Highmark's Weekly Capitol Hill Report

Issues for the week ending July 12, 2024

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Federal Issues

Regulatory

ONC Releases HTI-2 Proposed Rule

The Office of the National Coordinator for Health Information Technology (ONC) released the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule to update standards, certification criteria, and other policies. The HTI-2 proposed rule builds on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) final rule, published in January 2024.

Why this matters: The proposed rule would establish two sets of new certification criteria to enable health IT for public health and for health plans to be certified under the ONC Health IT Certification Program. The certification criteria were developed in coordination with CMS to support technical requirements for the application programming interfaces (APIs) included in the CMS Interoperability and Prior Authorization proposed rule. These criteria would be

available for health IT developers, including health plans and other developers providing technology to health plans, seeking voluntary certification for health IT products supporting CMS-required data exchange.

The proposal includes new certification criteria requirements for developers of certified health IT to build the capability for providers to use electronic prior authorization. The functionality would be required by January 1, 2027 – aligning with requirements for plans in federal programs.

Go Deeper: View the ONC press release and fact sheets here.

Insurer Perspective:
AHIP's Statement: "AHIP appreciates that ONC's proposed rule includes requirements for aligning health plans, providers, and health IT developers in the implementation of electronic prior authorization. Electronic prior authorization can help ensure patients receive safe, evidence-based care, while reducing decision times and administrative burdens on providers and plans.

"AHIP will continue to review the proposed rule, including proposed payer certification standards, particularly as plans are not subject to the requirements of the ONC certification program."

Times More for Common Cancer Drugs
- **How Medicare Advantage Supports Rural Health Systems**
- **Early 2024 Snapshot and Full Year 2023 Average Effectuated Enrollment**
- **2023 Marketplace Issuer-Level Enrollment and Disenrollment Data**

White House Releases 2024 Spring Unified Agenda

The Administration released its regulatory blueprint for the remainder of 2024 and beyond, including a suite of health care regulations over the coming months:

- **July:** Expanded final regulations requiring insurers to treat mental health care on the same terms as other care, payment rules for doctors under Medicare, a key proposed health IT rule, final modifications to the Medicaid drug rebate program and a final notice on transitional coverage for emerging medical devices.
- **September:** Rules for prescribing controlled substances via telemedicine are expected. The name of the regulation has changed since a previous iteration, suggesting it could address virtual care across state lines.
- **October:** Proposed major food allergen labeling regulations for alcohol.
- **December:** Bolstered cybersecurity requirements for health care organizations are expected.

CMS Issues Three Annual Payment Updates

CY 2025 Physician Fee Schedule Proposed Rule

The Centers for Medicare & Medicaid Services July 10 released its calendar year 2025 proposed rule for the physician fee schedule. The rule proposes to cut the conversion factor by 2.8%, to $32.36 in CY 2025, as compared to $33.29 in CY 2024. This reflects the expiration of the 2.93% statutory payment increase for CY 2024; a 0.00% conversion factor update under the Medicare Access and Children's Health Insurance Program Reauthorization Act; and a .05% budget-neutrality adjustment.

CMS also makes several proposals designed to improve payment for and access to behavioral health care services. This includes a proposal to expand payments for opioid treatment programs for new FDA-approved overdose reversal medications and extend flexibilities for the use of telehealth modalities by OTPs.

In addition, CMS proposes extension of certain telehealth waivers through 2025 including the waiver allowing for reporting of enrolled practice address instead of home addresses when providers perform services from their home, the waiver for federally qualified health centers and rural health clinics to bill for telehealth services, and the waiver for virtual supervision for residents in all teaching settings when the services are provided virtually.

For the Quality Payment Program, CMS proposes six new, optional Merit-based Incentive Payment System Value Pathways for reporting beginning in 2025. CMS also solicits comment on whether to mandate MVP participation beginning with the CY 2029 reporting period.

CMS also includes proposals regarding the Medicare Shared Savings Program. For example, it would mitigate the impact of significant, anomalous, and highly suspect (SAHS) billing activity for CY 2024 and subsequent years. Specifically, CMS proposes to exclude payment amounts from financial calculations for the relevant calendar year for which the SAHS billing activity is identified, as well as from historical benchmarks used for reconciliation.

CMS will accept comments on the proposed rule through Sept. 9.

CY 2025 Hospital Outpatient, Ambulatory Surgical Center Proposed Rule

The Centers for Medicare & Medicaid Services July 10 issued a proposed rule that would increase Medicare hospital outpatient prospective payment system rates by a net 2.6% in calendar year 2025 compared to 2024. This includes a proposed 3.0% market basket update, offset by a 0.4 percentage point cut for productivity.

In addition, CMS proposes to adopt three measures related to health equity for the outpatient, ambulatory surgical center and rural emergency hospital quality reporting programs and to extend voluntary reporting of data for two hybrid measures in the Inpatient Quality Reporting Program.

CMS also proposes several changes to payment for drugs. Among these are proposals that would provide separate payment for diagnostic radiopharmaceuticals with per-day costs above a threshold of $630, exclude certain qualifying cell and gene therapies from packaging under the comprehensive ambulatory payment classification policy, and pay for HIV pre-exposure prophylaxis in hospital outpatient departments.

The agency also proposes new conditions of participation for hospitals and critical access hospitals focused on obstetrical services and maternal care. Among other policies, CMS would require hospitals and CAHs with obstetrical care units to adopt certain processes for the organization, staffing and delivery of obstetrical care services and to incorporate maternal and obstetrical care into their quality assessment and performance improvement programs. CMS also proposes to require hospital emergency services to have protocols for addressing obstetrical emergencies, complications and immediate post-delivery care. Lastly, the agency proposes to require hospitals to have written policies and procedures for transferring patients under their care, including transfers both within and outside of the hospital.

CMS will accept comments on the proposed rule through Sept. 9

CY 2025 Home Health PPS Proposed Rule

The Centers for Medicare & Medicaid Services June 26 issued its calendar year 2025 proposed rule for the home health prospective payment system, which would reduce net home health payments by an estimated $280 million, or -1.7%, in calendar year 2025 relative to the current year. This update includes a 3.0% market basket update, reduced by a 0.5% productivity adjustment. However, CMS is also proposing to reduce the base payment rate by 4.1% due to the implementation of the Patient-driven Groupings Model, which reduce total payments by 3.6%. CMS also is proposing to adjust the fixed-dollar loss amount for high-cost outliers, which it estimates will reduce payments by an additional 0.6%, or $100 million.

CMS also proposes to update the HHA Conditions of Participation to add a new standard that would require HHAs to develop, consistently apply, and maintain a policy for accepting patients to service. While CMS does not propose to adopt or remove any quality measures from the HH Quality Reporting Program, the agency proposes to adopt and modify certain patient assessment items related to health-related social needs; HHAs would be required to collect and report specific data elements related to living situation, food and utilities beginning with the CY 2027 HH QRP. The agency would also remove an element found to be redundant. As finalized in previous rulemaking, CMS will end the suspension of all-payer data collection also beginning with CY 2027 and proposes practices for this requirement.

Finally, CMS proposes to revise the infection prevention and control requirements for long-term care facilities to extend reporting to the Centers for Disease Control and Prevention of a subset of the current COVID-19 data elements and also require reporting for data related to influenza and RSV to begin Jan. 1, 2025.

CMS will accept comments on the proposed rule through Aug. 26.

Why this matters: Annually, CMS proposes updates to the various payment systems for different parts of the healthcare system. In addition, these annual rules also include very important and often significant policy changes that impact healthcare operations and delivery.

State Issues

New York
Regulatory

Artificial Intelligence Circular Letter
The Department of Financial Services last week issued a final Circular Letter on the use of artificial intelligence systems (AIS) and external consumer data and information sources (ECDIS) in underwriting and pricing of insurance products.

The CL outlines the Department's expectations for how insurers in New York State develop and manage the integration of ECDIS, AIS, and other predictive models, with insurers expected to:

- Analyze ECDIS and AIS for unfair and unlawful discrimination, as defined in state and federal laws;
- Demonstrate the actuarial validity of ECDIS and AIS;
- Maintain a corporate governance framework that provides appropriate oversight of the insurer's overall outcome of the use of ECDIS and AIS; and
- Maintain appropriate transparency, risk management, and internal controls, including over third-party vendors and consumer disclosures.

Essential Plan Doula Coverage

The NY State of Health last week stated that the effective date of the doula services benefit for the Essential Plan is being delayed, with NYSOH pushing back the start of the new benefit to January 1, 2025. The Department of Health has also decided to delay the Medicaid Managed Care carve-in to January 1, 2025. The change is to allow more time to increase provider enrollment, which currently stands at only 80 doulas.

State Issues

Pennsylvania

Legislative

Pennsylvania Legislative Update: Budget Update, PBMs, House & Senate Actions

- **BUDGET:** On Thursday, June 11th the House and Senate passed the FY 2024-2025 budget, tax, and fiscal codes, which were all signed into law by Governor Shapiro. Included in the fiscal code was language authorizing a transfer of up to $50 million for subsidies for PENNIE. While the transfer is authorized, there is no specific details as to the total amount which will be transferred to the Insurance Department or how it will be dispersed.

  With the completion of the budget package, both the House and the Senate recessed for their summer break and are expected to both return to session September 23 and September 16, respectively.

- **PBMs:** House Bill 1993, Representative Benham's Pharmacy Benefits Management legislation, which is the House companion to Senate Bill 1000 received a

comprehensive amendment which was agreed to by all stake holders. As amended, the bill passed the Senate by a vote of 48-1 and received concurrence from the House by a vote of 172-30. It has been presented to the Governor, who has indicated that he will sign the legislation into law.

- **Noncompete Clauses:** House Bill 1633, Representative Frankel's legislation prohibiting the practice of certain noncompete clauses for health care providers and providing for a Pennsylvania Health Care Cost Containment Council study on the matter, received further amendments on the Senate Floor. The legislation was approved by the Senate by a vote of 48-1, with the legislation receiving concurrence from the House by a vote of 155-46. The bill has been presented to the Governor for his signature.

- **Provider Reimbursement:** House Bill 1664, Representative Scott's "Virtual Credit Card" legislation, outlining means which insurers can reimburse providers, received concurrence to Senate Amendments with a unanimous vote and has been presented to the Governor for his signature.

HOUSE ACTIONS:

- **Price Transparency:** House Bill 2339, Representative Kahn's hospital price transparency legislation, was passed by a vote of 168-34. It has been received in the Senate and received in the Senate Health & Human Services Committee.

SENATE ACTIONS:

- **Data Privacy:** House Bill 1201, Representative Neilson's data protection bill was re-referred to the Senate Communications & Technology Committee after receiving Second Consideration on the Senate Floor. The referral back to committee was requested by Committee Chair Senator Pennycuick to work with additional stakeholders for further amendments.

- **Contraceptives:** House Bill 1140, Representative Krueger's legislation expanding the availability of contraceptives, was received in the Senate and has been referred to the Banking and Insurance Committee.

- **Speech Therapy:** House Bill 2268, Representative Markosek's legislation expanding mandated coverage for pediatric speech therapy, was received in the Senate and has been referred to the Banking and Insurance Committee.

State Passes FY 2024-2025 Fiscal Year Budget

Last week, the General Assembly passed, and Governor Josh Shapiro signed two bills that, together make up the state budget for the 2024–2025 fiscal year. **Senate Bill 1001** provides annual appropriations and **House Bill 2310** provides direction for specific programs by amending the commonwealth's Fiscal Code.

This year's budget includes $47.6 billion in General Fund commitments, a $2.7 billion increase over 2023–2024. The total amount of spending was a significant source of tension between Democrats and Republicans during this year's negotiations. Democrats cited record surpluses and new revenue streams as reasons to invest more in key priorities while Republicans stressed that structural deficits require careful stewardship of funds to ensure a sound fiscal future for the commonwealth. The General Assembly's final package trimmed the governor's initial request by roughly $740 million.

Hospital Priorities Included:

Rural Hospitals

- $10 million to make one-time supplemental payments to hospitals in counties of the fourth through eighth classes. The Department of Human Services (DHS) is directed to consult with HAP and representatives from hospitals that participate in the Pennsylvania Rural Health Model and to seek federal matching funds. It is estimated that the state investment may yield $39 million in total payments to rural hospitals.
- $17.5 million to the Department of Community and Economic Development to the Hospital and Health System Emergency Relief Fund line item, which was adjusted to also allow funds to be used to research rural health and alternative payment methods for rural health care, including data collection and modeling.

Maternal Health

- $10.68 million in Medicaid supplemental payments for obstetric and neonatal services, a $7 million (190%) increase over 2023–2024.

Additional Medicaid Supplementals

- $15.88 million Critical Access Hospitals ($1.4 million, 9.8% increase).
- $8.66 Trauma Centers (level funding).
- $4.44 Burn Centers (level funding).

Behavioral Health

- $67.5 million increase (7.6%) in state funds to the overall mental health services line for DHS. Additional analysis is necessary to accurately determine the commitments and distribution of these funds.

Workforce

- $25 million for a new budget line associated with the Grow Pennsylvania Scholarship Program, which provides scholarships of up to $5,000 per year to students who participate in approved courses of study for "in-demand" occupations. Nursing and allied health are explicitly included as approved courses of study and "in-demand" occupations will be determined on an ongoing basis. Recipients must begin working in Pennsylvania within a year of completing their degree and stay for 12 months for each academic year they received a grant.

- $2 million increase (19%) to support apprenticeship training programs at the Department of Labor and Industry.

Key Legislation Passed of Importance to Hospitals:

Telehealth

- On July 3, the governor signed **Senate Bill 739 (Act 42 of 2024)** into law. The measure requires that insurers cover health care services delivered via telemedicine in accordance with the terms and conditions of the provider's contract. The contract may not prohibit payment solely because a covered service is delivered via telemedicine.

Interstate Compacts

- On July 9, **House Bill 2200** reached the governor's desk and is currently awaiting his signature. This long-awaited measure removes a federal administrative barrier to full implementation of multistate licensing compacts by requiring people who apply for a health care practitioner license, certificate, registration, or permit to submit fingerprints as part of a criminal history background check.

Industry Trends

Policy / Market Trends

FTC's PBM Report

The Federal Trade Commission (FTC) published an interim staff report on pharmacy benefit managers (PBM) as part of the Commission's ongoing inquiry launched in 2022.

FTC Claims: The report purports to detail how PBM competition affects the prescription drug market. The FTC claims market concentration and vertical integration negatively impact prices and accessibility. The report argues certain PBM business practices should "warrant further scrutiny and potential regulation." The Commission voted 4-1 to allow staff to issue the report, with Commissioner Melissa Holyoak voting no.

The FTC indicated that:

- In 2024, the top six PBMs by market share (CVS Caremark, Express Scripts, OptumRx, Humana Pharmacy Solutions, MedImpact, and Prime Therapeutics) managed 94% of drug claims, while 60 other PBMs managed 6% of drug claims (Prime Therapeutics accounts for 3% of claims);

- The market share of the three largest PBMs (CVS Caremark, Express Scripts, and OptumRx) increased from 52% in 2004 to 79% in 2024;

- The parent companies of the three largest PBMs have expanded into private drug labeling in addition to vertically integrating themselves with distributors, mail order pharmacies, and retail pharmacies;

- Pharmacies affiliated with the three largest PBMs make up almost 70% of specialty drug revenue;

- 55% of specialty drug prescriptions in commercial plans are filled by affiliated pharmacies, while 22% of specialty prescriptions in Part D plans are filled by affiliated pharmacies; and

- Vertically integrated PBMs satisfy the Medical Loss Ratio (MLR) rule while retaining revenue and profits by shifting funds between themselves, plans, and pharmacies.

The Bottom Line: The FTC report overlooks PBMs' key role in countering manufacturers' pricing power and making prescription drugs more affordable for plan sponsors and the consumers they serve.

Fact Check: Following release of the report, AHIP published a fact check that sets the record straight and spotlights the root causes of high drug prices: drug manufacturers often holding monopoly power over medicines and undermining competition to keep drug prices as high as possible.

By the Numbers:
- Research has found the median annual price among new drugs approved by the U.S. Food and Drug Administration (FDA) in 2023 reached **$300,000**, 35% higher than the previous year.
- A 2023 analysis found "anti-competitive patent abuse tactics used by big pharmaceutical companies cost U.S. consumers an additional **$40.7 billion** in prescription drug expenses in one year alone."
- More than **22 cents of every dollar** spent on health insurance premiums goes to pay for prescription drugs – more than any other individual category.

Additionally, the Pharmaceutical Care Management Association issued a statement criticizing the report and highlighting the PBM industry's work to lower drug costs by promoting generics and biosimilars and contracting with pharmacies to promote patient access.

Go Deeper: Read the full FTC interim staff report and AHIP's fact check.

FTC to Sue PBMs after Report Finds Affiliate Pharmacies Received 200 Times More for Common Cancer Drugs

Health Payer Specialist reported the Federal Trade Commission (FTC) plans to sue the three largest pharmacy benefit managers (PBMs) following a study which found they paid their own mail-order pharmacies as much as 200 times more than the price at independent pharmacies for common cancer drugs, generating at least $1 billion in excess revenue. The FTC estimated increased reimbursement rates for two specialty generic drugs (Zytiga and Gleevec) led to $1.6 billion in excess revenue for pharmacies affiliated with the three largest PBMs between 2020 and 2022.

How Medicare Advantage Supports Rural Health Systems

A new blog from the Coalition for Medicare Choices (CMC) underscores how Medicare Advantage (MA) ensures access to affordable, quality care for the 4 million Americans living in rural areas who actively choose MA for their health coverage.

Topline: MA enrollment has grown rapidly in rural communities. Seniors and people with disabilities can choose from more MA plan offerings than ever before. In addition to providing substantial cost savings for beneficiaries, the program allows plans to address health-related social needs, such as a lack of transportation services, by providing access to telehealth services and in-home care.

As more Americans in rural communities choose MA, research shows that the program's growth can increase financial stability and reduce hospital closure risks. MA delivers on affordability, quality, health outcomes and access when serving rural Americans.

Go Deeper:

- Read how MA beneficiaries have better outcomes than people in fee-for-service Medicare.
- Learn about some of the MA benefits that beneficiaries love.
- Check out MA by the numbers.

Early 2024 Snapshot and Full Year 2023 Average Effectuated Enrollment

CMS published the Early 2024 Snapshot and Full Year 2023 Effectuated Enrollment Report.

Why this matters: This release includes information on average monthly effectuated enrollment and financial assistance, detailing the number of individuals receiving advanced payment of premium tax credits (APTCs) or cost-sharing reductions for the individual market Federal and State-based Marketplaces for February 2024 and the entire 2023 plan year.

The February 2024 snapshot provides an initial look at 2024 effectuated enrollment, based solely on effectuated coverage as of March 15, 2024. The full year effectuated enrollment data is based on the average number of effectuated enrollments over the entire 2023 coverage year, also as of March 15, 2024. In February 2024, 20.8 million consumers had effectuated coverage through the Marketplaces, a 33 percent increase from 15.7 million consumers in February 2023 and a 50 percent increase from 13.8 million consumers in February 2022. This also represents 97 percent of consumers who made plan selections during the 2024 Open Enrollment Period (21.4 million).

The postings are live here. :

Direct links here:

Effectuated Enrollment: Early Snapshot 2024 and Full Year 2023 Average (PDF)
February Effectuated Enrollment Tables (XLSX)

Full Year Effectuated Enrollment Tables (XLSX)

2023 Marketplace Issuer-Level Enrollment and Disenrollment Data
CMS published the HealthCare.gov Issuer-Level Enrollment Public Use File and the State-based Marketplace Issuer-Level Enrollment Public Use File data. CMS is releasing 2023 effectuated health and dental plan enrollment at the issuer, plan, and county level for the HealthCare.gov Marketplaces, and a separate file of 2023 effectuated health enrollment at the plan variant level for the State-based Marketplaces. At a national and state level, the data details how many consumers, on a monthly average in 2023, have effectuated enrollment and, for HealthCare.gov states, how many have disenrolled.

The data is posted 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/.**

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