Highmark's Weekly Capitol Hill Report

Issues for the week ending December 13, 2024

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Federal Issues

Legislative

CBO Estimates Impact of Loss of Enhanced ACA Tax Credits

The Congressional Budget Office (CBO) released a new report that details how millions would lose coverage and face higher costs without extension of enhanced premium tax credits in the individual market.

What CBO is saying: "Not extending the credit will increase the number of people without health insurance and raise the average gross benchmark premiums for plans purchased through the marketplaces."

In this Issue:

By the numbers: CBO estimates millions would lose coverage and see premiums increase by almost 8 percent if the tax credits are not extended permanently. An analysis by Oliver Wyman supports these findings, projecting that as many as 5 million Americans will lose their health coverage without extension of the tax credits. A KFF study also notes how almost all enrollees will see premiums rise sharply.

Why this matters: The broad-based coalition Keep Americans Covered (KAC) also highlighted CBO's warnings and called on Congress to extend the tax credits, which are set to expire after 2025.

Request for Information (RFI) Regarding Individual Coverage Health Reimbursement Arrangements (ICHRAs)

Representative Kevin Hern (R-OK-1) released an RFI regarding ICHRAs, including how to improve utilization and accessibility, compliance and administration, and employee choice and flexibility. Responses to the RFI are due on January 3, 2025.

The RFI seeks feedback on a variety of policy issues related to ICHRAs, including:

- Utilization and Accessibility
- Ease of Compliance and Administration
- Employee Choice and Flexibility

- **HHS Office of the General Counsel Releases Advisory Opinion on 1115 Waivers Imposing Work Requirements**

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Federal Issues

Regulatory

Sanofi Latest Drug Manufacturer to Announce Rebate Model for 340B Entities but Government Pushes Back

Sanofi is the latest pharmaceutical manufacturer to announce that it will replace upfront 340B discounts with backend rebates for 25 of its drugs starting next month. In a Nov. 22 letter to 340B covered entities, Sanofi said it would be effectuating 340B discounts via the new credit model as of Jan. 6, 2025, for disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals.

Background: In August, J&J announced a new policy that would fundamentally change access to 340B pricing from an upfront "discount" to a back-end "rebate" for certain 340B hospitals on two of their products: Stelara and Xarelto. This new policy would require 340B hospitals to purchase these drugs at a higher price (e.g., wholesale acquisition cost or group purchasing organization price) and submit certain claims data elements to J&J. Upon verification of that data (including patient eligibility), J&J would rebate 340B hospitals the difference between the higher price paid and the 340B price for that drug. In effect, 340B hospitals would be floating dollars to J&J, while waiting for J&J to issue a rebate.

J&J's announcement came on the heels of the Centers for Medicare & Medicaid Services' own announcement that the prices for 10 drugs, which included Stelara and Xarelto, had been negotiated by the agency as part of the Inflation Reduction Act.

Although the Health Resources and Services Administration (HRSA) was able to successfully halt J&J's plans to implement this rebate, the threat of a 340B rebate model remains, and more drug companies, particularly those subject to Medicare price negotiations under the IRA, may seek to pursue a similar policy in the future. On Nov. 12, J&J sued HRSA, seeking to bar the agency from blocking J&J's implementation of a rebate model. Since then, Eli Lilly, Sanofi and Bristol Meyers Squibb have all sued HRSA to pursue a similar rebate model.

Government action: Last week, HRSA sent a strongly worded letter to Sanofi, stating that the drugmaker's plan to impose 340B rebates violates federal law and warning Sanofi of potential sanctions if the company proceeds, including referral for civil monetary penalties (CMPs) or termination of its pharmaceutical pricing agreement (PPA), which could lead to Sanofi losing Medicaid and Medicare Part B coverage for all its drugs. The announcement comes less than a day after hospital industry trade associations called on HRSA to act immediately against Sanofi's rebate proposal and to take the same firm stance the agency has taken against other drugmakers' rebate proposals.

HRSA's communication notes that the Health and Human Services (HHS) Secretary has not authorized rebates and informs Sanofi that implementing rebates without Secretarial approval is unlawful under the 340B statute. HRSA also emphasizes that forcing hospitals to purchase drugs at prices above the legally established 340B ceiling price—regardless of rebates—violates the program's statutory requirements. "HRSA expects Sanofi to cease implementation of its credit proposal immediately and to inform HRSA no later than December 20, 2024." The agency warns that it expects Sanofi to cease implementation of its unlawful rebate plans and that failure to do so could result in CMPs of up to $7,000 per violation and termination of the company's PPA, which would cut off access to Medicaid and Medicare Part B markets for its drugs.

Why this matters: Of significant concern is drug manufacturer plans to apply their own rules for hospitals subject to the model that will exclude claims from 340B pricing using criteria that the government has neither published nor authorized. This move represents a clear attempt by these manufacturers to illegally narrow the number of claims that would be eligible for 340B.

304B hospitals applaud HRSA for announcing that it will take strong enforcement actions against Sanofi and other manufacturers for these unlawful rebate plans. Hospitals will continue pursuing all advocacy and legal options to block these rebates from taking effect.

Deadline Extended for January Coverage on Healthcare.gov

CMS announced a 3-day extension of the deadline to enroll in coverage that begins January 1, 2025 for Marketplace consumers in the 31 states that use Healthcare.gov. Consumers in these states now have until midnight local time on December 18, 2025 (no later than 5 a.m. EST on Thursday, December 19) to secure coverage that begins January 1, 2025.

Marketplace Open Enrollment runs through January 15 on Healthcare.gov. Consumers who enroll after the December 18 extended deadline will have coverage starting February 1, 2025. Consumers in D.C. and the 19 states that operate their own State-based Marketplace can visit their state Marketplace website for information on deadlines and effective dates for coverage.

Nearly 988,000 new consumers who don't currently have coverage have signed up for plan year 2025 coverage through the marketplaces since the start of open enrollment on November 1, according to new data from CMS. Last year, 21.4 million people signed up during open enrollment and those who don't actively sign up will be automatically renewed.

Cumulative 2025 plan selections since November 1:

- Total: All Marketplace Plans – 5,364,197
- New Consumers – 987,869
- Returning Consumers – 4,376,328

Why this matters: The individual market is working for millions of Americans. A highly competitive market offers affordable, stable options that provide a record number of Americans the health, security, and peace of mind that comes with quality, affordable coverage.

Go deeper: Read more about how the enhanced tax credits significantly lower costs for individuals who purchase coverage on the individual market.

Compliance with HIPAA Reproductive Health Privacy Rule Becomes Mandatory Dec. 23

The HIPAA Journal reminds readers the December 23, 2024 deadline for compliance with the HIPAA Privacy Rule Reproductive Healthcare Final Rule is approaching.

Why this matters: This rule, enacted in response to the Dobbs v. Jackson decision, protects reproductive healthcare information from being used to investigate or penalize individuals. Covered entities must now obtain attestations that requests for such information are not for prohibited purposes. While a legal challenge is underway in Texas, compliance remains mandatory until the rule is changed. OCR is actively enforcing the rule, as evidenced by a recent settlement.

CMS Innovation Center Announces Termination of Medicare Advantage VBID Model After 2025

The Centers for Medicare & Medicaid Services (CMS) issued the attached notice announcing that the agency is terminating the Medicare Advantage (MA) Value-Based Insurance Design (VBID) model at the end of CY 2025 “due to the model’s substantial and unmitigable costs to the Medicare Trust Funds, as required by statute.” CMS indicates in its related blog post that “additional analyses of model performance and policy options demonstrated that these substantial costs were driven in part by increased risk score growth and Part D expenditures and that no viable policy modifications could address these excess costs.”

In addition to the notice and blog post, CMS has also published an executive summary of the forthcoming evaluation report and additional analyses of the MA-VBID model risk score impact by intervention and plan type.

CMS Issues Guidance on Medicare Advantage Coverage of Part B Drug Qalsody

On December 9, CMS issued an HPMS memo in response to concerns some MA plans are inappropriately denying Part B coverage for Qalsody (tofersen), used for treatment of amyotrophic lateral sclerosis or ALS. CMS notes it is impermissible for MA plans to have a blanket coverage policy that excludes Qalsody by considering it experimental and investigational as it has obtained accelerated FDA approval and is covered under Part B.

Why this matters: CMS expects all plans that currently classify Qalsody as experimental and investigational for treatment of adults with ALS will immediately discontinue use of those policies and contact impacted enrollees.

CMS Updates and Announcements

- **CMS Issues Guidance Reminding MA and Part D Plans of Legal Obligations to Safeguard PHI**: On December 11, CMS issued an HPMS memo reminding MA organizations and Part D sponsors of their legal obligations to safeguard protected health information (PHI) and to maintain business operations following any natural or manmade disasters including cyberattacks. CMS specifically cites the Change Healthcare cyberattack earlier this year and notes it has observed a varying degree of cyber resiliency that has been limited by overreliance on a single vendor and overall consolidation within the industry.

- **CMS Releases Comprehensive Medicaid Integrity Plan:** Last month, the Center for Medicare & Medicaid Services (CMS) released its Comprehensive Medicaid Integrity Plan (CMIP) for Fiscal Years 2024-2028. The CMIP outlines CMS initiatives across five key areas of program integrity oversight: Medicaid managed care oversight, access to care and program sustainability, high-risk vulnerabilities, data sharing and collaboration, and education and technical assistance. Managed care oversight activities described in the report include conducting analyses to compare utilization and access between fee-for-service and managed care arrangements, using Unified Program Integrity Contractors (UPICs) to enhance oversight of program integrity activities, auditing medical loss ratios, providing technical assistance to states on manage care oversight and reviews of managed care contracts, rates and state directed payments. Read More

- **CMS Releases Updated Informational Bulletin on HRSN Coverage Opportunities:** CMS released an updated informational bulletin outlining opportunities available under Medicaid and the Children's Health Insurance Program to provide coverage for clinically appropriate and evidence-based services and supports that address health-related social needs (HRSN). States can address HRSN through coverage of clinically appropriate and evidence-based HRSN services and supports; care delivery transformations, including improvements in data sharing; and performance measurement to create accountability for HRSN screening and connecting to needed supports as part of successful care management. Read More

- **CMS Releases 2024 Medicaid and CHIP Scorecard:** CMS released the 2024 Medicaid and Children's Health Insurance Plan (CHIP) Scorecard (MAC Scorecard). The MAC scorecard draws from multiple data sets derived from state and federal reporting efforts, and includes measures related to care delivery, eligibility and enrollment, expenditures, quality and more. Read More

USPSTF Comment Opportunity on Draft Recommendation on Screening for Cervical Cancer

The U.S. Preventive Services Task Force (USPSTF) released a draft recommendation statement and draft evidence review on screening for cervical cancer. The USPSTF recommendation has an "A" grade and recommends screening for cervical cancer every 3 years with cervical cytology alone in women ages 21 to 29 years and then every 5 years with clinician- or patient-collected high-risk human papillomavirus (HPV) primary screening in women ages 30 to 65 years. As an alternative to HPV primary screening for women ages 30 to 65 years, the USPSTF recommends continued screening every 3 years with cervical cytology alone or screening every 5 years with high-risk HPV testing in combination with cytology (cotesting). The USPSTF recommends against screening in cervical cancer screening in women younger than age 21 years, women older than age 65 years or women with a prior hysterectomy and no cervix.

This recommendation is consistent with the 2018 USPSTF recommendation on screening for cervical cancer except that this draft includes a recommendation that HPV primary screening every 5 years is the preferred screening strategy starting at the age of 30 years and now includes patient-collected HPV screening.

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 Jan. 13.

HHS Office of the General Counsel Releases Advisory Opinion on 1115 Waivers Imposing Work Requirements

The Department of Health & Human Services (HHS) Office of the General Counsel (OGC) has released Advisory Opinion 24-01 on Medicaid Section 1115 Demonstrations Imposing Work Requirements. The Advisory Opinion states that the Secretary of HHS lacks the authority to approve Medicaid 1115 waivers that impose requirements to work, look for work, study, volunteer, or undertake related activities as a condition of Medicaid eligibility or continued enrollment. It reasons that such conditions conflict with the core objective of Title XIX of the Social Security Act to furnish medical assistance, rehabilitation, and other services to eligible people.

The Advisory Opinion details the statutory background, procedural background, history of work requirements, and analysis that supports the opinion. It also notes that the Advisory Opinion represents the current views of the OCG and is not a final agency action or final order.

State Issues

New York

Legislative

Governor Signs and Vetoes Several Health Care Bills

Last week, the Governor signed several industry-related bills, included legislation mandating coverage of neuropsychological exams for dyslexia (A.2898-A/S.54841-A) and limiting cost-sharing for EpiPens (S.7114-A/A.6425A).

The Governor also signed a bill requiring coverage of scalp cooling therapies for people undergoing cancer treatment (S.2063-A/A.38-A), but the approval was conditioned on the Legislature approving a chapter amendment that will limit the new requirements to large group policies. She also approved legislation requiring health plans to report to the state's Physician Profiles database details of health care plan participation by physicians (S.3472/A.7214).

- The New York Health Plan Association opposed the bill arguing that the information for the Physician Profiles, as well as plans' own provider directories, relies on data being supplied by the physicians themselves and, therefore, the onus for providing information should be placed on providers not health plans.

Governor Hochul vetoed the proposal to limit co-payments for physical therapy services to no more than a co-payment for a primary care visit (S.1470/A.6345).

- In her veto message, the Governor said, "While I support the goal of protecting consumers from high cost-sharing for physician and occupational therapy, this bill would prevent health plans from designing their plans in a way that encourages insureds to seek care first from their primary care provider or osteopath" and acknowledged technical flaws that could have the unintended effect of raising costs for consumers in these instances.

The final bill of note for the 2024 legislative session is the step therapy bill, (S.1267-A/A.901-A), which was delivered to the Governor's office on December 12. There are active chapter amendments being considered and promoted during the 10-day consideration period.

Regulatory

Network Adequacy and Access Standards for Behavioral Health Services

The DOH has issued ***revised*-proposed regulations** setting forth standards for managed care organization (MCO) network adequacy for mental health and substance use disorder treatment services, including sub-acute care in a residential facility, assertive community

treatment services, critical time intervention services, and mobile crisis intervention services to improve access to behavioral health services.

The Department of Financial Services has issued ***revised*-proposed regulations** that mirror the DOH regulation, and will apply to “health care plans” to include commercial insurers, article 43 corporations, article 47 municipal cooperative benefit plans, and student health plans.

The initial proposed regulation was posted in the **January 10, 2024** issue of the State Register.

The revised proposed regulation has several material revisions from the earlier draft. It is now subject to an extended comment period with comments due by January 27, 2025.
Public Notices: The following Public Notices of proposed amendments to the Medicaid State Plan were posted in the **December 11, 2024** issue of the State Register.

Industry Trends

Policy / Market Trends

Federal Court Halts ACA Coverage for Dreamers

A North Dakota federal judge has temporarily blocked the Biden administration's rule allowing Dreamers (undocumented immigrants brought to the U.S. as children) to access Affordable Care Act (ACA) subsidies and marketplace coverage, according to a report by The Hill. The ruling, granting a preliminary injunction sought by Kansas and 18 other states, argues that the administration overstepped its authority by redefining "lawfully present" to include Dreamers. The judge stated that the ACA doesn't grant CMS the power to circumvent congressional intent regarding who qualifies for benefits. While the CMS is reviewing the decision, the ruling represents a victory for states challenging the rule and highlights ongoing legal battles surrounding healthcare access for undocumented immigrants.

CDC Expands Pneumonia Vaccine Eligibility to Age 50

Scientific American reports the CDC has expanded eligibility for pneumococcal pneumonia vaccines to adults aged 50 and older, significantly increasing the number of people who can benefit from this preventative measure. Pneumonia, a leading cause of death in older adults and young children, is a lung infection caused by various pathogens. While bacterial pneumonia is treatable with antibiotics, vaccines targeting *Streptococcus pneumoniae* (a common cause) significantly reduce severe illness and hospitalization risk. The new guidelines lower the previous age recommendation from 65 to 50, addressing health disparities and making vaccination easier in settings like pharmacies. Two pneumococcal conjugate vaccines (PCV20 and PCV21) are recommended, offering broader protection against various strains. While long-term effectiveness data is limited, studies show substantial protection against

pneumonia and invasive infections, particularly in younger age groups. Future recommendations regarding booster shots are anticipated.

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/.**