



## Health Policy Briefing

May 9, 2016

### Members Urge CMS to Withdraw Proposed Part B Drug Payment Model

A group of 242 members of the House of Representatives have sent a letter to the Centers for Medicare and Medicaid Services (CMS) Acting Administrator Andy Slavitt demanding that the proposed Part B drug payment model be withdrawn. The lawmakers express concern about the scope of the proposed experiment and the possibility that it will drive physicians to refer patients to a hospital outpatient department. They also are worried that the model will hinder physician efforts to participate in delivery and payment reforms. The Part B proposal has drawn criticism from both sides of the aisle. The letter was led by Reps. Tom Price (R-Ga.), John Shimkus (R-Ill.), and Charles Boustany (R-La.) and was signed by four democrats: Brad Ashford (D-Neb.), Dutch Ruppersberger (Md.), Kyrsten Sinema (D-Ariz.), and Collin Peterson (D-Minn.). Senators Heitkamp (D-N.D.), Tester (D-Mont.), Udall (D-N.M.), Heinrich (D-N.M.), and Donnelly (D-Ind.) sent a separate letter to CMS that states “it is clear more stakeholder engagement is necessary, and CMS must engage in a meaningful dialogue with the impacted community. Further, until these concerns are resolved, we urge CMS not to move forward with the demonstration.” Rep. Bill Pascrell Jr. (D-N.J.) sent an individual letter to CMS outlining concerns he’s heard and asking that they be addressed in the final rule. In contrast, AARP announced a letter urging CMS to move forward with the demonstration which was signed by 25 organizations including a number of insurance companies and unions.

#### Zika Update

Vaccine testing for the Zika virus will begin in September, according to Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID). This first phase of testing will enroll 80 people in the United States. If it is determined that the vaccine is safe to use, the next testing phase to determine whether it is effective would involve thousands of participants in South America and the Caribbean, areas with much higher rates of Zika infection. Larger clinical trials for a vaccine would likely begin in early 2017. In the House, Rep. Vern Buchanan (R-Fla.) has become the first Republican to publically back the President’s request for \$2 billion in emergency funding to combat the Zika virus. His home state is at particular risk of an outbreak as early as next month. Senator Marco Rubio (R-Fla.) has already called for the approval of the full funding amount.

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### ***CDC Releases New Antibiotic Use Data***

The Centers for Disease Control and Prevention (CDC) has unveiled **findings** related to new data published in the Journal of the American Medical Association (JAMA) indicating that approximately one in three antibiotic prescriptions are unnecessary. Each year, 154 million prescriptions for antibiotics are written. The unnecessary prescriptions are usually in response to respiratory conditions caused by viruses that do not respond to antibiotics.

### ***Cost of Prescription Painkillers is Decreasing for Patients***

According to a new study published in Health Affairs, the cost of prescription painkillers has been gradually shifting from patients to insurers. Out-of-pocket spending on prescription painkillers comprised 53 percent of the total \$2.3 billion in spending in 1999. This percentage decreased to just 18 percent by 2012, despite the fact that the total amount of money spent on these drugs tripled to approximately \$7.4 billion. The study also shows that Medicare Part D spent double the amount on opioid drugs for its small group beneficiaries under the age of 65 – \$1.8 billion – than it has for its entire over-65 population, just \$637 million. Medicare and Medicaid are also covering an increasing share of the cost of painkillers. In 1999, the programs covered nine percent of the costs. This figure increased to 35 percent by 2012. Researchers indicate that this cost shift could be partially responsible for the significant increase in the use of the drugs over the last decade. During this time period, deaths from opioid overdoses in the U.S. quadrupled.

### ***House to Consider Opioid Legislation***

On Wednesday, the House of Representatives is scheduled to consider under suspension of the rules 12 pieces of legislation related to the prescription drug and heroin abuse epidemic. The House Rules Committee meets on Tuesday to consider H.R. 4641, a bill to provide for the establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication; and H.R. 5046, the Comprehensive Opioid Abuse Reduction Act of 2016. Later in the week, the House is scheduled to consider H.R. 5046, subject to a rule, as well as consideration of House Amendment to S. 524, the **Comprehensive Addiction and Recovery Act of 2016 (CARA)** and a Motion to go to Conference on S. 524, and a possible Democrat Motion to Instruct Conferees.

### ***Democrats Call for Opioid Funding; Surgeon General Pushes Prescriber Education***

A group of 53 Democratic lawmakers in the House have **written** to Speaker Paul Ryan (R-Wis.) calling for \$600 million in new funding to fight the opioid abuse epidemic. The lawmakers wish to see the money attached to a package of bills aimed at addressing the opioid crisis that is expected to be voted on by the chamber this week. Also last week, U.S. Surgeon General Vivek Murthy called for more robust training for prescribers of painkillers as a key part of addressing the epidemic of opioid overdose deaths in this country. He pointed toward prescribing practices and overprescribing as reasons for the supply of misused painkillers in the nation's medicine cabinets.

### ***FDA to Use Intercenter Coordination***

The Food and Drug Administration (FDA) has decided to begin partnering officials in different agency centers with expertise in oncology products in an attempt to streamline the review process. The largely virtual Oncology Center of Excellence was first proposed in the President's budget as a part of the Cancer Moonshot initiative, but Commissioner Robert Califf announced last week that he intends to create the Center regardless of whether Congress mandates the change or provides funding for its creation. Currently, the FDA reviews new cancer treatments separately across the drug, device, and biologic centers within the agency. The goal of the Oncology Center of Excellence would be to break down these silos to better engage the disease specific knowledge of regulatory scientists. FDA plans to establish and staff the Center between October 1, 2016 and September 30, 2017.

## ***Policymakers Inquire About FDA Use of Guidance Documents***

A group of Republican senators have **written** to Commissioner of the Food and Drug Administration (FDA) Robert Califf to express concern over the agency's use of non-binding guidance instead of formal rules and regulations to enact significant policy changes. The lawmakers inquire as to why the FDA has increasingly relied on guidance documents, and urge the FDA to either finalize or withdraw guidances that are still in draft form. The letter was signed by Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.), and committee members Johnny Isakson (R-Ga.), Richard Burr (R-N.C.), and Orrin Hatch (R-Utah).

## **Upcoming Congressional Meetings and Hearings**

***Senate Finance Committee hearing on “Can Evidence Based Practices Improve Outcomes for Vulnerable Individuals and Families?” 10:00 a.m., 215 Dirksen Bldg.; May 10***

***House Rules Committee meeting to consider opioid legislation (H.R. 4641 and H.R. 5046); 5:00 p.m., H-313 Capitol; May 10***

***House Energy and Commerce Health Subcommittee hearing on “Health Care Solutions: Increasing Patient Choice and Plan Innovation;” 10:00 a.m., 2322 Rayburn Bldg.; May 11***

***House Ways and Means Health Subcommittee hearing on “Implementation of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA);” 2:00 p.m., 1100 Longworth Bldg.; May 11***

***Senate Finance Committee hearing on the nominations of Charles Blahous III and Robert Reischauer, each to be a member of the Board of Trustees of the Federal Hospital Insurance Trust Fund, member of the Board of Trustees of the Federal Supplementary Medical Insurance Trust Fund, and member of the Board of Trustees of the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund; 3:00 p.m., 215 Dirksen Bldg.; May 11***

***House Energy and Commerce Oversight and Investigations hearing on “Concussions in Youth Sports: Evaluating Prevention and Research;” 9:30 a.m., 2123 Rayburn Bldg.; May 13***

## **Recently Introduced Health Legislation**

***H.R. 5164 (introduced by Rep. Jenkins of Kansas): A bill to provide for a permanent extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; May 3***