Highmark's Weekly Capitol Hill Report

Issues for the week ending November 22, 2024

Federal Issues

Regulatory

Sanofi Becomes Third Drugmaker to Push Illegal 340B Rebates

Last week, the drug company Sanofi announced its intention to impose a rebate pricing model for 340B-eligible drugs. This will make Sanofi the third drugmaker, following Johnson & Johnson (J&J) and Eli Lilly, to attempt to unilaterally overhaul the 340B program in a way that violates the program's statute and undermines its mission to support safety-net providers.

Sanofi released a notice stating that starting early next year, it will offer 340B discounts only through post-purchase rebates for 25 of its drugs, contingent upon the submission of extensive pharmacy and medical claims data. The drugmaker says its "340B Credit Model" will take effect Jan. 6, 2025, for disproportionate share (DSH) hospitals, critical access hospitals (CAHs), sole community hospitals (SCHs), and rural referral centers (RRCs). Sanofi will require consolidated health centers (CHs) to use the model starting March 1, 2025.

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Sanofi's model imposes its own "patient definition" rules for hospitals it is subjecting to the rebate model. Failure to comply with these rules may result in denial of the 340B rebate, which the hospital can try to overturn by submitting additional information. Sanofi plans to require hospitals to submit specific health care encounter data to prove that Sanofi's criteria are met.

Sanofi does not state in the notice whether it has sought approval from the Health Resources and Services Administration (HRSA) to implement its rebate model. HRSA has made it clear that implementing such a model without secretarial approval would violate the 340B statute, which currently operates as an upfront discount program. The agency emphasized that "any unilateral action to impose rebate models would significantly and unilaterally alter the administration of the program." HRSA also has not disclosed whether Sanofi has communicated its plans to the agency or asked for federal permission to implement rebates.

This announcement follows lawsuits against HRSA from J&J and Lilly as part of their efforts to push similar rebate schemes. In response to J&J's earlier attempt to implement a rebate model, HRSA threatened to revoke the company's access to Medicaid and Medicare markets unless the drugmaker withdrew the plan. J&J ultimately paused implementation of its rebate proposal, but the company and Lilly have since filed lawsuits against HRSA, signaling a broader industry effort to erode 340B protections.

Why this matters: Sanofi, like J&J and Lilly, does not have the legal authority to change how the 340B payment model works. Moving to a rebate scheme would violate the 340B statute's requirement that drugmakers provide eligible drugs 'for purchase at or below the applicable ceiling price' and would

conflict with HRSA's longstanding interpretation of that language as requiring upfront discounts.

This unlawful rebate scheme undermines the very foundation of the 340B program, which is designed to provide discounted pricing at the time of purchase. What's more, this shift would impose massive financial and administrative burdens on 340B hospitals, which serve vulnerable patients and underserved communities.

DEA Extends COVID-19 Telemedicine Prescribing Flexibilities

The Drug Enforcement Administration (DEA) released a third temporary extension of COVID-19 telemedicine flexibilities for the prescribing of controlled medications. This extends the full set of telemedicine flexibilities regarding prescription of controlled medications put in place during the COVID–19 Public Health Emergency (PHE), through Dec. 31, 2025. This extension authorizes all DEA-registered practitioners to prescribe schedule II-V controlled medications via telemedicine through that date.

This follows the Notices of Proposed Rulemaking (NPRM) on Telemedicine Controlled Substance Proposed Rule and Induction of Buprenorphine via Telemedicine Encounter, both of which were released in March 2023 by the DEA in concert with the Department of Health and Human Services (HHS).

Administration Releases Resources on Medicaid Eligibility Renewals

The Administration released several new resources related to Medicaid eligibility renewals:

1. CMS released new guidance and an accompanying slide deck detailing the future availability of Medicaid unwinding-related waivers. MCO-related notes in the guidance include:
    - The MCO renewal support strategy will continue as an optional State Plan strategy.
    - The MCO auto-reenrollment strategy back to 120 days will be discontinued; states may use the regular authority of automatic reenrollment for two months or less.
1. CMS approved 1,115 demonstration amendments to provide additional years of continuous eligibility for children and individuals leaving incarceration in Colorado, Hawaii, Minnesota, New York, and Pennsylvania.
2. ASPE released a report on the impact streamlined *ex parte* renewal strategies.

Go deeper: NORC also released an analysis examining the Medicaid unwinding's impact on dual eligibles, finding that 17% of dual eligibles lost coverage during redeterminations and 2.1% have lost coverage and re-enrolled in Medicaid so far during the unwinding.

CMS Releases Tip Sheet for Agents/Brokers When Calling the Marketplace Call Center

On November 21, 2024, CMS released a tip sheet containing tips and best practices for agents and brokers when calling the Marketplace Call Center. The tip sheet highlights recent changes to Agent/Broker processes, what to expect when speaking with the Marketplace Call Center, available language services, and the consumer disclosure and authorization process.

USPSTF Comment Opportunity on Draft Recommendation on Screening for Syphilis Infection in Pregnant Persons

The U.S. Preventive Services Task Force (USPSTF) released a draft recommendation statement and draft evidence review on screening for syphilis infection in pregnant persons. The USPSTF recommendation has an "A" grade and recommends early screening for syphilis infection in all asymptomatic pregnant persons. This recommendation is consistent with the 2018 USPSTF recommendation on screening for syphilis infection in asymptomatic pregnant persons.

Following the June 2024 circuit court ruling in the *Braidwood Management, Inc. v. Becerra* case, health plans subject to the ACA preventive services mandate will continue to be required to cover all applicable preventive services recommendations from the Health Resources and Services Administration (HRSA), the Advisory Committee on Immunization Practices (ACIP) and USPSTF issued before and after 2010 without cost-sharing.

The USPSTF is accepting public comments until Dec. 23.

State Issues

New York

Legislative

Legislation Vetoed Regarding Physician Assistants' Role in Medicaid

Governor Hochul vetoed legislation (A.7725/S.2124) that would have allowed physician assistants to act as primary care providers for Medicaid patients.

The Health Plan Association (HPA) opposed the bill and urged the Governor to veto it, saying that while physician assistants play an important role in providing primary care services and seek to provide high-quality primary care services to Medicaid managed care members, physician collaboration remains an important part of how PAs practice. Moreover, HPA noted that many community-based primary care practices already utilize

physician assistants to increase their panel size, with appropriate physician oversight, making this legislation unnecessary.

Regulatory

Final PBM Regulation Issued

The Department of Financial Services issued the final regulation related to licensure standards of pharmacy benefit managers (PBMs). **According to DFS, the regulation requires the following:**

- **Allow Home Delivery.** Prohibit PBMs from barring any in-network pharmacies from providing mail order or delivery services, which will increase patients' access to home delivery from their community pharmacy;
- **List Pharmacy Directories.** Increase transparency to consumers and employers by requiring PBMs to list formularies and pharmacy directories online, and prohibiting PBMs from punishing a consumer who relies on said information;

- **Address Consumer Inquiries.** Require PBMs to post a telephone number and email address for consumers to direct their questions to, and PBMs must respond in a reasonable amount of time;

- **Prohibit Steering.** Prohibit anti-competitive practices that steer consumers away from their community pharmacy to larger pharmacies affiliated with the PBM;

- **Treat Pharmacies Fairly.** Prohibit PBMs from unfairly passing losses onto pharmacies when the PBM mistakenly approved dispensing a drug and then seeks to retroactively deny reimbursement to the pharmacy;

- **Allow Electronic Submissions.** Reduce administrative burdens and costs on small pharmacies by allowing them to submit information to and receive information from PBMs electronically; and

- **Apply Same Standards.** Prevent the abuse of audits against small pharmacies who are not affiliated with a PBM by requiring PBMs to apply the same audit standards across all in-network pharmacies.

CMS Approves 1115 Waiver re: Medicaid & CHP

The NYS Department of Health announced the Centers for Medicare and Medicaid Services (CMS) recent approval of an 1115 Medicaid Redesign Team (MRT) waiver amendment to offer children under age six continuous eligibility in Child Health Plus and Medicaid.

The waiver amendment revises the state's current MRT 1115 waiver by modifying existing eligibility criteria for children in Medicaid and Child Health Plus, to allow them continuous enrollment even if the child's family circumstances change.

The full 1115 Waiver Amendment approval letter, issued by CMS on November 14, 2024, can be found 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/.**