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Health Policy Briefing

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HHS Announces Overhaul of Part B Drug Reimbursement

President Trump joined U.S. Secretary of Health and Human Services (HHS) Alex Azar last week to deliver remarks on the cost of prescription drugs and to announce significant changes to the reimbursement of drugs in Medicare Part B. HHS released a corresponding report on Thursday examining drug prices that are charged to wholesalers and distributors in the United States compared to those charged abroad.

HHS' Advance Notice of Proposed Rulemaking (ANPRM) proposes a payment plan for doctor-administered drugs in an effort to shift prices to a level more in line with prices in other countries and reduce what Americans pay for some treatments. The proposal from the Centers for Medicare and Medicaid Services (CMS) would establish an international pricing index to be used as a reference in setting reimbursement for drugs paid for through Medicare Part B. The new model will encompass 50% of Part B drug expenditures and initially target drugs made by a single manufacturer. Over time, the goal of the model is to reduce the cost of those medications by 30 percent. The administration projects that this proposal would save $17.2 billion over the next five years.

The President also announced plans to change the way physicians are paid under Part B. Under the proposal, physicians participating in the demo would be paid a flat fee instead of a percentage add-on to the average sales price (ASP) and third party vendors would assume the financial risk physicians currently assume in today's buy-and-bill system. The administration plans to issue an official proposed rule in the spring of 2019, with the five-year demo beginning in the spring of 2020. Secretary Azar stressed that the actions announced on Thursday are just a part of a series of steps the administration plans to take to lower drug costs.

CMS Loosens 1332 Waiver Rules

CMS issued new guidance last week to reform 1332 state innovation waivers. 1332 waivers were created by the Affordable Care Act (ACA) and serve as a vehicle to allow states to waive some of the law's coverage requirements and consumer

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protections and make changes to state health insurance markets. CMS Administrator Seema Verma has characterized the current waiver process as too restrictive, and the latest guidance aims to increase flexibility for states. Under the 2010 health care law, waiver programs must provide coverage that is equally comprehensive and must cover a comparable number of people. The agency's new policy, however, focuses on access to coverage rather than level of coverage. It will allow states to count people with short-term insurance as having coverage, even though such plans do not cover all of the essential health benefits included in Obamacare-compliant plans. This change paves the way for states to use ACA subsidies, previously reserved for Obamacare plans, to pay for short-term and association health plan coverage. The administration recently issued regulations expanding the availability of such plans, which are cheaper than ACA plans but offer less comprehensive coverage options and fewer of the law's consumer protections. The new guidance also overhauls the current waiver process, allowing governors to take action on waiver plans, which previously had to be approved by state legislatures. Both changes are in response to an October 2017 executive order instructing federal agencies to loosen restrictions around coverage options.

The administration argues that these recent moves will increase competition, expand consumer choice, and lower costs for individuals who have been priced out of the ACA market. Democrats, however, warn that the changes will lead to higher health care costs, particularly for those with preexisting conditions, and result in many Americans purchasing inadequate 'junk' insurance plans. There are also concerns that the change in regulations will destabilize the individual health insurance market and lead to parallel systems – one for healthy people seeking cheaper plans, and another for sick patients who remain in ACA coverage but face rising premiums.

The 1332 guidance takes effect immediately but will not be used until 2020. ACA premiums and plans have already been set for 2019; enrollment opens on November 1. CMS plans to publish a list of potential waiver applications in the coming weeks.

Opioid Bill Signed into Law

President Trump has signed H.R. 6, the ***SUPPORT for Patients and Communities Act***, into law. H.R. 6 is a bipartisan, comprehensive legislative package aimed at curbing the opioid crisis.

HHS Secretary Alex Azar stated last week that the number of drug overdose deaths has plateaued after reaching a record high last year, citing preliminary statistics from the Centers for Disease Control and Prevention (CDC). "We are so far from the end of the epidemic, but we are, perhaps, at the end of the beginning," Azar stated, cautioning that drug overdoses are not declining, but rather are increasing at a slower rate than previously observed. He credited federal, state, and local government efforts for the progress.

Sens. Elizabeth Warren (D-Mass.) and Patty Murray (D-Wash.) highlighted a report last week which they argue demonstrates that the administration has taken almost no meaningful action in response to the opioid epidemic. The Government Accountability Office (GAO) report details the three emergency authorities used by the Trump Administration related to the opioid crisis: one to assess prescribing trends for a medication used to treat opioid use disorder and the barriers to prescribing it, one to speed the development and approval of state pilot programs related to substance-use disorder (SUD) treatment, and one to expedite research on opioid use disorder treatments and the dissemination of information on opioid misuse and addiction. The GAO identifies 14 other authorities that became available as a result of the declaration of a public health emergency that have not been used by the administration.

The Department of Justice (DOJ) has also announced the creation of the Appalachian Regional Prescription Opioid (ARPO) Strike Force. The strike force will combine federal and state enforcement resources with a focus on stopping illegal opioid prescriptions. It will include representatives from the FBI, DOJ, HHS Office of Inspector General (OIG), and the Drug Enforcement Administration (DEA). Strike Force prosecutors can pursue both narcotics violations as well as medical necessity cases.

Grassley Questions NIH Vetting Process

Senate Judiciary Committee Chairman Chuck Grassley (R-Iowa) has written to the Director of the National Institutes of Health (NIH) Francis Collins regarding the vetting process for foreign researchers. According to Grassley, the NIH is investigating cases in which researchers who received federal grants may not have disclosed financial contributions from foreign governments. "Congress requires a better understanding of these processes and the steps NIH has taken to ensure their integrity," Grassley writes. He asks for a description of the process by which NIH conducts background checks of researchers and institutions prior to awarding NIH grants.

Lawmakers Comment on ACO Rule Changes

A bipartisan group of lawmakers have written to CMS requesting changes to the agency's latest rule on the Medicare Shared Savings Program (MSSP). The letter outlines concerns that the new rule will negatively impact the ability of accountable care organizations (ACOs) to participate in the program. The rule would reduce the amount of time organizations can spend in upside-only risk models from six years to two years and decrease the shared savings rate from 50 percent to as low as 25 percent. The letter was signed by Reps. Diane Black (R-Tenn.), Suzan DelBene (D-Wash.), Gene Green (D-Texas), Tom Reed (R-N.Y.), Roger Marshall (R-Kansas), Peter Welch (D-Vt.), David Roe (R-Tenn.), Greg Gianforte (R-Mont.), and Brad Wenstrup (R-Ohio).

Hatch Considers Policing of Online Drug Sales

Senate Finance Committee Chairman Orrin Hatch (R-Utah) has written to two drug safety nonprofits asking for help in curbing the sale of counterfeit online prescriptions. In letters to the Alliance for Safe Online Pharmacies and the Pharmaceutical Security Institute, Sen. Hatch requests details about how the organizations respond when fraudulent medicines are identified.

Paulsen, DelBene Seek to Increase Access to CAR T Therapy

Reps. Erik Paulsen (R-Minn.) and Suzan DelBene (D-Wash.) are circulating a sign-on letter among their colleagues asking CMS to create a technical expert panel (TEP) to determine a sustainable way to reimburse for chimeric antigen receptor (CAR) Tcell therapies in the inpatient and cancer hospital setting. CAR T therapies are currently used in the treatment of relapsed and refractory cancers, but the inadequacy of current Medicare reimbursement threatens to limit seniors' access to such treatment. The lawmakers recommend that CMS establish a TEP to develop unique payment options to ensure greater Medicare beneficiary access to CAR T therapies.

Pelosi Pitches Idea of Transitional Speakership

House Minority Leader Nancy Pelosi (D-Calif.) is floating the idea of a transitional speakership should Democrats win the House in next month's midterm election. Pelosi would serve as Speaker of the House until the end of next Congress, giving the party more time to choose a successor to be the next Democratic leader. Pelosi has led House Democrats since 2003. Although there is no clear rival to challenge Pelosi, her transition pitch has been met with a mixed reaction among younger members of the party seeking fresh leadership. Democratic leadership elections will take place at the end of November, with a formal vote for Speaker of the House slated for early January.

Upcoming Congressional Hearings and Meetings

Senate Health, Education, Labor, and Pensions Committee hearing "Reducing Health Care Costs: Improving Affordability through Innovation"; 10:00 a.m., 430 Dirksen Bldg.; November 28