



Federal Issues

Regulatory

CMS Repeals Final Rule on MCIT and Definition “Reasonable and Necessary”

The Centers for Medicare & Medicaid Services (CMS) [rescinded](#) the Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” (MCIT/R&N) final rule because of concerns the provisions in the final rule may not have been sufficient to protect Medicare patients.

Why this matters: The final rule would have established a new Medicare coverage pathway for FDA-approved breakthrough devices and was scheduled to go into effect on December 15, 2021.

CMS stated it intends to work with the FDA, Agency for Healthcare Research and Quality (AHRQ), medical device manufacturers, and other stakeholders to develop an expeditious process to cover innovative devices that benefit Medicare patients. CMS also plans to hold at least two stakeholder public meetings in CY 2022 to inform future policymaking in this area.

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COVID-19 Updates

- Pfizer requested to amend its emergency use authorization for COVID-19 booster shots to include all adults. A Phase 3 trial involving more than 10,000 participants found boosters were safe and had an efficacy of 95% against symptomatic COVID-19 compared with the two-dose vaccine.

At present, booster shots from Moderna and Pfizer-BioNTech are available six months after a person's second dose to groups who are 65 and older, are high-risk for COVID-19 because of medical conditions, or have increased chances of exposure. The Johnson & Johnson booster shot is available to anyone 18 and older two months after receiving the company's single shot.

- **HHS Announces Funding for COVID-19 Testing and Vaccine Initiatives:** The Department of Health and Human Services (HHS) announced two separate initiatives funded through the American Rescue Plan related to the COVID-19 response:
 - HHS [announced](#) a \$650 million investment to increase the availability of rapid diagnostic testing. The initiative is primarily focused on increasing the manufacturing capacity of high-quality COVID-19 diagnostic tests administered in a health care setting, made to confirm the positive result of an at-home test, for instance.
 - The White House [announced](#) \$785 million in funding “to support community-based organizations building vaccine confidence across communities of color, rural areas, and low-income populations.” The funding allocation comes in response to the recommendation of the COVID-19 Health Equity Task Force, which delivered its [final report](#) to the White House today.

CMS Announces 2022 Medicare Part A and Part B Premiums and Deductibles

The Centers for Medicare & Medicaid Services (CMS) on Friday issued a [press release](#), [fact sheet](#), and pre-publication versions of three Federal Register notices announcing the 2022 Medicare [Part B premiums and deductibles](#), the [Part A deductible](#), and the [Part A premium](#).

Notably, Part B monthly premiums will increase by \$21.60 from 2021, to \$170.10 in 2022. In addition, the Medicare Part B deductible will be \$233 for 2022, a \$30 increase from the 2021 deductible. CMS indicates that the increase in the Part B premium and deductible are due to rising prices and utilization across the

health care system, prior Congressional action that limited the 2021 Medicare Part B monthly premium increase during the COVID-19 pandemic, and uncertainty regarding the potential use of the Alzheimer's drug, Aduhelm™, by people with Medicare. While Medicare is still determining whether it will pay for Aduhelm yet, federal actuaries have to plan for a "high-cost scenario of Aduhelm coverage," regulators said.

In separate notices addressing Medicare Part A, CMS indicates that the Part A deductible will be \$1,556 in 2022, compared to \$1,484 in 2021, and the Part A premium, paid by about one percent of beneficiaries, will be \$499 in 2022, compared to \$471 in 2021.

State Issues

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Legislative

House Advances Mental Health and Substance Use Disorder Confidentiality Alignment Legislation

On Tuesday, November 9, the House advanced the following bills:

- [House Bill 1561](#) (Farry, R-Bucks) would update the Mental Health Procedures Act to bring PA into alignment with HIPAA standards to permit providers, facilities, and health plans to share appropriate patient mental health and substance use disorder-related information.
- [House Bill 1563](#) (Cutler, R-Lancaster) would update the Drug and Alcohol Abuse Act to bring PA into alignment with HIPAA standards to permit providers, facilities, and health plans to share appropriate patient mental health and substance use disorder-related information.

House Bills 1561 and 1563 passed unanimously in the House and now await consideration from the Senate Health and Human Services Committee.

House Committee Advances CHIP Premium Delinquency Legislation

On Monday, November 15, the House Insurance Committee advanced [House Bill 2072](#) (M. Mackenzie, R-Northampton). House Bill 2072 would permit contractors to submit applications to the Department of Human Services for delinquent CHIP premium reimbursement stemming from the PHE. House Bill 2072 specifies the application can be for nonpayment of premiums for three different periods: March 1, 2020, through June 30, 2020, July 1, 2020, through June 30, 2021, and July 1, 2021, through December 31, 2021.

Industry Trends

Policy / Market Trends

CMS Releases Enrollment Snapshot for First Week of Open Enrollment

The Centers for Medicare & Medicaid Services (CMS) has released the first Weekly Enrollment [Snapshot](#) providing data on plan selections in the 33 states using healthcare.gov during the first week (November 1-6) of 2022 individual market Open Enrollment.

CMS reports the plan selections totaled 774,000 during this time, with 17% of these plan selections attributed to new customers. The 2022 total plan selections during this first week is a 5.4% decrease in enrollment, when compared solely to the first full week (November 1-7) of 2021 open enrollment. However, as a reminder, three states (Kentucky, Maine, and New Mexico) transitioned to their own State-based Marketplace platforms for 2022 and thus are not on the HealthCare.gov platform for 2022 coverage. In addition, 2.1 million people signed up for health coverage during the 2021 Special Enrollment Period (SEP), which ran from February 15 through August 15.

CMS will be issuing enrollment snapshots for the HealthCare.gov platform on a weekly basis throughout the 2022 Open Enrollment Period. The agency notes that these snapshots only report new plan selections and active plan renewals, without indicating how many consumers have paid premiums to effectuate their enrollment.

If you have any questions regarding information included in Government Affairs *Capitol Hill Report*, please contact any of the following individuals:

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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/>.

If you have any questions about a DE, NY, PA, WV, or congressional bill, contact the Government Affairs Department at (717).302.3978.

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