solvency of the HI Trust Fund would be extended to 2048. Read the full Medicare Trustees Report and corresponding fact sheet.

AHIP Spotlights Mental Health Coverage

In recognition of National Mental Health Awareness Month this May, AHIP is spotlighting how health insurance providers have made progress in helping Americans get the mental health care they need.

Highlights Include:

- The number of in-network mental health providers grew by an average of **48% in 3 years** among commercial health plans.
- Almost **40% of visits** for psychotherapy were conducted through a telehealth appointment in 2020, compared to less than 1% in 2019.

- Nearly **3-in-4 insured Americans** said it was easy to get the mental health support they needed.
- **88% of voters** who received care were satisfied with the mental health support they received through employer-provided health plans.
- **89% of health plans** are actively recruiting mental health support providers, including practitioners who reflect the diversity of the people they serve (83%).
- Patients spent less than **$15 in out-of-pocket costs** for most drugs prescribed to treat mental health conditions.

AHIP's spotlight also details how health insurance providers are taking action to provide quality and equitable care, including integrating mental health in primary care, expanding telehealth access, and increasing the number of mental health professionals in health plan networks.

New Research Shows Rural FFS Beneficiaries Spend More on Healthcare than MA Enrollees

According to new data released by the Better Medicare Alliance (BMA), Medicare Advantage (MA) beneficiaries in rural areas save more on health care costs and are more likely to utilize preventative services than those enrolled in Fee-for-Service Medicare (FFS). The research finds that FFS beneficiaries who live in rural areas spend 49% more on health care premiums and out-of-pocket costs than MA enrollees.

Other key takeaways include:

- **Cost:** Medicare Advantage enrollees are half as likely to be burdened by their health care costs as those in Fee-for-Service Medicare in rural areas.
- **Satisfaction:** Medicare Advantage beneficiaries are more likely to report satisfaction with the ease of getting to the doctor than those in Fee-for-Service Medicare. Overall, Medicare Advantage and FFS Medicare enrollees in rural areas report similar rates of positive health care experiences.
- **Preventive Care:** Medicare Advantage enrollees are more likely to report using critical preventative care services, such as mammograms and annual wellness visits, and are less likely to report outpatient visits than those in Fee-for-Service Medicare.
- **Demographics:** In rural areas, Medicare Advantage enrollees are nearly three times as likely to be Black and more likely to be Latino than those in FFS.
- **Enrollment:** Individuals living in rural areas benefit from an average of 27 Medicare Advantage plans from which to choose.

Go Deeper: Read the research here.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: **http://legis.delaware.gov/.**
New York Legislation: **https://nyassembly.gov/leg/**
Pennsylvania Legislation: **www.legis.state.pa.us.**
West Virginia Legislation: **http://www.legis.state.wv.us/**
For copies of congressional bills, access the Thomas website – **http://thomas.loc.gov/.**