Highmark's Weekly Capitol Hill Report

Issues for the week ending January 26, 2024

Federal Issues

Legislative

Senate Finance Committee Releases White Paper on Drug Shortages, Probes Medicare Advantage Marketers

On Thursday, the Senate Finance Committee released a bipartisan white paper entitled, "Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs." The paper outlines concerns raised in testimony during a December 5, 2023, Finance Committee hearing, as well as ideas the Committee is exploring to address factors contributing to shortages.

Highlights of the Committee's interest include:

- Medicare Part A and B payment reforms to stabilize the supply of generic sterile injectable (GSIs) medicines;
- New incentives for providers and other prescription drug supply chain stakeholders to engage in shortage prevention and mitigation activities, such as maintaining buffer inventory and developing sustainable contracts, and increasing supply chain stakeholder transparency;
- Reforms or new pilot programs in Medicare Part D to bolster incentives for pharmacies to purchase generic medicines from drug

In this Issue:

manufacturers that invest in shortage mitigation, quality, and drug supply chain resilience; and
- Potential reforms to the Medicaid Drug Rebate Program targeting generic medicines in shortage.

Also this month, Finance Committee Chairman Ron Wyden (D-OR) sent letters to eHealth, GoHealth, Agent Pipeline, SelectQuote, and TRANZACT seeking information on how these companies use insurance agents, lead generators, and other data to target, market to, and direct seniors towards certain Medicare Advantage (MA) plans. The probe is part of an ongoing effort by Wyden to address marketing abuses in the MA program.

West Virginia
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- **Biomarker Testing Mandate & Health Sharing Ministries Legislation**

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- **Over 21M Sign Up for ACA Marketplace Plans During 2024 Open Enrollment**
- **HRSA Announces New Maternal Health Initiative**

House Education & Workforce Committee Requests Input on ERISA

The House Committee on Education and the Workforce released a request for information (RFI) seeking feedback on ways to build upon and strengthen the Employee Retirement Income Security Act (ERISA) related to employer-sponsored health benefits. The Committee noted they are examining proposals to increase the affordability of ESI coverage while improving quality and access to care. Responses are due by March 15, 2024.

Specifically, the Committee requested input from stakeholders on several topics, including:

- Preemption
- Reporting Requirements
- Data Sharing
- Cybersecurity
- Medical Loss Ratio
- Consolidated Omnibus Budget Reconciliation Act (COBRA) & Portability
- Specialty Drug Coverage

Go Deeper: Read the RFI here.

BCBSA & AHIP Respond to Senate RFI on Cell & Gene Therapy Coverage

BCBSA & AHIP responded to Sen. Bill Cassidy's (R-LA), the Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee request for information (RFI) on cell and gene therapy (CGT) coverage and financing.

Why this matters: As conversations around these emerging breakthrough therapies evolve, providing health plans' collective perspective, experience and policy solutions position insurers as a trusted resource and partner to Congress and CMS as they seek to improve patient access to affordable therapies.

AHIP's comments that the CGT market is too new for generalized practices to become widespread. As such, their comments address the broader state of CGT coverage and financing, and policy options Congress may consider to encourage a sustainable market for CGT. Their comments centered on commercial health insurance plans. CGT financing presents unique challenges for both Medicare and Medicaid – and AHIP offered to work with Sen. Cassidy in discussions on how to finance CGT through those programs.

Other topics addressed in AHIP's response include:

1. Health Insurance Providers Currently Providing Access to CGT
2. Market-Based CGT Risk Solutions Available to Limit Cost Exposure
3. A Federal Entitlement for CGT Would Likely Be Costly and Inefficient
4. Incentives to Facilitate Appropriate Private Market Uptake of CGT Risk Solutions
5. CGT Risk Solution Providers Are Well-Positioned to Leverage Innovative Contracts
6. Approval Pathways and the Need for Ongoing Patient Follow-Up

Meanwhile, BCBSA's comment letter responds to specific questions raised in the RFI as well as highlighting the effectiveness of the current market's risk mitigation products and strategies to finance cell and gene therapies. **BCBSA also:**

- **Identified** four challenges to implementing financing models and risk mitigation strategies
- **Recommended** five principles for federal policymakers aiming to improve patient access to these therapies
    - Federal intervention should be targeted and only triggered if a therapy threatens market stability in the future.
    - Existing coverage should not be duplicated or disrupted.
    - Incentives should encourage reasonable pricing.
    - Remove barriers to outcomes-based contracts.
    - Policy solutions should be at the federal level.
- **Raised** concerns with the long-term effectiveness and noted significant challenges in using traditional reimbursement models
- **Cautioned** against mandating coverage prematurely as mandates could discourage drug companies from engaging in innovative contracts with payers to tie reimbursement of a therapy with its effectiveness over time

Yes, and: BCBSA highlighted how The Blues are already providing solutions with the launch of the Synergie Medication Collective, which has introduced financing products that include a stop-loss and reinsurance product, a patient navigation program to identify the highest-quality providers, and negotiation of outcomes-based arrangements.

BCBSA believes it is premature to mandate coverage of cell and gene therapies given that the long-term outcomes of treatments are unknown. The current market is producing outcome-based contracts and warranty agreements that in part will provide patient access to treatments and track outcomes over time, thereby producing real-world evidence on the durability of these therapies. A coverage mandate for all cell and gene therapies could reverse this trend and discourage drug companies from engaging in innovative contracts with payers to tie reimbursement of a therapy with its effectiveness over time.

Federal Issues

Regulatory

CMS Announces Medicare Advantage Transparency-Focused RFI

The Centers for Medicare & Medicaid Services (CMS) released a request for information (RFI) to solicit feedback from the public on how best to enhance Medicare Advantage (MA) data capabilities and increase public transparency.

Why this matters: CMS indicates that it is interested in data-related recommendations including but not limited to the following areas:

- Beneficiary access to care, including provider directories and networks;
- Prior authorization and utilization management, including denials and appeals as well as use and reliance on algorithms;

- Supplemental benefits including cost and use data;
- Marketing and consumer decision-making;
- Care quality and outcomes, including value-based care arrangements and health equity;
- Competition in the market, including the impact of mergers and acquisitions, enrollment concentration, effects of vertical integration, and data topics related to Medicare Advantage prescription drug plans (MAPDs); and
- Certain enrollee populations including dual eligible individuals, individuals with end stage renal disease (ESRD), and other enrollees with complex conditions.

What's next? The CMS deadline for comments on this RFI is July 22, 2024. The feedback will be used to shape plan policies and improve the agency's MA data capabilities, CMS noted.

Tri-Departments Issue New FAQ on Contraception Access

The Departments of Labor, Health and Human Services (HHS), and the Treasury (the Tri-Departments) issued new FAQ to reinforce the requirements of health insurance providers and plan issuers to provide access to contraceptive products and services without cost sharing, as required under the Affordable Care Act.

The new FAQ reiterates that health plans and issuers must provide access without cost sharing to a full range of contraceptive care, which are U.S. Food and Drug Administration (FDA)-approved, -cleared, or -granted contraceptives, effective family planning practices, and sterilization procedures. The FAQ reinforces that products and services under this definition include screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period). Contraceptive care also includes follow-up care (e.g., management, evaluation, and changes, including the removal, continuation, and discontinuation of contraceptives).

The FAQ states support for the use of "reasonable medical management" for contraceptives, but provided additional details on what falls under this definition: limiting medical management use to situations where the frequency, method, treatment, and setting are not otherwise specified; ensuring patients have access to a FDA-recognized therapeutic equivalent; and providing an exceptions process for the patient to access the specific contraceptive products without cost sharing, when determined to be medically necessary.

The Tri-Departments indicate that they are aware of reports that plans and issuers continue to impose widespread barriers to contraceptive coverage, and that they are aware of investigations that have documented potentially unreasonable medical management techniques used by plans and issuers.

Finally, the FAQ provides information for consumers on how to report plan or issuer compliance concerns.

Secretary of HHS Xavier Becerra also sent a letter to payers emphasizing the Administration's commitment to supporting reproductive health.

State Issues

New York

Legislative

Legislature Holds Hearing on Health Provisions in Governor's Proposed Budget

The Senate Finance and Assembly Ways and Means committees along with the Health committees of both houses held a joint hearing last week on the health proposals in Governor Hochul's 2025 Executive Budget plan. Lawmakers heard from more than 36 witnesses over the course of more than 11 hours, including approximately three and a half hours devoted to questions directed to the Commissioner of Health, Medicaid Director and Superintendent of the Department of Financial Services.

New York Health Plan Association President and CEO Eric Linzer testified on behalf of HPA members, focusing on three key issues:

- **Opposing the 1% proposed cut to health plan rates:** HPA noted that, if enacted, the proposal would result in a cut to plans of more than $400 million for FY25. The cut would make it more difficult for health plans to make the investments necessary to fulfill the goals of advancing health equity, reducing health disparities, and enhancing care coordination envisioned in the State's recently approved 1115 Medicaid Waiver.

- **Restoring and fully fund the Medicaid Quality Incentive Program funding**: HPA's testimony focused on the importance of this funding in supporting a broad range of collaborative programs that benefit low-income New Yorkers, and that health plans only receive incentive funds for achieving results that meet or exceed State metrics.

- **Rejecting the proposed procurement of the Medicaid program:** HPA's testimony raised concerns with patient disruption that a procurement would cause, as well as the impact the timing of a procurement in the midst of State's effort to implement the newly approved 1115 waiver. Further, the comments questioned the need for this proposal when it would not generate any projected savings this year, and remined lawmakers they had rejected a similar plan two years ago, urging them to do the same again in this year's final budget.

HPA's full testimony is available here.

State Issues

Pennsylvania

Regulatory

Pennsylvania's State Based Health Insurance Marketplace Set New Enrollment Record

Pennsylvania's official health insurance marketplace, known as Pennie, announced that a record number of nearly 435,000 Pennsylvanians are now covered through coverage offered through the marketplace.

According to Pennie, this represents a 17% increase compared to this time last year, far exceeding the average annual increase of 1%.

Additionally, according to the announcement the recent success is also due in part to Pennie's collaboration with Pennsylvania's Department of Human Services (DHS) to ensure individuals who are no longer eligible for Medicaid have a clear path to enroll through Pennie. The full announcement is available at: https://www.media.pa.gov/Pages/Insurance-Details.aspx?newsid=532

State Issues

West Virginia

Legislative

Biomarker Testing Mandate & Health Sharing Ministries Legislation

The House Banking & Insurance Committee, as anticipated, advanced HB 4753 mandating biomarker testing coverage and HB 4809 regarding Health Sharing Ministries on to the House Judiciary Committee for further review.

The legislative fight between CRNAs and Anesthetists over prospective independent practice rights for CRNAs reached the House floor last week—with the CRNAs prevailing rather decisively in overturning the Health Committee vote in support of the Anesthetists' position. HB 4432 is expected to encounter difficulties in the Senate, where two physicians are the key decision-makers on matters of health policy in that body.

340B: An escalating legislative and economic fight is quickly developing between 340B eligible entities and the pharmaceutical industry over the right of 340B entities (led by the West Virginia Hospital Association in this case) to have an unlimited ability to contract with pharmacies where the 340B discounts can be made available to patients. The Senate Health Committee advanced SB 325 to the Finance Committee on this topic and a House committee has advanced HB 4892 on to the Health Committee for further consideration. The bill does seem likely to pass, but also seems destined for immediate challenge in federal court by the pharmaceutical manufacturing industry.

There are a number of major legislative proposals affecting health plans under the jurisdiction of either the Health or Banking & Insurance committees in the House and Senate but no recent activity to report.

At the top of the active monitoring list for health plans so far in this legislative session are:

- SB 443—Mandating specific types of oral health and cancer treatment coverage.
- SB 444—Clarifying and mandating certain types of emergency medical coverage.
- SB 486—Mandating specific and expanded breast cancer screening coverage.
- HB 5103—Mandating ambulance non-transport reimbursement.

- HB 5183—Mandate for coverage for biomedical hormone coverage.

Another issue has arisen and become a concern for the entire employer community—HB 4759, which proposes to require every employer with more than 15 workers to utilize the federal E-verify system prior to hiring any new staff. The state's business community is united in opposition because of the costs and liabilities for employers in a state without an illegal immigration problem.

Industry Trends

Policy / Market Trends

Over 21M Sign Up for ACA Marketplace Plans During 2024 Open Enrollment

The Centers for Medicare & Medicaid Services (CMS) announced more than 21.3 million Americans selected an Affordable Care Act (ACA) Marketplace health plan since the start of the 2024 Open Enrollment, marking another year of record-breaking Marketplace enrollment.

Why this matters: Of the more than 21 million signups, over 5 million are new to the Marketplaces for 2024, and more than 16 million returned to their respective Marketplaces.

Signups Continue: Notably, open enrollment continues in four states and Washington, D.C., through January 31. State-specific and SBM deadlines are available in the State-based Marketplace Open Enrollment Fact Sheet

HRSA Announces New Maternal Health Initiative

Health Resources and Services Administration (HRSA) Administrator Carole Johnson, joined by Rep. Lauren Underwood (D-IL), co-chair of the Black Maternal Health Caucus, launched a year-long Enhancing Maternal Health Initiative. **The HRSA Enhancing Maternal Health Initiative aims to:**

- **Achieve** measurable progress in maximizing the impact of HRSA grants and programs to address maternal mortality and improve maternal health;
- **Foster** new partnerships and collaborations among HRSA grantees in high-need, high-opportunity jurisdictions to address maternal mortality and improve maternal health; and
- **Strengthen** HRSA's internal capacity to maximize the impact of HRSA's maternal health grants, programs, and resources.

The efforts support the White House Blueprint for Addressing the Maternal Health Crisis. Throughout the year, HRSA will bring together HRSA grantees from across the states of focus to foster cross-program and cross-state relationships to drive progress in maternal health and end the maternal mortality crisis. Read more about the initiative 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/.**