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Health Policy Briefing

April 17, 2017

Federal Hiring Freeze to be Lifted

The White House announced last week that it will lift President Trump's federal hiring freeze. The announcement came as a part of guidance ordering federal departments and agencies to submit restructuring plans to the Office of Management and Budget (OMB). Agencies are directed to begin taking actions to reduce the size of their workforce over the long term, in accordance with the President's budget outline (which includes cuts to the National Institutes of Health (NIH). Agencies were instructed to develop a plan to maximize employee performance by June 30. President Trump had signed an executive order during his first full day in the White House that temporarily halted all non-military federal hiring. The decision had been widely criticized by many who believed that a blanket hiring freeze would impede the government from carrying out its core functions. The freeze's impact on the Food and Drug Administration (FDA) and its ability to implement the 21st Century Cures Act was of particular concern. Director of the OMB Mick Mulvaney stressed that the federal hiring freeze will be replaced with a strategic plan including more targeted limits for hiring. Mr. Mulvaney has not specified how many of the vacancies that exist in the federal government will be filled after the freeze is lifted. He explained that the Administration's plans for restructuring could involve the elimination or consolidation of offices or agencies. These changes would then be included in the President's fiscal year (FY) 2019 budget.

Freedom Caucus Seeks to Avoid Government Shutdown

Chairman of the House Freedom Caucus Mark Meadows (R-N.C.) has offered assurances that conservative Republicans will not act in a way that causes a shutdown of the federal government when the current continuing resolution (CR) expires on April 29. He says that he and his colleagues will be flexible in negotiating the $1 trillion spending bill that will keep the government funded through September 30. Last week, Administrator of the Centers for Medicare and Medicaid Services (CMS) Seema Verma confirmed that the defunding of Planned Parenthood would be dealt with in the Republican health care bill. This measure could have been a sticking point in the Senate were it to be included in omnibus spending legislation. The House is expected to vote on a funding measure soon after they return from a two-week recess on April 25. The federal government is funded through April 28, 2017.

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UFA Discussion Draft Released

Lawmakers have released a discussion **draft** of legislation to reauthorize user fee agreements (UFAs) for the Food and Drug Administration (FDA). The bill from the House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions (HELP) Committee is bipartisan, and would give the FDA authority to continue collecting user fees from pharmaceutical and medical device manufacturers. The prescription drug user fee amendments (PDUFA), medical device user fee amendments (MDUFA), generic drug user fee amendments (GDUFA), and biosimilar user fee amendments (BsUFA), last authorized in 2012, all must be updated and reauthorized by Congress before the current user fee agreements expire on September 30. PDUFA VI would support patient-focused drug development, biomarker development and qualification, the creation and review of rare disease treatments, guidance for combination products, and the modernization of clinical trials. MDUFA IV will also focus on the collection of real world safety and effectiveness evidence, and improving the de novo device review process. GDUFA II aims to improve support for small businesses, and would establish priority review timelines. BsUFA II will continue to build the agency's biosimilars program, and support guidance for product developers. If reauthorization does not occur before the August recess, the FDA will initiate procedures to notify more than 5,000 agency employees of possible lay offs. Both Republican and Democratic leadership on the authorizing committees have stressed the importance of completing their work prior to that point. User fees account for 70 percent of the brand drug review budget, 36 percent of the medical device review budget, 75 percent of the generic drug review budget, and 29 percent of the biosimilar review budget.

Bipartisan Opioid Legislation Introduced in Senate

Sens. Kirsten Gillibrand (D-N.Y.) and John McCain (R-Ariz.) introduced S.892, the Opioid Addiction Prevention Act a bill aimed at reducing opioid misuse and addiction. The legislation would limit opioid prescriptions for acute pain to seven days. The limit would not apply to treatments for cancer care, palliative care, hospice, or end-of-life care. The bill is modeled after legislation that has been passed in several states, including New York and Arizona. Medical professionals would be required to certify, as a part of their Drug Enforcement Agency (DEA) registration, that they will not prescribe an opioid as an initial treatment for acute pain in an amount that exceeds a seven-day supply, and may not provide a refill.

White House Appoints Drug Czar

Rep. Tom Marino (R-Pa.) will leave his position as a member of the House of Representatives to lead the Office of National Drug Control Policy. Rep. Marino has served in the House since 2011, and has been a member of the Judiciary Committee as well as the Energy and Commerce Committee, which has worked to combat the opioid epidemic.

Recently Introduced Health Legislation

S.892 (introduced by Sen. Kirsten E. Gillibrand): A bill to amend the Controlled Substances Act to establish additional registration requirements for prescribers of opioids, and for other purposes; Judiciary

S.898 (introduced by Sen. Amy Klobuchar): A bill to provide incentives to physicians to practice in rural and medically underserved communities, and for other purposes; Judiciary

S.Res.125 (introduced by Sen. Tom Udall): A resolution supporting the goals and ideals of National Public Health Week; Health, Education, Labor, and Pensions

S.Res.128 (introduced by Sen. Benjamin L. Cardin): A resolution designating April 2017 as "National Congenital Diaphragmatic Hernia Awareness Month"; Judiciary