Wednesday, January 13, 2021

HHS Won't Appeal Rulings in Most Favored Nation Lawsuits

On December 28, a federal judge in California granted a motion for a preliminary injunction blocking the Centers for Medicare and Medicaid Services (CMS) from moving forward with the Most Favored Nation (MFN) Model until it completes the requisite rulemaking process. On January 8, 2021, the Department of Health and Human Services (HHS) notified the D.C. District Court that it will not appeal the preliminary injunction issued in this case. **Read below.**

Outcome of Georgia Run-offs Flips Senate to Democratic Control, Changing Healthcare Prospects

Democratic candidates Raphael Warnock and Jon Ossoff defeated Georgia's incumbent Republican Senators Kelly Loeffler and David Perdue in two run-off elections for United States Senate held January 5. **Read below.**

HHS Secretary Alex Azar Renews COVID-19 Public Health Emergency

On January 7, HHS Secretary Alex Azar extended the COVID-19 public health emergency (PHE) that had been scheduled to expire January 21. The PHE will be renewed for 90 days unless the secretary declares the emergency to be ended before then. **Read below.**

Hospital Price Transparency Rule Goes into Effect

On January 1, a new federal rule went into effect that mandates hospitals publicly post the prices for every service, drug and supply they provide onto their websites. **Read below.**

HHS Sides with 340B Providers in Contract Pharmacy Dispute

On December 30, the Office of General Counsel at the Department of Health and Human Services issued an advisory opinion that stated pharmaceutical companies are required to offer 340B discounts to providers via contract pharmacies. **Read below.**

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HHS Won't Appeal Rulings in Most Favored Nation Lawsuits

On December 28, a federal judge in California granted a motion for a preliminary injunction in the case *California Life Sciences Association, et al. v. Center for Medicare and Medicaid Services, et al.,* blocking the Centers for Medicare and Medicaid Services (CMS) from moving forward with the Most Favored Nation (MFN) Model until it completes the requisite rulemaking process. This ruling followed a separate, 14-day temporary restraining order issued by a federal judge in Maryland on December 23, 2020, which prohibited CMS from implementing the Medicare Part B payment model on January 1, 2021.

On January 8, 2021, the Department of Health and Human Services (HHS) notified the D.C. District Court that it will not appeal the preliminary injunction issued in *California Life Sciences Association, et al v. CMS, et al.* The notification was included in HHS' Status Report filed regarding the *Community Oncology Alliance, Inc. v. HHS* case.

While the Biden Administration could move forward with the rulemaking process for the MFN Model, it is also possible that it will pursue its own drug pricing initiatives. President-elect Joe Biden said on the campaign trail that he would address the rising costs of prescription drugs, but the Biden transition team has not weighed in publicly on the MFN Model.

Outcome of Georgia Run-offs Flips Senate to Democratic Control, Changing Healthcare Prospects

Democratic candidates Raphael Warnock and Jon Ossoff defeated Georgia's incumbent Republican Senators Kelly Loeffler and David Perdue in two run-off elections for United States Senate held January 5. The balance of power in the Senate, which now stands at 50-50, is expected to flip to the Democrats after President-elect Biden is inaugurated and Vice President-elect Kamala Harris is able to cast the tie-breaking vote for control of the upper chamber.

With Democrat control of the chamber, Senator Patty Murray (D-WA) will assume leadership of the Senate Health, Education, Labor and Pensions Committee and Senator Ron Wyden (D-OR) will become chairman of the Senate Finance Committee.
Narrow control of the Senate creates new prospects for the Democratic Party's healthcare policy agenda. While more ambitious proposals would likely not be able to secure the support of moderates, the Senate could still prioritize legislation to:

- Nullify the pending GOP lawsuit against the Affordable Care Act
- Shore up the ACA, including making premiums more affordable and creating enrollment flexibilities
- Incentivize states to expand Medicaid
- Reduce drug prices
- Provide additional coronavirus relief
- Address social determinants of health

The Senate may revisit the bipartisan drug pricing bill introduced last year by Sens. Chuck Grassley (R-IA) and Ron Wyden (D-OR) and passed out of the Senate Finance Committee. The bill would require drug manufacturers to pay rebates to Medicare if they increase the price of drugs more rapidly than the rate of inflation, redesign Medicare Part D, and cap patient out-of-pocket costs in Part D.

H.R. 3, which passed the House of Representatives last year and would require Medicare to negotiate drug prices and tax drug manufacturers who refuse to participate, is less likely to be supported by moderates; however, it could be used to offset the cost of other policy priorities as it is projected to save the Medicare system as much as $500 billion over the next decade.

Senator Joe Manchin (D-WV) has said he will oppose ending the filibuster, so most legislative proposals would still have to meet a 60-vote threshold. Democrats could use "budget reconciliation" to enact legislation with only 51 votes, but the process is complex and limited in scope.

A Democrat-controlled Senate also raises the prospect of Congress overriding regulations that were finalized by the Trump Administration at the end of last year. Under the Congressional Review Act, Congress can repeal regulations finalized within 60 legislative days of their enactment by a joint resolution that only requires a simple majority approval in both chambers.

Democrats will also hold a very slim majority in the House of Representatives (where they can only afford to lose four votes and still pass legislation), leaving little room for intraparty disputes and creating the potential for more bipartisan cooperation.

HHS Secretary Alex Azar Renews COVID-19 Public Health Emergency

On January 7, HHS Secretary Alex Azar extended the COVID-19 public health emergency (PHE) that had been scheduled to expire January 21. The PHE will be renewed for 90 days into April unless the secretary declares the emergency to be ended before then.

This action marks the fourth time HHS has extended the PHE since January 31, 2020. CMS has used this authority to issue a series of waivers creating flexibilities to address the COVID-19 pandemic.

Hospital Price Transparency Rule Goes into Effect

On January 1, a new federal rule went into effect that mandates hospitals to publicly post the prices for every service, drug and supply they provide onto their websites. By allowing consumers to estimate how much they may be charged for care and compare the costs across hospitals, the rule represents a step towards price transparency in the nation’s notoriously opaque healthcare system. In addition to potentially lowering overall healthcare costs, the new price transparency rule may be particularly beneficial for uninsured patients or those with high-deductible plans to help them make decisions about where, how, and what types of care they wish to receive.

Going beyond previous rules that required hospitals to publicly display “chargemasters,” or list prices that don’t accurately reflect what consumers and insurers pay, the new rule obligates hospitals to post estimates for every item and service they provide. The data they will now be required to provide include gross charges; the actual prices negotiated with payers, including de-identified minimum and maximum negotiated charges; and the cash price they offer patients who are uninsured or not using their insurance. Hospitals must now also post the costs for over 300 “shoppable” services including certain surgeries and imaging scans, to help consumers better understand how much they may be charged.

CMS is auditing a sample of hospitals to see if the facilities are in compliance. If the hospitals fail to post the required information, they could face a corrective action plan or a fine of $300 per day. The rule went into effect after several legal challenges by hospital groups, who argue that revealing the rates negotiated by payers could lead to higher prices for consumers. On December 29, the U.S.

Court of Appeals for the District of Columbia affirmed a lower-court decision that previously upheld the rule.

To read more about the rule, CLICK HERE.

To read the US. Court of Appeals' decision to allow the rule to move forward, CLICK HERE.

HHS Sides with 340B Providers in Contract Pharmacy Dispute

On December 30, the Office of General Counsel at the Department of Health and Human Services (HHS) issued an advisory opinion that stated pharmaceutical companies are required to offer 340B discounts to providers via contract pharmacies. Though the advisory does not have the force of law and is not a final agency action, the document outlines HHS' belief that the method that 340B providers utilize to dispense drugs does not impact the drug makers' obligation to provide discounts. Sanofi, AstraZeneca, and Novartis, however, have already said their policy will not change and they will continue to restrict 340B discounts through contract pharmacies.

The advisory opinion was issued against the backdrop of the ongoing legal battle between drug companies and 340B providers such as Ryan White Clinics, community health centers, hospitals, and pharmacists. The 340B providers have asked federal courts to require HHS to step in and stop the drugmakers' restrictions.

The Ryan White Clinics and community health centers had also argued that part of the problem was the long-overdue 340B administrative dispute resolution (ADR) guidance. The Health Resources and Services Administration (HRSA) unexpectedly issued a final rule implementing this process in December.

Pharmaceutical Researchers and Manufacturers of America (PhRMA) has said the 340B ADR rule is flawed and does not take into account the changing healthcare landscape since it was first proposed in 2016: "Over the last 4 years, evidence has shown there are serious problems in the 340B program, including violations of diversion of medicines and duplicate discounts by covered entities exploiting the lack of clear program guidance. The administration should not have finalized an ADR process without first finalizing a precise definition of 'patient' and implementing improved manufacturer audit procedures, two essential elements to a well-functioning ADR process. PhRMA has serious concerns with this failed regulation."