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Health Policy Briefing

December 2, 2019

Congress Aims to Fund Government, Wrap Up Legislative Agenda by December 20

Congress currently has 15 working days to complete its work on key agenda items, including legislation to fund the federal government, address rising drug prices, and protect patients from surprise insurance gaps. While appropriators have reached an agreement on top-line spending figures for fiscal year (FY) 2020, Congress still needs to pass spending bills or another continuing resolution (CR) by December 20 to avoid a government shutdown. This effort could be complicated by the President's insistence upon retaining transfer authority to repurpose funding from other departments for the construction of a border wall. Lawmakers are currently scheduled to leave Washington by December 13, but are prepared to stay later into the month if necessary.

The White House continues to negotiate with Congress on drug pricing legislation and is hopeful that the Senate will pass the bipartisan Finance Committee's proposal by the end of the year. The administration is currently working to add a monthly out-of-pocket cap on drug costs for Medicare beneficiaries to the bill.

The House Ways and Means Committee is expected to soon release its own legislation to address the issue of surprise insurance gaps. Latest reports indicate that the bill will settle payment disputes between physicians and payers for out-of-network services by setting a benchmark rate at the mean, in-network rate. Those reports also suggest that instead of providing for an independent dispute resolution (IDR) process, the bill would create an appeals process for health care providers run by the U.S. Department of Health and Human Services (HHS). The panel is expected to mark up the bill during the first half of December. The House Energy and Commerce and Senate Health, Education, Labor, and Pensions (HELP) committees are still in discussions; it is unclear

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how the addition of a proposal from Ways and Means will impact this work. And, the House Education and Labor Committee may also want to weigh in on any changes, which may affect ERISA plans. Some lawmakers hope to use the end of the year spending package as a vehicle for surprise billing, as it would reduce federal spending, while others are pushing to ensure that, if it is included in any end-of-the-year package, the payment and dispute resolution process is appropriately balanced. In a November 27 op-ed in USA Today, White House Domestic Policy Council Director Joe Grogan urged Republicans to ignore pressure from interest groups and pass legislation to address surprise billing. He argues that if Congress is not successful in quickly moving a solution, Democrats will use the situation to garner more support for solutions which "throw in the towel on private markets altogether," like Medicare for All.

The Senate returns from Thanksgiving recess today; the House of Representatives will reconvene tomorrow.

House of Representatives CY 2020 Schedule

The House of Representatives has released its calendar for 2020. The Senate calendar is expected to be released soon.

Kamala Harris Releases Mental Health Reform Proposal

Democratic presidential candidate Sen. Kamala Harris (Calif.) has released her plan to expand access to mental health care. Her proposal would increase federal funding for mental health treatment research and provide for additional spending on research through the departments of Defense and Veterans Affairs on post-traumatic stress disorder (PTSD), military sexual trauma, and traumatic brain injury. The plan would establish a student loan forgiveness plan for mental health care professionals who choose to work in underserved areas of the country and increase reimbursement for mental health care providers. It would also double the number of treatment beds in the U.S., prioritizing states currently facing shortages, and repeal the Medicaid prohibition against federal funding for large mental health institutions. Sen. Harris has not specified how her plan would be paid for.

Lawmakers Ask IRS to Make Dietary Supplements HSA Eligible

A group of bipartisan lawmakers are asking the Internal Revenue Service (IRS) to allow certain categories of nutritional and dietary supplements to be considered medical expenses for the purposes of health savings accounts (HSAs), flexible spending accounts (FSAs), and health reimbursement arrangements (HRAs). The lawmakers suggest that products which are labeled with a health claim authorized by the Food and Drug Administration (FDA), bear statements describing how they are intended to affect the structure or function of the human body, or bear statements characterizing the mechanisms by which the product acts to maintain such structure or function could be allowed for purchase using HSA, FSA, and HRA funds. Currently, nutritional supplements are only eligible for reimbursement through an HSA, FSA, or HRA with a letter of medical necessity from a physician. The House letter was signed by Reps. Buddy Carter (R-Ga.), Glenn Grothman (R-Wis.), Barry Loudermilk (R-Ga.), Brian Mast (R-Fla.), Bill Posey (R-Fla.), Adrian Smith (R-Neb.), Christopher Smith (R-N.J.), and Mark Walker (R-N.C.). The Senate letter was signed by Sens. Tim Scott (R-S.C.), Kyrsten Sinema (D-Ariz.), Mike Braun (R-Ind.), Rand Paul (R-Ky.), John Boozman (R-Ark.), and Mike Lee (R-Utah).

FDA Takes Steps to Reduce Use of EtO in Device Sterilization

In a press release issued last week, the Food and Drug Administration (FDA) outlined new steps the agency is taking to advance innovation in ethylene oxide (EtO) medical device sterilization. The FDA has selected 11 applications for its two new innovation challenges, which aim to identify new sterilization methods and technologies that are alternatives to those that use EtO, and to identify strategies or technologies that can significantly reduce the amount of EtO used to sterilize devices. The FDA is also moving forward on recommendations stemming from a related public advisory committee meeting held last month, encouraging device manufacturers to begin, as soon as possible, to reduce the amount of paper that is included in a sterile device package, and to move to electronic materials where feasible and safe for device users. This will lessen the amount of EtO required for effective sterilization. In an effort to mitigate device shortages and expedite approvals of changes to EtO sterilization methods, processes, and facilities, the FDA will launch an EtO Sterilization Master File Pilot Program. Under this voluntary program, facilities that sterilize single-use devices using fixed chamber processes will submit a master file to the FDA when making changes to the location of the sterilization facilities or processes that utilize reduced EtO concentrations. This submission could then be used in support of subsequent premarket submissions. Manufacturers and sponsors of class III devices could also participate in the pilot program by referencing the master file submitted by their sterilization provider in a post approval report rather than a premarket approval (PMA) supplement.

CDC Schedules Vaping Lung Illness Update Webinar

The Centers for Disease Control and Prevention (CDC) will provide an update on the agency's response to e-cigarette and vaping product use associated lung injury (EVALI) during a webinar scheduled for December 4. More than 150 CDC and field staff members are currently working with the Food and Drug Administration (FDA), state health departments, and public health and clinical partners to investigate EVALI. The latest findings on the EVALI outbreak suggest that most cases are linked to products containing THC, particularly those products from informal sources like friends, family members, or illicit sellers. During the webinar, CDC will discuss the current status of the emergency and recommendations and resources for the public, health care providers, and health departments.

FDA Issues Warning Letters on CBD Marketing

The Food and Drug Administration has issued 15 warning letters to various companies that are marketing untested cannabidiol (CBD) products intended for children and infants. The agency has only approved one drug containing CBD and is still working to determine how to safely regulate the compound contained in marijuana. FDA Principal Deputy Commissioner Amy Abernethy recognized the knowledge gaps surrounding the science, safety, and quality of these products, stating that the agency will continue to monitor the marketplace, take action against companies as needed, and work together with stakeholders given the significant public interest in CBD.

DOJ, Generics Consider Deferred Prosecution Agreements

A group of generic pharmaceutical manufacturers, including Teva Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Ltd., are currently in discussions with the U.S. Justice Department (DOJ) about resolving a multi-year criminal antitrust probe of alleged price-fixing by the companies. Prosecutors have been investigating allegations that more than a dozen generic drug makers conspired to raise the prices of certain popular treatments for more than five years. The discussions are being held with the companies individually. While the timeline for the negotiations is unclear, one possible outcome could be deferred prosecution agreements, in which the companies would admit to certain allegations but be shielded from indictment, in exchange for cooperating with the investigation and paying fines. Deferred prosecution agreements would allow the companies to continue doing business with the Medicare and Medicaid programs.

CSIS Issues New Report on Global Health Security

The Center for Strategic and International Studies (CSIS) has issued a new report on global health security. The report was issued by the CSIS Commission on Strengthening America's Health Security, which included several members of Congress – Reps. Ami Bera (D-Calif.), Susan Brooks (R-Ind.), Tom Cole (R-Okla.), Anna Eshoo (D-Calif.), and Sens. Patty Murray (D-Wash.) and Todd Young (R-Ind.). The report urges policymakers to "replace the cycle of crisis and complacency that has long plagued health security preparedness with a doctrine of continuous prevention, protection, and resilience." The report makes seven recommendations to Congress and the administration: restore health security leadership at the White House National Security Council, commit to full and sustained multi-year funding for the Global Health Security Agenda, establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness, ensure rapid access to resources for health emergencies, establish a U.S. Global Health Crises Response Corps., strengthen the delivery of critical health services in disordered settings, and systematically confront the need for new vaccines and therapeutics and the public health communications crisis.

Upcoming Congressional Hearings and Markups

Senate Health, Education, Labor, and Pensions (HELP) Committee executive session to consider several nominations, including the nomination of Stephen Hahn, M.D. to be Commissioner of Food and Drugs, Department of Health and Human Services; 10:00 a.m., 430 Dirksen Bldg.; December 3

Senate Commerce, Science, and Transportation Committee hearing "Examining Legislative Proposals to Protect Consumer Data Privacy;" 10:00 a.m., 216 Hart Bldg.; December 4

House Energy and Commerce Subcommittee on Health hearing "Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety;" 10:00 a.m., 2322 Rayburn Bldg.; December 4

House Energy and Commerce Subcommittee on Oversight and Investigations hearing "Flu Season: U.S. Public Health Preparedness and Response;" 10:30 a.m., 2123 Rayburn Bldg.; December 4

House Oversight and Reform Subcommittee on Economic and Consumer Policy hearing "Broken Promises: Examining the Administration's Retreat on Banning Vaping Flavors;" 2:00 p.m., 2154 Rayburn Bldg.; December 4

Senate Armed Services Subcommittee on Personnel hearing to examine testimony about servicemember, family, and veteran suicides and prevention strategies; 2:30 p.m., 222 Russell Bldg.; December 4

House Armed Services Subcommittee on Military Personnel hearing "Military Health System Reform: A Cure for Efficiency and Readiness?" 2:00 p.m., 2118 Rayburn Bldg.; December 5

Recently Introduced Health Legislation

H.R.5254 — To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of digital retinal imaging with remote interpretation; Sponsor: Rep. Sewell, Terri A. [D-AL-7]; Committees: House - Energy and Commerce; Ways and Means

H.R.5257 — To direct the Federal Communications Commission to establish a program to be known as the "Expanding Telehealth Program"; Sponsor: Rep. Cox, TJ [D-CA-21]; Committees: House - Energy and Commerce

H.R.5262 — To amend title XVIII of the Social Security Act to protect beneficiaries with limb loss and other orthopedic conditions by providing access to appropriate, safe, effective, patient-centered orthotic and prosthetic care, to reduce fraud, waste, and abuse with respect to orthotics and prosthetics, and for other purposes; Sponsor: Rep. Thompson, Mike [D-CA-5]; Committees: House - Energy and Commerce; Ways and Means