



Wednesday, December 1, 2021

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[Read below.](#)

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Robert Califf Officially Nominated to Head FDA

On November 12, President Biden announced that he would nominate Robert Califf as the next FDA Commissioner. If confirmed by the Senate, it would be his second stint as Commissioner, as he previously served in the role for 10 months under President Obama. [Read below.](#)

CMS Announces Largest Medicare Part B Premium Increase in 15 Years

On November 12, the Centers for Medicare & Medicaid Services (CMS) released Medicare Part A and Part B premiums, deductibles, and coinsurance rates for the 2022 calendar year. [Read below.](#)

CMS Finalizes Rule Requiring Health Plans to Submit Data on Prescription Drug Costs & Rebates

On November 17, the Centers for Medicare & Medicaid Services (CMS) issued an interim final rule requiring private payers—including employer-sponsored health plans—to report prescription drug costs to the Departments of Health and Human Services (HHS), Labor and Treasury. [Read below.](#)

FULL STORIES

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Designed to provide higher quality cancer care at the same or lower cost to Medicare, the OCM is part of an effort to shift Medicare to a more value-based approach. These new findings show that the 14 participating practices have been successful, saving Medicare \$54 million in just the last 6-month performance period while still achieving top quality measurement scores.

Approximately a quarter of the total practices participating in the OCM program are affiliated with the Network and those practices have enrolled over 110,000 patients. Throughout the current performance period, Network practices have seen the lowest use of patient emergency department use and utilized telehealth, nurse navigation, and enhanced triage for patients in need of immediate attention. The practices also made significant improvements in pain management and depression screening.

To see the latest announcement from The Network, [CLICK HERE](#)

The Network Joins Oncology Stakeholders in Letter to Congressional Leadership Regarding Physician Fee Schedule Cuts & RO Model

On November 19, over two dozen stakeholders representing providers, patient advocates and industry sent a letter to Congressional leadership requesting that lawmakers pass legislation this year to prevent looming Medicare payment cuts for radiation oncology services that threaten patient access to lifesaving care.

The combined impact of an 8% cut in the 2022 Physician Fee Schedule and further cuts stemming from the mandatory Radiation Oncology (RO) Model that was finalized this year are projected to reduce reimbursement for radiation oncology services by \$300 million starting January 1, 2022.

“The combined cuts will be disastrous for radiation oncology clinics across the country. Practices inside and outside of the RO Model will have difficulty financially supporting the sophisticated technology and high-skill staff essential for a modern radiation therapy clinic. This is particularly dire as patients present with more advanced stage disease requiring more expensive treatment, following delays in diagnosis and surgeries related to COVID-19,” the stakeholders write. “Further, the combined cuts will exacerbate health care disparities in cancer treatment among rural and minority populations. Practices treating underserved populations will be hit hardest, preventing them from providing critical patient support services, such as care navigation and transportation.”

This letter follows additional efforts across the physician community asking Congressional leaders to prevent pending cuts to Medicare. The current government funding bill is set to expire on Friday, December 3, and stakeholders would like to see these cuts averted in legislation to continue government funding, but it is unclear whether Congress can reach an agreement to do so by the end of the week.

To read the letter, [CLICK HERE](#).

House Passes Build Back Better Act Containing Significant Health Reforms

On November 19, the House of Representatives passed the Build Back Better Act (H.R. 5376) on a party-line vote (220 to 213) with all but one Democrat voting in favor. The vote came after the Congressional Budget Office released a final cost estimate of the bill indicating it will increase the deficit by approximately \$367 billion over 10 years.

In addition to paid family leave, universal prekindergarten, expanded financial aid for college, hundreds of billions of dollars in housing support, home, and community care for the elderly and a half-trillion-dollar investment to combat climate change, the Build Back Better Act – which is projected to spend \$2.2 trillion over the next 10 years – contains a number of healthcare provisions including:

- **Drug Pricing Reform:** The bill allows Medicare to negotiate prices for a limited number of drugs under Parts B and D without generic or biosimilar competition, creates a temporary, 5-year add-on payment for biosimilars of ASP + 8%, penalize drug manufacturers who raise prices faster than the rate of inflation, caps annual out of pocket drug costs at \$2,000 in Part D and caps insulin copays at \$35 per month for anyone with public or commercial coverage.
- **Health Insurance Subsidies:** The bill extends federal subsidies for individuals purchasing insurance coverage on ACA-exchanges many of which were originally included in the American Rescue Plan passed earlier this year.
- **Closing the Medicaid Coverage Gap:** Residents in the 12 states that did not expand Medicaid under the ACA will be given additional subsidies to allow them to buy coverage on the state/federal insurance exchanges. The enhanced subsidies will last through 2025.

Having passed the House, the bill now heads to the Senate where lawmakers plan to use the budget reconciliation process to pass the bill with all 50 Democratic votes. Senate leadership have announced their intent to finalize the bill by the end of the year; however, several Senators, most notably Joe Manchin (D-WV) and Krysten Sinema (D-AZ), have already voiced objections to several of the bill's provisions.

To read the Build Back Better Act, [CLICK HERE](#).

To read more about the healthcare provisions in the bill, [CLICK HERE](#).

To read a section-by-section summary of the entire bill, [CLICK HERE](#).

Robert Califf Officially Nominated to Head FDA

On November 12, President Biden formally nominated Robert Califf as the next FDA Commissioner. If confirmed by the Senate, it would be his second stint as Commissioner, as he previously served in the role for 10 months under President Obama. While he was confirmed by a wide bipartisan majority in 2016, several key Senators including Joe Manchin (D-WV) and Richard Blumenthal (D-CT) voted against him. Senator Bernie Sanders (I-VT) also expressed concerns about Califf at that time. All three Senators have again signaled their opposition to Califf's nomination due his ties to the pharmaceutical industry.

While at the FDA, Califf spent two years as deputy commissioner of medical products and tobacco office and coordinated closely with then-Vice President Biden to launch the Cancer Moonshot Initiative. Califf also helped form the FDA's Oncology Center of Excellence. Following his tenure at

the agency, Califf worked at the Duke Clinical Research Institute and directed medical strategy at Verily, which is owned by Alphabet, the parent company of Google.

In announcing his intention to nominate Califf, President Biden noted that Califf is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in the peer-reviewed literature. Advocates hope that Califf's expertise will help revamp the FDA's clunky and expensive system for conducting clinical trials.

During his time in the Obama Administration, Califf proposed creating the National Medical Evidence Generation Collaborative and is expected to continue facilitate easier access to data to make actionable insights.

To read a statement from President Biden about his intention to nominate Califf, [CLICK HERE](#).

CMS Announces Largest Medicare Part B Premium Increase in 15 Years

On November 12, the Centers for Medicare & Medicaid Services (CMS) released Medicare Part A and Part B premiums, deductibles, and coinsurance rates for the 2022 calendar year. Citing rising inflation and potential impact of the new Alzheimer's drug, Aduhelm, on Medicare's finances, monthly Part B premiums are expected to rise to \$170.10 in 2022 – up from \$148.50 this year. Part B deductibles will also increase to \$233, a \$30 increase from this year.

In a press release about the decision, CMS Administrator Chiquita Brooks-LaSure said the rising Part B premium underscores the need for drug pricing reform. "The increase in the Part B premium for 2022 is continued evidence that rising drug costs threaten the affordability and sustainability of the Medicare program. The Biden-Harris Administration is working to make drug prices more affordable and equitable for all Americans, and to advance drug pricing reform through competition, innovation, and transparency."

In a separate statement, House Energy & Commerce Chairman Frank Pallone (D-NJ) said the Part B premium increase "confirms the need for Congress to finally give Medicare the ability to negotiate lower prescription drug costs and establish a rebate for drugs that increase faster than inflation."

To read the press release from CMS, [CLICK HERE](#).

To read a fact sheet from CMS, [CLICK HERE](#).

To read the press release from Chairman Pallone, [CLICK HERE](#).

CMS Finalizes Rule Requiring Health Plans to Submit Data on Prescription Drug Costs & Rebates

On November 17, the Centers for Medicare & Medicaid Services (CMS) issued an interim final rule requiring private payers—including employer-sponsored health plans—to report prescription drug costs to the Departments of Health and Human Services (HHS), Labor and Treasury. Once insurance companies submit the data for calendar year 2020, HHS is expected to analyze it in order to better understand trends in drug pricing, as well as the impact of industry rebates on consumers' out-of-pocket spending and insurance premiums.

The findings will be released in a public report every two years, the first of which is anticipated to be published in June 2023. The rule represents the latest effort for HHS to implement provisions

included by Congress in the No Surprises Act and the Consolidated Appropriations Act of 2021.

To read the announcement from CMS, [CLICK HERE](#).

To read a fact sheet about the interim final rule, [CLICK HERE](#).

To read the text of the interim final rule in the Federal Register, [CLICK HERE](#).

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