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## Health Policy Update – July 27, 2021

### Senate Democrats Unveil \$3.5 Trillion Budget Plan, Talks Continue on Bipartisan Infrastructure Bill

Earlier this month, the Democratic members of the Senate Budget Committee unveiled a partisan \$3.5 trillion budget resolution that is expected to be the main vehicle for passing the bulk of President Biden’s “human infrastructure” priorities contained in the American Families Plan. The finer points of the agreement – which is a compromise between the panel’s progressive and moderate members, along with the White House – have not yet been worked out, but the proposal’s healthcare provisions are expected to include the addition of hearing, vision, and dental benefits to Medicare, a plan to expand Medicaid in states having not yet expanded under the ACA (known as closing the Medicaid “coverage gap”), and additional provisions aimed at reducing prescription drug costs, among other things.

The plan would be paid for through a series of tax and health policies, including an increase in the corporate tax rate – which was lowered as a part of the 2017 Tax Cuts and Jobs Act – and increased enforcement of existing tax laws by devoting more resources to the IRS. Regarding prescription drug prices, the plan could allow for direct negotiation in Medicare, the imposition of drug price inflation caps, and likely a delay or repeal of the Trump Administration’s finalized rebate rule. Democratic lawmakers plan to pass this legislation using the budget reconciliation process, which only requires a simple majority in the Senate and would allow the bill to pass on a party-line vote.

Meanwhile, a bipartisan group of Senators continue negotiations on a traditional infrastructure bill expected to invest more than \$1 trillion in roads, bridges, waterways, and broadband over the next ten years. Last Wednesday, Senate Republicans rejected a procedural vote to move forward with the framework citing the lack of legislative text. Lawmakers on both sides of the aisle remain optimistic that text and a cost estimate will be completed as soon as this week.

To offset the cost of the traditional infrastructure bill, some lawmakers have advocated for delaying – or outright repealing – the Trump Administration’s rule that would have prohibited Medicare Part D rebates. The “rebate rule” is currently slated to take effect in 2023 after being delayed for a year by the Biden Administration.

To view a set of White House talking points on the budget framework, [CLICK HERE](#).

### CMS Releases CY 2022 Physician Fee Schedule Proposed Rule

On July 13, the Centers for Medicare & Medicaid Services (CMS) released the CY 2022 Medicare

Physician Fee Schedule (PFS) proposed rule. The agency plans to reduce the conversion factor to \$33.58 – a decrease of \$1.31 from last year's \$34.89 – reflecting the expiration of the temporary 3.75% conversion factor increase Congress enacted for CY 2021 to help providers weather the pandemic.

The PFS proposed rule would also continue reimbursing services added temporarily to the Medicare telehealth list through CY 2023 while soliciting feedback on whether the policies should be made permanent in the future. CMS plans to move forward with 7 new MIPS Value Pathways (MVPs) beginning in 2023 while setting the following weights for MIPS performance categories in 2022: Quality - 30%; Cost - 30%; Promoting Interoperability - 25%; and Improvement Activities - 15%.

Stakeholder reaction to the rule was mixed. While provider organizations were mostly supportive of the new MVPs and extension of telehealth flexibilities, the conversion factor cut was not well received. Groups, including the American College of Surgeons, the American Association of Medical Colleges, and the Medical Group Management Association, argued that the cuts will harm patients' access to care and should be reversed – especially in light of the reimposition of sequestration in 2022 and the possibility of additional Medicare cuts due to the Statutory Pay-As-You-Go Act.

On July 21, the American Medical Association sent a letter to congressional leaders urging them to address looming Medicare reimbursement cuts scheduled to take effect in January. AMA CEO James L. Madara, M.D., said, "All this financial uncertainty comes at a time when physician practices are still recovering from the financial impact of the COVID-19 public health emergency, including continued infection control protocols that, while necessary, have increased the cost of providing care." The AMA estimates that without intervention, physician practices may face cuts of nearly 10% beginning in January.

Similarly, on July 23, more than 100 organizations representing more than 1,000,000 healthcare providers sent a letter to Congress urging action to increase the conversion factor by 3.75% *through at least calendar years 2022 and 2023*.

To view a fact sheet on the CY 2022 PFS proposed rule, [CLICK HERE](#).

To view the CY 2022 PFS proposed rule, [CLICK HERE](#).

To read the AMA press release and letter sent to congressional leaders, [CLICK HERE](#).

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

## Radiation Oncology Model Included in CY 2022 OPPS Rule

On July 19, the Centers for Medicare & Medicaid Services (CMS) released the CY 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule, which included a revised Radiation Oncology (RO) Model slated to begin on January 1, 2022. Under the proposed rule, the RO Model would see modest changes.

CMS proposed reducing both the professional and technical component discount factors by 0.25% (to 3.5% and 4.5%, respectively), eliminating lung cancer and brachytherapy from the model, and adopting an “extreme and uncontrollable circumstances” policy, among other changes.

In a press release in response to both the revised RO Model proposed rule and the CY 2022 Physician Fee Schedule proposed rule, American Society for Radiation Oncology (ASTRO) Chair Thomas J. Eichler, M.D., said CMS’ proposed rules single out radiation oncology for payment cuts, jeopardizing radiation therapy professionals’ ability to care for their patients and threatening cancer patients’ access to high-quality care. The group noted that many clinics are still facing significant challenges caused by the ongoing COVID-19 pandemic. ASTRO called for Congress and the Administration to take action to address the cuts.

To read a fact sheet on the CY 2022 OPPTS/RO Model proposed rule, [CLICK HERE](#).

To read the CY 2022 OPPTS/RO Model proposed rule, [CLICK HERE](#).

To read ASTRO’s statement, [CLICK HERE](#).

To read more about the industry’s response to the proposed rule, [CLICK HERE](#).

## CMS Plans to Increase Penalties for Hospital Non-Compliance with Transparency Rule

In the CY 2022 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) proposed rule, the Centers for Medicare & Medicaid Services (CMS) put forward new policies to strengthen the enforcement of price transparency requirements and separately, to maintain cuts to the 340B program. According to CMS, the policies are intended to help address growing healthcare spending through the Medicare program.

Reinforcing transparency requirements set in motion by the Trump Administration, the proposed rule would increase the maximum penalty for hospitals that fail to publicly post service prices online from \$109,500 to \$2 million per year, depending on facility size. The price transparency policy is an effort to help America’s patients better understand how much they may be charged for services provided at different hospitals—and hopefully encourage competition and lower costs. As expected, hospital groups, including the American Hospital Association (AHA) and America’s Essential Hospitals, bristled at the proposal and urged CMS to delay the price transparency requirements because of the ongoing challenges posed by the pandemic.

To date, few hospitals have complied with the rule, prompting CMS to propose strengthening the penalties for noncompliance. According to a new report released by Patients Rights Advocate, the vast majority of American hospitals (over 80%) are noncompliant with price transparency regulations requiring them to post their prices online for patients to review. Just 6% of hospitals have fully complied with the regulation since it went into effect in January.

In another blow to hospitals, CMS proposed maintaining its methodology for determining payment rates for the 340B Drug Pricing Program. If finalized as written, the CY 2022 OPPTS proposed rule

would keep rates at average sales price (ASP) minus 22.5 percent for qualifying outpatient drugs acquired under the program. Hospital groups have long maintained that the cuts are causing hospitals to reduce services, limiting patient access to care. In 2017, the AHA first brought suit against CMS for the 340B cuts, which were upheld by the U.S. Court of Appeals in July 2020. The AHA subsequently petitioned to the Supreme Court, which has indicated it will review the case in its upcoming term.

To read a fact sheet on the CY 2022 OPPS/ASC proposed rule, [CLICK HERE](#).

To read the CY 2022 OPPS/ASC proposed rule, [CLICK HERE](#).

To read more about the price transparency and 340B rules, [CLICK HERE](#) and [HERE](#).

To read the new report by Patients Rights Advocate, [CLICK HERE](#), and [HERE](#).

## House Oversight Committee Report Shows Pharma Spends More on Buybacks, Dividends, and Executive Compensation than R&D

The House Committee on Oversight and Reform recently released a report analyzing the financial data of 14 of the largest drug companies in the world. The Committee's analysis shows that between 2016 and 2020, the 14 largest drug companies spent \$56 billion more on stock buybacks and dividends than they spent on R&D—totaling \$577 billion. The report also claims the companies spent significant portions of their R&D budget finding ways to suppress generic and biosimilar competition as they continued to raise drug prices – arguing the companies are using price increases to boost payouts to their investors and executives, whose compensation grew 14% over the same five-year period.

Rep. Carolyn Maloney (D-NY), Chairwoman of the Committee, said the report “makes clear that Congress needs to act to rein in out-of-control prescription drug prices.” Democratic lawmakers plan to use the report's findings to build support for H.R. 3, the Elijah E. Cummings Lower Drug Prices Now Act, that would allow Medicare to directly negotiate drug prices— saving taxpayers an estimated \$456 billion over 10 years, according to CBO.

To read the Committee's press release, [CLICK HERE](#).

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