HHS | Hart Health Strategies Inc.

Health Policy Briefing

August 29, 2016

EpiPen Price Hikes Draw Significant Attention

The pharmaceutical company Mylan has come under scrutiny by lawmakers on both sides of the aisle for the price of it's EpiPen Auto-Injector, used in emergency treatment of life-threatening allergic reactions. Since Mylan acquired EpiPen in 2007, the price of two injectors has risen over 400 percent and now totals approximately $500. A bipartisan group of senators have **written** to the Food and Drug Administration (FDA) asking for an explanation about why EpiPens don't have more competition in the United States. The lawmakers point out that there are generic alternatives available in other countries, where the prices for the devices are significantly lower. The letter was signed by Chuck Grassley (R-Iowa), Amy Klobuchar (D-Minn.), Ron Johnson (R-Wis.), Patrick Leahy (D-Vt.), and Richard Blumenthal (D-Conn.). Rep. Elijah Cummings (D-Md.), the ranking member of the Committee on Oversight and Government Reform, called for a hearing in September to examine the controversial price increase. The Senate Special Aging Committee has also asked to meet with Mylan staff for a briefing within the next two weeks on the issue. The company drew criticism from Democratic presidential nominee Hillary Clinton, who called on the company to immediately reduce the price of the injections. Mylan's pricing decisions have also been criticized by the American Medical Association (AMA), which urged Mylan to do all it can to rein in the "exorbitant costs." In response to the uproar, Mylan announced that it would provide a savings card worth up to $300 for people who had been paying the full price for the EpiPen out of pocket. The move would effectively reduce the cost of the device by 50 percent. The company will also make it easier to qualify for its patient assistance program, which eliminates out of pocket costs for uninsured and underinsured people altogether. This decision did not mollify most policymakers, however, who characterized the coupons as more of a PR strategy than a comprehensive response to the problem.

Inside

Zika Update

Following the emergence of five cases of Zika in Miami Beach, the Centers for Disease Control and Prevention (CDC) has warned that pregnant women should avoid traveling there. It was also announced last week that the U.S. Department of Health and Human Services (HHS) would begin funding the development of a Zika diagnostic test for use in physician offices. The lateral-flow serological test being developed by Chembio Diagnostic Systems, Inc. could provide a Zika diagnosis for patients in less than thirty minutes in a health care provider's office. Serological tests look for antibodies produced by the immune system in response to a virus, which become present two weeks after infection and up to three months later. Because most people infected with the Zika virus do not develop symptoms and are therefore unlikely to seek testing while the virus is still present in their blood, this test could be critical in determining whether a person has recently acquired the Zika virus. The Biomedical Advanced Research and Development Authority (BARDA) will provide $5.9 million over the next year for the continued development, manufacturing, and clinical trial evaluation of the test.

Medical Device User Fee Deal Announced

Medical device companies have agreed to pay almost $1 billion in user fees to the Food and Drug Administration (FDA) between 2018 and 2022 in a deal announced last week. This is a 68 percent increase over the $595 million the industry pays under the current user fee agreement settled in 2012. These user fees will provide resources to reduce the total review time for devices. Independent analyses will also be conducted to examine how the agency manages the review process. FDA has committed to providing industry with feedback at least five days before meetings regarding forthcoming applications, and to testing how real-world evidence can support pre-market requirements. Further details about the agreement will be published for public comment in the coming weeks, and final recommendations are scheduled to be delivered to Congress in January 2017. The FDA still has to finalize negotiations with the drug industry. The user fee programs are expected to be combined into a single legislative package and passed before the existing agreements expire on September 30, 2017.

CMS Releases 2015 ACO Data

Accountable care organizations (ACOs) reduced Medicare program spending by $466 million in 2015, according to new data released by the Centers for Medicare and Medicaid Services (CMS) last week. This is an increase over the $411 million saved during the previous year. The 392 Medicare Shared Savings Programs (MSSP) cut spending by $429 million, while the 12 Pioneer ACO models saved $37 million. In total, thirty percent (or 125 ACOs) reduced spending enough to qualify to receive a share of the savings. More ACOs shared savings in 2015 compared to 2014, and CMS notes that those ACOs with more experience tend to perform better over time. Of the MSSP ACOs that started in 2012, 42 percent qualified for shared savings payments, compared to only 21 percent of those ACOs that started in 2015.

Upcoming Congressional Hearings and Markups

House Committee on the Budget hearing titled "Center for Medicare and Medicaid Innovation: Scoring Assumptions & Real-World Implications;" 10:00 a.m., 210 Cannon Bldg.; September 7

House Committee on Veterans' Affairs hearing titled "From Tumult to Transformation: The Commission on Care and the Future of the VA Healthcare System;" 10:30 a.m., 334 Cannon Bldg.; September 7