



Health Policy Briefing

September 16, 2019

Another Physician Heads to Washington

Republican Greg Murphy, MD defeated Democratic opponent Allen Thomas in the race for North Carolina’s 3rd Congressional District by more than 20 points last week. The special election was held to fill the seat vacated following the death of Rep. Walter Jones Jr. (R-N.C.) earlier this year. Dr. Murphy is a board certified urologist who ran a private practice prior to joining the North Carolina state legislature in 2015. During his campaign, he stated support for “healthcare reforms that put the decision making process of doctor choice and treatment options in the hands of the citizens and will look for new and innovative ways to implement such changes.”

Draft Version of Pelosi Drug Pricing Plan Leaked

A draft of House Speaker Nancy Pelosi’s (D-Calif.) plan to lower drug prices was leaked last week. The bill, which has been in the works for months, would direct the U.S. Department of Health and Human Services (HHS) Secretary to negotiate the prices of the 250 drugs that are most expensive to Medicare each year and that lack the competition of at least two other generic drugs, biologics, or biosimilars. Pharmaceutical manufacturers that do not negotiate or are unable to reach an agreement with the government would face a 75 percent penalty of the gross sales of the drug from the previous year – a reversal of an earlier proposal to involve an arbiter if negotiations fail. Speaker Pelosi’s plan would also cap drug prices at 1.2 times the average international price of Australia, Canada, France, Germany, Japan, and the U.K., similar to a concept proposed by the Administration related to Part B. The lower drug prices would apply to both Medicare and private insurers. Savings resulting from the lower-priced drugs would be directed to the National Institutes of Health (NIH) for the development of new drugs and treatments. The legislation also proposes to instate a \$2,000 cap on Medicare beneficiary out-of-pocket spending starting in 2022. Senior leadership staff has clarified that the leaked draft is no longer current and could still change before it is formally introduced, and House committees begin holding hearings on the measure later this year.

House Democratic Caucus Chairman Hakeem Jeffries (N.Y.) expressed confidence that the bill could pass this year and stated that the Speaker is currently discussing the plan with House Ways and Means Committee Chairman Richard Neal (D-Mass.) and House Energy and Commerce Committee Chairman Frank

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Pallone (D-N.J.). According to a recent statement by Chairman Neal, the House plans to prioritize smaller, bipartisan drug pricing bills like the STAR Act (H.R. 2113), which would require manufacturers to publicly justify certain price increases. Although the Pelosi proposal is unlikely to be supported by many Senate Republicans, proponents of the bill are hopeful that it will gain the White House's endorsement due to its similarity to some of the President's rhetoric and campaign promises.

Meanwhile, Senate Finance Committee Chairman Chuck Grassley (R-Iowa) is using the bill to garner support for his panel's own drug pricing proposal, characterizing it as a more moderate alternative. That bill was advanced out of committee despite significant Republican opposition to a provision that would require manufacturers to issue rebates to the Medicare program if prices rise faster than inflation, which some GOP members characterized as government price-fixing. The White House has reiterated its support for the Senate Finance Committee's plan, stating that the administration has been in discussions with Speaker Pelosi on the subject of drug pricing but has not been provided with a specific proposal or legislative text.

Ways and Means Stalled on Surprise Billing Measure

House Ways and Means Committee Chairman Richard Neal (D-Mass.) stated that his panel has yet to reach an agreement on a method of payment to settle billing disputes between insurers and providers and may not mark up a bill to address the issue of surprise insurance gaps until late October. He also told reporters last week that Ways and Means is not discussing the inclusion of policies to impact air ambulances in their surprise billing legislation. While the House Energy and Commerce Committee's bill also excludes air ambulances, the Senate Health, Education, Labor, and Pensions (HELP) legislation would tie their out-of-network charges to the median rate of a geographic area. According to Chairman Neal, Ways and Means is still developing timelines for several pieces of major legislation, including drug pricing and surprise billing.

HELP Committee Chairman Lamar Alexander (R-Tenn.) plans to meet with Sen. Bill Cassidy (R-La.) this week to further discuss HELP's surprise billing legislation. Sen. Cassidy is pushing for the addition of an independent dispute resolution (IDR) process under which arbiters would be required to base their payment decisions on commercially reasonable rates.

In other related news, the House Energy and Commerce Committee has opened an investigation into the impact of private equity control of health care companies on rising health care costs and surprise medical billing.

FY 2020 Appropriations Remain In Flux

The House of Representatives plans to consider a clean continuing resolution (CR) this week in an effort to avoid a federal government shutdown at the end of the fiscal year (FY) on September 30. The short-term spending bill is expected to extend current government funding into late November or early December.

The Senate Appropriations Committee approved spending allocations for all 12 subcommittees last week, along with the Defense and Energy and Water Development spending bills. While appropriators had planned to vote on the Labor-Health and Human Services-Education and State-Foreign Operations bills as well, proceedings were postponed due to abortion-related disputes regarding Title X grant funding and the Mexico City policy. The 302(b) top-line spending caps for FY 2020 were decided without input from House appropriators, who have already advanced the majority of their panel's spending bills, by a party-line vote of 16-15. Agriculture-FDA will receive \$23.1 billion, Labor-HHS-Education will receive \$187.7 billion, and Military Construction-VA will receive \$105.5 billion. Ranking Member Patrick Leahy (D-Vt.) stated that it was "unacceptable" that the Labor-HHS-Education measure would only receive a one percent increase over FY 2019 levels.

Lawmakers Push to Restrict E-Cigarettes

Sen. Mitt Romney (R-Utah) has [written](#) to U.S. Department of Health and Human Services Secretary Alex Azar questioning whether a recall by the Food and Drug Administration (FDA) of e-cigarettes is appropriate in light of the mysterious, vaping-related illness that has sickened approximately 380 people and resulted in at least six deaths across the country. Sen. Romney urges both the FDA and the Centers for Disease Control and Prevention (CDC) to “report to Congress and to the public any new findings related to the investigation into severe pulmonary disease, or other diseases, stemming from the use of e-cigarettes.”

A bipartisan group of senators led by Dick Durbin (D-Ill.) met with FDA Acting Commissioner Ned Sharpless on the issue of e-cigarettes last week. The lawmakers, including Sens. Lisa Murkowski (R-Alaska), Maggie Hassan (D-N.H.), Mitt Romney (R-Utah), Patty Murray (D-Wash.), Jeff Merkley (D-Ore.), Mazie Hirono (D-Hawaii), and Richard Blumenthal (D-Conn.), praised the agency for announcing its intention to ban flavored vaping products. They urged the FDA to remove both e-cigarette flavors and illegal vaping devices from the market as quickly as possible. According to Secretary Azar, the number of children reported to have used e-cigarettes increased to 5 million in 2018 from 3.6 million the previous year.

Senate Finance Members Request Change to DIR Policy

A bipartisan group of senators has [written](#) to leadership at the U.S. Department of Health and Human Services (HHS) asking the administration to broaden Medicare’s definition of direct and indirect remuneration (DIR). The lawmakers cite an analysis from the Centers for Medicare and Medicaid Services (CMS) that pharmacies experienced a 45,000 percent increase in DIR fees between 2010 and 2017. They characterize this increase as “an untenable trend for pharmacies” that causes higher prices for beneficiaries at the pharmacy counter and suggest that HHS “redefine ‘negotiated price’ to include all pharmacy price concessions at the point-of-sale and establish a broader definition of ‘price concession’” in time for the 2021 plan year.

Number of Uninsured Rises by 2 Million

New data from the 2018 Census Bureau Report shows that the number of people in the U.S. without health insurance increased by two million since 2017 to a total of 27.5 million in 2018. It is the first time census officials have reported an increase in the number of uninsured since 2009 – rising from a rate of 7.9 percent in 2017 to 8.5 percent in 2018. Officials attribute the increase to a reduction in the number of adults and children covered by public programs. The number of uninsured children rose by 425,000, or 0.6 percent, reaching 4.3 million children. Children living in the south are more likely than children living in other parts of the nation to be without health insurance, and Hispanic children are more likely than children of other ethnicities to be uninsured. Congressional Democrats used the new data to criticize the administration’s overall health care agenda and current support for a lawsuit that would overturn the Affordable Care Act (ACA), while highlighting their efforts to strengthen the 2010 health care law and stabilize health insurance markets.

Upcoming Congressional Hearings and Markups

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

House Appropriations Subcommittee on the Departments of Labor, Health and Human Services, Education, and Related Agencies oversight hearing “Mental Health Needs of Children in HHS Custody;” 10:00 a.m., 2358-C Rayburn Bldg.; September 18

House Committee on Veterans’ Affairs hearing “Critical Impact: How Barriers to Hiring at VA Affect Patient Care and Access;” 2:05 p.m., 210 Capitol Bldg.; September 18

House Energy and Commerce Subcommittee on Consumer Protection and Commerce hearing “Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System;” 10:30 a.m., 2322 Rayburn Bldg.; September 19

House Energy and Commerce Subcommittee on Oversight and Investigations hearing on the public health impacts and regulatory authorities related to e-cigarette manufacturing, sales, and use; time and place TBD; September 25

House Energy and Commerce Subcommittee on Health field hearing on the public health threat posed by gun violence; time TBD, University of Chicago Medical Center; October 3

Recently Introduced Health Legislation

H.R.4228 — To expand and improve the programs and activities of the Department of Health and Human Services for awareness, education, research, surveillance, diagnosis, and treatment concerning rare diseases and conditions; Sponsor: Rep. Carson, Andre [D-IN-7]; Committees: House - Energy and Commerce

H.R.4243 — To amend the Public Health Service Act to improve obstetric care in rural areas; Sponsor: Rep. Torres Small, Xochitl [D-NM-2]; Committees: House - Energy and Commerce

H.R.4244 — To provide for a pathway for chemically synthesized insulin to be approved under an abbreviated new drug application submitted under the Federal Food, Drug, and Cosmetic Act, and for other purposes; Sponsor: Rep. Kelly, Mike [R-PA-16]; Committees: House - Energy and Commerce

S.2443 — A bill to amend the Public Health Service Act to provide for investment in tomorrow’s pediatric health care workforce; Sponsor: Sen. Reed, Jack [D-RI]; Committees: Senate - Health, Education, Labor, and Pensions

S.2446 — A bill to provide certain coverage of audiologist services under the Medicare program, and for other purposes; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Finance

H.Res.550 — Expressing support of the designation of September 2019 as Peripheral Artery Disease Awareness Month; Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Oversight and Reform

S.2451 — A bill to amend chapter 171 of title 28, United States Code, to allow suit against the United States for injuries and deaths of members of the Armed Forces caused by improper medical care, and for other purposes; Sponsor: Sen. Kennedy, John [R-LA]; Committees: Senate - Judiciary

H.R.4281 — To amend chapter 17 of title 38, United States Code, to direct the Secretary of Veterans Affairs to allow a veteran to receive a full year supply of contraceptive pills, transdermal patches, and vaginal rings, and for other purposes; Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Veterans’ Affairs

H.R.4282 — To direct the Secretary of Veterans Affairs to develop a training session and a counseling session in suicide prevention and lethal means tailored to veterans who served in the Armed Forces after September 11, 2001, and for other purposes; Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Veterans' Affairs

H.R.4296 — To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, and for other purposes; Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce, Education and Labor

H.R.4327 — To amend the Higher Education Act of 1965 to promote comprehensive campus mental health and suicide prevention plans, and for other purposes; Sponsor: Rep. Wild, Susan [D-PA-7]; Committees: House - Education and Labor

S.2477 — A bill to establish a National Commission on Fibrotic Diseases; Sponsor: Sen. Gillibrand, Kirsten E. [D-NY]; Committees: Senate - Health, Education, Labor, and Pensions