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Health Policy Update – February 23, 2021

Becerra Faces Confirmation Hearings, President Biden Nominates Chiquita Brooks-LaSure to lead CMS, Elizabeth Fowler for CMMI

This week, two Senate committees will hold hearings on President Biden's nominee for Secretary of the Department of Health and Human Services, Xavier Becerra. The hearings, which will be held by Senate Health, Education, Labor, & Pensions (HELP) and Finance Committees, respectively, are expected to focus on the federal COVID-19 response, the future of the Affordable Care Act, and Becerra's record as California Attorney General, including his decision to sue the state's largest hospital system for alleged anti-competitive practices. If confirmed, Becerra will be the first Latino to lead HHS.

Last week, President Biden also announced plans to nominate Chiquita Brooks-LaSure to serve as the next Centers for Medicare & Medicaid Services' (CMS) Administrator. Brooks-LaSure is currently a managing director at the healthcare consulting firm Manatt Health and previously served as deputy director of the Center for Consumer Information and Insurance Oversight (CCIIO) at CMS. As a former staffer on the House Ways and Means Committee, she helped draft the Affordable Care Act when Becerra was a lawmaker on the committee. The CMS Administrator position is subject to Senate confirmation.

President Biden also nominated Elizabeth Fowler to lead the Center for Medicare and Medicaid Innovation (CMMI), the agency tasked with developing and testing innovative healthcare payment and delivery models. Fowler is currently an executive vice president at the Commonwealth Fund, a nonprofit foundation focused on healthcare policy. Previously, she held a variety of roles in the public and private sectors as Vice President for Global Health Policy at Johnson & Johnson, as a special assistant to the National Economic Council and several other positions at HHS, and as chief counsel for the Senate Finance Committee. This position does not require Senate confirmation.

Another key nominee for the new administration is Neera Tanden, who President Biden selected to serve as Director of the White House Office of Management and Budget (OMB). The OMB plays a crucial role in developing the administration's policy priorities and overseeing the regulatory process. This position requires Senate confirmation, and late last week, Democratic Senator Joe Manchin (D-WV) announced he would vote against Tanden's confirmation, followed by Republican Senators Susan Collins (R-ME) and Mitt Romney (R-UT). With the 50-50 split in the US Senate, these announcements cast doubt on whether Tanden will be confirmed to the OMB post.

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.

Hospital Groups Appeal 340B, Site Neutral Payment Rulings to the Supreme Court

On February 10, a group of hospital stakeholders officially petitioned the US Supreme Court to appeal lawsuits against Medicare Part B reimbursement cuts for 340B-acuired drugs, and separately, for site-neutral payment reductions to certain hospital outpatient departments (HOPDs) finalized under the Trump Administration.

The petitions – led by the American Hospital Association and supported by dozens of other hospital stakeholders – seek to reverse appeals court decisions on the two policies rendered last summer. Both petitions challenge HHS's authority to establish the payment policies under the *Chevron* deference doctrine, which generally gives federal agencies significant latitude in implementing ambiguous laws.

The Supreme Court has not signaled whether or not it will accept the hospital groups' petitions to hear the cases. If it declines, the 340B and site-neutral payment policies will remain in effect, unless or until the Biden Administration proposes changes.

Separately, a federal court in California dismissed a lawsuit brought by the AHA and several other hospital groups that sought to force the Health Resources and Services Administration (HRSA) to take action to stop drug manufacturers from limiting 340B discounts available via contract pharmacies. Over the past few months, drug manufacturers have taken steps to limit 340B discounts at certain contract pharmacies in response to concerns that hospitals were abusing the process and potentially receiving duplicate discounts.

In dismissing the suit, the presiding judge said the hospitals should take their concerns through HRSA's administrative dispute resolution (ADR) process before going to court. The rule establishing the 340B ADR process was finalized by the Trump Administration late last year.

To read the 340B-related petition to the Supreme Court, CLICK HERE.

To read the site-neutral payment petition to the Supreme Court, CLICK HERE.

House Lawmakers Continue Work on COVID-19 Relief Bill

Last week, several House committees, including the Ways & Means (W&M) Committee held a mark-up of provisions comprising roughly half of the $1.9 trillion COVID-19 relief package, referred to by the White House as the American Rescue Plan. The committee reviewed proposals ranging from unemployment insurance extensions, additional stimulus checks to individuals, and provisions to expand insurance coverage under the Affordable Care Act (ACA). Some of the proposals would reduce healthcare premiums for low and middle-income families by increasing the ACA premium tax credits for 2021 and 2022, extend employer-based health coverage by subsidizing COBRA costs through the end of the fiscal year, and create subsidies for unemployed workers who are ineligible for COBRA, among other changes.

The House Energy & Commerce Committee also held a mark-up of the COVID-19 relief package, eyeing significant expansions of state Medicaid programs. To help pay for these expansions, the committee included a Medicaid drug pricing policy to eliminate the so-called "Medicaid rebate cap" starting in 2023. Under federal law, pharmaceutical manufacturers agree to extend Medicaid rebates in exchange for coverage of nearly all FDA-approved drugs. These rebates are currently capped at 100% of the drug product's Average Manufacturer Price (AMP). Proponents of eliminating or raising the cap believe it would put downward pressure on drug list prices, while manufacturers argue the policy could force them to provide drugs to Medicaid at a loss. According to the Congressional Budget Office, the Medicaid proposal would save the federal government nearly $16 billion over 10 years. In its June 2019 report, MACPAC supported the elimination of the cap.

Committee mark-ups of the COVID-19 relief bill are just one of the initial steps toward passage under the complex budget reconciliation procedures being utilized for the measure. Now that the House Budget Committee has compiled and reported the consolidated bill, it will head to the House floor for full consideration. After House passage, the bill will head to the Senate where it will face increased scrutiny under the budget reconciliation process, which only requires a simple majority vote to pass (51 votes rather than the traditional 60). Democratic leaders have signaled their intention to pass the bill and have it signed into law by mid-March – aligning with the expiration of increased unemployment benefits.

The view the W&M Committee mark-up statement, CLICK HERE.

To view the E&C Committee mark-up statement, CLICK HERE.

To view the CBO score of the Medicaid proposal, CLICK HERE.

To view the MACPAC report, CLICK HERE.

Hospitals Push Back on Insurer White & Brown Bagging Practices

Hospital industry stakeholders are stepping up their opposition to insurer cost-control practices that they claim restrict patient access to care and can lead to negative health outcomes. In a letter to CMS, the American Hospital Association (AHA) urged the agency to take action against insurers who use these practices – namely UnitedHealthcare.
So-called "white bagging" policies mandate that providers obtain outpatient drugs from specialty pharmacies preferred by the insurer in order to get reimbursed. UnitedHealthcare implemented a white bagging policy for certain drugs beginning in April 2020, reportedly directing providers to use its own vertically integrated pharmacies. Similarly, hospitals are also concerned with "brown bagging" requirements, in which the insurer's preferred specialty pharmacies dispense drugs directly to patients, often through the mail. Patients are then responsible for bringing the drug to the provider's office for administration.

Providers, including The Network, have raised serious concerns with both white and brown bagging mandates and the patient safety issues they present. In addition to exposing patients to unnecessary safety risks, white/brown bagging polices can also lead to preventable care delivery

delays and create financial challenges for many independent practices, ultimately forcing patients to receive care in more expensive settings rather than at their community-based clinic.

In a series of recommendations accompanying the organization's letter, the AHA urged CMS to ban the practice of brown bagging entirely and set specific criteria for when white bagging applies.

To view the AHA letter, CLICK HERE.

Analysis: One-Third of Hospitals Not Complying with Price Transparency Rule

A new analysis by consulting firm Guidehouse reports that approximately 30 percent of hospitals are not complying with a new Centers for Medicare & Medicare Services (CMS) rule requiring hospitals to make payer-negotiated rates publicly available.

The new rule, which took effect January 1, requires hospitals to post prices in one of two ways:

- A machine-readable file containing all standard charges for the facility's items and services
- A consumer-friendly file that lists 300 shoppable services

The analysis found that more hospitals are opting to comply with the consumer-friendly shoppable services file option. For hospitals using the machine-readable file approach, there appears to be a general lack of consistency in format and content, which makes the available data difficult to understand and digest, signaling a need for improved guidance as more hospital systems work to comply with the rule. The analysis also concluded that larger health systems are complying more readily with the rule than smaller hospital systems.

For their analysis, Guidehouse surveyed more than 1,000 hospital providers in 27 states.

To view the Guidehouse analysis, CLICK HERE.

To read the price transparency rule, CLICK HERE.

Biden Administration Changes DOJ's Position in Pending Supreme Court ACA Case

On February 10, the Department of Justice submitted a letter to the Supreme Court stating that, following the change in administration, the Department is no longer aligned with the conclusions of a brief filed by the previous administration in support of the plaintiffs in the case challenging the constitutionality of the Affordable Care Act. As oral arguments have already been heard, the move was primarily a symbolic one, and will not affect the course of the litigation.

The question of severability was at the heart of *California v. Texas*, which was brought by a group of Republican state attorneys general. The plaintiffs argued that the entire ACA must be invalidated following Congress' decision in 2017 to reduce the penalty for not complying with the law's

individual insurance mandate to zero. The Trump Administration endorsed this viewpoint last year when it filed a brief in support of the plaintiffs. The ACA's defenders include a group of Democratic attorneys general led by Xavier Becerra of California, who is now President Biden's nominee for HHS Secretary, as well as the Democratic-controlled House of Representatives.

Though oral arguments were heard in November of last year, the Supreme Court has yet to release a decision in the case. Some legal experts have speculated that the Supreme Court is likely to strike down the individual mandate but will not invalidate the rest of the ACA.

To read the Biden Administration's letter notifying the change in position CLICK HERE.