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Health Policy Update – January 25, 2022

Senate HELP Committee Advances Biden's FDA Commissioner Nominee

On January 13, the Senate Committee on Health, Education, Labor and Pensions (HELP) narrowly advanced President Biden's nomination to lead the Food and Drug Administration (FDA) on a 13-8 vote. Dr. Robert Califf, who previously served as FDA Commissioner under President Obama and was confirmed by a wide margin, is facing renewed scrutiny ahead of his final confirmation vote.

Many influential Democrats have announced their intention to vote against Dr. Califf on the Senate floor. Citing his track record on opioids, Senators Joe Manchin (D-WV), Bernie Sanders (I-VT), Maggie Hassan (D-NH), and Ed Markey (D-MA) have all expressed their opposition to Dr. Califf's confirmation. Though he is expected to garner support from some Republicans –including HELP Committee Ranking Member Richard Burr (R-NC) – other GOP Senators have announced their opposition to Dr. Califf due to his support of the FDA's recent decision to ease access to abortion medication.

If confirmed to again lead the FDA, Dr. Califf signaled he would prioritize publishing the agency's long-delayed "Nonprescription Drug Product with an Additional Condition for Nonprescription Use" proposed rule, which would permit certain prescription drugs to be sold to consumers over the counter, a key part of President Biden's plans to lower drug costs. In the lead-up to the Senate HELP Committee vote, Dr. Califf also publicly urged Congress to draft legislation to hasten and centralize the collection of post-market data on drugs that have been approved under FDA's Accelerated Approval Program. Absent quicker access to the post-market data, the Centers for Medicare and Medicaid Services (CMS) would continue having difficulty determining coverage for new drugs.

To read more about the "Nonprescription Drug Product with an Additional Condition for Nonprescription Use" proposed rule, CLICK HERE.

To read more about the FDA's Accelerated Approval Program, CLICK HERE.

Stakeholders Call for Permanent Telehealth Flexibilities as HHS Extends Public Health Emergency

On January 13, over 100 healthcare stakeholder organizations sent a letter to House and Senate leaders urging Congress to reinstate the telehealth flexibilities for 32 million Americans in the employer market with high-deductible health plans coupled with Health Savings Accounts (HDHP-HSAs) that expired at the end of last year.

Addressed to Senate Finance Chair Ron Wyden (D-OR), Ranking Member Mike Crapo (R-ID), House Ways & Means Chair Richard Neal (D-MA) and Ranking Member Kevin Brady (R-TX), the letter called for beneficiaries of HDHP-HSAs to continue receiving telehealth benefits from their employer or health plan pre-deductible as Congress specified in the CARES Act passed in 2020. The groups credited the telehealth flexibility for helping ensure access to virtual primary care and behavioral health services prior to meeting plan deductibles. While the provision was still in effect, it led approximately 96 percent of the nation's employers to adopt

pre-deductible coverage for telehealth services, according to the Employee Benefit Research Institute (EBRI).

Separately, HHS Secretary Xavier Becerra renewed the COVID-19 public health emergency (PHE) on January 14, extending it for another 90 days.

Renewing the PHE extended important telehealth waivers that allowed healthcare providers to provide telehealth services to patients using remote communication technologies, even if the technologies do not fully abide by the Health Insurance Portability and Accountability Act (HIPAA). The waivers also expanded telehealth-eligible services available to patients and lifted geographic and site origination restrictions.

While many healthcare stakeholders welcomed the latest extension of the waivers, some fret that temporary extensions make the future of telehealth uncertain, disincentivizing long-term investments. To address these concerns, many providers are advocating for legislative solutions to permanently extend these flexibilities.

To read the letter submitted to House and Senate leadership, CLICK HERE.

To read the EBRI report, CLICK HERE.

To read Secretary Becerra's declaration to extend the COVID-19 PHE, CLICK HERE.

CMS Proposes Restricting Medicare Coverage for Aduhelm to Clinical Trial Participants

On January 12, the CMS issued a preliminary National Coverage Determination (NCD) limiting coverage for Aduhelm (aducanumab) – Biogen's therapy for Alzheimer's whose approval by the FDA last June attracted significant controversy. Though directed at Aduhelm, the only drug of its kind currently on the market, the NCD encompassed all types of monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease and would be expected to include treatments that are still under development by Eli Lilly, Roche as well as two more in Biogen's pipeline.

According to CMS' coverage memo, Medicare will only pay for the drug if the patient is enrolled in a CMS-approved Phase 3 clinical trial conducted in a hospital-based outpatient setting or through a trial supported by the National Institutes of Health.

Stakeholders representing the pharmaceutical industry as well as several patient organizations strongly criticized CMS' decision arguing that it would severely restrict access to the new therapy from those who could potentially benefit and hamper the development of future therapies within the same class.

However, supporters of the decision argued that the move was necessary given the limited evidence on which Aduhelm was approved by the FDA. Widespread coverage of the drug would have had a significant impact on Medicare's finances. Ahead of the decision, CMS officials announced a 14.5% increase in Medicare Part B premiums for 2022 – the highest in decades – in anticipation of high public spending on the drug. Following the preliminary NCD, HHS Secretary Becerra announced the agency would reassess the premium increase.

Public comments on the proposed NCD are due February 12 and a final decision is expected in April.

To view the preliminary NCD, CLICK HERE.

To read more about the NCD and controversy in *Health Affairs*, CLICK HERE.

Top CMS Officials Outline 2022 Strategic Direction for Medicare

Writing in *Health Affairs*, CMS Administrator Chiquita Brooks-LaSure, Medicare Director Meena Seshamani and CMMI Director Elizabeth Fowler provided an update on the Administration's plans for the Medicare program through the rest of this year.

"We believe that Medicare can contribute to the meaningful, sustainable changes necessary in our health system to put the person at the center of care," the officials write. The administration's goals, first articulated roughly a year ago, consist broadly of advancing health equity; expanding access to affordable coverage and care; driving high quality, person-centered care; and promoting affordability and the sustainability of the Medicare trust funds.

Speaking at the J.P. Morgan Health Care Conference, Administrator Brooks-LaSure announced the CMS will increase its engagement with the private sector to address affordability and health equity. In addition to reiterating the administration's support for enabling Medicare to negotiate prescription drug prices, she also highlighted how employers are banding together to negotiate better prices for healthcare services and how the investor community has taken a sharper focus on supporting tools that improve patient engagement and experience.

To view the officials' article in *Health Affairs*, CLICK HERE.

MedPAC Addresses Physician Payment and MA Growth at January Meetings

The Medicare Payment Advisory Commission (MedPAC) met January 13-14 to assess payment adequacy and consider updates to provider reimbursement in a variety of Medicare settings from hospitals to post-acute care facilities.

At the meeting, MedPAC unanimously recommended freezing independent physician pay under the Physician Fee Schedule in 2023, however some commissioners expressed concerns that a pay freeze would not adequately account for inflation and could have a negative impact on the healthcare workforce. At the same time, the Commission voted to increase payment to hospitals as determined under current law, which one commissioner noted would create a potentially troublesome imbalance.

At the January meeting, Commissioners also reviewed the status of the Medicare Advantage (MA) program, which according to MedPAC, has surged in popularity in recent years with 46% of eligible beneficiaries currently enrolled in MA plans. Because MA plans are available to nearly all Medicare beneficiaries and the number of plan options continues to increase, MedPAC predicts that enrollment will exceed 50% in 2023.

To view the MedPAC presentation on physician payment adequacy, CLICK HERE.

To view the MedPAC presentation on the Medicare Advantage program, CLICK HERE.

American Cancer Society Report: Cancer Death Rate on Decline

According to a January report from the American Cancer Society (ACS), the U.S. cancer death rate fell by 32% between 1991 and 2019, suggesting that the overall risk of dying from cancer continues to drop at an accelerating rate. The ACS attributes this decline in mortality in part to earlier detection of cancers and the fact that patients with the disease are living longer after diagnosis.

Other key outcomes of the report include:

- Cancer remains the second most common reason for death in the U.S. after heart disease.
- An estimated 1.9 million new cancer cases are expected in 2022.
- The falling mortality rate translates to about 3.5 million fewer cancer deaths over a 28-year period from 1991 and 2019.
- The risk of death from cancer dropped about 2% from 2015 to 2019.

According to the report, this decline demonstrates the importance of prevention, screening, early diagnosis and treatment. Further, they note that continued progress requires more investment on the national, state and local levels in cancer research and targeted cancer control interventions.

To view the ACS press release, CLICK HERE.

To view the ACS research, CLICK HERE.

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