Highmark's Weekly Capitol Hill Report

Issues for the week ending June 7, 2024

Federal Issues

Regulatory

House Energy and Commerce Oversight and Investigations Subcommittee Holds 340B Drug Pricing Program Hearing

The House Energy and Commerce Oversight and Investigations Subcommittee held a hearing last week on the 340B Drug Pricing Program that has faced questions from lawmakers considering additional oversight and transparency measures, as well as eligibility changes.

Chair Cathy McMorris Rodgers (R-WA) said in her opening remarks, “This hearing is an opportunity for us to evaluate recent trends and developments in the health care system that impact the 340B Drug Pricing Program. The 340B program was created by Congress to ‘enable covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.’ It's a worthy goal and a seemingly straightforward one.”

Rogers added, “This Committee has focused so much effort over the past two years on increasing transparency in health care,

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tackling incentives in the prescription drug market that push up health care costs for Americans, and addressing site neutrality and other reforms that are driving consolidation. It should be a bipartisan goal for every member on this Committee to apply the same principles to the 340B program as well."

Following testimony, Pennsylvania Rep. John Joyce (R-13) discussed the importance of the 340B program to providers in the state and its "staggering" growth in Pennsylvania. He also stressed that any reform of the program cannot come at the cost of patient access to needed medications.

Among the hearing's takeaways:

- Committee members heard from industry leaders about how the 340B program is working and, if necessary, how it could be improved.
- On May 28, U.S. Representatives Larry Buschon, MD (R-IN), Buddy Carter (R-GA), and Diana Harshbarger (R-TN), introduced new **legislation** that would enforce rules, reinforce federal oversight, change the definition of a "patient" and determine criteria for contract pharmacy arrangements.
- Notable testimony came from Matthew Perry, president and CEO of Genesis HealthCare System who said in his **written** remarks, "Without robust 340B support for such comprehensive care, Genesis simply would not be financially viable, and taxpayers would be approached to cover the shortfalls to retain locally provided care. Patient care would be irreparably damaged, and some patients would fall through the cracks if this situation occurred. If patients in southeastern Ohio lost access to the services and support Genesis provides, they would need to travel significant distances to receive that care. Many would not be able to make that trip."

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Regulatory

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The committee has 10 days to submit additional questions to the witnesses for the record. Witnesses will have 10 days to provide responses.

Written remarks and video from today's hearing are available **online**.

Why this matters: Hospitals continue to highlight the importance of the 340B Drug Pricing Program to support access to care.

- **Hospitals provided nearly $42 billion in uncompensated care in 2019 alone**, of which 340B hospitals roughly made up 68% of that number.

- In addition, in 2020, **340B hospitals provided $84.4 billion in total community benefits**, a nearly 25% increase from the prior year. 340B hospitals are providing these high levels of uncompensated care and community benefits despite operating on razor-thin margins.

- **And the community benefit efforts are only increasing:** a recent study found that between 2017 and 2020, the growth in community benefits provided by 340B hospitals far outweighed the growth in their program savings.

Federal Issues

Regulatory

OCR Updates Change Healthcare FAQs on Breach Notification

On May 31, the HHS Office for Civil Rights (OCR) released updated frequently asked questions (FAQs) on the Change Healthcare cyber incident. The updates address questions HHS has received concerning who is responsible for breach reporting to OCR, impacted individuals, and where applicable, the media per the HIPAA Privacy, Security, and Breach Notification Rules.

Specifically, the updated FAQs make clear that:

- Covered entities affected by the Change Healthcare breach may delegate to Change Healthcare the tasks of providing the required HIPAA breach notifications on their behalf.
- Only one entity – which could be the covered entity itself or Change Healthcare – needs to complete breach notifications to affected individuals, HHS, and where applicable the media.
- If covered entities work with Change Healthcare to perform the required breach notifications in a manner consistent with the HITECH Act and HIPAA Breach Notification Rule, they will not have additional HIPAA breach notification obligations.

Additionally, given that business associate notification to covered entities has not yet occurred, OCR states it "will not consider the 60-day calendar period from discovery of a breach by a covered entity to start until affected covered entities have received the information needed from Change Healthcare or UnitedHealth Group."

Next Steps: OCR notes affected covered entities should contact Change Healthcare if they want Change to provide breach notification on their behalf. AHIP continues to actively engage with HHS, Congress, and other key stakeholders on issues impacting health plans and their members related to the Change Healthcare cyberattack.

Go Deeper: On May 2, 2024, AHIP joined a stakeholder letter to HHS requesting updated federal guidance on covered entities' notification obligations after the breach. Read the letter here.

AHIP Responds to RFI on Consolidation in Health Care Markets

AHIP submitted a response to a request for information from the Department of Justice, Federal Trade Commission, and the Department of Health and Human Services on consolidation in health care markets.

Why this matters: AHIP's comments underscore how health care provider geographic horizontal monopolies and private equity acquisition of health care providers tend to raise costs for patients, employers, and health plans, while often decreasing the quality of care.

Other Comment Highlights:

- Explaining how provider access is geographically constrained and health plan pricing, administrative costs, and profits are heavily regulated through medical loss ratios (MLRs) and rate reviews.
- Spotlighting the impact of provider monopolies on rates and quality of care.
- Showcasing the impact of private equity engagement in health care settings and its impact on rates and quality of care.

Go Deeper: The RFI response also shared our recent resources on private equity, hospital acquisition of physician practices, and a Senate hearing statement on consolidation and competition.

HHS Releases New Data on Coverage Gains in Minority Communities and Announces Navigator Funding Opportunities

The Centers for Medicare & Medicaid Services (CMS) announced a notice of funding opportunity (NOFO) for organizations serving as Navigators in states with a Federally-facilitated Exchange (FFE). In addition, the Department of Health and Human Services (HHS) issued five new reports today showing historic gains in health care coverage and highlighting increases in coverage among minority communities since the implementation of the Affordable Care Act's (ACA) coverage provisions.

New Funding for Navigators

- CMS announced it expects to award a total of $500 million in grants for Navigators over the next five years, provided in five annual budget periods. For the first 12-month budget period, to be awarded this fall, $100 million is available, the largest investment in the Navigator program to date. The NOFO is available here and a set of frequently asked questions is available here.
- CMS also announced a separate and new NOFO for states, the "Expanding Access to Women's Health Grant," which will provide funding to states for a 24-month period to enhance and expand access to reproductive health and maternal health coverage and services. That NOFO is available here.

CMS Releases February Medicaid Redetermination Data

The Centers for Medicare & Medicaid Services (CMS) reported the latest batch of Medicaid Redeterminations data reported under the Consolidated Appropriations Act, 2023; click here to access. CMS posted a summary of outcomes for the renewals due in February 2024, including:

- 6.8 million people were due for renewal in February (up from 6.2 million in January). However, 1.2 million (18%) people due for renewal were still pending with their state at the end of the month (similar to 1.2 million or 18.7% of those due in January).
- Of those due for renewal, almost two-thirds (63.8%) were successfully reenrolled in Medicaid and CHIP (higher than the 62.8% renewed in January), and 71.6% of renewals were done through an *ex parte* data review (lower than the 72.7% renewed via *ex parte* in January).

Overall, the volume of redeterminations has declined since December 2023 when it was 7 million and then fell to 6.2 million in January 2024. Despite the increase in renewal volume in February, it has been low compared to the latter half of 2023 when monthly renewal volume was consistently well over 7 million. Successful reenrollment rates have been holding fairly steady as well since December. *Ex parte* renewal rates have stayed relatively stable since increasing significantly the latter half of 2023. The percentage of pending renewals has been hovering around 18%-19% since December which is also an improvement compared to earlier months. The February 2024 National Summary of Renewal Outcomes (click here to access) includes additional analysis from CMS.

CMS also released several new batches of data on the Monthly Data Reports page, under "Most Recently Released Unwinding Data," including:

- March 2024 Preliminary Medicaid and CHIP Renewal Outcomes;
- Updated Medicaid and CHIP Renewal Outcomes for September and October 2023; and
- December 2023 Separate CHIP Report.

State Issues

Delaware

Legislative

House Introduces Cost Sharing Waiver for Certain Pain Management Treatments

HB 441 would eliminate cost-sharing and expands the prohibition on annual or lifetime

numerical limits for physical therapy, occupational therapy, and neuromuscular massage therapy services for the treatment of any chronic or acute musculoskeletal pain or post-surgical therapy.

It is an effort to encourage patients to choose these therapies as a safe alternative to opioid use for managing acute and chronic pain. This Act applies to all policies, contracts, or certificates - including Medicaid and the State of Delaware - issued, renewed, modified, altered, amended, or reissued after December 31, 2025 and expires December 31, 2030.

Why this matters: Eliminating cost-sharing could result in higher premiums for the fully insured. There is no evidence that removing caps from Physical, Occupational and Chiropractic services lead to any reduction in opioid prescriptions/addictions. This bill has a Sunset provision after 5 years.

State Issues

New York

Legislative

2024 Legislative Session Adjourns

The 2024 Legislative Session ended last week. The legislature acted on nearly 690 during the session, including giving approval in the final week to a number of bills affecting health plans:

- **Restrictions on the use of step therapy (S.1267-A (Breslin)/A.901-A (McDonald))** – This bill amends legislation adopted in 2016 that set strict requirements around step therapy protocols, further limiting plans' use of step therapy.
- **PReP and PEP copayments (S.9842 (Hoylman-Sigal)/A.10461 (Simone))** – This bill clarifies that insurers cannot require copayments for PrEP so as long as it has an "A" or "B" rating in the current recommendations of the United States Preventive Services Task Force.
- **Copay restrictions for physical therapy (S.1470 (Breslin)/A.6345 (Weprin)) –** This bill would limit the amount an insurer can require for cost sharing to the amount of a primary care visit.
- **Physician Assistants in Medicaid (A.7725 (Paulin)/S.2124 (Rivera))** – The bill will allow physician assistants to practice as primary care physicians for Medicaid members without the supervision of a licensed physician.
- **Dyslexia exam mandate (A.2898-A (Carroll)/S.5481-A (Hoylman-Sigal))** – The bill requires insurance policies to cover neuropsychological exams for dyslexia.

These bills will not be effective until the Governor signs them, and stakeholders will continue to advocate for changes via chapter amendments or outright vetoes. The Governor has until 12/31/24 to act on these and other pieces of passed legislation.

Regulatory

Disaster Planning Circular Letters

The Department of Financial Services last week issued its annual circular letters on disaster planning, preparedness and response today. The circular letters, which apply to the Life and Health insurance industries, require each regulated entity to submit to DFS a disaster response plan and responses to disaster response plan and business continuity plan questionnaires by August 16, 2024.

State Issues

Pennsylvania

Legislative

Legislative Update: PBMs, Scope of Practice, Telemedicine, & PENNIE Subsidy Wrap

- **Telemedicine: SB 739** providing for the regulation of insurance coverage for telemedicine was amended and reported from the House Insurance Committee on June 3. Various versions of this legislation have been extensively explored in previous legislative sessions to get to its current form and is awaiting further action from the House of Representatives this week.

- **PENNIE Subsidy Wrap:** The House of Representatives passed **HB 2234**, Insurance Committee Chairperson Kim's Subsidy Wrap Proposal by a vote of 106-96. This legislation, based off of Governor Shapiro's budget proposal to expand subsidies for the Pennsylvania State-Based Exchange System, has been referred to the Senate Banking & Insurance Committee where it awaits further action.

PHARMACY ISSUES

- **PBMs:** The Senate Health & Human Services Committee amended and reported **SB 1000**, Senator Judy Ward's PBM legislation on June 4 with a unanimous vote. This legislation will add new regulations on business operations of PBMs, including prohibiting the use of spread pricing and patient steering. Additionally, it would add new pharmacy dispensing fees and prohibit reimbursement to pharmacists that do not cover the cost of acquisition for the pharmacists. Further work and negotiations with all stakeholders is ongoing and additional amendments are expected.

- The House Health Committee will meet to consider **HB 1993**, Representative Benham's PBM legislation this week. This legislation, while similar to SB 1000, has had more input from the Insurance Department and Administration and includes their priorities. Conversations with the House are ongoing with this legislation.
    - **Why this matters:** Highmark shared concerns with the committees, specifically with the proposal to eliminate network design flexibility, the prohibition on spread pricing, and the state mandated dispensing fee.
        - The legislation would force Highmark members to pay the same out of pocket costs regardless of the cost or value any particular pharmacy can provide to members.
        - Prohibiting spread pricing will not benefit members, customers or even pharmacies; the prohibition only serves to force health insurers into a different payment arrangement for PBM services. This likely will increase administrative costs insurers face for pharmacy administration, ultimately resulting in higher premiums for Pennsylvanians.
        - House Bill 1993 & Senate Bill 1000 do not decrease costs; Pennsylvania businesses and individuals going to the pharmacy for their medications will pay more without receiving any additional value.
- **Scope of Practice: HB 2037**, seeking to amend the Pharmacy Act, would allow Pharmacy technicians to provide immunizations under the direct observation of a pharmacist to patients five years of age and older. It is the belief that this may help offset costs and provide additional revenue streams to pharmacies by allowing them to provide additional services, while helping to reduce healthcare deserts in underserved areas. This legislation was reported from the House Children & Youth Committee on June 5 and was re-committed to the House Rules Committee.

Momnibus: The House of Representatives continues to work on the multi bill package referred to the Momnibus, a comprehensive set of legislation seeking to reduce maternal mortality rates amongst minority mothers and mothers in maternal care deserts.

- **HB 2127:** This legislation was amended on the floor of the House of Representatives, providing for education to new mothers on post-partum depression as well as other mood and anxiety disorders at well-baby checkups. The amendment removed this education as being required and made it an optional requirement to address concerns that physicians may not have the adequate resources or training to provide full screenings for post-partum depression. This legislation has ben re-committed to the House Appropriations Committee.
- **HB 2137:** This legislation, establishing the Maternal and Newborn Supply Kit Fund and establishing requirements for the Department of Health and birthing centers to supply new mothers with kits of items mothers and newborns may need, was

amended and passed by the House of Representatives by a vote of 123-79, and has been referred to the Senate Health & Human Services Committee.

Regulatory

Pennsylvania Professional Boards Issue Statements of Policy Condemning the Use of Conversion Therapy

The State Boards of Medicine, Nursing, Osteopathic Medicine, Psychology and Social Work Examiners on June 8 in the Pa. Bulletin issued Statements of Policy denouncing the use of conversion therapy, also known as sexual orientation change efforts or reparative therapy, to treat LGBTQIA+ Pennsylvanians under the age of 18. The statements of policy are intended to provide guidance to Board-regulated practitioners and to the general public. The statements of policy became effective upon publication in the *Pennsylvania Bulletin*.

Why this matters: According to the Statements of Policy, which essentially mirror each other, "The Commonwealth has a compelling interest in protecting the physical and psychological well-being of minors, including lesbian, gay, bisexual, transgender, queer/questioning, intersex and asexual (LGBTQIA+) youths, and in protecting minors against exposure to the severe harms caused by conversion therapy. Likewise, the Board has an interest in and a duty to protect the public from practices that create a danger for patients and is dutybound to enforce the provisions of the act and its regulations. These duties compel the Board to take steps to guard against the dangers posed by conversion therapy."

The Statements of Policy also state, "Conversion therapy is a term that describes a wide range of interventions by mental health professionals that seek to change an individual's sexual orientation or gender expression, including efforts to change behaviors, gender identity or gender expressions, or to reduce or eliminate sexual or romantic attractions or feelings toward an individual of the same gender." The use of conversion therapy, however, can pose critical health risks to LGBTQIA+ people, including but not limited to suicidality, substance abuse, confusion, depression, and more. Because of the lack of scientific evidence supporting conversion therapy and the potential risk of harm to minors the practice is strongly opposed by the State Boards listed above as well as by other national associations.

On August 16, 2022, Governor Tom Wolf signed Executive Order 2022-02, which was published at 52 Pa.B. 5788 (September 10, 2022), to protect residents of this Commonwealth from conversion therapy by directing State agencies to discourage the practice of conversion therapy. See 4 Pa. Code §§ 7.921—7.924 (relating to protecting Pennsylvanians from conversion therapy and supporting LGBTQIA+ Pennsylvanians). This position was reaffirmed earlier this year by the Shapiro Administration.

These statements of policy clarify that it is the position of the Boards to Board-regulated practitioners that the Board may find the use of conversion therapy on an individual under 18 years of age to be unprofessional or immoral conduct. Additionally, under this statement of policy, a Board-regulated practitioner who uses conversion therapy on an

individual under 18 years of age may be subject to discipline by the Board. No sunset date is being established for the statements of policy. The need and efficacy will be periodically monitored by the Board.

The Statements of Policy are available here:

State Board of Medicine

https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol54/54-23/792.html

State Board of Nursing

https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol54/54-23/793.html

State Board of Osteopathic Medicine

https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol54/54-23/794.html

State Board of Psychology

https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol54/54-23/795.html

State Board of Social Work Examiners
https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol54/54-23/796.html

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Industry Trends

Policy / Market Trends

New Data on Coverage Gains in Minority Communities

HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) released four new reports that provide in-depth data on gains in health care coverage in minority communities between 2010 and 2022. The uninsurance rate for the following populations declined as follows from 2010-2022, based on available census data:

- Black Americans: 20.9% to 10.8%
- Latinos: 32.7% to 18%
- Asian Americans, Native Hawaiians and Pacific Islanders (AANHPI): 16.6% to 6.2%
- American Indians and Alaska Natives (AI/AN): 32.4% to 19.9%

The reports discuss how the ACA increased availability of affordable coverage options via Medicaid expansion in participating states and Marketplace coverage with premium

subsidies, which helped narrow racial and ethnic health disparities in coverage and access to care.

HHS also released an issue brief titled, "Improving Access to Affordable and Equitable Health Coverage: A Review from 2010 to 2024," which discusses recent ACA-related policy initiatives to support and strengthen health insurance coverage, with a focus on the non-elderly population.

AFHC Spotlights MedPAC Chair's Site-Neutral Payment Recommendations to Congress

The Alliance to Fight for Health Care (the Alliance) recently published an article highlighting the Medicare Payment Advisory Commission (MedPAC) Chair, Michael Chernew's recommendations to Congress on expanding site-neutral payments to improve payment accuracy in the Medicare program.

Highlights: During an April 16 House Energy and Commerce Subcommittee on Oversight and Investigations hearing, Chernew testified that Medicare "payment rates for the same service often differ across three ambulatory settings: hospital outpatient departments (HOPDs), ambulatory surgical centers (ASCs), and freestanding clinician offices." He noted that these payment differences "encourage consolidation of physician practices with hospitals" and shift care "towards the settings with the highest fees, which increased total Medicare spending and beneficiary cost sharing without significantly improving patient outcomes."

Chernew further explained that even if implemented in a budget-neutral manner, site-neutral payments "would reduce incentives for providers to make site decisions based on the financial rather than clinical factors, which could eventually result in lower aggregate spending" and lower Medicare beneficiaries' cost-sharing.

Context: In December, the House passed the *Lower Costs, More Transparency Act*, which includes provisions to expand site-neutral payments to certain outpatient drugs and ensure fair billing practices for care provided by off-campus HOPDs. The Alliance to Fight for Health Care strongly supports these provisions and urges the Senate to quickly adopt these proposals, which have broad stakeholder support representing physicians, employers, patient advocacy groups, and more.

Go Deeper: Read the Alliance's highlights here. Read Chernew's testimony here.

AFHC: Taxing Health Care Coverage Will Increase Costs

The Alliance to Fight for Health Care (AFHC) issued a new press release cautioning against policy proposals that cap workers' tax exclusion for employer-provided coverage.

Key Quote: "*If the government taxes workers on their employer-sponsored health coverage the math doesn't add up. That's because for every dollar of foregone tax*

revenue, employers are currently spending on average $5.36. So it would cost families far more if they had to buy coverage in the individual insurance market and cost the federal government far more if it had to provide the same level of financial protection directly through expanded public programs." – James Klein, American Benefits Council

Why this matters: More than 180 million Americans rely on access to high-quality, affordable health care through their employers. Workers with EPC report broad satisfaction, including the convenience it brings, the access it offers to high-quality services, and the value of coverage.

Go Deeper: Read the AFHC press release

Coalition Spotlights Patent Thickets

The Campaign for Sustainable Rx Pricing (CSRxP) published a new article spotlighting a recent *Forbes* column from The Foundation for Research on Equal Opportunity (FREOPP) President Avik Roy on federal legislation that would make it harder to challenge patent thickets.

Context: S. 2220, *The Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act,* would limit the number of actors who can petition the Patent Trial and Appeal Board to challenge patents. The bill would require "PTAB challengers to 'have been sued or threatened with a patent infringement lawsuit before filing a PTAB challenge.'"

The Impact: If passed, only companies creating a competitor product that may potentially infringe on an existing company's patents would be able to challenge those patents – and those challenges would come much later in the patents' lifecycle. This means brand name drug companies would have longer to charge higher prices, and even increase prices, while facing no competition.

Alternative Solutions: CSRxP urges Congress to advance bipartisan, market-based solutions that focus on accountability and abuse of the patent system.

Go Deeper: Read more on how patent abuse tactics drive increased costs for consumers and the U.S. health care system.

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/.**