



Health Policy Briefing

December 16, 2019

Surprise Billing Legislation May Be Pushed to 2020

Despite a deal being reached on bipartisan, bicameral legislation, Congress may delay consideration of a measure to protect patients from surprise medical bills until 2020. The House Energy and Commerce Committee (E&C) and the Senate Health, Education, Labor, and Pensions (HELP) Committee recently announced that an agreement had been reached to resolve out-of-network billing disputes between providers and insurance companies. The agreement was the culmination of months of negotiations. It would automatically pay for out-of-network care at the median price of in-network providers in the geographic area. The measure would also lower the threshold for doctors to dispute payments from insurers from \$1,250, as outlined in Energy and Commerce’s original bill, to \$750. The original Senate HELP legislation had not included an independent dispute resolution (IDR) process. The latest bill includes provisions to raise the tobacco purchasing age to 21 and extend funding for federal health programs like community health centers. Despite an endorsement from the White House, however, the *No Surprises Act* is not expected to pass this year. Sponsors of the bill had been pushing for its inclusion in a year-end government funding package expected to pass by the December 20 deadline. A rival proposal released by the House Ways and Means Committee on Wednesday is being cited for the delay.

Leadership of the House Ways and Means Committee support delaying the issue of surprise insurance gaps until next year, following the release of a one-page [outline](#) of the panel’s own surprise billing fix. Their proposal would set patient cost-sharing for out-of-network bills at the in-network rate for a geographic area. It would allow providers and payers to address billing disputes themselves, but would provide for an outside mediation process if the two parties cannot reach an agreement. The losing party would be responsible

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for paying a reconciliation process fee. The solution also preserves existing state laws on surprise billing and would set timely billing requirements. It remains unknown when the bill text will be released or when the committee will mark up the legislation.

Members of the House Education and Labor Committee have indicated that they want more time to vet the bicameral surprising billing agreement as well; their panel is also considering introducing its own surprise billing policy for consideration.

In related news, Senate Commerce Committee Chair Roger Wicker (R-Miss.) has expressed opposition to the air ambulance policy contained in the HELP/E&C surprise billing deal, arguing that it could result in shortages in air ambulance bases, limiting patient access to care and reducing the number of providers in rural areas. Wicker's panel has jurisdiction over the Federal Aviation Administration, and the Chairman is trying to increase support for amending or removing provisions related to air ambulances and surprise medical bills. The current compromise reached by the E&C and HELP committees would set out-of-network air ambulance bills at the median in-network rate for a geographic area, and the threshold for triggering IDR would be set at \$25,000. Wicker supports the exclusive use of IDR to settle air ambulance surprise bills while more data is collected on air ambulance payment rates.

Senate Passes OTC Reform, VA Suicide Legislation

The Senate has passed legislation that would make changes to the way in which the Food and Drug Administration (FDA) regulates over-the-counter (OTC) drugs. The ***Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019*** (S. 2740) passed by a vote of 91-2. The bill would speed the process by which the agency reviews such products, and would create a user fee program to support the regulatory improvements. The bill will now be sent to the House, which already passed similar legislation earlier this year.

The Senate also passed the ***Support for Suicide Prevention Coordinators Act*** (H.R. 2333) by a vote of 95-0 last week. The bill would require the Government Accountability Office (GAO) to study and report on the Department of Veterans Affairs' support for suicide prevention coordinators. Recent accounts have suggested that coordinators are overworked and unable to complete their responsibilities. The legislation passed the House of Representatives earlier this year, and will now be sent to the President's desk for his signature.

Hahn Confirmed by Senate to Lead FDA

The Senate confirmed the President's nominee for Commissioner of Food and Drugs, Dr. Stephen Hahn, by a vote of 72-18 last week. During the confirmation process, the Texas oncologist and MD Anderson executive faced scrutiny over how he plans to address the youth vaping epidemic. Senate HELP Committee Ranking Member Patty Murray (Wash.), Minority Leader Chuck Schumer (N.Y.), and Finance Committee Ranking Member Ron Wyden (Ore.) were among the Democrats who voted against the nomination.

House Passes Pelosi's Lower Drug Costs Now Act

The House of Representatives passed Speaker Nancy Pelosi's ***Lower Drug Costs Now Act*** (H.R. 3) last week. The bill passed along a largely party-line vote of 230-192. Republicans Brian Fitzpatrick (Pa.) and Jaime Herrera Beutler (Wash.) voted in support of the bill, and no Democrats voted against it. The legislation aims to reduce the cost of prescription drugs by allowing the Secretary of the U.S. Department of Health and Human Services (HHS) to negotiate the price of certain treatments and capping annual out-of-pocket costs for Medicare beneficiaries at \$2,000. The Secretary would be required to negotiate lower prices for a minimum of 50 drugs per year, up to a maximum of 250 drugs, capping a drug's price at 120 percent of their cost in certain other wealthy nations. Progressive Democrats reached a deal with the Speaker's office to increase the minimum number of drugs to be subject to negotiation from 35 to 50 shortly before passage of the bill. Lower prices would apply to both the Medicare program and private insurance. If a manufacturer refuses to negotiate, the company would be penalized with a tax up to 95 percent of their drug's revenue. Republicans argue that such a steep penalty would effectively result in a government mandated price.

The Congressional Budget Office (CBO) estimates that the legislation would lower the prices of drugs subject to negotiation by 50 percent and save \$456 billion over the next decade. Savings would be used to expand the Medicare benefit to include hearing, dental, and vision care. CBO expects the bill to raise wages for people with employer-sponsored health insurance by \$116 billion over the same time period. CBO also predicts, however, that the bill would result in the development of eight fewer drugs over the next 10 years because manufacturers would cut back on research and development due to reductions in revenues as a result of the bill. CBO estimates that approximately 30 fewer drugs would be introduced over the subsequent decade.

The White House has issued a veto threat for H.R. 3, arguing that the bill would impose price controls on the industry and ultimately harm individuals in need of innovative new treatments. The administration is instead urging Congress to take up the bipartisan drug pricing legislation advanced out of the Senate Finance Committee. The ***Prescription Drug Pricing Reduction Act*** (S. 2543) would lower Medicare enrollee's out-of-pocket expenses in the initial phase of a prescription drug plan from 25 percent to 20 percent and would allow beneficiaries the option to more evenly divide what they pay each month for their medications, capping out-of-pocket costs at \$3,100 per year. It would also require drug companies to pay rebates to Medicare if they raise the price of their product more than inflation. Majority Leader Mitch McConnell (R-Ky.) has said that he will not bring H.R. 3 up for a vote, and it remains unclear if he will allow for consideration of the Finance package.

Lawmakers Reach Deal in Principle on FY2020 Funding

House Appropriations Chair Nita Lowey (D-N.Y.) and Senate Appropriations Chair Richard Shelby (R-Ala.) announced that they had reached a deal in principle to fund the federal government for the remainder of fiscal year (FY) 2020. While the details of the agreement remain unclear, Democrats have reportedly received assurances that the President will sign the appropriations bills. A vote on the legislation in the House is scheduled for Tuesday, and House Majority Leader Steny Hoyer (D-Md.) expects the bills to be grouped into at least two packages to be introduced today. The current stop gap spending measure expires on December 20.

House to Delay E-Cigarette Vote

The House of Representatives will wait until early next year to vote on legislation to ban flavored e-cigarette products, according to cosponsor of the bill Donna Shalala (D-Fla.). Shalala blamed the limited number of working days remaining in 2019, and the focus on funding the federal government, for the delay. She had previously stated that the bill would get a vote by the end of the year. The legislation would also increase the tobacco purchasing age to 21 and restrict the online sale of e-cigarettes.

USMCA Removes Biologic Exclusivity Provision

The White House has reached an agreement with House Democrats on the U.S.-Mexico-Canada trade agreement (USMCA). The House plans to vote on the deal this week. While the administration has stated that it will push to implement the bill before the end of the year, Senate Majority Leader Mitch McConnell (R-Ky.) said that the Senate will not take up the USMCA until after the President's impeachment trial next year. Representatives from Canada, Mexico, and the U.S. met on Tuesday to sign the amendments to the trade agreement. The revised deal removes a provision that would have guaranteed 10 years of data protection for biologic drugs, a change strongly supported by Democrats. Despite this and other several other concessions to Democrats, Republicans in both chambers have expressed confidence that the trade agreement will pass.

Bipartisan Lawmakers Raise Concerns with Medicare Plan Finder

Bipartisan committee leaders in the House have [written](#) to the Centers for Medicare and Medicaid Services (CMS) to express concerns about the accuracy of the Medicare Plan Finder. The letter was sent following reports from consumer advocates, volunteers, and other Medicare counselors that the tool was confusing, provided incorrect results, and led beneficiaries to choose plans with lower premiums but higher overall costs. The letter was signed by E&C Chairman Frank Pallone (D-N.J.), Ranking Member Greg Walden (R-Ore.), Ways and Means Chairman Richard Neal (D-Mass.), and Ranking Member Kevin Brady (R-Texas). The lawmakers urge CMS Administrator Seema Verma to evaluate and correct errors with the Plan Finder as necessary. Because Medicare open enrollment has closed, the letter also requests that beneficiaries who used Plan Finder be included in a special enrollment period to allow them to make changes to their plan selection. The leaders request a response from CMS by December 30.

Acting HHS IG to Retire

Joanne Chiedi, acting inspector general (IG) of HHS, has announced her plans to retire at the end of the year. Chiedi has served in the IG position at HHS since June, leading the administration's efforts to revise anti-kickback statute regulations. Her successor has not yet been named.

Kennedy Calls for CMS Administrator's Resignation

Rep. Joe Kennedy (D-Mass.) is calling on CMS Administrator Seema Verma to resign amidst reports that she asked taxpayers to cover the cost of jewelry stolen during travel for work. Verma has also been criticized in recent months for her spending on public relations contractors. Kennedy characterized Verma's actions as a "gross misuse of public funds" to "elevate her own position." Rep. Kennedy, who is an outspoken critic of the administration's health care agenda, is the first lawmaker to call for Verma's resignation.

Van Drew To Join Republican Party

Freshman Rep. Jefferson Van Drew (D-N.J.) is expected to leave the Democratic Party and join the GOP. Van Drew, a former dentist, was elected by a historically Republican district and is a vocal opponent of impeaching President Trump. If he chooses to switch parties, Van Drew will forfeit his current committee assignments. The House GOP Conference would then decide his committee assignments.

Upcoming Congressional Hearings and Markups

Senate Judiciary Committee hearing to examine tackling the opioid crisis, focusing on a whole-of-government approach; 10:00 a.m., 226 Dirksen Bldg.; December 17

House Foreign Affairs Committee markup of various measures including H.R. 5338, Global Hope Act, and S. 1340, Ebola Eradication Act of 2019; 10:00 a.m., 2172 Rayburn Bldg.; December 18

Recently Introduced Health Legislation

H.Con.Res.78 — Supporting the goals and ideals of World AIDS Day; Sponsor: Rep. Lee, Barbara [D-CA-13]; Committees: House - Energy and Commerce; Foreign Affairs

H.R.5333 — To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program, and for other purposes; Sponsor: Rep. DelBene, Suzan K. [D-WA-1]; Committees: House - Ways and Means; Energy and Commerce

H.R.5338 — To authorize the Secretary of State to pursue public-private partnerships, innovative financing mechanisms, research partnerships, and coordination with international and multilateral organizations to address childhood cancer globally, and for other purposes; Sponsor: Rep. McCaul, Michael T. [R-TX-10]; Committees: House - Foreign Affairs

H.R.5357 — To amend the Public Health Service Act to authorize a pilot program to develop, expand, and enhance the commercialization of biomedical products, and for other purposes; Sponsor: Rep. Peters, Scott H. [D-CA-52]; Committees: House - Energy and Commerce

H.Res.750 — Expressing the sense of the House of Representatives that individual choice in health insurance should be protected; Sponsor: Rep. Burgess, Michael C. [R-TX-26]; Committees: House - Energy and Commerce; Ways and Means

H.R.19 — To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Food and Drug Administration, and for other purposes; Sponsor: Rep. Walden, Greg [R-OR-2]; Committees: House - Energy and Commerce; Ways and Means; Judiciary

H.R.5364 — To require the Secretary of Health and Human Services to establish an annual reference price for insulin products for purposes of Federal health programs, and for other purposes; Sponsor: Rep. Beatty, Joyce [D-OH-3]; Committees: House - Energy and Commerce; Ways and Means; Armed Services; Veterans' Affairs; Oversight and Reform; Natural Resources

S.Res.448 — A resolution designating December 3, 2019, as "National Phenylketonuria Awareness Day". Sponsor: Sen. Isakson, Johnny [R-GA]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.2997 — A bill to revise and extend health workforce programs under title VII of the Public Health Service Act; Sponsor: Sen. Reed, Jack [D-RI]; Committees: Senate - Health, Education, Labor, and Pensions

S.2999 — A bill to amend the Internal Revenue Code of 1986 to allow individuals with direct primary care service arrangements to remain eligible individuals for purposes of health savings accounts; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Finance

S.3000 — A bill to amend title XVIII of the Social Security Act to allow PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA-PD plans to share with enrollees a portion of savings from switching to lower cost therapeutic alternative medications; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Finance

S.3001 — A bill to provide for certain extensions with respect to the Medicare and Medicaid programs under titles XVIII and XIX of the Social Security Act, and for other purposes; Sponsor: Sen. Toomey, Pat [R-PA]; Committees: Senate – Finance

H.R.5381 — To amend the Federal Food, Drug, and Cosmetic Act to require the label of a drug to list the country of origin of each of the drug’s active ingredients; Sponsor: Rep. DesJarlais, Scott [R-TN-4]; Committees: House - Energy and Commerce

H.R.5382 — To create a mechanism whereby insulin manufacturers may sell directly to consumers at current net prices; Sponsor: Rep. Fortenberry, Jeff [R-NE-1]; Committees: House - Energy and Commerce

H.R.5386 — To amend the Health Information Technology for Economic and Clinical Health Act to require consideration, in certain circumstances, of whether a covered entity or business associate has adequately demonstrated that it had recognized security practices, and for other purposes; Sponsor: Rep. McNerney, Jerry [D-CA-9]; Committees: House - Energy and Commerce; Ways and Means

S.Res.452 — A resolution commemorating and supporting the goals of World AIDS Day; Sponsor: Sen. Isakson, Johnny [R-GA]; Committees: Senate - Foreign Relations

S.3006 — A bill to amend the Public Health Service Act to establish a program to improve the identification, assessment, and treatment of patients in the emergency department who are at risk or suicide, and for other purposes; Sponsor: Sen. Murkowski, Lisa [R-AK]; Committees: Senate - Health, Education, Labor, and Pensions

S.3010 — A bill 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: Sen. Portman, Rob [R-OH]; Committees: Senate – Finance

S.3013 — A bill to amend title XVIII of the Social Security Act to allow for the offering of additional prescription drug plans under Medicare part D; Sponsor: Sen. Toomey, Pat [R-PA]; Committees: Senate – Finance

H.R.5397 — To amend title II of the Higher Education Act of 1965 with respect to partnership grants for the establishment of rural teaching residency programs, and for other purposes; Sponsor: Rep. Bost, Mike [R-IL-12]; Committees: House - Education and Labor

H.R.5400 — To establish the “Biomedical Innovation Fund”, and for other purposes; Sponsor: Rep. Clarke, Yvette D. [D-NY-9]; Committees: House - Energy and Commerce; Rules; Budget

H.R.5402 — To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to conduct a study on high-risk, high-reward drugs, and for other purposes; Sponsor: Rep. Gottheimer, Josh [D-NJ-5]; Committees: House - Ways and Means; Energy and Commerce

S.3020 — A bill 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: Sen. Baldwin, Tammy [D-WI]; Committees: Senate - Veterans’ Affairs

S.3021 — A bill to amend the Federal Food, Drug, and Cosmetic Act to require the label of a drug that is intended for human use and contains an ingredient that is derived directly or indirectly from a gluten-containing grain to identify each such ingredient, and for other purposes; Sponsor: Sen. Blumenthal, Richard [D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

S.3023 — A bill to amend the Public Health Service Act to authorize the Director of the National Institutes of Health to make awards to outstanding scientists, including physician-scientists, to support researchers focusing on pediatric research, including basic, clinical, translational, or pediatric pharmacological research, and for other purposes; Sponsor: Sen. Ernst, Joni [R-IA]; Committees: Senate - Health, Education, Labor, and Pensions

H.Con.Res.79 — Expressing the sense of the Congress that assisted suicide (sometimes referred to using other terms) puts everyone, including those most vulnerable, at risk of deadly harm; Sponsor: Rep. Correa, J. Luis [D-CA-46]; Committees: House - Energy and Commerce

H.R.5411 — To direct the Secretary of Health and Human Services to establish a Task Force on Local Mental Health Needs, and for other purposes; Sponsor: Rep. Harder, Josh [D-CA-10]; Committees: House - Energy and Commerce

H.R.5415 — To provide the Food and Drug Administration with authority to conduct microbial sampling on concentrated animal feeding operations as necessary to facilitate a foodborne illness outbreak investigation, determine the root cause of an outbreak of foodborne illness, or address other public health needs; Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Committees: House - Energy and Commerce

H.R.5421 — To amend the Controlled Substances Act to list fentanyl-related substances as schedule I controlled substances; Sponsor: Rep. Luetkemeyer, Blaine [R-MO-3]; Committees: House - Energy and Commerce; Judiciary

S.3029 — A bill to amend titles XVIII and XIX of the Social Security Act to make premium and cost-sharing subsidies available to low-income Medicare part D beneficiaries who reside in Puerto Rico or another territory of the United States; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Finance

S.3041 — A bill to amend title 38, United States Code, to ensure that medical professionals employed by the Veterans Health Administration are properly credentialed, and for other purposes; Sponsor: Sen. Hassan, Margaret Wood [D-NH]; Committees: Senate - Veterans' Affairs

S.3049 — A bill to amend title XVIII of the Social Security Act to provide for certain amendments relating to reporting requirements with respect to clinical diagnostic laboratory tests, and for other purposes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Finance