

Health Policy Update – December 19, 2019

House Passes Drug Pricing Legislation, Republicans Introduce Alternative

On December 12, the House of Representatives passed the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), which would allow the federal government to directly negotiate the price of up to 250 drugs that lack competition using an international price index and extend those prices to the commercial market. Manufacturers who refuse to enter into negotiations or who leave the negotiation before a maximum fair price is agreed to would be subject to an escalating excise tax based on the selected drug's annual gross sales. The bill would also cap out-of-pocket drug expenses for Medicare beneficiaries at \$2,000.

The savings generated from allowing the government to negotiate drug prices would be put towards adding dental, vision and hearing coverage to Medicare, additional drug research at the National Institutes of Health, additional funding for community health centers and other programs aimed at lowering costs and expanding coverage for Medicare and Medicaid beneficiaries. H.R. 3 passed the House by a mostly party-line vote of 230-192. The Senate is not expected to consider the legislation.

An analysis of the bill from the Congressional Budget office found that the provisions allowing for drug price negotiations would save the federal government approximately \$456 billion over the next decade. However, the CBO analysis also found that approximately eight fewer drugs would be introduced to the U.S. market in the next 10 years and about 30 fewer drugs could be developed over the subsequent decade. The Food and Drug Administration currently approves about 30 new drugs per year — or about 300 over a ten-year period.

Separately, a group of House Republicans released their own legislation to address high drug prices. The Lower Costs, More Cures Act (H.R. 19) contains a number of provisions which have already received bipartisan support such as a policy to enact a \$3,100 cap on out-of-pocket drug expenditures for Medicare beneficiaries that would be broken out into monthly caps.

The Republican bill would also require site neutral payments for Part B drug administration and allow generic companies to access samples of brand-name drugs to bolster generic development, the basis for the bipartisan CREATES Act. It also caps co-payments for insulin at \$50 per month under Medicare, establishes a “chief pharmaceutical negotiator” to represent American patients in international trade negotiations, and requires drug companies to include a medication's list price in television ads, mirroring a Trump administration proposal that was struck down in court earlier this year. In addition, drug manufacturers would be responsible for 10 percent of drug costs at every stage of coverage in Medicare Part D plans.

To view a summary of H.R. 3, [CLICK HERE](#).

To view the CBO analysis of H.R. 3, [CLICK HERE](#).

To view a summary of H.R. 19, [CLICK HERE](#).

CMS to Repay 2019 Site Neutral Payment Cuts; Continue Cuts for 2020

CMS recently said it will repay hospitals that sued over payment changes for clinic visits that went into effect in January 2019. A federal judge ruled in September that HHS had exceeded its authority when it implemented site neutral payments for clinic visits at off-campus hospital facilities. CMS said it started paying hospitals the higher payment rate

on November 4 and Medicare Administrative Contractors will automatically reprocess 2019 claims paid at the reduced rate beginning January 1, 2020.

However, CMS has also said it intends to continue to implement site neutral payments for clinic visits at off-campus hospital facilities for 2020, a policy finalized in the CY 2020 hospital outpatient payment rule. CMS has argued that the court's decision on the 2019 rule does not affect the 2020 rule. Additionally, on December 12, HHS formally appealed the September ruling on the 2019 policy.

Hospital Groups Oppose 340B Survey

Hospital groups strongly criticized a proposal from the Centers for Medicare & Medicaid Services (CMS) to survey hospitals that participate in the 340B drug discount program about their acquisition costs for certain covered drugs. CMS released its proposal to survey hospitals about these costs in response to a December 2018 court ruling that struck down the agency's cuts to 340B hospitals. The court ruled that CMS didn't have the authority to make these changes in part because CMS hadn't collected the necessary data to set payment rates based on acquisition costs.

The groups — which included the American Hospital Association, the Association of American Medical Colleges, 340B Health, and others — argued that calculating payments based on acquisition costs was flawed and that Congress intended for the program to allow hospitals to purchase drugs at a heavily discounted rate so that the savings could be used to provide other services to low income people. The groups also noted that responding to the survey will be a significant cost burden for some hospitals and could result in human error that may contribute to inaccuracies in reported data.

Groups representing community physicians however, noted that criticizing the survey was an attempt to prevent CMS from collecting the data needed to properly calculate the payments.

To view CMS' proposed 340B survey, [CLICK HERE](#).

Hospitals Sue HHS Over Price Transparency Rule, Insurers Ask for Delay

On December 4, a group of hospital trade associations filed a lawsuit in federal court against the Department of Health and Human Services in an attempt to block a recently finalized rule that would compel them to disclose their negotiated rates with insurers.

The hospital groups claim that the rule would violate their First Amendment rights and would go beyond the statutory intent of the Affordable Care Act which required hospitals to make their standard charges public. With hospital rates skyrocketing in recent years, the Administration believes that transparency and price disclosure would help cut healthcare spending and spur greater competition. However, the hospital groups say that the regulation would cost millions in compliance spending, force them to share confidential contractual information, and could actually lead to higher prices.

On the same day the lawsuit was filed, America's Health Insurance Plans (AHIP) and the Blue Cross Blue Shield Association — two of the country's top insurance industry groups — urged the Administration to delay a comment period on a proposed rule that would force payers to provide real-time out-of-pocket cost estimates. The proposed rule, introduced in November by the Departments of Treasury, Labor, and Health and Human Services, would require insurance companies to provide personalized, real-time estimates of expected out-of-pocket costs to patients and publicly post the rates for in-network providers, devices, and drugs including historic spending amounts on out-of-network providers. Citing fears of a "significant" disruption to healthcare markets, the groups asked for a 90-day delay in the comment period for the proposed rule.

To read a fact sheet on both rules, [CLICK HERE](#).

To read the final the hospital price transparency rule, [CLICK HERE](#).

To read the proposed insurer coverage transparency rule, [CLICK HERE](#).

Two Committees Reach Agreement on Legislation to Lower Health Care Costs

On December 8, the Senate HELP and House Energy & Commerce Committees reached a bipartisan, bicameral agreement on legislation to lower health care costs. The bill includes a compromise on surprise billing, several drug pricing provisions, raises the purchasing age for tobacco to 21 and increases funding for community health centers. The surprise billing provision sets a benchmark payment rate for out-of-network bills at the median in-network rate for a geographic area and allows insurers or providers to use independent arbitration if the median in-network payment is above \$750.

The bill's drug pricing section includes provisions to prohibit pharmacy benefit managers from engaging in spread pricing and require them to pass 100 percent of rebates or discounts to health insurance plan sponsors.

While supporters of the compromise were hopeful the bill would be passed before the end of the calendar year, the House Ways & Means Committee complicated matters by releasing its own bipartisan plan to address surprise billing.

To view the HELP and Energy & Commerce agreement, [CLICK HERE](#).

Senate Unveils Updated Drug Pricing Bill with White House Support

On December 6, the Senate Finance Committee released an updated version of its bipartisan drug pricing bill, the Prescription Drug Pricing Reduction Act of 2019 (S. 2543) that was approved by the Committee in July. The updated bill contains several new additions meant to further lower prescription drug costs for Medicare beneficiaries. It caps Medicare Part D beneficiary annual out-of-pocket spending at \$3,100 and closes the so-called "doughnut hole." Beneficiaries in the initial coverage phase would be responsible for 20 percent of drug costs while manufacturers and insurers are responsible for seven and 73 percent of costs, respectively. Beneficiaries who hit their out-of-pocket maximum enter the catastrophic phase where manufacturers, insurers, and beneficiaries split costs. Beneficiaries would be responsible for five percent of drug costs, drug manufacturers 14 percent — down from the 20 percent they currently pay — with insurers responsible for the remainder of the costs.

Other provisions of the bill include a requirement that brand-name and biologic manufacturers reimburse Medicare when the prices of their drugs increase faster than inflation and site neutral payments for Part B drug administration.

The White House has endorsed the new Senate bill, adding additional pressure on Senate Republicans to support the bipartisan legislation.

To view the updated Senate bill, [CLICK HERE](#).

Senate Confirms FDA Nominee Dr. Hahn

On December 12, the Senate confirmed Stephen Hahn as the next commissioner of the Food and Drug Administration by a vote of 72-18. The Senate Committee on Health, Education, Labor and Pensions voted 18-5 in favor of advancing

Hahn's confirmation. Some Democrats, including HELP Committee Minority Leader Patty Murray (D-WA) voted against Hahn, claiming that he did not thoroughly explain his stance on e-cigarettes at a time when the Trump Administration is weighing additional regulations.

Hahn, the top official at MD Anderson Cancer Center in Houston, received considerable support among healthcare groups. More than 40 organizations, including the American Society of Clinical Oncology, American Cancer Society Cancer Action Network, and the National Organization for Rare Disorders, submitted a letter to the Senate HELP committee highlighting Hahn's scientific integrity, focus on innovation, understanding of patient needs, and commitment to improving public health.

To read the letter from the provider groups, [CLICK HERE](#).