Health Policy Update - November 11, 2020

Joe Biden Elected 46th President of the United States

On November 7, Joseph R. Biden, Jr. was projected the winner of the 2020 Presidential Election. California Senator Kamala Harris will become the first woman, first Black person, and first person of South Asian descent to be Vice President. The final results of the election were delayed by several days as officials in key battleground states tabulated an unprecedented number of mail ballots that were cast this year. Biden received key victories in Wisconsin, Michigan, and Pennsylvania – three states that were narrowly won by President Donald Trump in 2016 and were crucial to his victory in that election. Biden is also projected to be the victor in Arizona and Georgia, two states that have consistently voted for Republicans in presidential elections over the last several decades.

Biden also won the national popular vote. While the final tally has not yet been determined, Biden currently leads with approximately 77 million votes to Trump's 72 million. President Trump has yet to publicly concede.

At the Congressional level, control of the Senate now depends on Georgia. While Democrats gained seats in Arizona and Colorado, they lost a seat in Alabama and failed to win elections in North Carolina and Maine where public polling showed the Democratic candidates were favored. The outcome of both Senate elections in Georgia will be determined on January 5, 2021 since none of the candidates were able to clear the 50 percent threshold necessary to avoid a runoff as stipulated in Georgia's election laws.

If both Democratic candidates prevail, the party will effectively take control of the chamber with the partisan split being 50-50. In that scenario, the Vice President can cast the tie-breaking vote to on measures requiring a simple majority for passage.

With a number of races still too close to call, the Democratic party will retain control of the House of Representatives albeit with a much narrower majority. House Republicans won back several of the seats they lost in 2018, with a net gain of 6 seats so far, and will add at least 13 women to their ranks.

President-Elect Biden Announces COVID-19 Advisory Board to Aid Transition Team

On November 9, President-elect Joe Biden announced the formation of a COVID-19 advisory board to assist his Presidential transition team as it prepares to address the pandemic. The advisory board will be co-chaired by Dr. David Kessler, former Commissioner of the FDA from 1990-1997, Dr. Marcella Nunez-Smith, the associate dean for health equity research at Yale University and Dr. Vivek Murthy, former U.S. Surgeon General from 2014-2017.

According to the transition team, the advisory board plans to consult with state and local health officials on how to best prevent the spread of COVID-19, reopen schools and businesses, and address the racial disparities that have left communities of color harder hit than others by the pandemic. In addition to the co-chairs, the advisory board will include:

- Luciana Borio, former assistant FDA commissioner
- Rick Bright, former BARDA director
- **Zeke Emanuel**, former Obama administration health policy adviser
- Atul Gawande, Brigham and Women's hospital professor of surgery
- Celine Gounder, NYU Grossman School of Medicine assistant professor
- Julie Morita, former Chicago public health commissioner
- **Michael Osterholm**, director of the Center for Infectious Disease Research and Policy at the University of Minnesota
- Loyce Pace, executive director of the Global Health Council
- Robert Rodriguez, UCSF emergency medicine professor Eric Goosby, former Ryan White Care Act director

To view the Biden transition team's announcement of the COVID-19 advisory board, CLICK HERE.

The Network's Dr. Marcus Neubauer and Ben Jones Discuss Impact of COVID-19 on Value-Based Care and Path Forward in AJMC Article

On October 30, The American Journal of Managed Care (AJMC) published an article by Marcus Neubauer, MD, Chief Medical Officer of The US Oncology Network, and Ben Jones, Vice President of Government Relations and Public Policy for The Network. In the article, titled, "Uncertainty from COVID-19 Delays Progress on the Road to Value-Based Cancer Care," Dr. Neubauer and Jones say COVID-19 may have interrupted progress toward value-based care, but practices need to continue delivering high-quality, high-value care through value-based models - even if the pandemic persists.

The article highlights the impact of COVID-19 on the Oncology Care Model (OCM) and adjustments the Center for Medicare and Medicaid Innovation (CMMI) has made to OCM in response, at the request of The Network and other stakeholders. The adjustments pertain to financial methodologies, quality reporting, and model timelines.

Dr. Neubauer and Jones warn that shying away from value-based care in turbulent times is not the answer, as value-based care is not going away and CMS remains strongly committed to moving away from fee-for-service. "The need for value-based care will only become more important and urgent as the government looks for ways to recoup the trillions of dollars spent on the COVID-19 response. Arbitrary cuts can be imposed, but the more thoughtful way is to pursue reimbursement models that incentivize good care but do so in a value-based manner that promotes buy-in from the physician community," the authors argue.

To read the article in AJMC, CLICK HERE.

Appeals Court Denies Hospitals' Request to Revisit 340B, Site Neutral Payments Cases

On October 16, the U.S. Court of Appeals for the D.C. Circuit declined to rehear challenges to two actions from CMS regarding the 340B drug discount program and the agency's site neutral payment policy. With the Court's ruling, the only option remaining to the American Hospital Association (AHA), which led the legal challenge along with several other groups, is to appeal the case directly to the Supreme Court. The AHA has 60 days from the date of the Court's decision to appeal.

The 2018 Hospital Outpatient Prospective Payment System (OPPS) rule implemented new rates for 340B drug reimbursement, tying payment to the average sales price (ASP) of the drug minus 22.5 percent for drugs acquired through the 340B drug discount program. The 2019 OPPS rule expanded the payment reduction to additional hospital locations.

CMS' site neutral payments policy was included in the 2019 OPPS rule which implemented payment parity for Evaluation and Management (E/M) between hospital outpatient department and physician offices sites of service. In both cases, a lower court had ruled in AHA's favor, but the U.S. Court of Appeals for the D.C. Circuit overturned those rulings this past July.

To view the AHA's petition to reconsider the 340B and site neutral payment cases, CLICK HERE.

HHS Releases Insurer Price Transparency Final Rule

On October 29, the Administration issued a final rule requiring nearly all insurers and self-insured plans to publicly disclose, in machine readable format, in-network and out-of-network rates that they negotiate with providers. It will also require plans to develop online price transparency tools for patients.

An initial list of 500 services – which will be determined jointly by the Departments of Labor, Treasury and HHS – will need to be made available to patients by the start of 2023. Information on all other services and items will need to be available to enrollees by 2024.

Insurance industry associations led by America's Health Insurance Plans (AHIP) and the Alliance for Community Affiliated Plans (ACAP) were immediately critical of the rule, arguing that the measure would do little to lower costs and might end up confusing patients. The associations also expressed concern that the new transparency rule could reduce insurers' negotiating power with providers and might end up actually increasing costs in the process.

The insurer price transparency rule is an addition to a separate hospital price transparency rule that is set to take effect in January 2021. That rule is facing a lawsuit from the American Hospital Association though the courts appear likely to uphold the rule.

To view the final rule, <u>CLICK HERE</u>.

To view a CMS fact sheet on the rule, CLICK HERE.

JAMA: Independent Oncology Practices in the COVID-19 Era—Does U.S. Cancer Care Need a Bailout?

A recently published article in *JAMA Oncology* argues that national policymakers should do more to prioritize the short-term solvency of independent oncology practices in order to preserve patients' access to cancer care and prevent further consolidation within the sector.

According to the article, roughly half of U.S. oncology practices are independent, physician-owned practices that are the sole providers of cancer care in their communities. Unfortunately, many of these practices struggled financially before COVID-19, and the pandemic has only amplified the struggles. National guidelines recommending cancer treatment be delayed were issued to reduce the spread of the virus. These guidelines caused outpatient cancer visits to drop by 50%, and chemotherapy administration to drop by 13%, drastically diminishing revenue for oncology practices. The authors believe the financial strain of COVID-19 is only exacerbating the financial stressors that have engulfed these independent oncology practices for years, such as growing expenses, rising cancer care complexity, and an inadequate reimbursement system.

The authors argue that vertical integration will forfeit patient access to care by forcing underserved patients to travel even further for oncology care; increase hospitalization rates, intensive care unit utilization, and spending; and increase spending while reducing affordability.

Instead, the authors say policymakers should make an effort to identify critical access practices (CAPS) whose closure or acquisition would dramatically undermine access to affordable cancer care and pursue policies that would ensure their financial solvency. These include reducing the capital expenditures required for drug acquisition which can be achieved through a temporary extension of 340B pricing to independent practices that don't currently qualify as well as overhauling reimbursement rates so they accurately reflect the time, effort, and expertise necessary to provide high-quality, complex, and patient-centered oncology care.

To view the article in JAMA, CLICK HERE.

USPSTF Issues Updated Draft Recommendations for Colorectal Cancer Screening

On October 27, the U.S. The Preventive Services Task Force (USPSTF) posted a draft recommendation statement on screening for colorectal cancer, the third leading cause of cancer deaths in the United States. The USPSTF found that despite strong evidence that screening for colorectal cancer is effective, about roughly a quarter of people between the ages of 50-75 have never had a screening.

To remedy this testing gap, USPSTF is recommending people begin getting screened for colorectal cancer at the age of 45. This recommendation is the result of new science that studies colorectal cancer in young people which, "has enabled [us] to expand our recommendation to screen all adults starting at age 45, especially Black adults who are more likely to die from this disease," says USPSTF member Michael Barry, M.D.

USPSTF has given its new recommendation a "B" grade but continues to urgently recommend that adults between ages 50 and 75 get screened for the disease. The task force has also issued a recommendation that screening for people between the ages of 76 and 85 be done at the patient's discretion but may be strongly recommended based on their conditions.

The Task Force's draft recommendation statement, draft evidence review and draft modeling report have been posted for public comment on the Task Force website at www.uspreventiveservicestaskforce.org. Comments can be submitted until November 23, 2020.

To view the USPSTF report, **CLICK HERE**.