



Health Policy Briefing

February 11, 2019

State of Government Funding Negotiations Remain Unclear

Reports from late last week indicated that the lawmakers tasked with negotiating a government funding and border security deal were close to reaching a bipartisan agreement that would include less than \$2 billion for physical barriers along the southern border. While this is far short of the \$5.7 billion that President Trump has requested for a border wall, the White House was reportedly preparing to accept the deal. Over the weekend, however, Senate Appropriations Committee Chairman Richard Shelby (R-Ala.) stated that congressional talks are stalled. Negotiators had set a goal of completing a deal by Monday. Formal filing of legislation is still possible today, according to a Democratic aide. Because of the House’s 72-hour rule, which requires that a bill be released three days before a floor vote, this is the latest point at which the bill could be finalized without necessitating a short-term continuing resolution (CR) when government funding expires on Feb. 15. While an agreement between Congress and the White House would avert a new partial government shutdown, it is unclear whether the President would still use executive action to secure additional wall funding and circumvent the approval of Congress. Such a decision could trigger court challenges or votes of congressional disapproval.

President Trump Delivers Third SOTU Address

President Trump outlined several of his health care priorities for the coming year in his State of the Union address last week. The President discussed childhood cancer, stating that there have been no new therapies developed in decades. His forthcoming budget request will include \$500 million over the next decade for childhood cancer research. The President did not specify whether the White House budget would be adding to what the National Cancer Institute (NCI) already spends on pediatric cancer research.

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Congressional Democrats have criticized this figure as inadequate, given the NCI's \$6 billion annual budget.

The President also announced his plan to reduce new HIV infections by 75 percent over the next five years and 90 percent over the next 10 years, with the goal of ending new HIV transmissions by 2030. The U.S. Department of Health and Human Services (HHS) would increase investments through programs like the Ryan White HIV/AIDS Program in the 48 counties in the nation that are considered geographic HIV-transmission hotspots, use data to identify where HIV is spreading most rapidly, and launch a new HIV HealthForce and program through community health centers to target high-risk populations. The President did not offer any details as to how the plan would be paid for.

During his speech, President Trump also emphasized his support for protections for individuals with pre-existing conditions and celebrated the success of his administration's drug pricing strategy. He asked Congress to pass bipartisan legislation that addresses "global freeloading" and delivers real price transparency for Americans. The White House released additional detail including his commitment to take action to increase price transparency to prevent surprise billing.

Senators Request Data to Inform Surprise Billing Legislation

A bipartisan group of senators are [asking](#) insurance companies and medical providers for information about billing and payment procedures. The lawmakers plan to use the data as they draft legislation to protect patients from surprise medical bills, while preventing disruption in the health care system. They request responses by Feb. 18. The letter was signed by Sens. Bill Cassidy (R-La.), Michael Bennet (D-Colo.), Todd Young (R-Ind.), Tom Carper (D-Del.), Lisa Murkowski (R-Alaska), and Maggie Hassan (D-N.H.).

Grassley Reintroduces Bipartisan CREATES, ACE Kids Legislation

Sens. Chuck Grassley (R-Iowa) and Patrick Leahy (D-Vt.) have reintroduced the CREATES Act, a bill that aims to speed the entry of generic drugs to the market. CREATES currently has 28 co-signers in the Senate. The ACE Kids Act was also reintroduced last week, by Grassley and Sen. Michael Bennet (D-Colo.). The legislation would improve care coordination and health outcomes for children with complex medical conditions in the Medicaid program.

Senators Urge CMS to Strengthen MA Program

A bipartisan group of over 60 senators have [written](#) to the Centers for Medicare and Medicaid Services (CMS) to urge the administration to strengthen and stabilize the Medicare Advantage (MA) program. For plan year 2020, the lawmakers encourage CMS to "implement policies that promote innovation, provide predictable funding to support long-term, value-based arrangements, and ensure that any substantive changes include sufficient time for thorough evaluation and stakeholder engagement." The letter was led by Sens. Cory Gardner (R-Colo.), Catherine Cortez Masto (D-Nev.) and Mike Crapo (R-Idaho).

Pallone, Wyden Request Clarification on 1332 Guidance

House Energy and Commerce Committee Chairman Frank Pallone (D-N.J.) and Senate Finance Committee Ranking Member Ron Wyden (D-Ore.) have [written](#) to the Government Accountability Office (GAO) questioning whether the administration's 2018 guidance on 1332 State Innovation Waivers is subject to the Congressional Review Act (CRA). State Innovation Waivers allow states to waive some of the Affordable Care Act's (ACA) requirements in order to test innovative strategies for providing health insurance coverage to their residents. The 2018 guidance expands the scope of such waivers and loosens the standards states must meet to receive waiver approval from CMS. The lawmakers argue that the guidance is a rule, as defined by the Administrative Procedure Act (APA), because it is applicable to all states, it is designed to interpret and implement existing law, and it establishes substantial new policies and revises CMS' interpretation of the law.

Pharma Companies to Appear Before Senate Finance

All seven pharmaceutical companies invited by Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and Ranking Member Ron Wyden (D-Ore.) will testify before the panel in a Feb. 26 hearing, the second Finance Committee hearing in a series on drug pricing. Lawmakers will hear from AbbVie, AstraZeneca, Johnson & Johnson, Bristol-Myers Squibb, Pfizer, Sanofi, and Merck. House Oversight and Reform Committee Chairman Elijah Cummings (D-Md.) also plans to invite manufacturers to testify before his panel, but a date has not been set and the specific companies to be invited have not been named.

Brown, Doggett, Introduce Medicare Negotiation Legislation

Sens. Sherrod Brown (D-Ohio) and Tammy Baldwin (D-Wis.), alongside Rep. Lloyd Doggett (D-Texas), have introduced legislation that would allow Medicare to negotiate prescription drug prices and to license generic versions of products when a pricing agreement cannot be reached. Doggett, Chairman of the House Ways and Means Health Subcommittee, plans to bring the measure before his panel in March.

House Dems Introduce Bill to Block Expansion of Short-Term Plans

Reps. Lauren Underwood (D-Ill.) and Mark DeSaulnier (D-Calif.) have introduced legislation that would block the Trump administration's recent rule to expand short-term, limited-duration health plans that are cheaper than traditional insurance but are not required to comply with the ACA's consumer protections, such as coverage of pre-existing conditions. Under the recent Trump administration rule, insurers are allowed to sell the plans for up to one year at a time and renew the plans for another three years. The availability of such plans was previously limited to three months. Democrats characterize the plans as "junk" insurance and have raised concerns that expansion of short-term insurance plans will raise costs for individuals who remain in the ACA marketplace. While the measure could garner enough support to pass the House, it is unlikely to be taken up in the Republican-controlled Senate.

Grassley Releases OIG Report on Research Integrity

Senate Finance Committee Chairman Chuck Grassley (R-Iowa) has released a [report](#) from the HHS Office of the Inspector General (OIG) finding that at least a dozen scientists funded by the National Institutes of Health (NIH) have been flagged by the agency due to concerns about foreign government influence on their medical research. The researchers were referred for investigation due to allegations of a failure to disclose foreign government affiliations. The report was issued in response to a request from Grassley, who has stated his intent to continue to scrutinize foreign threats to taxpayer-funded research and the security of intellectual property. According to Grassley, the OIG is currently assessing the NIH's vetting and oversight processes related to research integrity.

WH Budget Request Expected March 11

The President is expected to send a top-line budget request for fiscal year (FY) 2020 to lawmakers the week of March 11, with more detailed information coming the following week. The White House budget proposal was technically due last week but was delayed due to the 35-day partial government shutdown.

Longest Serving Member of Congress, John Dingell, Dies

Michigan Democrat John Dingell Jr., the longest-serving congressman in U.S. history, died last week. He was 92. Dingell served in the Army during World War II. He won a special election to succeed his father in Congress in 1955. Dingell remained in the House until January 2015, when he was succeeded by his wife, Debbie Dingell. During his time in Congress, he served as the chairman of the Energy and Commerce Committee twice. He also presided over the House floor proceedings that led to the both the creation of Medicare and, 40 years later, the ACA.

HHS Personnel Updates

HHS announced several new appointments and departures from the department last week. **Amanda Anger**, professional staff member of the Committee on House Administration, has been appointed to serve as Director of Congressional Relations in the Office of the Assistant Secretary for Financial Resources. **Bryan Shuy** has been appointed to serve as Deputy Assistant Secretary and Chief of Staff for the Assistant Secretary for Preparedness and Response. He previously served in the Office of Congressman Andy Harris (R-Md.) and has also held roles at the American Academy of Child and Adolescent Psychiatry and the American Society of Anesthesiologists. **Scott Blakeman** has been appointed Assistant Speechwriter in the Office of the Assistant Secretary for Public Affairs. He formerly worked as a communications strategist in the House Natural Resources Committee. **Cheryl Vincent** will serve as Director of Legislative Affairs at the Administration of Children and Families. She previously served as professional staff in the House Committee on Ways and Means. **Courtney Bradway** has been appointed to serve as Director of the Office of Congressional Liaison in the Office of the Assistant Secretary for Legislation. She joins HHS from the office of Senator Bob Corker (R-Tenn.). **Jordan Cox** has been appointed to serve as an advisor in the Office of the Assistant Secretary for Legislation. Cox previously served as a legislative assistant for Congresswoman Vicky Hartzler (R-Mo.). **Nicholas Uehlecke** has been appointed to serve as an advisor in the Office of the Secretary. He comes to HHS from the House Committee on Ways and Means.

HHS also announced the departures of Renee Ellmers, Regional Director – Region IV, Emily Felder, Director of the HCMS Office of Legislation, and Stephen Waskiewicz, Deputy Assistant Secretary for Congressional Relations in the Office of the Assistant Secretary for Financial Resources.

Upcoming Congressional Hearings and Meetings

Senate Health, Education, Labor, and Pensions (HELP) Committee hearing “Managing Pain During the Opioid Crisis;” 10:00 a.m., 430 Dirksen Bldg.; February 12

House Ways and Means Committee hearing “The Cost of Rising Prescription Drug Prices;” 10:00 a.m., 1100 Longworth Bldg.; February 12

House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies hearing “Food and Drug Administration – Status of Operations;” 10:00 a.m., 2358-A Rayburn Bldg.; February 12

House Energy and Commerce Health Subcommittee hearing “Strengthening Our Health Care System: Legislation to Reverse ACA Sabotage and Ensure Pre-Existing Conditions Protections;” the committee will discuss H.R. 986, the “Protecting Americans with Preexisting Conditions Act of 2019;” H.R. 987, the “Marketing and Outreach Restoration to Empower Health Education Act of 2019;” and H.R. 1010, To provide that the rule entitled “Short-Term, Limited Duration Insurance” shall have no force or effect; 10:30 a.m., 2322 Rayburn Bldg.; February 13

House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies hearing “Long Term Healthcare Challenges and Long Term Care;” 2:00 p.m., HT-2 Capitol Bldg.; February 13

Senate Appropriations Subcommittee on Labor, HHS, and Education, and Related Agencies hearing to examine the Ebola outbreak in the Democratic Republic of the Congo and other emerging health threats; 10:00 a.m., 124 Dirksen Bldg.; February 14

Senate Finance Committee hearing on drug pricing, featuring the testimony of seven major pharmaceutical companies; time and place TBD; February 26

Recently Introduced Health Legislation

H.Res.95 — Expressing support for designation of February 4, 2019, as National Cancer Prevention Day; Sponsor: Rep. Dingell, Debbie [D-MI-12]; Committees: House - Energy and Commerce

H.R.955 — To improve the reproductive assistance provided by the Department of Defense and the Department of Veterans Affairs to severely wounded, ill, or injured members of the Armed Forces, veterans, and their spouses or partners, and for other purposes; Sponsor: Rep. Larsen, Rick [D-WA-2]; Committees: House - Veterans' Affairs, Armed Services

S.317 — A bill to amend title XIX of the Social Security Act to provide States with the option of providing coordinated care for children with complex medical conditions through a health home; Sponsor: Sen. Grassley, Chuck [R-IA]; Committees: Senate - Finance

S.318 — A bill to authorize the Secretary of Veterans Affairs to furnish medically necessary transportation for newborn children of certain women veterans; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Veterans' Affairs

S.319 — A bill to improve the reproductive assistance provided by the Department of Defense and the Department of Veterans Affairs to severely wounded, ill, or injured members of the Armed Forces, veterans, and their spouses or partners, and for other purposes; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Veterans' Affairs

S.340 — A bill to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products; Sponsor: Sen. Leahy, Patrick J. [D-VT]; Placed on Senate Legislative Calendar under Read the First Time.

H.R.962 — To amend title 18, United States Code, to prohibit a health care practitioner from failing to exercise the proper degree of care in the case of a child who survives an abortion or attempted abortion; Sponsor: Rep. Wagner, Ann [R-MO-2]; Committees: House - Judiciary

H.R.965 — To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products; Sponsor: Rep. Cicilline, David N. [D-RI-1]; Committees: House - Energy and Commerce, Judiciary

H.R.973 — To amend the Public Health Service Act to provide for additional programs funded by grants to strengthen the healthcare system's response to domestic violence, dating violence, sexual assault, and stalking, and for other purposes; Sponsor: Rep. Dingell, Debbie [D-MI-12]; Committees: House - Energy and Commerce

H.R.985 — To amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible product developers have competitive access to approved drugs and licensed biological products, so as to enable eligible product developers to develop and test new products, and for other purposes; Sponsor: Rep. Welch, Peter [D-VT-At Large]; Committees: House - Energy and Commerce

H.J.Res.43 — Providing for congressional disapproval under chapter 8 of title 5, United States Code, of the final rule of the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services relating to "Short-Term, Limited-Duration Insurance"; Sponsor: Rep. Castor, Kathy [D-FL-14]; Committees: House - Energy and Commerce, Education and Labor, Ways and Means

H.R.986 — To provide that certain guidance related to waivers for State innovation under the Patient Protection and Affordable Care Act shall have no force or effect; Sponsor: Rep. Kuster, Ann M. [D-NH-2]; Committees: House - Energy and Commerce, Ways and Means

H.R.987 — To amend the Patient Protection and Affordable Care Act to provide for Federal Exchange outreach and educational activities; Sponsor: Rep. Blunt Rochester, Lisa [D-DE-At Large]; Committees: House - Energy and Commerce, Budget

H.R.990 — To amend the Federal Food, Drug, and Cosmetic Act and the Securities Exchange Act of 1934 to prevent the inter partes review process for challenging patents from diminishing competition in the pharmaceutical industry and with respect to drug innovation, and for other purposes; Sponsor: Rep. Flores, Bill [R-TX-17]; Committees: House - Energy and Commerce, Financial Services

H.R.996 — To amend the Internal Revenue Code of 1986 to exclude from gross income certain federally-subsidized loan repayments for dental school faculty; Sponsor: Rep. Clarke, Yvette D. [D-NY-9]; Committees: House - Ways and Means, Energy and Commerce

H.R.1005 — To direct the Secretary of Veterans Affairs to amend the schedule for rating disabilities to add a diagnostic code and evaluation criteria for obliterative bronchiolitis, and for other purposes; Sponsor: Rep. Castro, Joaquin [D-TX-20]; Committees: House - Veterans' Affairs

H.R.1010 — To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect; Sponsor: Rep. Castor, Kathy [D-FL-14]; Committees: House - Energy and Commerce, Education and Labor, Ways and Means

S.344 — A bill to amend the Federal Food, Drug, and Cosmetic Act and the Securities Exchange Act of 1934 to prevent the inter partes review process for challenging patents from diminishing competition in the pharmaceutical industry and with respect to drug innovation, and for other purposes; Sponsor: Sen. Tillis, Thom [R-NC]; Committees: Senate - Health, Education, Labor, and Pensions

S.348 — A bill to amend title XVIII of the Social Security Act to provide for the distribution of additional residency positions, and for other purposes; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Finance

S.350 — A bill to restore the application of the Federal antitrust laws to the business of health insurance to protect competition and consumers; Sponsor: Sen. Daines, Steve [R-MT]; Committees: Senate - Judiciary

S.359 — A bill to amend the Internal Revenue Code of 1986 to exclude from gross income certain Federally-subsidized loan repayments for dental school faculty; Sponsor: Sen. Cardin, Benjamin L. [D-MD]; Committees: Senate - Finance

S.366 — A bill to shorten monopoly periods for prescription drugs that are the subjects of sudden price hikes; Sponsor: Sen. Durbin, Richard J. [D-IL]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.111 — Supporting the goals and ideals of National Black HIV/AIDS Awareness Day; Sponsor: Rep. Lee, Barbara [D-CA-13]; Committees: House - Energy and Commerce

H.R.1034 — To amend title XVIII of the Social Security Act to require pharmacy-negotiated price concessions to be included in negotiated prices at the point-of-sale under part D of the Medicare program, and for other purposes; Sponsor: Rep. Collins, Doug [R-GA-9]; Committees: House - Energy and Commerce, Ways and Means

H.R.1035 — To amend title XVIII of the Social Security Act to provide for pharmacy benefits manager standards under the Medicare prescription drug program and Medicare Advantage program to further transparency of payment methodologies to pharmacies, and for other purposes; Sponsor: Rep. Collins, Doug [R-GA-9]; Committees: House - Energy and Commerce, Ways and Means, Oversight and Reform

H.R.1041 — To amend title XVIII of the Social Security Act to remove the 96-hour physician certification requirement for inpatient critical access hospital services; Sponsor: Rep. Smith, Adrian [R-NE-3]; Committees: House - Ways and Means

H.R.1046 — To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of prescription drugs furnished under part D of the Medicare program; Sponsor: Rep. Doggett, Lloyd [D-TX-35]; Committees: House - Energy and Commerce, Ways and Means

H.R.1052 — To amend title XVIII of the Social Security Act to provide for direct payment to physician assistants under the Medicare program for certain services furnished by such physician assistants; Sponsor: Rep. Sewell, Terri A. [D-AL-7]; Committees: House - Energy and Commerce, Ways and Means

H.R.1058 — To reauthorize certain provisions of the Public Health Service Act relating to autism, and for other purposes; Sponsor: Rep. Smith, Christopher H. [R-NJ-4]; Committees: House - Energy and Commerce

H.R.1082 — To plan, develop, and make recommendations to increase access to sexual assault examinations for survivors by holding hospitals accountable and supporting the providers that serve them; Sponsor: Rep. Jayapal, Pramila [D-WA-7]; Committees: House - Energy and Commerce, Ways and Means, Education and Labor

H.R.1092 — To amend title 38, United States Code, to expand health care and benefits from the Department of Veterans Affairs for military sexual trauma, and for other purposes; Sponsor: Rep. Pingree, Chellie [D-ME-1]; Committees: House - Veterans' Affairs, Armed Services

H.R.1093 — To amend the Internal Revenue Code of 1986 to establish an excise tax on certain prescription drugs which have been subject to a price spike, and for other purposes; Sponsor: Rep. Pocan, Mark [D-WI-2]; Committees: House - Energy and Commerce, Ways and Means

H.R.1098 — To gather information about the illicit production of illicit fentanyl in foreign countries and to withhold bilateral assistance from countries that do not have emergency scheduling procedures for new illicit drugs, cannot prosecute criminals for the manufacture or distribution of controlled substance analogues, or do not require the registration of tableting machines and encapsulating machines; Sponsor: Rep. Sensenbrenner, F. James, Jr. [R-WI-5]; Committees: House - Foreign Affairs

S.374 — A bill to amend title 38, United States Code, to expand health care and benefits from the Department of Veterans Affairs for military sexual trauma, and for other purposes; Sponsor: Sen. Tester, Jon [D-MT]; Committees: Senate - Veterans' Affairs

S.377 — A bill to amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of prescription drugs furnished under part D of the Medicare program; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Finance

S.378 — A bill to amend the Internal Revenue Code of 1986 to establish an excise tax on certain prescription drugs which have been subject to a price spike, and for other purposes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Finance

S.400 — A bill to gather information about the illicit production of illicit fentanyl in foreign countries and to withhold bilateral assistance from countries that do not have emergency scheduling procedures for new illicit drugs, cannot prosecute criminals for the manufacture or distribution of controlled substance analogues, or do not require the registration of tableting machine and encapsulating machines; Sponsor: Sen. Toomey, Pat [R-PA]; Committees: Senate - Foreign Relations

S.402 — A bill to plan, develop, and make recommendations to increase access to sexual assault examinations for survivors by holding hospitals accountable and supporting the providers that serve them; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions

S.417 — A bill to direct the Secretary of Health and Human Services to amend the mission statement of the Food and Drug Administration; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.418 — A bill to establish procedures regarding the approval of opioid drugs by the Food and Drug Administration; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.419 — A bill to require the Food and Drug Administration to revoke the approval of one opioid pain medication for each new opioid pain medication approved; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.425 — A bill to amend the Internal Revenue Code of 1986 to establish a stewardship fee on the production and importation of opioid pain relievers, and for other purposes; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Finance

S.427 — A bill to amend the Public Health Service Act to enhance activities of the National Institutes of Health with respect to research on autism spectrum disorder and enhance programs relating to autism, and for other purposes; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions