Health Policy Update – August 25, 2020

Biden Chooses Kamala Harris as Vice Presidential Running Mate

On August 11, former U.S. Vice President and 2020 Democratic party presidential nominee Joe Biden named Senator Kamala Harris (D-CA) as his running mate. Senator Harris, who had also sought the presidency in the 2020 Democratic primaries has several established positions on healthcare policy.
Senator Harris is among the 14 Democratic senators who co-sponsored the Medicare for All Act of 2019 (S. 1129/H.R. 1384), which would expand the federally administered Medicare program to cover nearly all Americans over a four-year period. However, as a presidential candidate she backed away from that position and instead released her own plan for universal healthcare that would be phased in over 10 years. While described as a variation of Medicare for All, Senator Harris' plan would continue to rely on private health insurance companies competing within a government framework, similar to the current Medicare Advantage program.

Harris is in favor of enabling Medicare to negotiate prices with drug manufacturers using the prices of other developed countries as a basis for negotiations. She has also expressed openness to removing barriers for undocumented immigrants to receive healthcare coverage and has sponsored legislation to address maternal mortality issues which disproportionately affect Black women.

Last week, both former Vice President Biden and Senator Harris formally accepted their party's nominations for President and Vice President of the United States, respectively. President Donald Trump will formally accept the Republican nomination for the 2020 presidential election Thursday, the last day of the Republican National Convention. The general election will take place on November 3, 2020.

No Agreement in Sight on Next Phase of COVID-19 Relief

As of this week, Congress is no closer to reaching an agreement on a package to help individuals, businesses, and state and local governments weather the effects of the COVID-19 pandemic than it was two weeks ago. Talks between both parties broke down shortly before the House and Senate left Washington for their August state and district work periods as President Trump signed a series of executive orders intended to mitigate damage from expiring provisions of the CARES Act passed in March 2020.

Meanwhile, the House of Representatives convened a rare weekend session between the party's conventions to consider legislation that would allocate additional funding to the U.S. Postal Service (USPS). Newly appointed Postmaster General Louis DeJoy announced a series of operational changes within the USPS earlier this summer in an effort to improve the service's financial position. A number of these changes were met with opposition, exacerbating concerns that the changes were

intended to disrupt the 2020 general election as millions of Americans are expected to cast ballots by mail due to COVID-19. With this increased pressure on the USPS, there have been bipartisan calls for additional funding and a reversal of previously enacted operational changes. The bill passed by the House would revert USPS policy back to policies in effect on January 1, 2020 and would appropriate an additional $25 billion to the service.

One emerging complaint of the USPS is the slower delivery of packages, including mail-order prescriptions that have risen due to COVID-19. Pharmacy groups have argued delays in the delivery of prescriptions can pose adherence challenges for patients. In response to these concerns, House Energy and Commerce Committee Democrats announced an investigation into the USPS changes on the delivery of prescription drugs. Last week Postmaster General DeJoy announced the USPS would suspend certain operational changes until after the general election.

On a related note, Senate Republicans also began circulating a “skinny” relief package last week as another starting point for COVID-19 and USPS negotiations. The plan, which has not been formally released, includes many provisions of the party’s HEALS Act with some new funding available for the USPS.

To read the text of the House USPS legislation, CLICK HERE.

To read more about the Senate Republicans’ “skinny” relief bill, CLICK HERE.

Federal Appeals Court Overturns North Dakota Law Regulating PBMs

On August 7, the United States Court of Appeals for the Eighth Circuit overturned a North Dakota state law that limited the fees pharmacy benefit managers (PBMs) can charge pharmacies, arguing that it is preempted by the Employee Retirement Income Security Act (ERISA).

Enacted in 2017, the North Dakota law permitted the state regulation of drug copayments, including the metrics PBMs use to evaluate pharmacy performance. By extension, the law set limits on pharmacy fees, known as direct and indirect remuneration (DIR), which PBMs charge pharmacies after the point of sale. The Pharmaceutical Care Management Association (PCMA), the national trade group that represents PBMs, filed suit (*PCMA v. Mylynn Tufte*) and sought an injunction to prevent the law from taking effect. That motion was originally denied by a District Court but was later vacated by the Eighth Circuit.

PBM industry advocates have argued that the North Dakota law would increase drug costs and risk patient safety by restricting PBMs’ ability to encourage pharmacies to perform at high standards. In contrast, pharmacies say that PBMs often penalize them using metrics that are beyond their control.

This is one of several state lawsuits working through the court system regarding state authority to regulate PBMs. Another case from Arkansas, *PCMA v. Rutledge,* was scheduled for oral arguments before the U.S. Supreme Court in April but has subsequently been rescheduled for October due to COVID-19.

To view the ruling in *PCMA v. Mylynn Tufte,* CLICK HERE.

To view the Supreme Court docket files in *PCMA v. Rutledge*, CLICK HERE.

Drug Companies Seek Information on 340B Provider Discounts

Earlier this summer, several large drug manufacturers began questioning 340B drug discounts provided through contract pharmacies - testing the limits of the Health Resources and Services Administration's (HRSA) regulatory guidance that allows 340B providers to qualify for program discounts fulfilled by contract pharmacies.

AstraZeneca and Eli Lilly have both recently put restrictions on how 340B providers can contract with pharmacies and are now only allowing contract pharmacies to obtain program discounts if the 340B covered entity does not have its own in-house pharmacy. The companies cite the growth of the 340B contract pharmacy program – which can result in duplicate discounts – as the chief motivation for these changes and argue that the use of contract pharmacies is not included in the statues governing the program.

Other drug manufacturers including Merck, Sanofi and Novartis have begun asking providers for detailed claims data about Medicaid, commercial, and Medicare Part D rebates and have threatened to restrict discount availability through contract pharmacies if the providers don't comply.

The restrictions and data requests have predictably drawn significant pushback from the 340B provider community, who claim that manufacturer efforts will undermine provider participation in the program, hurting their ability to provide care to underserved patient populations. Further, the drug manufacturers request for claims data raises additional questions about patient privacy and the exchange of confidential and proprietary information with unauthorized parties.

While HRSA has urged manufacturers to continue providing 340B discounts through contract pharmacies, the agency has also been vocal about its limited statutory authority to regulate and enforce program participation.

House Lawmakers Urge Leadership to Stop CMS' Scheduled Reimbursement Cuts to Specialists

On August 11, a group of 93 bipartisan lawmakers in the U.S. House of Representatives sent a letter to Speaker Nancy Pelosi (D-CA) and Minority Leader Kevin McCarthy (R-CA) urging leadership to pass legislation to stop significant reimbursement cuts scheduled to take effect in 2021. The cuts were finalized in the 2020 Physician Fee Schedule final rule issued in November 2019, before the emergence of the ongoing COVID-19 pandemic. If the policy is implemented as finalized on January 1, 2021, some specialties could see cuts as high as 11 percent.

Under current law, any reimbursement adjustments in excess of $20 million must be applied in a budget neutral manner. While primary care and some specialties are estimated to see significant reimbursement increases under the shift in E/M payment, specialties with less reliance on E/M are projected to see payment cuts. For this reason, many members of Congress are urging a waiver to the budget neutrality rules.

“It has come to our attention that many specialists are being targeted for ill-conceived and sizeable cuts that simply no longer make sense to implement,” the bipartisan lawmakers wrote in the letter, which was spearheaded by Rep. Bobby Rush (D-IL). “Our healthcare system is already under tremendous financial strain, as it continues to grapple with both the economic and health consequences of the coronavirus. Now is not the time to implement these reckless cuts.”

To read the letter to House Leadership, CLICK HERE.

CMS Announces New Alternative Payment Model for Rural Health

On August 11, the Centers for Medicare and Medicaid Innovation (CMMI) unveiled a new alternative payment model (APM) for rural healthcare providers called the Community Health Access and Rural Transformation (CHART) model. Following President Donald Trump’s early August executive order for federal agencies to improve rural health access, the new CHART demonstration program is designed to transform how care is delivered in rural America by providing Medicare payments up front, operational and regulatory relief, and technical and educational support. Ultimately, CMMI hopes that the new APM will increase rural providers' financial stability, ease administrative burdens on providers, and improve beneficiaries' access to healthcare in these traditionally underserved areas.

The CHART demonstration will give providers two options to participate: a community transformation track and an accountable care organization track. Under the former, up to 15 rural communities will receive as much as $2 million in initial funding to reform care delivery and make capitated payments to providers. It will offer regulatory flexibilities such as allowing rural outpatient departments to be paid at the same rates as hospitals and make it easier for rural providers to expand telehealth services.

Meanwhile, the affordable care organization track will allow 20 rural focused ACOs to receive advanced payments as part of joining the Medicare Shared Savings Program (Shared Savings Program) in order to encourage more participation in value-based payment approaches.

To read more about the details of the CHART demonstration, CLICK HERE.

To read the President’s executive order on rural healthcare, CLICK HERE.