Health Policy Update – September 22, 2020

White House Unveils Most Favored Nation Drug Pricing Executive Order, Expands Scope to Include Part D Drugs

On September 13, the President signed a new Executive Order (EO) expanding the Administration's most favored nation (MFN) drug pricing proposal to include Medicare Part D drugs in addition to Part B. The EO, titled "Executive Order on Lowering Drug Prices by Putting America First," replaces a July 24 order by the same name that was never publicly released. It directs the Department of Health and Human Services (HHS) to test payment models using MFN prices. The proposal lacks detail and is subject to interpretation and implementation by HHS. It is not yet clear if the administration can implement the EO prior to the November elections.

The order states that under the payment model, Medicare should pay no more than the MFN price, defined as "the lowest price, after adjusting for volume and differences in national gross domestic product, that the drug manufacturer sells in a member country of the Organization for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product."

The EO was met with significant opposition from the pharmaceutical industry and other stakeholders throughout the drug supply chain. The Pharmaceutical Manufacturers and Researchers of America (PhRMA) issued a statement calling it "an irresponsible and unworkable policy that will give foreign governments a say in how America provides access to treatments and cures for seniors and people struggling with devastating diseases."

The Part B Access for Seniors and Physicians Coalition issued a statement calling on the Administration to "abandon the most favored nation policy and focus on patient-centered reforms so we can protect provider-patient relationships and the high-quality care they foster."

To view the Executive Order, CLICK HERE.

To view the PhRMA statement, CLICK HERE.

To view the Part B Access Coalition Statement, CLICK HERE.

Partisan Divide Casts Bleak Outlook on Coronavirus Relief Deal Before November Elections

President Trump and a growing number of congressional lawmakers have urged compromise on another round of COVID-19 relief ahead of the November elections. But calls for action have done little to move the needle. Concerns remain over the scope, cost, and necessity of additional

legislation. Further, the untimely death of Justice Ruth Bader Ginsburg and the creation of a new Supreme Court vacancy only adds complexity to the fraught legislative negotiations.

On September 16, the bipartisan Problem Solvers Caucus, a group of several dozen moderate Democratic and Republican members of the House, unveiled a $1.5 trillion economic relief proposal in an effort to break a months-long deadlock over the next round of relief for individuals and businesses impacted by the COVID-19 pandemic. The proposal was met with cautious optimism by President Trump, though its prospects for action largely fizzled by the end of the week.

The bipartisan Problem Solvers Caucus proposal includes another round of $1,200 direct relief payments; an extension of unemployment assistance; funding for COVID-19 testing, state and local governments, schools and childcare centers, and the US Postal Service; and liability protections for businesses, among other provisions.

Throughout the summer, Congressional Republicans have been wary of what they consider to be too much federal spending. While the Democratic-led House passed a $3 trillion package in May, the Republican-led Senate floated an alternative $1 trillion proposal that was met with resistance by House and Senate Democrats. In early September, the Senate held a procedural vote on a pared down, “skinny” version of the GOP proposal. It did not garner sufficient votes to initiate formal debate in the chamber.

To view the Problem Solver’s Caucus relief proposal, CLICK HERE.

Taskforce on Telehealth Policy (TTP) Releases Recommendations

On September 15, the Taskforce on Telehealth Policy (TTP) released final findings and recommendations on the use of telehealth in response to the COVID-19 public health emergency. The TTP conducted its work in three distinct subgroups. Each subgroups’ findings are summarized as follows:

- Patient Safety: The use of telehealth has proven to prevent care delays, reduce exposure to pathogens, and minimize travel needed for in-person care. The TPP recommends research on telehealth best practices for patient safety.
- Program Integrity: Emerging artificial intelligence offers tools to audit claims and other data to deter fraud and detect aberrant behaviors. Integrating new program integrity tools into enforcement processes and mechanisms may help reduce telehealth risks.
- Quality: Telehealth should be held to the same standards and quality measures as in-person care wherever possible and appropriate. In cases where the unique characteristics of telehealth dictate a change in a given measure, it should be adapted without altering standards and expected outcomes for services provided via telehealth.

The TTP also recommended policymakers take steps to permanently adopt COVID-19 policy changes, including:

- Lifting geographic restrictions and limitations on originating sites.
- Allowing telehealth for various types of clinicians and conditions.
- Acknowledging, as many states now do, that telehealth visits can meet requirements for establishing a clinician/patient relationship if the encounter meets appropriate care standards

or unless careful analysis demonstrates that, in specific situations, a previous in-person relationship is necessary.
- Eliminating unnecessary restrictions on telehealth across state lines.

The TTP was formed to assess impacts under the flexibilities granted by Congress and CMS during the public health emergency and to build a consensus among diverse stakeholders on recommendations that will help realize telehealth's potential to drive well-coordinated, patient-centered, and value-optimized care. The TPP recommendations were informed by more than 300 written comments and a virtual townhall attended by nearly 1,000 stakeholders.

To read the TTP findings and recommendations, CLICK HERE.

To learn more about the TTP, CLICK HERE.

340B Providers Plan Their Next Move As Congress Weighs In

In the latest developments of the ongoing 340B drug pricing dispute, community health centers have announced that they are preparing to take legal action to prevent pharmaceutical manufacturers from limiting 340B discounts to contract pharmacies. In addition, more than 1,100 hospitals submitted a letter to HHS Secretary Alex Azar arguing that the "collective actions to deny access to 340B pricing are clear violations of the 340B statute that will set a dangerous precedent."

The National Association of Community Health Centers and 340B Health are both considering lawsuits in order to compel the Health Resources and Services Administration (HRSA) to wield its regulatory authority to stop drug manufacturers from denying access to 340B pricing. In response, HRSA said it was considering potential sanctions including civil monetary penalties if the drug companies' actions are found to run afoul of federal health law.

On September 14, a bipartisan group of lawmakers sent a letter to HHS Secretary Alex Azar urging him to take immediate action to ensure covered entities continue to receive drug discounts through the 340B program. The letter was signed by more than half of members in the House of Representatives and was led by Representatives David McKinley (R-WV), Greg Gianforte (R-MT), Dusty Johnson (R-SD), Diana DeGette (D-CO), Peter Welch (D-VT), and Doris Matsui (D-CA). The lawmakers express strong support for the 340B program and declared that the recent actions taken by pharmaceutical companies are in "in violation of the statutory requirement that drug companies charge no more than the 340B ceiling price when selling their products to 340B providers."

This was followed the next day by a letter to PhRMA signed by 22 Senate Democrats asking the organization what "steps were being taken by the industry to end denials of 340B pricing for drugs dispensed through contract pharmacies and demands for contract pharmacy claims data no later than September 29, 2020."

Related, the American Hospital Association released a study earlier this month suggesting that

safety net hospitals who participate in the 340B drug discount program generated $64.3 billion in total benefits to community programs and services tailored to help low-income patient populations in 2017, the last year for which data is available. This represents an increase of roughly $8 billion from the year before.

To read the hospital letter to Secretary Azar, CLICK HERE.

To read the House of Representatives letter to Secretary Azar, CLICK HERE.

To read the Senate Democrats' letter to PhRMA leadership, CLICK HERE.

To read the new analysis from the American Hospital Association, CLICK HERE and HERE.

CMS Releases New Value Based Care Guidance for Medicaid

On September 15, the Centers for Medicare & Medicaid Services (CMS) announced new guidance to state Medicaid directors regarding how to advance value-based care (VBC) across their healthcare systems, including Medicaid programs. The guidance includes an assessment of key lessons learned from working to implement early VBC reforms at the state and federal level, as well as a toolkit to help state leaders adopt payment reforms within their Medicaid programs. If successful, CMS believes that VBC policies will help lower costs and improve the quality of care for the country's nearly 74 million Medicaid beneficiaries. Ultimately, CMS hopes that VBC will improve the sustainability of the Medicaid program.

In sending the letter to state Medicaid directors, CMS outlined a series of non-mutually exclusive models that states can potentially adopt to align payer and provider incentives as they work to implement value-based payments. The models outlined by CMS include elements of the current fee-for-service architecture, payments for episodes of care, and total cost of care accountability. While CMS encourages states to adopt VBC reforms, it does not require states to adhere to any specific approach or payment methodology.

To read CMS' press release about the guidance, CLICK HERE.

Study Shows Substantial Increase in Healthcare Provider Consolidation

In its latest issue, the journal *Health Affairs* published a new study on the rapid consolidation of healthcare providers between 2016 and 2018. The study, co-authored by researchers at the Agency for Healthcare Research and Quality (AHRQ) and the think tank Mathematica, examined consolidation into vertically integrated health systems in recent years. As of 2018, more than 50% of all US physicians and nearly three-quarters (72%) of hospitals were affiliated with one of 637 health systems.

The number of health systems across the country increased from between 2016 and 2018, driven by mergers and acquisitions. Health systems grew in size too, with the median number of

physicians increasing from 285 to 369, a nearly 30% rise. While all categories of providers became more consolidated during the timeframe in question, the percentage of physicians (51%) and primary care physicians (49%) working in vertically integrated health systems increased the most. Meanwhile, the shares of hospitals and hospital beds in systems increased slightly in 2018, to 72% and 91%, respectively.

While the study does not examine the drivers of consolidation and the variation across ownership and geographic types, it paints a vivid picture of the growing market concentration and provider integration in the US healthcare system.

To read the full study, CLICK HERE.

Public Health Agencies Face Allegations of Political Interference

Over the past several weeks the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) faced mounting allegations that political appointees interfered with the work of career civil servants regarding the government's response to the COVID-19 pandemic.

Multiple reports surfaced that HHS Assistant Secretary for Public Affairs Michael Caputo repeatedly tried to edit the CDC's Morbidity and Mortality Weekly Reports -which are traditionally shielded from political appointees - in order to portray the Administration's pandemic response in a more positive light. Caputo, along with Dr. Paul Alexander, an assistant professor of health research at McMaster University in Canada who Caputo brought to the agency as a scientific advisor, reportedly worked to downplay the CDC's findings regarding the risks of contracting COVID-19 in order to align the reports with statements made by the President regarding the state of the pandemic. Caputo announced on September 16 that he would be taking a temporary, medical leave of absence from his post.

In response, Senate Minority Leader Chuck Schumer (D-NY) called on HHS Secretary Azar to resign, citing Azar's silence regarding the attempts to manipulate the CDC's reports as proof that he has lost control of the agency.

Azar has also come under fire following reports that he pressured officials at the FDA to loosen its oversight of lab-developed COVID-19 tests. In late August, Azar allegedly overrode FDA Commissioner Stephan Hahn and revoked the agency's ability to regulate the tests, a policy long sought by test manufacturers, but which attracted criticism from public health experts who are concerned the market could be flooded by potentially unsafe and inaccurate tests.

To view media reports about political interference at the CDC, CLICK HERE and HERE.

To read more about HHS interference in the FDA's oversight of lab-developed tests, CLICK HERE.