



## Health Policy Briefing

September 9, 2019

### Lawmakers Consider CR, Appropriations Bills as End of FY Approaches

Congress must pass spending legislation to avoid a government shutdown by October 1, leaving lawmakers with just 16 working days to pass updated funding for fiscal year (FY) 2020 or agree upon a continuing resolution (CR). While the House has passed 10 of its annual spending bills, the Senate has not passed or even introduced any appropriations legislation due to the lengthy negotiations that preceded the two-year budget deal agreement struck in July. The Senate Appropriations Subcommittee on Labor-Health and Human Services-Education is scheduled to meet on September 10 to mark up its FY 2020 spending bill, which has not yet been released. The full Appropriations panel will begin voting on bills on September 12. The Committee will also vote on top-line spending numbers for the 12 individual spending bills this week.

In a Dear Colleague letter to House Democrats, House Majority Leader Steny Hoyer (D-Md.) outlined a plan to bring a clean CR up for a vote in the House the week of September 16. The bill is expected to fund the government through late November or early December. While lawmakers have generally acknowledged that some stopgap spending measure will be necessary, Senate appropriators are hopeful that they will be able to send at least one significant spending package to the President for his signature, limiting the portion of the federal government that will need to be funded by a CR. Appropriations Chairman Richard Shelby (R-Ala.) has proposed combining spending for defense; labor, health and human services, and education; and energy and water.

The Office of Management and Budget (OMB) sent lawmakers the White House's list of requested anomalies – changes to current spending levels – should Congress decide to use a stopgap spending measure to avoid a shutdown given the September 30 deadline for funding the federal government. No additional funds were requested for health care-related issues. The House and Senate return to Washington from August recess today.

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### ***House Democratic Drug Pricing Bill Expected by October***

House Speaker Nancy Pelosi (D-Calif.) will formally introduce the Democratic leadership's drug pricing proposal in late September or early October, according to recent reports. The bill is expected to be designated as H.R. 3, a gesture indicating that it is a major part of the House Democratic policy agenda. It will likely be marked up by both the Energy and Commerce and Ways and Means committees. The bill will allow the government to negotiate prices for products that account for a major portion of Medicare and Medicaid spending, and manufacturers that raise the prices of older drugs would face new penalties. The savings from such measures could be used to create an out-of-pocket cap for beneficiaries in Medicare Part D.

### ***FDA Under Pressure to Take Action Against Juul***

Chairman of the House Oversight and Reform Subcommittee on Economic and Consumer Policy Raja Krishnamoorthi (D-Ill.) has [written](#) to Acting Commissioner of Food and Drugs Ned Sharpless asking the Food and Drug Administration (FDA) to determine whether e-cigarette manufacturer Juul is violating current regulations by "making unapproved express and implied claims that its product helps users stop smoking cigarettes and is safer than cigarettes" and to "take all appropriate enforcement action." The letter cites testimony provided by the company during a two-day hearing before the panel in July implying that Juul's devices can help smokers quit. Juul supports the regulation of its products by the FDA as tobacco products, and not as smoking cessation devices, which must meet more rigorous regulatory standards. The FDA has stated that Juul's marketing practices are a part of the agency's broader, ongoing investigation into the company.

### ***OIG to Investigate Potential Payments by CMS to Chinese-Linked Companies***

In response to a request from Senate Finance Committee Chairman Chuck Grassley (R-Iowa), the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) will investigate whether the Centers for Medicare and Medicaid Services (CMS) has made payments to U.S. companies with ties to the Chinese government for genetic testing. Inspector General Joanne Chiedi plans to examine whether the agency has a risk-based approach in place to assess threats to national security when it certifies laboratories that conduct genetic testing.

### ***President Considers Short-list of FDA Candidates***

Dr. Stephen Hahn, MD is under consideration by President Trump for the position of Commissioner of Food and Drugs. Hahn, chief medical executive of the MD Anderson Cancer Center, met with the President last week. Current Acting Commissioner Ned Sharpless, MD, Director of the National Cancer Institute (NCI), was hand-picked by former Commissioner Scott Gottlieb upon his departure from the Food and Drug Administration (FDA). Vacancy appointment law requires Sharpless to step down from his position as acting commissioner by November 1 if he has not been formally nominated to serve in the role permanently. Sharpless has stated that he is among the finalists being considered for the top FDA job. It has been reported that Admiral Brett Giroir, MD, Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS), is also in the running for nomination.

## Upcoming Congressional Hearings and Markups

*House Energy and Commerce Subcommittee on Health hearing “Improving Maternal Health: Legislation to Advance Prevention Efforts and Access to Care;” 10:00 a.m., 2322 Rayburn Bldg.; September 10*

*House Veterans’ Affairs Committee Member Day hearing; 10:00 a.m., 215 Capitol Bldg.; September 10*

*Senate Appropriations Subcommittee on Departments of Labor, Health and Human Services, and Education, and Related Agencies business meeting to markup an original bill making appropriations for the Department of Labor, Department of Health and Human Services, Department of Education, and Related Agencies for the fiscal year ending September 30, 2020; 11:30 a.m., 124 Dirksen Bldg.; September 10*

*House Veterans’ Affairs Subcommittee on Health legislative hearing on H.R. 3636; H.R. 2972; H.R. 3036; H.R. 2798; H.R. 2645; H.R. 2681; H.R. 3224; H.R. 2982; H.R. 2752; H.R. 2628; H.R. 2816; H.R. 1527; H.R. 1527; H.R. 1163; H.R. 3798; H.R. 3867; H.R. 4096; Draft bill, to establish in the Department of Veterans Affairs the Office of Women’s Health, and for other purposes; 10:00 a.m., 210 Capitol Bldg.; September 11*

*House Financial Services Subcommittee on Capital Markets and Government Sponsored Enterprises hearing “Examining Private Market Exemptions as a Barrier to IPOs and Retail Investment;” 10:00 a.m., 2128 Rayburn Bldg.; September 11 [legislation to be considered includes the “[Rare Disease Fund Act](#)” which would establish the R&D Investment Fund to encourage the development of high-risk, high-return therapies for rare diseases]*

*House Small Business Committee hearing “Utilization Management: Barriers to Care and Burdens on Small Medical Practice;” a list of witnesses can be found [here](#); 11:30 a.m., 2360 Rayburn Bldg.; September 11*

*House Oversight and Reform Subcommittee on Civil Rights and Civil Liberties hearing titled “The Administration’s Apparent Revocation of Medical Deferred Action for Critically Ill Children;” 12:00 p.m., 2154 Rayburn Bldg.; September 11*

*Senate Appropriations Committee business meeting to markup an original bill making appropriations for the Department of Labor, Department of Health and Human Services, Department of Education, and Related Agencies for the fiscal year ending September 30, 2020, and 302(b) subcommittee allocations of budget outlays and new budget authority allocated to the committee in H.Con.Res.71, establishing the congressional budget for the United States Government for fiscal year 2018 and setting forth the appropriate budgetary levels for fiscal years 2019 through 2027; 10:30 a.m., 106 Dirksen Bldg.; September 12*

*Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights oversight hearing to examine enforcement of the antitrust laws; 2:30 p.m., 226 Dirksen Bldg.; September 17*