

HALL RENDER'S THIS WEEK IN WASHINGTON - FEBRUARY 1, 2019

HHS PREVIEWS 2019 REGULATORY AGENDA

At a symposium on Tuesday, Deputy HHS Secretary Eric Hargan and CMS Administrator Seema Verma outlined the administration's health care strategy for 2019, which includes advancing the use of technology, adjusting payments in rural areas and testing new ways to reward high-quality care and reforms to the Stark and Anti-Kickback regulations. According to Administrator Verma, CMS will be "...repositioning the government's role from one prescribing processes through heavy regulation to one focused on safeguarding outcomes and taxpayers' dollars." She highlighted an overall push of moving towards a value-based care model, citing that only 14 percent of Medicare providers are in value-based agreements.

One way the agency plans to expand the use of technology is through its first mobile app, which launched on Monday, that educates consumers on whether a product or service is covered by Medicare. The agency is also focusing on improving access to rural communities by using technology to determine new ways to deliver health care to rural populations as efficiently as possible. Administrator Verma did not provide any information on rumored plans to convert Medicaid into a voluntary state block grant program using Section 1115 waivers. She also reaffirmed the administration's commitment to lowering prescription drug costs by strengthening the Medicare Part D drug program and Medicare Advantage.

Deputy Secretary Hargan noted that much-anticipated proposed rules to reform Stark Law and the Anti-Kickback regulations are likely to come sometime this year. The administration sought feedback on proposed changes to Stark from stakeholders last year, several of which were recommendations given to Administrator Verma by the Hall Render Stark Law Coalition. Deputy Secretary Hargan also described new privacy initiatives addressing concerns with HIPAA and 42 CFR Part 2, a regulation requiring explicit patient consent to share certain medical records involving substance use.

HOUSE AND SENATE HOLD HEARINGS ON DRUG PRICING

On Tuesday, the Senate Finance and the House Oversight and Reform committees held hearings on potential solutions to address high drug costs. The hearings featured academics and patient advocates as lawmakers in both chambers investigate why drug prices are high and what Congress can do about it. In the Senate Finance hearing, three drug pricing experts testified that paying physicians a six percent markup over a drug's average sales price in the Medicare Part B outpatient program was incentivizing doctors toward prescribing higher-cost drugs.

There was bipartisan interest in patent gaming, branded drug monopolies and the role of rebates in drug pricing and lack of transparency among pharmacy benefit managers, which is also a top focus of the Trump administration. However, it was clear after the hearings that there will be a battle between Senate Republicans and House Democrats over how to address rising drug prices overall and who to hold accountable. Leaders from both parties announced that future hearings will focus more on legislative proposals. While any drug pricing legislation will need bipartisan consensus to get through a deeply divided Congress, lawmakers seemed optimistic about their ability to work together on this issue.

HHS RELEASES DRUG REBATE RULE

On Thursday, HHS released a **proposed rule** to change the Medicare Part D rebate program to encourage manufacturers to pass discounts directly to patients and provide transparency to prescription drug markets. Under the proposal, Medicare and Medicaid plan sponsors will no longer be permitted to retain rebates from pharmaceutical manufacturers. Instead, it would create a new safe harbor for prescription drug discounts offered directly to patients, as well as fixed fee service arrangements between drug manufacturers and pharmacy benefit managers. HHS is hoping to begin this proposal in early 2020.

While the new rules would apply only to Medicare and Medicaid plan sponsors, it is likely the effects would resonate throughout the entire insurance pharmaceutical industry since the government programs typically set the tone for private insurers. The administration says it will need Congress to implement similar rules for private insurers, which is possible because Sen. Chuck Grassley (R-IA), Chairman of the Senate Finance Committee, has indicated that addressing high drug prices will be a major focus of the committee.

HEALTH-RELATED BILLS INTRODUCED THIS WEEK

Rep. Mike Thompson (D-CA) introduced **H.R. 945** to amend Title XVIII of the Social Security Act to provide for the coverage of marriage and family therapist services and mental health counselor services under part B of the Medicare program. Sen. John Barrasso (R-WY) released this bill in the Senate, **S.286**.

Rep. Stephanie Murphy (D-FL) introduced **H.R. 944** to require the Medicaid and CHIP Payment and Access Commission to publish an annual report on the estimated impact in each state of the Medicaid expansion added by the Patient Protection and Affordable Care Act, including the estimated impact that adopting such expansion would have in states that have not expanded their Medicaid coverage.

Rep. Kurt Schrader (D-OR) introduced **H.R. 937** to amend Title XIX of the Social Security Act to prevent the misclassification of drugs for purposes of the Medicaid drug rebate program.

Sen. Susan Collins (R-ME) introduced **S.304** to reauthorize section 340H of the Public Health Service Act to continue to encourage the expansion, maintenance and the establishment of approved graduate medical residency programs at qualified teaching health centers.

Rep. Derek Kilmer (D-WA) introduced **H.R. 900** to amend Title XVIII of the Social Security Act to improve the way beneficiaries are assigned under the Medicare shared savings program by also basing such assignment on primary care services furnished by nurse practitioners, physician assistants and clinical nurse specialists.

Sen. Bill Cassidy (R-LA) introduced **S.228** to amend Title XVIII of the Social Security Act to restructure the payment adjustment for non-emergency ESRD ambulance transports under the Medicare program.

NEXT WEEK IN WASHINGTON

Since there are two weeks until the temporary government funding bill expires, Congress will likely continue to negotiate outstanding immigration issues to avoid a subsequent government shutdown. On February 5, the Senate HELP Committee holds a hearing on "How Primary Care Affects Health Care Costs and Outcomes." House lawmakers will continue their examination of pre-existing conditions next week when the House Education and Labor Committee holds a hearing on "Examining Threats to Workers with Preexisting Conditions" on February 6.

The Energy and Commerce Health Subcommittee will hold a hearing on February 6 on the lawsuit *Texas v. United States*, which argues that the Affordable Care Act is unconstitutional. In December, a judge held President Obama's landmark health care law unconstitutional, but the decision has since been stayed pending appeal. The subcommittee's majority plans to examine how the ruling will impact today's health care system.

THIS WEEK IN WASHINGTON IN HISTORY

1865, 154 years ago this week: The House of Representatives passes the 13th Amendment to the Constitution, abolishing slavery in America. The amendment read, "Neither slavery nor involuntary servitude...shall exist within the United States, or any place subject to their jurisdiction."

1835, 184 years ago this week: Andrew Jackson narrowly escapes an assassination attempt in Washington, D.C. He becomes the first American president to experience an assassination attempt. As Jackson left a congressional funeral held in the House chamber of the Capitol building, Richard Lawrence, an unemployed house painter, approached Jackson and shot at him, but his gun misfired.

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