

## Health Policy Update – April 25, 2019

### Bipartisan Bill to Limit Step Therapy Introduced

On April 10, Representatives Raul Ruiz (D-CA) and Brad Wenstrup (R-OH) introduced a bipartisan bill to require employer-sponsored group health plans to place reasonable parameters around their use of step therapy.

The Safe Step Act (H.R. 2279) would create a clear and transparent process for patients with employer-sponsored insurance to seek exemptions from step therapy and would establish a clear timeframe for granting those exceptions. Insurers would also be required to consider a patient's medical history and their medical provider's expertise before denying a patient a prescribed medically necessary treatment.

Separately, a group of twenty-five patient and provider organizations sent a letter to Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma urging her agency to immediately add patient safeguards to the agency's proposal allowing Medicare Advantage (MA) plans to utilize step therapy for Part B drugs, which took effect in January.

Though CMS included some patient safeguards to the proposal in last year's Medicare Part D and Medicare Advantage proposed rule, they aren't set to take effect until the beginning of next year and may not go far enough. In their letter, the groups also urged CMS to go further to protect patients, asking CMS to include additional clarifications and exceptions to step therapy in the regulations governing MA plans.

To view the text of the Safe Step Act, [CLICK HERE](#).

To read the patient and provider group's letter, [CLICK HERE](#).

### Site Neutral Payments Lawsuit: Hospitals Argue CMS Can't Ignore Statute

In a brief filed in federal court earlier this month, the American Hospital Association, the Association of American Medical Colleges and several other hospital systems argued that CMS ignored the law when it established site neutral payments for hospital off-campus departments (HOPDs) in the 2019 Hospital Outpatient Prospective Payment final rule. Under the final rule, clinic visits at all HOPDs would be paid at a rate that is equivalent to the Medicare Physician Fee Schedule.

The hospital groups sued CMS late last year over the payment reductions, arguing that CMS' site neutral policy violated Congress' intent to treat excepted HOPDs differently than those subject to the law's site neutral policy. The 2015 Bipartisan Budget Act specifically exempted facilities that were already established at the time of the bill's passage.

The brief filed this month argues that CMS is not able to target only clinic pay rates or specific services and instead must make budget neutral cuts or across-the-board changes. Doing otherwise would undermine the 2015 statute and go beyond CMS' authority the hospitals argue.

To read the brief, [CLICK HERE](#).

On April 9, the Senate Finance Committee held a hearing featuring testimony from Pharmacy Benefit Manager (PBM) executives about their role in prescription drug pricing. Lawmakers from both parties criticized PBMs, which manage prescription drug benefits for insurers, for a lack of transparency in their drug formularies and accused the companies of profiting from the rebates they negotiate from drug manufacturers.

Witnesses included:

- Steve Miller, MD, Executive Vice President And Chief Clinical Officer, Cigna Corporation
- Derica Rice, Executive Vice President And President, CVS Health and CVS Caremark
- William Fleming, Pharm.D., Segment President, Healthcare Services, Humana Inc.
- John Prince, Chief Executive Officer, OptumRx
- Mike Kolar, JD, Interim President & CEO, Senior Vice President And General Counsel, Prime Therapeutics LLC

After the hearing, Committee Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) called for the Department of Health and Human Services Inspector General to investigate PBM's use of "spread pricing" in state Medicaid programs, a practice where the companies pocket the difference between the amount they bill insurers and the price they pay for a prescription.

To view the hearing and testimony, [CLICK HERE](#).

To view the Grassley/Wyden letter, [CLICK HERE](#).

## **Drug Price Transparency Bill Passes House Ways and Means Committee**

On April 9, the House Ways and Means Committee unanimously passed the STAR Act (H.R. 2113), a bipartisan bill designed to address high drug costs through transparency steps including requiring manufacturers to publicly justify major price hikes.

The bill, if enacted, would require pharmaceutical companies to justify price hikes for drugs whose prices rise more than 10 percent or \$10,000 over one year, 25 percent or \$25,000 over three years, or those with a launch price of more than \$26,000. It would also encourage greater transparency by requiring pharmacy benefit managers (PBMs) to report aggregate rebates manufacturers provide, as well as how much of those rebates are passed on to health plans.

The bill also would require drug and device manufacturers to report the value of free samples they give to healthcare providers and aims to improve drugmakers' reporting of average sales price (ASP) data, which is used to calculate Medicare Part B drug payments.

To read the text of the STAR Act, [CLICK HERE](#).

## **Medicare Expected to Announce CAR-T Coverage Decision Soon**

On April 13, the *New York Times* reported that Medicare is expected to soon finalize a national coverage determination for the innovative cancer treatment known as CAR-T. Research has shown that some patients who

have undergone CAR-T therapy made remarkable recoveries after they had exhausted all other medical options, though more than 450 studies on the effectiveness of the promising therapy are still underway across the country.

CMS' proposal would only cover CAR-T in the hospital inpatient and outpatient setting, and many cancer patients, doctors and drug companies are urging the agency to expand coverage beyond the hospital so more patients can benefit from the treatment. However, insurers are urging the Administration to implement strict restrictions on CAR-T, citing the high cost of care involved. Two CAR-T therapies already approved by the Food and Drug Administration show a list price ranging from \$373,000 to \$475,000 per patient. UnitedHealth requested the Medicare coverage decision after expressing concern that "CAR-T therapies could create significant financial risks."

Medicare's final decision is expected to be announced in the next few weeks. What Medicare decides will influence commercial insurers and state Medicaid programs, which often follow its lead.

To read the *New York Times* story on CAR-T, [CLICK HERE](#).

To read a related op-ed by Dr. James Essell, Cellular Therapy Chair for The US Oncology Network, [CLICK HERE](#).

## **CMS Announces ACO Application Timeline to Begin in 2020**

On April 10, the Centers for Medicare & Medicaid Services (CMS) announced the timeline for its revamped accountable care organization (ACO) program, which was previously unveiled in a December 2018 final rule.

Starting June 11, CMS will begin accepting perspective notices from accountable care organizations that intend to join the revamped program in 2020. The agency announced that the application window will run from July 1 to July 29 with the goal of signing ACO agreements in December.

ACOs that applied for the first application cycle under the new rules will start on July 1.

To see CMS' ACO application types and timeline, [CLICK HERE](#).

To read the ACO final rule, [CLICK HERE](#).

## **Sanders Reintroduces Medicare for All Bill in the Senate**

On April 10, Senator Bernie Sanders (I-VT) reintroduced his "Medicare-for-all" bill, which would create a national single-payer healthcare system, prohibit private plans from competing with Medicare, eliminate cost-sharing, and institute a universal provision for long-term care in home and community settings. The bill is cosponsored by 14 Democratic senators, including four Democratic candidates for president: Kamala Harris (D-CA), Cory Booker (D-NJ), Kirsten Gillibrand (D-NY), and Elizabeth Warren (D-MA).

However, critics assert that the high cost of the bill, estimated to top \$30 trillion over 10 years, would create severe strain on the country's finances. Moreover, the bill faces strong opposition from conservatives and the insurance industry.

Several other Democratic presidential contenders have not expressed support for Sanders' Medicare-for-all proposal. Senator Amy Klobuchar (D-MN) favors a public option, while Beto O'Rourke favors a proposal known as Medicare-for-America, which guarantees universal coverage but still offers the option for Americans to use employer-sponsored insurance.

To read the text of the bill, [CLICK HERE](#).