

## Health Policy Update – June 21, 2018

### Secretary Azar Discusses Administration's Drug Pricing Blueprint Before Senate HELP Committee

On June 12, Secretary of Health and Human Services (HHS) Alex Azar appeared before the Senate Committee on Health, Education, Labor, and Pensions (HELP) to provide more details about the Administration's "American Patients First" blueprint to lower the cost of prescription drugs in the U.S.

In order to reduce list prices, Secretary Azar suggested requiring pharmaceutical companies to disclose costs in their direct-to consumer ads. The Secretary also told the committee that "more fundamentally, we may need to move toward a system without rebates, where PBMs and drug companies just negotiate fixed-price contracts."

Secretary Azar also highlighted the Administration's actions to increase approvals for generic drugs and suggested ways to bring negotiation to Medicare Part B in order to create more competition and savings. Azar stated that a proposal to move certain drugs from Part B coverage to Part D coverage could be structured as a demonstration model so that patient out-of-pocket costs could be offset using the savings from reduced drug prices.

To view a recording of the full committee hearing, [CLICK HERE](#).

### Congresswoman Matsui Introduces Bill to Reverse 340B Cuts

Last week, Congresswoman Doris Matsui (D-CA) introduced a bill to reverse recent cuts to the 340B program while clarifying that the intent of the program is to allow hospitals to use the savings generated in a variety of ways. The Stretching Entity Resources for Vulnerable (SERV) Communities Act (H.R. 6071) would reverse a decision made by the Centers for Medicare & Medicaid Services (CMS) late last year to reduce payments for drugs purchased through the 340B program as a part of the FY 2018 Medicare Outpatient Prospective Payment System (OPPS) rule. It would also direct the HHS Secretary to audit drug manufacturers and expand the program discounts to Substance Abuse and Mental Health Services Administration grantees.

To read a summary of the SERV Communities Act, [CLICK HERE](#).

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

### Senate HELP Committee Holds Hearing on 340B Drug Discount Program

On June 19, the Senate HELP Committee held a hearing to discuss transparency in the 340B Drug Discount Program and how proposed changes could improve government oversight of the program. Captain Krista M. Pedley, who serves as Director of the Office of Pharmacy Affairs at HHS, was the sole witness and testified that her office does not currently have the authority to monitor how hospitals use the savings from the program.

The hearing was the third and final hearing in its series examining potential challenges in administration of the 340B program.

To view a recording of the full committee hearing, [CLICK HERE](#).

## **Administration Declines to Defend ACA's Pre-existing Condition Ban in Federal Court**

On June 7, the Trump Administration announced it would not defend key parts of the Affordable Care Act in a federal lawsuit brought by a coalition of Republican state attorneys general. The attorneys generals' lawsuit contends that because the ACA's individual insurance mandate was repealed by Congress as a part of last year's tax reform package, and is therefore no longer constitutional, the consumer protections must also be invalidated.

In announcing its decision not to defend the law, the Administration argued that in the absence of the individual mandate's tax penalty – which will be officially reduced to \$0 in 2019 – the sections of the law that protect people with pre-existing conditions from rate hikes in the individual ACA marketplace should also be struck down.

While there is no official estimate for the number of Americans who have pre-existing conditions, previous research from the Kaiser Family Foundation estimated that approximately a quarter of Americans under 65 have a pre-existing condition. If the section is ultimately invalidated, a significant portion of the 21 million Americans who purchase insurance through an ACA marketplace could be affected.

To read the Administration's letter announcing its decision, [CLICK HERE](#).

## **Administration Issues Association Health Plan Final Rule**

On Tuesday, the Trump Administration finalized a rule that would expand consumer access to association health plans. The new policy broadens the definition of "employer" under the Employee Retirement Income Security Act, allowing more small businesses and self-employed workers to band together to purchase insurance. Unlike plans found on the individual market, these new association health plans would not have to offer coverage that is in line with the Affordable Care Act's Essential Health Benefits.

However, critics argue that expanding access to these plans could undermine the Affordable Care Act as it would encourage younger and healthier consumers to drop out of the individual market pool and instead opt for cheaper, but less comprehensive association plans. An estimate from Avalere Health found that as many as 4.3 million people could leave the individual market in favor of these new plans.

To view the association health plan final rule, [CLICK HERE](#).

## **House Passes Dozens of Bills to Address Opioid Crisis**

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This week, the House of Representatives passed nearly three dozen bills aimed at addressing the nation's opioid epidemic. The bills cover a variety of issues, from enhancing HHS and FDA's seizure authority over imported drugs, to amending the Public Health Service Act to provide for regional centers of excellence in substance-use disorder education. Many of the bills dealt with enforcement actions to be taken by HHS and FDA, while others were concerned with CMS coverage of various opioid-related treatments.

A bill to permanently allow nurse practitioners and physician assistants to prescribe buprenorphine and increase the number of patients providers can treat with the drug was also included.

To view a complete list of bills passed by the House, [CLICK HERE](#) and [HERE](#).

## **NIH Leaders Outline Plan to Fight Opioid Epidemic**

In an article for the Journal of the American Medical Association, the top leadership at the National Institutes of Health (NIH) outlined the agency's addiction medicine strategy, including a plan to spend the \$500 million so far appropriated by Congress.

The NIH will focus on improving treatments for opioid misuse and addiction and bolster strategies to manage pain. The effort will be conducted through the NIH's Helping to End Addiction Long-term (HEAL) initiative. NIH will evaluate improving opioid overdose reversal medications and ways to reformulate existing treatments to help improve adherence.

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