Health Policy Update – April 20, 2021

Biden Administration Releases FY 2022 Discretionary Budget Request

The Biden Administration formally kicked off the annual budget process on April 9 with the release of the discretionary spending portion of its fiscal year 2022 budget request. The $1.5 trillion proposal, known colloquially as the "skinny budget," includes significant increases in spending for healthcare, education, and environmental programs while maintaining current funding levels for defense and homeland security.

The administration's spending requests represent an overall increase of 8.4% in federal agency operating budgets for fiscal year 2022, and a 23% increase in spending for HHS discretionary programs specifically. Notable items within the HHS request include:

- An additional $6.5 billion to create an Advanced Research Projects Agency for Health (ARPA-H) within the National Institutes of Health, which would be tasked with driving "transformational innovation" in the areas of cancer care as well as other chronic diseases including Alzheimer's and diabetes.
- $8.7 billion in funding for the Centers for Disease Control and Prevention – the largest increase in two decades – to modernize public health data collection and workforce training.
- A $10.7 billion investment to support research, prevention, treatment, and recovery support services for individuals living with substance use disorders as part of a broader effort to combat the opioid epidemic.
- Additional investments in the areas of mental health, gender-based violence, HIV/AIDS, and gun violence prevention.

While the president's budget request is typically sent to Congress in February, it is often delayed in the first year of an incoming administration. It has also become more common to transmit the discretionary request separate from the mandatory request. President's Biden's mandatory request, which includes program proposals for Medicare, Medicaid, and Social Security is expected in in the coming weeks, likely in conjunction with forthcoming American Families Plan. Details may also be included in President Biden's first joint address to Congress scheduled for April 28.

To view a summary of the discretionary budget request, CLICK HERE.

Senate Finance Committee Held Confirmation Hearing for CMS Administrator, HHS Deputy Secretary

On April 15, the Senate Finance Committee held a confirmation hearing for CMS Administrator-nominee Chiquita Brooks-LaSure and HHS Deputy Secretary-nominee Andrea Palm.

Senators focused their questions on a number of topics, including drug pricing reform, telehealth policy permanence, Medicaid waivers, and child welfare issues at the southern border. Chairman Ron Wyden (D-OR) specifically expressed support for repealing Medicare Part D's non-interference clause and allowing the government to negotiate for prescription drugs. Ranking Member Mike Crapo (R-ID) expressed support for an out-of-pocket spending cap in Part D. Brooks-LaSure and Palm broadly commented on the need to lower drug prices and appeared to express support for telehealth permanence, though neither nominee detailed any specific positions or policy prescriptions in the hearing.

Brooks-LaSure has extensive health policy experience, having served as a staff member on the House Ways & Means Committee. She then served as deputy director of CMS' Center for Consumer Information and Insurance Oversight. Brooks-LaSure is currently a managing director for Manatt Health where she advises states on pathways for creating a public option health insurance program. Her consulting work has also included advising drug manufactures including Pfizer, Novo Nordisk, Gilead and Genentech.

Andrea Palm, President Biden's nominee for Deputy HHS Secretary was most recently secretary-designee for Wisconsin's Department of Health and Human Services. She has also held several positions in the Obama Administration, including acting assistant secretary and chief of staff to the Secretary of HHS.

To read Chiquita Brooks-LaSure's testimony, CLICK HERE.

To read Andrea Palm's testimony, CLICK HERE.

To view the hearing, CLICK HERE.

APMs, Private Equity, Clinical Lab Payment Rates Focus of MedPAC's April Meeting

The Medicare Payment Advisory Commission's (MedPAC) April 2021 meeting agenda included a number of notable topics, including recommendations to harmonize alternative payment models (APMs), further study healthcare provider ownership and explore ways CMS can improve its process for determining reimbursement rates for clinical laboratory services.

As a first step to improving how APMs work, MedPAC unanimously backed a proposal to direct CMS to reduce the number of existing APMs and harmonize the interaction among models. The Commission expects that while its recommendation might not affect Medicare spending over the course of five years, there could be longer term savings. MedPAC also suggested beneficiaries would receive better care coordination and improved health outcomes, and providers would experience fewer administrative burdens under its recommendation.

MedPAC also signaled that it will start looking into transparency and accountability of health care ownership. It is planning to include a chapter on the role of private equity in Medicare in its June 2021 report. The issue of private equity's involvement in healthcare - along with the broader issue of provider consolidation - has recently attracted the attention of policymakers. The House Way &

Means Committee asked the Commission in March to explore the private equity issue while a group of Democratic Senators led by Elizabeth Warren (D-MA) are planning an investigation into for-profit and private equity-owned nursing homes.

MedPAC also suggested that CMS's policy of basing Medicare laboratory reimbursement rates on commercial rates, which was enacted as a part of the Protecting Access to Medicare Act of 2018, could lead to substantial savings. The Commission also warned savings could vary based on test type and rates might be skewed in a way that negatively affects patient access because of independent labs' overrepresentation in the data. The Commission noted that it is preparing a June 2021 report that will explore the best way for CMS to collect commercial payer rates in a way that results in a representative sample of all laboratories. Clinical laboratory industry representatives have called CMS's current methodology deeply flawed and a threat to beneficiaries' access to laboratory services.

To view the full agenda, briefings, and presentations from MedPAC's April meeting CLICK HERE.

AMA Survey Finds Widespread Insurer Use of Prior Authorization

On April 7, the American Medical Association (AMA) released the results of its 2020 physician survey on prior authorization. Even as COVID-19 infections skyrocketed, 70% of physicians surveyed in December 2020 said that healthcare payers had either reimposed prior authorization policies since the start of the pandemic or never relaxed the policies at all.

As a result of prior authorization policies, appropriate patient care is often delayed, which can have serious health repercussions for patients. Of the 1,000 physicians surveyed, 30% said that prior authorization requirements have led to serious adverse events for patients, including hospitalization, disability, permanent bodily damage, and life-threatening episodes. The overwhelming number of physicians (90%) believe that prior authorization policies have a negative impact on clinical outcomes.

According to the survey results, prior authorization not only harms patient care, it often generates a significant administrative burden on physicians as well. The overwhelming majority (85%) of respondents believe the burdens associated with prior authorization are high or extremely high. On average, medical practices complete roughly 40 prior authorization requests per physician each week, taking up 16 hours of physician and staff time. To help manage with the paperwork, 40% of surveyed doctors reported hiring staff members who work exclusively on tasks related to prior authorization.

To view the 2020 AMA prior authorization physician survey, CLICK HERE.

Energy & Commerce Committee Leadership Urges HHS to Step Up Enforcement of Price Transparency Rules

On April 13, bipartisan leaders from the House Energy & Commerce Committee sent a letter to HHS Secretary, Xavier Becerra, regarding the implementation of the Hospital Price Transparency Final Rule, which went into effect on January 1. The letter – signed by Energy and Commerce Committee Chairman Frank Pallone (D-NJ), Ranking Member Cathy McMorris Rodgers (R-WA), Health Subcommittee Chairwoman Anna Eshoo (D-CA), and Health Subcommittee Ranking Member Brett Guthrie (R-KY) – urges Secretary Becerra to ensure HHS enforces full compliance with the rule.

With recent analyses and media reports suggesting many hospitals are not adequately sharing their standard charges for all items and services in a consumer-friendly format, the lawmakers call on CMS to conduct rigorous oversight to ensure the nation's hospitals are all in compliance with the Hospital Price Transparency Final Rule. The bipartisan group suggested using all appropriate tools for compliance including civil penalties, audits, written warnings, and requests for corrective action plans.

In addition to urging regulatory action, the lawmakers also requested a staff briefing on the implementation of the final rule and on HHS's audit of hospitals' compliance with the final rule.

To read the lawmaker letter to Secretary Becerra, CLICK HERE.

To read a recent analysis of the Hospital Price Transparency Rule, CLICK HERE.

CBO Report Analyzes Pharmaceutical R&D Spending as PhRMA Unveils New Policy Priorities

On April 8, the Congressional Budget Office (CBO) released a new report analyzing trends in research and development (R&D) by the pharmaceutical industry. The report found that pharmaceutical manufacturers spent $83 billion on R&D in 2019 alone, roughly a tenfold increase from annual R&D spending in the 1980s, adjusted for inflation. The increased investment in research has helped fuel more new drugs in company pipelines: between 2010 to 2019, the number of new drugs approved grew by 60% compared with the previous decade. With the level of R&D determined by the expected lifetime global revenues of each new drug, the CBO estimates the cost of developing a new drug can range from $1-$2 billion.

In a blog post on the CBO report, the Pharmaceutical Research and Manufacturers of America (PhRMA) championed the industry's robust investment in lifesaving and life-sustaining innovations, especially for some of the world's most challenging diseases such as cancer and autoimmune conditions.

PhRMA also released a new policy priority framework, which stresses the vital role of R&D in ending the COVID-19 pandemic and building a stronger, more resilient healthcare system. To ensure continued investment in R&D, the group urged the federal government to continue protecting intellectual property and research incentives. The policy framework also called on insurers to pass on more savings to America's patients in order to reduce the amount of money consumers spend on drugs. Finally, PhRMA called for a more equitable health system by addressing disparities and creating more diversity and inclusion in research.

To read the CBO report on pharmaceutical innovation, CLICK HERE.

To view PhRMA's blog post on the CBO report, CLICK HERE.

To view PhRMA's latest policy priorities, CLICK HERE.

Hospital Groups Seek Meeting with FDA Over Insurer "White Bagging" Policies

On March 31, the American Hospital Association (AHA) and the American Society of Health-System Pharmacists (ASHSP) sent a letter to Acting FDA Commissioner, Janet Woodcock, requesting a meeting to discuss their concerns with "white bagging." The groups argue that white bagging policies, in which payers mandate patients purchase certain physician administered drugs through the payer's own specialty pharmacy, jeopardize the stability of the drug supply chain and pose safety risks to patients.

While insurers argue that white bagging saves money and helps ensure more efficient spending in the health system, the AHA and ASHSP said that the practice disregards the Drug Supply Chain Security Act's (DSCSA) requirements for the wholesale distribution of drugs by requiring patient medications to be distributed through a narrow network of pharmacies affiliated with insurers. In their letter, they urged the FDA to heed their concerns and take quick enforcement action.

"Given the growing ubiquity of payer-mandated white bagging, we are concerned that this practice threatens DSCSA's underlying goals. Further, because hospitals do not have legal title to white bagged medications and the drugs are delivered outside of hospital-established supply chains, white bagging can raise additional patient safety risks by enabling diversion and heightening the possibility of drug spoilage/wastage. In addition, as white bagged drugs bypass established supply chain channels it also disrupts and significantly complicates the ability to respond to FDA drug recalls," the groups said.

To read the AHA and ASHSP letter, CLICK HERE.