

HALL RENDER'S THIS WEEK IN WASHINGTON - DECEMBER 23, 2019

MASSIVE FY 2020 FUNDING BILLS LOADED WITH HEALTH CARE-RELATED PROVISIONS

Just hours before another looming government shutdown, President Trump signed a two-part spending deal funding federal agencies that include CMS, FDA and NIH, among others. The **funding bill** contains several significant health policy provisions. Most notably, it will repeal three taxes enacted as part of the ACA – the medical device excise tax, the annual fee on insurers known as the health insurance tax (“HIT”) and the 40 percent excise tax on high-cost health insurance plans known as the “Cadillac Tax,” which is the largest cost of the bill at more than \$373 billion over 10 years. The measure also delays DSH pay cuts for another 5 months and raises the minimum age to purchase tobacco products to 21.

Several Medicare and Medicaid extenders will be funded through May 22, 2020, which are: 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; outreach and assistance for low-income programs; quality measure endorsement and selection; State Health Insurance Assistance Programs; Area Agencies on Aging; Aging and Disability Resource Centers; Certified Community Behavioral Health Clinic demonstration, along with some additional funding for substance-use disorder treatments; spousal impoverishment protections; and the Money Follows the Person demo. The May 2020 deadline is intended to create pressure for a Memorial Day deal on a comprehensive health care package for items such as prescription drug pricing and surprise billing.

Other health-related provisions in the spending deal include laboratory payment data reform and a prohibition to stop the administration from barring “silver loading” or the practice allowing insurance plans to add costs to the silver-tiered insurance plans purchased on the insurance exchanges. The CREATES Act is also included, which will make it easier for generic drug companies to access samples of brand-name drugs. The funding bill also extends the Patient-Centered Outcomes Research center for 10 years and adds research priorities such as maternal mortality and developmental disabilities.

Despite all of these provisions, the legislation leaves Congress with a lengthy health care to-do list for next year. Here’s what wasn’t included in the spending bill that is expected to come up again 2020:

Surprise Medical Bills: Despite an agreement between HELP Chairman Sen. Lamar Alexander and House Energy and Commerce leadership, surprise billing provisions were not included in the spending package. Because the temporary Medicare and Medicaid extenders expire in May, Congress has time to work out the details on a surprise billing package that could be included in the extenders legislation.

Prescription Drug Pricing: The CREATES Act is the only drug-pricing provision included in the spending bill. Congress is working on a larger, more ambitious package to potentially pass in May 2020.

Price Transparency and Other Health Cost Legislation: Proposals related to health costs, such as in hospital/insurance contracts and pharmacy benefit manager provisions, were not included in this package but are expected to be addressed next year.

ADMINISTRATION PROPOSES PRESCRIPTION DRUG IMPORT PLAN

On December 18, HHS moved forward with its plan to allow states and drug makers to import lower-cost prescription drugs from other countries. Specifically, the **proposed rule** would allow states to pursue pilot programs allowing importation of drugs from Canada. However, the import rule excludes controlled substances, biological products and intravenous drugs. The FDA also issued draft guidance allowing drug manufacturers to import their own products and sell them under different drug codes.

So what would be the impact of this proposal? **Todd Nova**, the attorney who leads Hall Render's pharma practice, answers, “this is really about the FDA taking more concrete steps to issue regulatory guidance using mechanisms already authorized by Congress. Ultimately, depending on what is contained in the final rule, it may be the case that the mere threat of importation could result in reduced pricing for common shortage drugs, decreasing the incentive for interested parties to go through the importation process. The true impact will really be seen once we see what barriers to entry are imposed in the final rule. To be sure, we anticipate both manufacturers and purchasers will submit a large number of comments both in support of and in opposition to this rule. Those comments will be due by March 8, 2020

assuming the anticipated publication timeline is met.”

PRESIDENT TRUMP IMPEACHED IN THE HOUSE

The House of Representatives voted to impeach President Trump before heading home for the holidays. Once House Speaker Nancy Pelosi (D-CA) transmits the articles of impeachment to the Senate, that body is expected to hold a trial in January to determine whether the president will be acquitted or removed from office. Given that Republicans control the Senate and it takes 67 votes to remove the president from office, it is very likely that he will be acquitted.

HEALTH-RELATED BILLS INTRODUCED THIS WEEK

Rep. Jan Schakowsky (D-IL) introduced **H.R. 5501** to amend the Public Health Service Act to establish an Office of Drug Manufacturing.

Sen. Tina Smith (D-MN) introduced **S. 3126** to amend the Public Health Service Act to authorize a special behavioral health program for Indians.

Rep. Adam Kinzinger (R-IL) introduced **H.R. 5481** To amend Title XVIII of the Social Security Act to restore state authority to waive for certain facilities the 35-mile rule for designating critical access hospitals under the Medicare program. Sen. Dick Durbin (D-IL) introduced **S. 3103** for this purpose in the Senate.

Rep. Gus Bilirakis (R-FL) introduced **H.R. 5473** to amend Title XVIII of the Social Security Act and the SUPPORT for Patients and Communities Act to provide for Medicare and Medicaid mental and behavioral health treatment through telehealth.

Sen. Mike Crapo (R-ID) introduced **S. 3085** to amend Title XVIII of the Social Security Act to modernize payments for ambulatory surgical centers under the Medicare program.

NEXT YEAR IN WASHINGTON

This Week in Washington's motto for 2020 is “New Year, New You.” Congress returns on January 7, and this publication will return on Monday, January 13, reporting on the first week back as *The Week in Washington*. *The Week in Washington* will publish on Mondays and have a new format while reporting on all of the exciting health policy developments in 2020.

Readers – we wish you happy holidays and a happy new year!

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