McKESSON

Health Policy Update – March 9, 2021

Congress Tees Up COVID-19 Relief Legislation

On March 6, the Senate passed a $1.9 trillion COVID-19 relief package on a party-line vote of 50-49. The House of Representatives is expected to pass the bill as soon as today, without additional changes. This would clear the bill for President Biden's signature, well before the expiration of unemployment benefits on March 14.

Among other provisions, the final bill includes an extension of enhanced unemployment benefits through the end of September, $1,400 stimulus checks for those with qualifying incomes, temporary COBRA subsidies, emergency funding for state and local governments, billions in additional funding for vaccine distribution and increased subsidies for Affordable Care Act plans. The bill includes $8.5 billion in new funding for rural healthcare providers for health-related expenses attributable to COVID-19. Unfortunately, an extension of sequestration relief was not included due to restrictions associated with the budget reconciliation process.

To read a summary of the final bill, CLICK HERE.

To read the text of the final bill, CLICK HERE.

Senate Floor Vote on Becerra Nomination Expected, Tanden Withdraws from Consideration to Lead OMB

After clearing two hearings on February 23 and 24, President Biden’s nominee to lead HHS is expected to receive a vote on the Senate floor soon.

In the hearings, Xavier Becerra, who currently serves as California’s Attorney General, emphasized that his focus will be on fighting COVID-19 and addressing health disparities in communities of color. Becerra also clarified that, as HHS Secretary, he will not work to implement a Medicare for All system, despite past calls to do so. Instead, he will focus on refining and expanding the Affordable Care Act – in line with the proposals President Biden promoted during his campaign. Becerra also clarified his stance on Medicare Advantage, saying he favors putting MA plans on a more “level playing field” with traditional Medicare.

Becerra's history of taking the fight to the pharmaceutical industry was a focus of the hearings. In December 2020, he led a sign-on letter of state attorneys general calling on then-HHS Secretary Azar to crack down on drug manufacturers’ efforts to limit hospital access to 340B drugs through contract pharmacies. Senator Bill Cassidy (R-LA) asked whether a statutory definition for contract pharmacies or patients was needed in the 340B program and Becerra said the 340B program was an indispensable program but did not respond to the question. During the hearing, he also

emphasized that if confirmed, he will ensure that HHS completes a “robust investigation of price transparency.” After being asked if he believes 100% of the drug rebates should be passed on to patients at the pharmacy counter, Becerra said he would have to explore the program further if he is confirmed.

The Senate Finance Committee split along party lines in the vote to advance Becerra's nomination. He is still expected to be confirmed by the full Senate, barring any unexpected Democrat defections.

On March 2, Neera Tanden, President Biden’s nominee to lead the Office of Management and Budget, withdrew her name from consideration. Tanden’s decision came after several key Republican Senators revealed they would not support her nomination citing her past partisan attacks against Republicans and some progressives during her tenure at the Center for American Progress.

To view Becerra’s confirmation hearing before the Senate HELP Committee, CLICK HERE.

To view Becerra’s confirmation hearing before the Senate Finance Committee, CLICK HERE.

Biden Yet to Name Choice for FDA Commissioner

As President Biden continues to nominate leaders for the top healthcare posts, he has not yet named a person to take the helm of the Food and Drug Administration (FDA), leading to speculation over who will ultimately get the nod. Two potential contenders include Janet Woodcock, the director of the FDA’s Center for Drug Evaluation and Research, and Joshua Sharfstein, who had previously served as Principal Deputy Commissioner of the FDA under President Obama.

Amid the ongoing COVID-19 pandemic, the FDA Commissioner will be one of the most influential health policy makers at a time when President Biden’s biggest priority is protecting public health.

Woodcock, who is strongly supported by the oncology provider community, is seen as more of an establishment candidate. According to longtime FDA-watchers, she has the potential to be a strong partner with the biopharmaceutical industry given her willingness to approve new drugs where there is an exceptional medical need even if the efficacy has not been completely demonstrated. She has led efforts to fast-track cancer therapies, helping the agency approve a record-breaking 17 cancer therapies in 2020. Woodcock is also expected to prioritize strengthening clinical trials and adopting newer practices such as adaptive platform trials, which examine multiple potential treatments for a disease simultaneously. In February, almost 100 of the nation’s top oncologists wrote an open letter calling on President Biden to nominate Woodcock; however, she has also faced opposition from senators representing states hit hard by the opioid epidemic.

By contrast, Sharfstein is expected to take a harder line against the biopharmaceutical industry and will likely push for greater transparency into how the FDA coordinates with drug companies. In the past, he has quipped that the purpose of good health policy “is not to make the stakeholders happy.” Given intense opposition from pharmaceutical manufacturers, he is expected to be tough on industry if nominated to head the FDA. There have also been reports that the White House is

looking for alternatives to the above candidates due to said opposition.

To read the oncologists' letter urging President Biden to nominate Woodcock, CLICK HERE.

Coalition of Cancer Care Stakeholders Share RO Model Concerns with CMS

On March 1, The Network joined a coalition of 27 cancer care stakeholder groups in sending a letter to CMS Acting Administrator Elizabeth Richter outlining concerns with the Radiation Oncology (RO) Model, as it is currently designed, in the hopes of working with the new Administration to achieve value-based radiation oncology care. Though the RO model was finalized by CMS last September, its start date has recently been delayed until January 1, 2022.

In addition to urging CMS to provide the radiation oncology community with the data used to formulate various elements of the model so that participants can fully anticipate its impacts and address issues prior to implementation, the coalition presented a series of recommendations to improve the RO model's payment methodology including the discount factor, national base rates, case mix adjustment, new equipment and services lines, clinical data elements, and monitoring elements, among other factors.

Specific recommendations made by the coalition include:

- reduce the discount factors to 3% or less to ensure that practices can continue to operate successfully under the RO Model in order to secure continued financially viability;
- blend the historical MPFS and HOPPS rates for the PC of each cancer type to establish a more accurate payment rate to more accurately account for the professional work taking place in both sites of service;
- consider Trend Factor guard rails that will prevent significant shifts in payment rates under the RO Model;
- provide information regarding the calculation of Case Mix Adjustment, Historical Experience, and Blend Factor methodologies, as well as the data used to determine the adjustments, so that practices compelled to participate in the RO Model can confirm their accuracy; and
- consider the application of a rate review mechanism or some other formula for recognizing the need for upgrades, new equipment and new service lines, that provides equal support for all radiation oncology modalities, departments, and practices.

To read all RO Model recommendations from the coalition to CMS, CLICK HERE.

House E&C Health Subcommittee Holds Telehealth Hearing

Telehealth has experienced a boom during the COVID-19 pandemic. During a March 2 hearing of the House Energy and Commerce Subcommittee on Health, many stakeholders expressed support for telehealth permanence and patients and providers have embraced the convenience and flexibility of receiving care from home.

The hearing, titled “The Future of Telehealth: How COVID-19 is Changing the Delivery of Virtual Care,” featured testimony from Megan Mahoney of Stanford Health Care, Ateev Mehrotra of Harvard Medical School, Elizabeth Mitchell of Purchase Business Group on Health, Frederic Riccardi of Medicare Rights Center and Jack Resneck of American Medical Association.

The hearing began with Health Subcommittee Chairwoman Anna Eshoo (D-CA) highlighting the millions of Medicare beneficiaries who received telehealth services during the pandemic, emphasizing telehealth as a tool to advance health equity and stating her support to make Medicare reimbursement for telehealth services permanent. Representative Frank Pallone (D-NJ), who heads the full E&C Committee urged the Committee to analyze telehealth with the following areas in mind: value, program integrity and equitable access to telehealth services.
Ranking Member Cathy McMorris Rodgers (R-WA) supported the increased use of telehealth while raising concerns of fraud and stressing the need for increased access to broadband and fraud prevention in telehealth. Her concerns are not relegated to the committee – HHS’ Principal Deputy Inspector General has also raised these concerns and noted in a statement that additional safeguards must be put in place to ensure virtual care is not be compromised by “telefraud".

Since January, more than a dozen bills have been filed in the House and Senate related to telehealth. Some of these measures seek the elimination of Medicare’s site of service restrictions, payment parity for virtual and audio visits, expansions of telehealth services, and provider flexibility in rendering telehealth services across state lines for the duration of the COVID-19 pandemic.

To view the E&C Health Subcommittee hearing, CLICK HERE.

To view the HHS OIG statement on telehealth fraud, CLICK HERE.

Patient Groups Urge Biden Administration to Reject Proposed Changes to Medicare’s Protected Drug Classes Policy

On February 26, a coalition of more than 130 patient advocacy groups sent a letter to the HHS nominee Xavier Becerra urging the Department to reject a Trump Administration proposal that would weaken patient protections in Medicare Part D. Current law establishes six protected drug classes in the Medicare program, and CMS rules require Part D plans to cover all drugs in these classes.

The Trump Administration proposal – which was finalized on January 19, a day before the change in Administration – would allow Medicare Part D plans that participate in the Center for Medicare and Medicaid Innovation’s Part D Payment Modernization Model to limit the drugs they cover in those classes. This could lead to plans denying patient access to medications used to manage complex conditions such as cancer, mental illness, HIV/AIDS, epilepsy, Parkinson’s and organ transplantation.

“The protected classes policy has been a cornerstone of Part D’s success: helping to ensure that Part D formularies serve the needs of all Medicare beneficiaries, including the most vulnerable

patients with the greatest need for drug coverage," the letter reads. "Accordingly, we implore you to reverse [the Trump administration] policy immediately."

To view the coalition letter, CLICK HERE.

New Study Highlights Cost Differences in Health Care Services by Site of Treatment

A recent study by the Employee Benefit Research Institute (EBRI) examined pricing failures and wasteful spending related to lab, imaging, and special medications for conditions such as multiple sclerosis, rheumatoid arthritis and other inflammatory disorders. According to the report, employers and workers would collectively save $11.2 billion if price differentials between hospital outpatient departments (HOPDs) and other sites of treatment were eliminated.

These findings lend support to the idea that implementing site neutral payments for certain healthcare services – as CMS did in 2019 for Evaluation and Management Services – would result in significant savings to the overall healthcare system. The EBRI analysis also highlighted the ongoing shift in care from physician offices and community practices to more costly HOPDs. According to the study, "For example, in 2004, approximately 94 percent of chemotherapy infusions were administered in physicians' offices but by 2014, that percentage had dropped to 57 percent with a corresponding shift toward HOPDs."

To read the report, CLICK HERE.

To view a summary of key takeaways published by the Alliance for Site Neural Payment Reform, CLICK HERE.

Leading Advocacy Groups Present Policy Recommendations & Practice Changes to Improve Equity in Cancer Care

On February 22, the National Comprehensive Cancer Network, American Cancer Society Cancer Action Network and the National Minority Quality Forum presented a set of recommendations for how to overcome inequality in the oncology field and directly address how medical systems in the United States often disproportionately fail minority patients, particularly those who are Black, Latino, and/or Indigenous.

The recommendations were developed by the newly convened 17-member Elevating Cancer Equity Working Group consisting of national experts representing patients and advocates, caregivers, healthcare providers, researchers and industry.

Workgroup recommendations include a new Equity Report Card to help providers, payers and accreditation entities advance equitable care delivery by establishing measurable practice changes to advance equity in oncology care. These changes include policies such as having health systems provide and require annual implicit bias training for all employees, making available culturally and

linguistically representative patient navigators or community health workers, and offering flexible hours for screening and treatment appointments.

These recommendations were informed by extensive polling data commissioned by the organizations to underscore the case for urgent action. According to the recent poll, 63% of Black and 67% of Latino patients, survivors, and caregivers said they had a negative experience with their oncology care team, such as having assumptions made about them or their financial situation, or trouble getting questions answered. By contrast, only 43% of white respondents reported such experiences. Additionally, about two-thirds of oncologists surveyed believed that non-white patients experienced worse outcomes from cancer care but only about a third felt those patient populations were receiving lower quality care or poorer communication during care.

To view a comprehensive list of the groups' recommendations, CLICK HERE.

To view the slide decks from a webinar outlining the recommendations, CLICK HERE.