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Health Policy Update – January 26, 2021

Joseph R. Biden, Jr. Sworn in as 46th President of the United States

On January 20, Joseph R. Biden, Jr. and Kamala D. Harris were sworn in as President and Vice President of the United States, respectively. That same day, the Senate flipped to Democratic control as three new Senators were sworn in with Vice President Harris holding the tie-breaking vote in the evenly divided chamber.

Hours later, the new Biden-Harris Administration issued a series of executive actions, many of which were centered around responding to the COVID-19 pandemic. The new administration also promised to press forward with a $1.9 trillion economic relief plan which is expected to face stiff opposition from Republican lawmakers and some moderate Democrats.

President Biden's plan includes another round of individual stimulus relief checks, raising the minimum wage to $15 an hour and $415 billion in emergency spending to fight COVID-19, including:

- $20 billion for a national vaccine distribution plan that emphasizes expanding eligibility, creating more vaccine sites, and increasing vaccine supply and distribution nationally;
- $30 billion to purchase supplies and protective equipment; and
- $50 billion for a robust testing program.

The relief plan also includes a proposal to expand the Affordable Care Act's premium tax credits and extend federal subsidies for COBRA coverage through September 2021.

At HHS, Norris Cochran was tapped to serve as Acting Secretary until President Biden's permanent nominee, Xavier Becerra, receives a confirmation vote by the Senate. A confirmation hearing on Becerra's nomination is scheduled before the Senate Committee on Health, Education, Labor and Pensions (HELP) on January 27. Mr. Cochran previously served as the assistant secretary of budget at the Department. President Biden also nominated current Pennsylvania Health Secretary Rachel Levine to serve as Assistant Secretary for Health at HHS.

While President Biden has yet to nominate an FDA commissioner or CMS administrator, the administration has tapped Micky Tripathi, a health technology industry veteran and pioneer of interoperability, to serve as the National Coordinator for Health IT and reappointed Dr. Francis Collins to continue serving as Director of the National Institute of Health.

Biden Administration Issues 60-Day Freeze on Pending & Recently-Finalized Regulations, Including Last-Minute Prior Authorization Rule

Hours after President Biden was sworn into office, White House Chief of Staff Ron Klain sent a memo to acting agency heads asking them to postpone for 60-days any rules not yet published in the Federal Register. For rules that have been published but have yet to take effect, agency heads were given discretion as to whether to postpone the rule and/or open a 30-day comment period to gather additional information about "issues of fact, law, and policy."

The move, common among incoming administrations, is expected to delay or stop outgoing Trump Administration efforts to finalize a series of rules, including proposals related to HIPAA, the elimination of prescription drug rebates in Medicare Part D, and a requirement for certain health plans to extend 340B discounts on insulin and epinephrine on to patients, among others.

The Trump Administration's prior authorization (PA) rule finalized January 15 – just 9 days after the comment period officially closed – is also subject to the freeze. The rule aims to reduce the burden of PA on providers and patients by requiring Medicaid, CHIP and Qualified Health Plans offered on federally-facilitated exchanges to build application programming interfaces (APIs) to support data exchange and electronic PA. Payers would also be required to make PA decisions within 72 hours for urgent requests and 7 days for standard requests.

The rule came under criticism from both provider and insurance industry stakeholders. The American Medical Association (AMA) suggested the new requirements wouldn't be worth it unless the rule covered more plans, particularly Medicare Advantage plans. Meanwhile, America's Health Insurance Plans (AHIP) expressed concern over the relatively short amount of time the rule gave plans to implement the required technology changes.

To view the White House memo announcing the regulatory freeze, CLICK HERE.

To view the final prior authorization rule, CLICK HERE.

Outgoing Trump Administration Finalizes 2022 Medicare Advantage/Part D Rule

On January 15, the outgoing Trump Administration finalized a last-minute rule meant to cut costs and improve transparency in Medicare Advantage and Part D. Under the rule, starting January 1, 2023, Medicare Part D plans would have to offer a real-time benefit comparison tool that enables beneficiaries to compare out-of-pocket costs and obtain information about lower-cost alternatives covered under their plan. Starting in 2022, Part D and Medicare Advantage plans would also be authorized to create additional "preferred" specialty tiers for certain drugs in order to give plans more leverage in price negotiations. Further, plans would be required to disclose to Medicare the pharmacy-performance measures used to recoup money from pharmacies in order to better inform future regulatory action.

The Centers for Medicare & Medicaid Services (CMS) estimates the new rule would save the federal government $75.4 million over ten years. The agency also released a new estimate showing that Medicare Advantage plans would get over 4% more in 2022 than they receive this year – an

increase of more than 1.25% compared to the rate in the advanced notice CMS released in October 2020.

Like other rules announced in the final days of the Trump Administration, the MA/Part D rule could be subject to the Biden Administration's 60-day regulatory freeze. A memo issued on January 20 by White House Chief of Staff Ron Klain gave acting agency heads the discretion to postpone and/or open a 30-day comment period for any final rule published in the Federal Register that has not yet taken effect.

To view the announcement of the new rule, CLICK HERE.

To view the rule as published in the Federal Register, CLICK HERE.

Pharmacy Benefit Manager Groups Sue HHS Over Drug Rebate Rule

On January 12, the Pharmaceutical Care Management Association (PCMA), an organization that represents pharmacy benefit managers (PBMs), initiated a lawsuit against the outgoing Trump Administration over a new rule that would end Medicare drug rebates that PBMs often negotiate with pharmaceutical manufacturers. Known as the "rebate rule," if it goes into effect as scheduled in 2022, it would end current safe harbor protections for rebates, replacing them with new safe harbors encouraging health plan sponsors, pharmacies, and PBMs to extend prescription discounts to patients at the pharmacy counter (point-of-sale).

Under the lawsuit, PBMs argue HHS does not have the authority to issue the rebate rule since the federal government is statutorily prohibited from instituting price structures for drug reimbursement under the Medicare Part D program, as well as from interfering in drug pricing negotiations between pharmaceutical companies and payers. Since the new regulation was announced so quickly, PBMs argue they do not have sufficient time to account for the new policy in their bids for next year.

Like most of the midnight rules issued at the end of the Trump Administration, the future of the rebate rule is uncertain. Under the regulatory freeze issued on January 20, the Biden Administration now has the opportunity to revisit the regulation, which may include postponing implementation, modifying the proposal, or withdrawing the rule altogether.

To read the PCMA's complaint, CLICK HERE.

Federal Trade Commission Looks into Hospital Acquisitions of Physician Practices

As part of an agency effort to understand the impact of mergers on healthcare delivery, the Federal Trade Commission sent orders to six health insurance companies to obtain patient level claims data concerning inpatient, outpatient, and physician service from 2015 to 2020.

UnitedHealthcare, Anthem, Aetna, Cigna, Florida Blue, and Health Care Service Corporation were among the companies that received orders. The FTC hopes to use the data to determine how

hospital acquisition of physician practices has affected competition, and better equip the agency to legally challenge mergers in the future. The data requested by the FTC includes the total billed charges of all health providers, total deductibles copays, and coinsurance paid by the patient. It also asked for data tied to each inpatient admission and outpatient and physician episode during the 5-year period in question.

The data request was cheered on by health economists who recognized the information will provide insight into how mergers affect labor markets. Emily Gee, a health economist at the Center for American Progress, tweeted that the request was an “Important step to advance FTC’s understanding of the market and could improve their ability to win cases.”

Though the FTC’s decision to analyze the impact of physician buy-ups will provide the agency with valuable data, it will still have to overcome states’ willingness to approve certificates of public advantage (COPA) that shield mergers from federal antitrust regulators in exchange for prolonged state oversight.

To read the FTC press release, CLICK HERE.

Drug Manufacturers Continue 340B Pharmacy Restrictions After HHS Non-Binding Opinion as Additional Companies Join Legal Challenge

On January 12, Eli Lilly, Sanofi and AstraZeneca all initiated separate lawsuits against the Department of Health and Human Services over an internal advisory opinion, which requires pharmaceutical companies to give 340B discounts to providers in the program via contract pharmacies. The next day, an administrative dispute request was lodged.

Though the December 30 advisory opinion does not carry the force of law and is not a final agency action, it would require drug companies to give contract pharmacies the same discounts they provide to health institutions under the 340B drug pricing program. The three drug makers launched legal challenges because they believe nothing in federal law statutorily requires manufacturers to utilize contract pharmacies or respect an unlimited number of covered entity- contract pharmacy relationships. In addition, the companies fear HHS will cite the advisory opinion as binding in administrative dispute request hearings, though it is not a final regulation.

The lawsuits represent the latest challenge to the 340B program, as pharmaceutical manufacturers have significantly reduced the number of contract pharmacies they provided discounted drugs to in 2020. While Eli Lilly, Sanofi and AstraZeneca argue the advisory opinion could cause companies to give multiple discounts for the same drug, health centers say removing contract pharmacies from the 340B discount list would be devastating for low-income patients.

To read the HHS advisory opinion announced on December 30, CLICK HERE.