



Issues for the week ending June 21, 2024

## Federal Issues

Regulatory

### **Court Issues Mixed Ruling on Preventive Services Provision in ACA**

The Fifth Circuit Court of Appeals has issued a decision in *Braidwood Management v. Becerra* in a closely watched case on the preventive services provision in the Affordable Care Act (ACA).

**Why this matters:** In the immediate term, there will be no practical impacts to the ACA preventive services mandate requirements except for those plans directly serving the plaintiffs.

**Health plans subject to the ACA provision will continue to be required to cover all applicable preventive services recommendations** from Health Resources and Services Administration (HRSA), the Center for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), and U.S. Preventive Services Task Force (USPSTF), issued before and after 2010 without cost-sharing.

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**However:** This ruling potentially creates significant opportunities for additional lawsuits by plaintiffs looking to circumvent the coverage of specific preventive services.

**The ruling established the following:**

- Consistent with the district court's ruling, **recommendations from HRSA and ACIP remain unchanged.** However, the 5th Circuit sent the issue back to the district court to review whether these recommendations should have been finalized through rulemaking.
- Consistent with the district court's ruling, the **5th Circuit agreed that the USPSTF, as a non-appointed or elected entity** - who have not been validly appointed under the Constitution because they were not appointed by the President and Confirmed by the Senate - **does not have the authority to issue recommendations with the force of a coverage mandate.**
- However, the **5th Circuit disagreed with the district court's application of a nationwide enforcement mandate**, removing the coverage requirements for all USPSTF recommendations after 2010 for all consumers protected by the ACA mandate. Instead, the 5th Circuit applied the ruling only to the plaintiffs of the case.

**Background:** In March 2023, U.S. District Judge Reed O'Connor initially blocked the preventive services mandate nationwide; however, this ruling had been on hold while the appeals court considered the case.

**Next Steps:** The case is likely to continue, both through potential appeals and through

the Fifth Circuit's instruction to the district court to reexamine legal questions about the legality of the appointments of members of the two other agencies statutorily tasked with issuing preventive-services recommendations: ACIP and HRSA.

We will continue to provide updates of further developments and federal actions.

BCBSA, AHIP, and other leading health care organizations launched [Promoting Health Through Prevention](#), a coordinated campaign to promote the availability of preventive services for no out-of-pocket cost through the ACA.



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## Updates on Change Healthcare Cyberattack

- **CMS Ends Change Healthcare Advanced Payment Program** : On June 17, the Centers for Medicare & Medicaid Services (CMS) [announced](#) it is ending the accelerated and advanced payment program for providers impacted by the Change Healthcare cyberattack next month on July 12. At that time, the agency will stop new applications for the program, which has offered more than \$3 billion in payments to thousands of providers and suppliers.
  - The agency noted that it will continue to monitor for other effects of the cyberattack on Medicare providers and suppliers and will continue to engage industry partners to address any remaining issues or concerns.
- **Change Healthcare Begins HIPAA Breach Notifications**: Change Healthcare has issued [consumer guidance](#) on the type of data that was compromised in the February cyberattack and noted it expects to issue letters to impacted consumers in late July. This comes after the Department of Health and Human Services' Office for Civil Rights (OCR) clarified that health plans could delegate the burdensome requirement of notifying affected consumers and regulators to Change. It is not yet clear if OCR has received an official HIPAA breach notification from Change Healthcare.
  - Change said it has reviewed more than 90% of affected files and found no evidence that doctors' charts or full medical histories were stolen, but said the compromised data taken likely includes individuals' contact information,

health insurance information, billing claims, and potentially even Social Security numbers.

- **Departments Issue Temporary Open Negotiation Process Exception Period for Disputing Parties Impacted by Change Healthcare Incident:** The Departments of Health and Human Services, Labor and Treasury (Departments) announced a 120-calendar-day exception period for disputing parties impacted by the recent Change Healthcare cybersecurity incident to initiate No Surprises Act open negotiation for impacted items or services. The exception period began June 14, 2024, and will end on Oct. 12, 2024. Providers, facilities, and providers of air ambulance services whose ability to timely initiate open negotiation for any item or service furnished on or after Jan. 1, 2024, was impacted by the Change Healthcare cybersecurity incident may choose to initiate open negotiation for such items or services at any point during the 120-calendar-day period. The Departments released an [incident attestation form](#) that disputing parties must furnish to invoke the exception period. For further information, see CMS' [notice](#) from June 14, 2024.
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### **USPSTF Issues Final Recommendation on Interventions for High BMI in Children and Adolescents**

The U.S. Preventive Services Task Force (USPSTF) released its [final recommendation statement](#) on interventions for high body mass index (BMI) in children and adolescents. The USPSTF's recommendation has a "B" grade and recommends that clinicians provide or refer children and adolescents 6 years or older with a high BMI ( $\geq 95$ th percentile for age and sex) to comprehensive, intensive behavioral interventions. This recommendation updates the 2017 USPSTF recommendation statement on screening for obesity in children and adolescents 6 years or older.

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### **Judge Rules in Favor of Hospitals Vacating HHS Online Tracking 'Bulletin' as Unlawful and Beyond Agency Authority**

A United States District Court Judge last week ruled the U.S. Department of Health and Human Services (HHS) guidance to restrict providers use of common third-party online tracking technologies on public-facing web pages was unlawful.

The AHA, joined by the Texas Hospital Association, Texas Health Resources, and United Regional Health Care System, last November sued the federal government to bar enforcement of an unlawful rule, masquerading as guidance, that has upended hospitals' and health systems' ability to share health care information with the communities they serve and analyze their own website traffic to enhance access to care and public health.

In response to the lawsuit, HHS Office of Civil Rights (OCR) in March issued updated guidance for HIPAA-covered entities and business associates on using online tracking technologies. The judge determined HHS overstepped its authority with the guidance related to third-party tracking tools (such as Google Analytics or Meta Pixel) and Health

Insurance Portability and Accountability Act (HIPAA) violations. Metadata extracted from these tools does not constitute an identifiable record under HIPAA, the judge noted.

**The decision:** The Court granted the Hospitals' request for declaratory judgment and declared that the Proscribed Combination, as set forth in the HHS Bulletin of March 18, 2024, is unlawful, as it was promulgated in clear excess of HHS's authority under HIPAA. "To hold otherwise would empower HHS and other executive entities to take increasingly expansive liberties with the finite authority granted to them. The Court is disinclined to set that precedent here," the decision said.

The decision vacates the [bulletin](#) and a recent update from the agency from March.

**Why this matters:** For more than a year, the AHA has been telling the Office for Civil Rights that its 'Online Tracking Bulletin' was both unlawful and harmful to patients and communities. Hospitals are pleased that the Court agreed with the AHA and held that OCR does not have 'interpretive carte blanche to justify whatever it wants.' As a result of the decision, hospitals and health systems will again be able to rely on these important technologies to provide their communities with reliable, accurate health care information.

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## Industry Trends

Policy / Market Trends

### CSRxP Examines Root Causes of High Drug Prices

The Campaign for Sustainable Rx Pricing (CSRxP) published a new [blog](#) breaking down the facts on drug prices, innovation, and patents.

#### Key Points:

- Price hikes continue to outpace inflation.
- The median annual cost for new prescription drugs launched in 2023 exceeded \$150,000 annually.
- Abuse of the patent system has distorted the prescription drug marketplace for decades, blocking competition from more affordable options.
- So-called patient assistance charities often undermine competition in the market and push patients toward high-priced brand name drugs.

**The Bottom Line:** Anti-competitive tactics and pricing practices, including repeated price hikes on existing drugs and increasingly out-of-control launch prices on new medicines, are a root cause of high prices.

**Go Deeper:** [Read the full CSRxP blog.](#)

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## MedPAC: MA Data Completeness Improved, but Gaps Remain

A report from the Medicare Payment Advisory Commission found that the completeness of encountered data provided by Medicare Advantage insurers to the federal government has improved from 2017 to 2021, but discrepancies and inconsistencies remain. To improve the completeness of MA encounter data, MedPAC urged Congress to create thresholds for accurate and complete data, evaluate the data submitted by MA plans and require CMS to offer feedback, and withhold a portion of MA plan payments if the provided data fail to meet thresholds.

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### **CBO: US Uninsured Rate Forecast to Climb to 8.9% by 2034**

A Congressional Budget Office analysis estimates that the percentage of uninsured Americans will increase from a record low of 7.2% last year to 8.9% by 2034 as a result of Medicaid redetermination, the expiration of enhanced Affordable Care Act premium subsidies and the recent growth in immigration. Enrollment in commercial coverage will range from 164 million to 170 million in 2034, accounting for the largest source of health insurance, while enrollment in Medicaid and the Children's Health Insurance Program are expected to drop from 92 million to 79 million between 2023 and 2034.

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### **Congressional Budget Committee Releases Updated Baseline**

The Congressional Budget Committee released its updated baseline [report](#).

- **APTCs:** CBO estimates that outlays for premium tax credits will increase by \$22 billion in 2024 (or 21 percent) and \$244 billion (23 percent) over the 2025-2034 budget window and attributes those increases to increased projections of the number of people who receive premium tax credits to enroll in ACA plans. Enrollment projections are 4 million higher in 2024 and 3 million higher, on average, per year over the 2025-2034 budget window. CBO attributes this increase in enrollment to several factors:
  - More people enrolling as Medicaid's continuous eligibility provisions unwind.
  - Enhanced subsidies have a larger effect on enrollment
  - Economic and demographic changes, including a surge in immigration
- **Medicaid:** CBO estimates Medicaid and CHIP enrollment will remain at about 79 million over the ten-year budget window. Outlays will increase over previous projections by \$47 billion (or 8 percent) in 2024 and by \$319 billion over the 2025-2034 period. Factors attributed to that growth:
  - Half of the growth stems from directed payments (ex: value-based payment arrangements) in Medicaid managed care. CBO updated its projections to increase the outlays of direct payments by \$4 billion in 2024 and \$85 billion over the 2025-2034 budget window. They attributed \$58 billion in increased outlays over the 2025-2034 budget window to a proposed rule that permits states to pay hospitals and nursing facilities at the average commercial rate,

which is higher than the Medicaid FFS rate. Given this is a proposed rule, the increase is only 50% of what CBO's estimated effects.

- CBO assumes less individuals will lose coverage because of the continuous coverage unwinding (+\$67 billion)
  - Accounts for second part of the two-part Streamlining Eligibility and Enrollment final rule which simplifies the enrollment and renewal process (+\$38 billion)
  - Increase in immigration (+\$29 billion)
  - Reduction in projected employment (+\$52 billion)
- **Medicare:** CBO reduced its projections for outlays in Medicare over the 2025-2034 period by about \$73 billion (or less than 1 percent), attributing the reduction to lower-than-expected outlays for prescription drugs in Part D and lower than expected prices for Medicare services. That reduction was a net effect of the reductions in those costs and cost increases from two other sources:
- Actual spending in FFS was higher than expected in 2023

Growth in coverage of GLP-1 drugs for the treatment of diabetes and chronic weight management in Part D.

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### **CBO: US Could Save \$2.4B With Drug Patent Legislation**

The new version of the Affordable Prescriptions for Patients Act would reduce federal budget deficits by about \$3 billion, cut federal spending by \$2.4 billion and increase federal revenue by \$585 million over the next 10 years, according to a Congressional Budget Office analysis. The legislation would prohibit pharmaceutical firms from using aggressive legal tactics such as evergreening or patent hopping to extend protections and block generic drug competition.

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**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](http://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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