

## Health Policy Update – October 26, 2018

### Lawmakers, Stakeholders Call on Administration to Rescind Step Therapy Proposal

On October 12, Congressman Erik Paulsen (R-MN) sent a letter to HHS Secretary Alex Azar urging the Administration to change course and not allow Medicare Advantage (MA) plans to begin implementing step therapy protocols that include Medicare Part B prescription drugs. In the letter, Congressman Paulsen outlines concerns he has heard from constituents including cystic fibrosis, multiple sclerosis and rheumatoid arthritis patients as well as their physicians on how step therapy will put patients at risk as they wait for the drugs and treatments they need.

In an op-ed by Congressman Paulsen, the legislator described step therapy as “time consuming” and a restriction on “a doctor’s ability to prescribe the medication which he or she thinks is best to treat a senior’s condition.”

In August, the Centers for Medicare & Medicaid Services (CMS) announced new policy that will allow Medicare Advantage (MA) plans to apply step therapy for Part B drugs, beginning January 1, 2019. Often referred to as “fail first,” step therapy is a method used by insurance agencies to force patients to try the company’s preferred treatment options over the medical recommendations of the patient’s doctor or caregiver. Not only are these “preferred” treatment options often cheap and ineffective, they also undermine a care provider’s clinical expertise by putting the decision-making responsibility in the hands of insurance companies.

In addition to Congressman Paulsen’s opposition to the proposed step therapy measures, advocates from the Part B Access for Seniors and Physicians (ASP) Coalition hosted a Capitol Hill briefing to discuss the implications of the step therapy policy. Speakers at the ASP Coalition briefing included a Medicare Part B policy expert, a rheumatologist and a patient advocate who addressed her experiences with step therapy and prior authorization which restricted her access to medications for rheumatoid arthritis (RA).

To read Congressman Paulsen’s letter to HHS, [CLICK HERE](#).

To learn about the ASP Coalition, [CLICK HERE](#).

### CMS Announces International Pricing Index (IPI) Model for Medicare Part B Drugs

On October 25, the Centers for Medicare & Medicaid (CMS) issued an Advance Notice of Proposed Rulemaking (ANPRM) on an expansive new demonstration project, the International Pricing Index (IPI) model, that would allow private-sector vendors in Part B to negotiate drug prices in order to purportedly align payments for physician-administered drugs to prices paid in other countries. The comment period for the ANPRM will close on December 24, 2018. CMS will review comments and is considering issuing a proposed rule for the IPI in the spring of 2019, with a potential model start in spring 2020.

The model would test wide-scale, broad changes to the current Part B system, including several concerning components that could have negative implications for patient access and safety. Please see a high-level summary of the IPI model below:

- The model would be phased in over a five-year period, apply to 50 percent of the country, and cover most drugs in Medicare Part B.

- CMS would use a randomized approach to determine which geographies in the country would participate in the model.
- Model participation would be mandatory for the physician practices, HOPDs, and potentially other providers and suppliers, in each of the selected geographic areas.

The IPI model would create a system in which private vendors procure drugs, take title to drugs, distribute them to physicians and hospitals, and take on the responsibility of billing Medicare. Vendors would aggregate purchasing, seek volume-based discounts, and compete for providers' business. Physicians and hospitals would pay the model vendor for distribution costs and would collect beneficiary cost-sharing, including billing supplemental insurers.

The model would begin with two broad groups of drugs – single source drugs and biologicals – but could expand to include multiple source drugs and Part B drugs provided in other settings. Instead of paying based on ASP, CMS would pay for the drug based on a Target Price derived from international price index and designed to draw down Part B drug prices toward international prices over the course of the model. The Target Price would be 126 percent of the average price other countries pay for the drug.

Instead of the current percentage-based add-on payment, physicians and hospitals would receive a set payment amount for storing and handling drugs that would not be tied to drug prices. The ANPRM considers a slight increase in the alternative add-on payment – so that total payments to physicians and hospitals for the add-on would reflect the full 6 percent rather than the 4.3 percent due to sequestration – for the model. CMS is also considering creating alternatives to the add-on payment amount for model participants, such as a set payment amount per encounter or per month for an administered drug, which would not vary based on the price of the drug itself. CMS is also considering whether to uniquely set the payment amount for each class of drugs, physician specialty, or physician practice (or hospital).

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

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

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

## President Trump Signs Package of Legislation to Combat Opioid Crisis

On October 24, almost a year after President Trump declared the opioid crisis a public health emergency, the President signed legislation, "SUPPORT for Patients and Communities Act," designed to combat the epidemic into law.

After passing the Senate 98-1, the legislation will, among other things, expand access to medication-assisted treatments similar to methadone, relax limits on Medicaid funds for addiction treatment and require state Medicaid programs to monitor the prescription of opioids as well as the prescribing of antipsychotic drugs to children.

Along with the final passage of this legislation, the White House has also announced further steps to combat the crisis, including the continuation of the Administration's anti-opioid advertising campaign and a series of speeches by First Lady Melania Trump designed to raise awareness of the epidemic.

To read a section-by-section summary of the opioid legislation (H.R. 6), [CLICK HERE](#).

To read President Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand, [CLICK HERE](#).

## **Trump Administration Issues New Requirements for Drug Advertising**

On October 18, the Trump Administration issued a proposed rule that would mandate drug makers publicly disclose prices in consumer ads. If implemented, the proposed rule would require pharmaceutical companies to list the wholesale monthly price of a product or the cost of a standard regimen for treatment if the drug exceeds \$35 for 30 days. The comment period on the proposed rule expires on December 17.

While the move is meant to address growing voter concern over high drug costs, it has received criticism from the pharmaceutical lobby who claim the disclosure of explicit list pricing without context would mislead consumers. Shortly before the Administration's announcement, PhRMA announced that it would begin directing consumers to drug makers' websites for additional price information in television drug ads starting April 15, 2019.

To view the proposed rule, [CLICK HERE](#).

## **Bipartisan Group of Lawmakers Urges CMS to Issue Guidance on Prior Authorization**

On October 10, a bipartisan group of 103 Representatives signed a letter asking the Centers for Medicare & Medicaid Services (CMS) to direct Medicare Advantage plans not to use prior authorization to inhibit beneficiaries' access to services. The letter asks CMS to issue guidance to plans on the use of prior authorization, make sure such requirements don't create inappropriate barriers to care and collect data on the scope of prior authorization use.

On October 16, CMS Administrator Seema Verma spoke about the need for prior authorization practices in the Medicare program at the America's Health Insurance Plans (AHIP) conference. Addressing the crowd, Verma said, "The Medicare program has extremely low administrative costs, but this isn't exactly something to brag about. The reality is we aren't focusing enough on critical program oversight functions like medical reviews of claims. We review less than two tenths of a percent of the over 1 billion claims that Medicare receives a year. Given the scope and size of the Medicare program, that is ridiculously low. We also lack adequate legal authority to do the types of prior authorization reviews that have become routine in the private sector, leading to a high frequency of improper payments and more fraud and abuse."

A recent report from the HHS Office of Inspector General (OIG), "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials," studied how the capitated payment model used in Medicare Advantage may encourage Medicare Advantage Organizations (MAOs) to inappropriately deny access to services and payment in an attempt to increase profits. OIG concluded when beneficiaries and providers appealed preauthorization and payment denials, MAOs overturned 75 percent of their own denials between 2014 and 2016, raising concerns some Medicare Advantage beneficiaries and providers were initially denied services and payments that should have been provided.

To view the lawmaker letter on prior authorization in MA plans, [CLICK HERE](#).

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

## Mississippi and Colorado Medicaid Programs Require Hospitals to Provide More Information on 340B Drugs

Mississippi and Colorado are among the first states to track 340B payments after reimbursements, as the Medicaid programs in the two states have asked hospitals to provide more drug discount information in an effort to address healthcare expenditures. Both states imposed a November 1 deadline for hospitals to hand over the information before the states would deny claims from hospitals who fail to comply. The Mississippi Medicaid policy addresses both medical claims and pharmacy point of sale claims, while Colorado's policy calls for hospital retail pharmacies to choose either 340B drugs or no 340B drugs for Medicaid beneficiaries.

The policies come as more stakeholders seek greater transparency for the 340B program. In June, the Government Accountability Office (GAO) recommended that the HHS Health Resources and Services Administration (HRSA) should take action to ensure that 340B participants use the savings properly.

To view the Mississippi policy, [CLICK HERE](#).

To view the Colorado notice, [CLICK HERE](#).

## Senate, House Party Control Up for Grabs in Looming Midterm Election

The much-anticipated midterm elections will take place on November 6 during which 35 Senate seats and all 435 seats in the US House of Representatives are up for reelection. In order to take control of the Senate, Democrats need to gain two seats, while maintaining all current seats. In order to take control of the House, Democrats will need to gain 23 seats.

According to the most recent Cook Political Report, control of the Senate will depend on eight "toss up" seats in Arizona, Florida, Indiana, Missouri, Montana, Nevada, Tennessee and Texas. In the House, the Cook Political Report identifies 30 "toss up" seats that will determine whether Democrats can take control of the House.

Current analysis show of the 35 seats up for election in the Senate:

- 21 seats are solid/likely/lean Democrat
- 8 seats are "toss ups"
- 6 seats are solid/lean Republican

Seats in the House lean:

- 196 seats solid Republican
- 30 seats are "toss ups"

- 209 seats are solid Democrat

To read the Cook Political Senate Report, [CLICK HERE](#).

To read the Cook Political House Report, [CLICK HERE](#).