



Health Policy Briefing

December 23, 2019

Congress Adjourns for the Year with Passage of FY 2020 Funding

Congress successfully passed and the President signed legislation to fund the federal government until October 1, 2020, ahead of Friday’s deadline to avoid a government shutdown. The 12 fiscal year (FY) 2020 spending measures totaling \$1.4 trillion were combined into two minibus packages for passage. The legislation increases spending by \$49 billion across the entirety of the federal government.

The Labor, Health and Human Services, and Education; Agriculture; State and Foreign Operations; Military Construction and Veterans Affairs; Transportation and Housing and Urban Development; Energy and Water; Interior and Environment; and Legislative Branch package (H.R. 1865) contained \$534.4 billion in discretionary spending. The Labor-HHS-Education portion of the bill totaled \$184.9 billion in discretionary appropriations, an increase of \$4.9 billion above fiscal 2019.

The legislation included repeal of the Affordable Care Act’s (ACA) 40 percent “Cadillac tax” on high-cost health plans, 2.3 percent medical device excise tax, and the annual fee on health insurers – all of which have been repeatedly suspended. Repeal of the taxes is not offset in the bill; the Congressional Budget Office (CBO) estimates that these provisions will cost the federal government \$377 billion in lost revenue over the next decade. The minibus to fund non-defense agencies will also prevent the administration from ending automatic re-enrollment in ACA plans and health insurer silver loading.

H.R. 1865 includes the **Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act**, which aims to address a tactic allegedly used by pharmaceutical

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manufacturers to delay generic competition. The bill would allow generic companies to sue innovators for the alleged misuse of Risk Evaluation and Mitigation Strategies (REMS) to withhold product samples from the generic firms. CREATES would help pay for a five-month delay of Medicaid disproportionate share hospital (DSH) cuts and a short-term extension of several federal health programs through May 22. Lawmakers hope to use this deadline to revisit the issues of surprise billing, drug pricing, and lowering health care costs more broadly.

Extenders contained in the funding package include community health centers; National Health Service Corps; Teaching Health Center Graduate Medical Education Program; Special Diabetes Program and Special Diabetes Program for Indians; Work Geographic Price Cost Index; State Health Insurance Assistance Programs; Area Agencies on Aging; Aging and Disability Resource Centers; Certified Community Behavioral Health Clinic demonstration, Money Follows the Person demo, and Health Profession Opportunity Grants. The bill would extend Medicaid funding for U.S. territories for an additional two years. The Patient-Centered Outcomes Research Trust Fund would be extended for 10 years and is directed to prioritize research in the areas of maternal mortality and intellectual and developmental disabilities.

The Food and Drug Administration (FDA) would receive a total of \$5.87 billion in funding, an increase of \$196.3 million above current levels. The domestic spending bundle would prevent products that are scheduled to transition from the drug to biological pathway in 2020 from receiving any additional exclusivity. The spending deal also includes a provision to raise the legal age for purchasing tobacco and nicotine vaping products to 21; the Agriculture-FDA report language calls for an analysis within 60 days of enactment of next steps to address reports of lung illnesses associated with the use of e-cigarette and vaping products.

The bill also increases funding for the National Institutes of Health (NIH) by \$2.6 billion. The Centers for Disease Control and Prevention (CDC) and the NIH will each receive \$12.5 million to research gun violence and ways to prevent it. It is the first time in more than 20 years that Congress has appropriated funds to study deaths and injuries from guns.

The bill also appropriates funding for opioid treatment, prevention, and research, including \$1.5 billion for state opioid response grants, \$475.6 million for opioid overdose prevention and surveillance through the CDC, and \$89 million for medication-assisted treatment (MAT) programs.

The Substance Abuse and Mental Health Services Administration (SAMHSA) would receive \$19 million for the Suicide Prevention Lifeline, an increase of \$7 million over last year. An additional \$7 million increase is provided for the Zero Suicide Program, which provides tools, training, and outreach to health care systems to adopt effective suicide prevention strategies.

The Veterans Health Administration (VHA) would receive \$93.1 billion, including \$87.6 billion in advance funds for fiscal 2021. The bill provides \$8.91 billion in fiscal 2020 and \$11.31 billion in fiscal 2021 to implement the *VA MISSION Act* and \$1.5 billion, an increase of \$393 million, for the VA's new electronic health record (EHR) system. It also includes policy provisions to require the Department of Veterans Affairs (VA) to provide immediate assistance from trained professionals when veterans call the department's toll-free suicide hotline and will bar the use of funds for certain medical research involving canines, felines, or nonhuman primates.

The bill provides \$5.93 billion for HIV/AIDS programs at the State Department and would designate \$1.56 billion for the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

The eight-bill minibuss was passed by the House by a vote of 297-120 on Tuesday and by the Senate on Thursday by a vote of 71-23. Opposition came from lawmakers concerned about increasing the deficit. The bill was signed into law by the President on Friday.

The House of Representatives has adjourned for the year and will reconvene for the second session of the 116th Congress on January 7. The Senate will reconvene on January 3, but no roll call votes are scheduled until January 6.

Lawmakers Expand Surprise Billing Probe

House and Senate lawmakers are requesting more information from physician-staffing companies and insurers regarding their billing policies and practices as a part of an ongoing investigation into surprise insurance gaps. The [letters](#), which were sent to Envision Healthcare, TeamHealth, Anthem, Cigna, CVS Health, Health Care Service Corporation, Highmark, and UnitedHealth Group, were signed by House Energy and Commerce Committee leadership Frank Pallone (D-N.J.) and Greg Walden (R-Ore.), and Senate Health, Education, Labor, and Pensions (HELP) Committee leadership Lamar Alexander (R-Tenn.) and Patty Murray (D-Wash.). The lawmakers request details about “why surprise billing occurs, the policies and practices that help protect individuals from surprise billing, and the current incentives behind the negotiations between providers and insurers.” They request a response from the companies by January 9.

Individual Mandate Struck Down by Federal Appeals Court

A federal appeals court has struck down the ACA’s individual mandate while skirting the question of the law’s overall constitutionality in a 2-1 ruling. The decision narrows a previous ruling from Texas District Judge Reed O’Connor declaring the entire law invalid because Congress eliminated the financial penalty for not having health insurance. The 5th Circuit Court of Appeals *Texas v. Azar* decision keeps the 2010 health care law in effect for the time being, while remanding the case back to the federal judge in Texas to determine how much of the rest of the ACA, if any, is also unconstitutional. The appeals court directed O’Connor “to employ a finer-toothed comb on remand the conduct a more searching inquiry into which provisions of the ACA Congress intended to be inseverable from the individual mandate.”

USMCA Passed by House, to be Considered by Senate in 2020

The U.S. House of Representatives passed legislation to implement the U.S.-Mexico-Canada Agreement (USMCA) last week with strong bipartisan support by a vote of 385-41. Democratic lawmakers reached a deal with the President on the updated North American Free Trade Agreement (NAFTA) earlier this month after months of intense negotiations. The deal removes a provision that would have guaranteed 10 years of data protection for biologic drugs. The Senate Finance Committee is expected to take up the pact on January 7, and the full chamber is expected to pass the measure sometime next year after the conclusion of the President’s impeachment trial. The USMCA legislation cannot be amended and only requires a simple majority to pass.

Lawmakers Question CMS Administrator’s Use of PR Consultants

Democratic House and Senate committee leaders have [written](#) to HHS Secretary Alex Azar to reiterate a previous request for information regarding Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma’s use of taxpayer funds for private public relations consultants. The lawmakers first asked for documents relevant to the administrator’s awarding of such private contracts in March. They argue that “these contracts appear to be a highly problematic use of federal funds,” and “call into question the Trump administration’s commitment to transparency, ethics, and responsible stewardship of taxpayer dollars.” If the administration fails to provide the requested information and documents by January 9, the letter states that the lawmakers may use alternative methods to obtain the information about the awarding of these contracts. The letter was signed by House Energy and Commerce Chairman Frank Pallone (D-N.J.), House Oversight and Reform Chairwoman Carolyn B. Maloney (D-N.Y.), Senate Finance Ranking Member Ron Wyden (D-Ore.) and Senate Health, Education, Labor, and Pensions (HELP) Ranking Member Patty Murray (D-Wash.).

SOTU Address Scheduled for Feb. 4

House Speaker Nancy Pelosi (D-Calif.) has invited President Trump to deliver his annual State of the Union address on February 4. The White House stated that the President has accepted the invitation. Pelosi’s letter was sent two days after the House of Representatives voted to impeach the President. Senate Majority Leader Mitch McConnell (R-Ky.) and Senate Minority Leader Chuck Schumer (D-N.Y.) have not yet reached a deal on the parameters of a trial, and it remains unclear when the articles of impeachment will be sent to the Senate and whether the trial will have taken place by the February 4 date.

Grassley, Young Request Report on U.S. Organ Procurement

Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and committee member Todd Young (R-Ind.) have [written](#) to HHS Acting Inspector General Joanne Chiedi to request that she examine the adequacy of the organ procurement and transplantation system in the U.S. The lawmakers praise a recent executive order that would overhaul organ donations, but state that there is “no question that more can be done right now to improve a system that is mired by inefficiency, waste, and a serious lack of accountability.” CMS has proposed a regulation to improve the measures used to assess organ procurement organization (OPO) performance, while a proposed rule from HRSA would remove financial barriers to living organ donation. The senators ask for details about the extent of HHS oversight of OPOs and previous relevant information gathered by the Office of the Inspector General (OIG).

ONDCP Falls Short on SUPPORT Act Requirements

Auditors at the Government Accountability Office (GAO) have found that the Office of National Drug Control Policy (ONDCP) has failed to meet statutory requirements mandated by the *SUPPORT for Patients and Communities Act*, which was signed into law last year. Among other issues, the GAO found that ONDCP has not yet developed a proposal to expand treatment for substance use disorders or published an online, searchable dashboard with drug control information and data on quantities of drugs and frequency of use. According to the GAO, the agency has also failed to submit its annual national drug control strategy in 2017 and 2018, as required.

Women’s Caucus Pushes for Increased Investment in STD Prevention

The bipartisan Women’s Caucus is [requesting](#) information from HHS Secretary Alex Azar and CDC Director Robert Redfield about what the administration is doing to address record rates of chlamydia, gonorrhea, and syphilis. “It is imperative that the administration undertake initiatives and allocate resources to mitigate the STD epidemic,” the letter states. The government funding package approved last week included a small increase in funding for STD prevention at the CDC, but far less than the amount included in the House’s spending bill. The lawmakers request a briefing on the issue by March 1.

Dem Health Leaders Raise Concerns About Idaho’s Insurance Marketplace

Democratic health committee leadership have [written](#) to HHS Secretary Azar and CMS Administrator Seema Verma urging them to protect patients from the short-term health plans that Idaho’s state-based marketplace plans to make available to consumers. The lawmakers characterize such plans as “junk insurance” because they “can charge more, cover less, and can discriminate against patients with pre-existing conditions.” The letter was signed by House Energy and Commerce Chairman Frank Pallone (D-N.J.), Ways and Means Chairman Richard Neal (D-Mass.), Senate Health, Education, Labor, and Pensions (HELP) Ranking Member Patty Murray (D-Wash.), and Finance Ranking Member Ron Wyden (D-Ore.).

Mark Meadows Announces Plans to Retire

Four-term North Carolina Rep. Mark Meadows (R) announced that he will not be running for re-election and instead plans to retire from Congress. Meadows is a top ally of the President on Capitol Hill, and some have speculated that he could go on to join the Trump Administration. Meadows has definitively stated that he does not plan to make a bid for the Senate in 2022, when Sen. Richard Burr (R-N.C.) plans to retire. Meadows represents the 11th District of North Carolina, which is expected to remain in GOP control.

Recently Introduced Health Legislation

H.R.5429 — To amend title XIX of the Social Security Act to enable greater participation by seniors and Medicare beneficiaries in State Medicaid programs for working people with disabilities; Sponsor: Rep. Stivers, Steve [R-OH-15]; Committees: House - Energy and Commerce

H.R.5432 — To amend title XVIII of the Social Security Act to count toward the determination of full time equivalency for graduate medical education under the Medicare program time spent in an approved medical residency training program for training in culturally and linguistically appropriate care; Sponsor: Rep. Mucarsel-Powell, Debbie [D-FL-26]; Committees: House - Ways and Means; Energy and Commerce

H.R.5438 — To direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to award grants to develop programs to increase health care providers' awareness of Valley fever, and for other purposes; Sponsor: Rep. Cox, TJ [D-CA-21]; Committees: House - Energy and Commerce; Ways and Means

H.R.5440 — To require the Secretary of Veterans Affairs to provide financial assistance to eligible entities to provide and coordinate the provision of post-traumatic stress disorder prevention services for veterans through the award of grants to such entities, and for other purposes; Sponsor: Rep. Meadows, Mark [R-NC-11]; Committees: House - Veterans' Affairs

H.R.5442 — To amend title XXVII of the Public Health Service Act and title XVIII of the Social Security Act to require pharmacies to disclose any differential between the cost of a prescription drug based on whether certain individuals use prescription drug coverage to acquire such drug, and for other purposes; Sponsor: Rep. Porter, Katie [D-CA-45]; Committees: House - Energy and Commerce; Ways and Means

H.R.5443 — To amend title XIX of the Social Security Act to clarify that the provision of home and community-based services is not prohibited in an acute care hospital, and for other purposes; Sponsor: Rep. Scanlon, Mary Gay [D-PA-5]; Committees: House - Energy and Commerce

S.3057 — A bill to modernize the Older Americans Act of 1965, and for other purposes; Sponsor: Sen. Collins, Susan M. [R-ME]; Committees: Senate - Health, Education, Labor, and Pensions

S.3058 — A bill to amend the Higher Education Act of 1965 to establish fair and consistent eligibility requirements for graduate medical schools operating outside the United States and Canada; Sponsor: Sen. Durbin, Richard J. [D-IL]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.5444 — To amend the Biologics Price Competition and Innovation Act of 2009 to streamline the transition of certain products from approval as a drug to licensure as a biological product, and for other purposes; Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Energy and Commerce

H.R.5453 — To amend title XVIII of the Social Security Act to add physical therapists to the list of providers allowed to utilize locum tenens arrangements under Medicare; Sponsor: Rep. Lujan, Ben Ray [D-NM-3]; Committees: House - Energy and Commerce; Ways and Means

H.R.5469 — To address mental health issues for youth, particularly youth of color, and for other purposes; Sponsor: Rep. Watson Coleman, Bonnie [D-NJ-12]; Committees: House - Energy and Commerce

S.3067 — A bill to amend title XVIII of the Social Security Act to combat the opioid crisis by promoting access to non-opioid treatments in the hospital outpatient setting; Sponsor: Sen. Capito, Shelley Moore [R-WV]; Committees: Senate - Finance

S.3070 — A bill to modify reporting requirements under the Controlled Substances Act; Sponsor: Sen. Feinstein, Dianne [D-CA]; Committees: Senate – Judiciary

S.3074 — A bill to amend the Public Health Service Act to provide for and support liver illness visibility, education, and research, and for other purposes; Sponsor: Sen. Duckworth, Tammy [D-IL]; Committees: Senate - Health, Education, Labor, and Pensions

S.3078 — A bill to amend title XVIII of the Social Security Act to improve the efficiency of the Medicare appeals process, and for other purposes; Sponsor: Sen. Grassley, Chuck [R-IA]; Committees: Senate – Finance

H.R.5497 — To amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited conditional approval pathway, subject to specific obligations, for certain drugs, and for other purposes; Sponsor: Rep. Westerman, Bruce [R-AR-4]; Committees: House - Energy and Commerce

H.R.5501 — To amend the Public Health Service Act to establish an Office of Drug Manufacturing; Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce

H.R.5516 — To amend title 38, United States Code, to authorize the Secretary of Veterans Affairs to enter into contracts with States or to award grants to States to promote health and wellness, prevent suicide, and improve outreach to veterans, and for other purposes; Sponsor: Rep. Levin, Mike [D-CA-49]; Committees: House - Veterans' Affairs

H.R.5524 — To direct the Secretary of Veterans Affairs to conduct annual surveys of veterans on experiences with medical facilities of the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. Rice, Tom [R-SC-7]; Committees: House - Veterans' Affairs

H.R.5525 — To amend title 38 and title 5, United States Code, to require the Secretary of Veterans Affairs and other officials of the Department of Veterans Affairs to receive health care from the Department, and for other purposes; Sponsor: Rep. Rice, Tom [R-SC-7]; Committees: House - Veterans' Affairs

S.Res.462 — A resolution designating January 2020 as “National One Health Awareness Month” to promote awareness of organizations focused on public health, animal health, and environmental health collaboration throughout the United States and to recognize the critical contributions of those organizations to the future of the United States; Sponsor: Sen. Feinstein, Dianne [D-CA]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Voice Vote.

S.3112 — A bill to amend the Internal Revenue Code of 1986 to expand and improve health savings accounts, and for other purposes; Sponsor: Sen. Cruz, Ted [R-TX]; Committees: Senate – Finance

S.3116 — A bill to enable States to better provide access to whole genome sequencing clinical services for certain undiagnosed children under the Medicaid program, and for other purposes; Sponsor: Sen. Collins, Susan M. [R-ME]; Committees: Senate – Finance

S.3122 — A bill to amend title 38, United States Code, to require the Secretary of Veterans Affairs to submit to Congress an annual report on suicide among veterans, and for other purposes; Sponsor: Sen. McSally, Martha [R-AZ]; Committees: Senate - Veterans' Affairs

S.3125 — A bill to amend the Internal Revenue Code of 1986 to allow for contributions to the Alzheimer's Research and Caregiving Trust Fund, and for other purposes; Sponsor: Sen. Blumenthal, Richard [D-CT]; Committees: Senate – Finance

S.3126 — A bill to amend the Public Health Service Act to authorize a special behavioral health program for Indians; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Indian Affairs

S.3129 — A bill to provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, and for other purposes; Sponsor: Sen. Crapo, Mike [R-ID]; Committees: Senate – Finance

S.3133 — A bill to amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited conditional approval pathway, subject to specific obligations, for certain drugs, and for other purposes; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.3137 — A bill to amend titles XIX and XXI of the Social Security Act to require hospitals and certain other participating providers under Medicaid or the Children’s Health Insurance Program to disclose the provider’s policy on parental access to the medical records of minors, and for other purposes; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate – Finance

S.3138 — A bill to amend titles XIX and XXI of the Social Security Act to require hospitals and certain other participating providers under Medicaid or the Children’s Health Insurance Program to disclose the provider’s policy on parental consent from the provision, withdrawal, or denial of life-sustaining treatment for minors, and for other purposes; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate – Finance

S.3147 — A bill to require the Secretary of Veterans Affairs to submit to Congress reports on patient safety and quality of care at medical centers of the Department of Veterans Affairs, and for other purposes; Sponsor: Sen. Manchin, Joe, III [D-WV]; Introduced in the Senate, read twice, considered, read the third time, and passed without amendment by Unanimous Consent.

S.3148 — A bill to amend the Controlled Substances Act to list fentanyl-related substances as schedule I controlled substances; Sponsor: Sen. Johnson, Ron [R-WI]; Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.