

HALL RENDER'S THIS WEEK IN WASHINGTON - NOVEMBER 30, 2018

CONGRESS UNLIKELY TO MAKE PROGRESS ON HEALTH CARE BILLS BEFORE YEAR-END

As government funding battles overtake Capitol Hill, it appears Congress will not use the lame duck to resolve outstanding health care issues. While the desire to steer clear of health care fights is something different from prior years, outgoing House Ways and Means Committee Chairman Kevin Brady (R-TX) said this week that health care legislation will not be a priority during what's left of the lame duck session. Furthermore, Democratic control of the House of Representatives that comes in January has caused many Democratic lawmakers to push their health care priorities into the New Year. However, some policy changes could still surface as additions to a year-end spending package that must be passed before December 7 in order to avoid a partial government shutdown. Luckily for a majority of health care programs, funding for most agencies within the Department of Health and Human Services ("HHS") was included in a giant spending package Congress passed in September. Those that remain to be funded include the FDA, which receives its funding through a separate bill and user fees. A [House Republican tax bill](#) was released on November 26, but it did not address any of the Affordable Care Act's taxes, such as the medical device tax and the "Cadillac" tax on health plans.

HHS RELEASES DRAFT STRATEGY TO REDUCE HEALTH IT BURDEN

HHS released a [draft strategy](#) on easing regulatory and administrative burdens associated with the use of electronic health records ("EHRs") and health information technology. The draft strategy was prepared by the HHS Office of the National Coordinator for Health Information Technology ("ONC"), in partnership with the Centers for Medicare & Medicaid Services ("CMS"), and was required by the 21st Century Cures Act.

The draft strategy reflects the input and feedback received by ONC and CMS from stakeholders, especially clinicians, expressing concerns that EHR burden negatively affects patients and ultimately the care delivery experience. The three overarching goals outlined in the strategy to reduce clinician burden are to: reduce the effort and time required to record health information in EHRs for clinicians; reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals and health care organizations; and improve the functionality and ease of use of EHRs. This draft strategy includes recommendations that will allow physicians and other clinicians to provide effective care to their patients with less burden on the delivery of care. Comments to ONC can be submitted [here](#) until 11:59 PM ET on January 28, 2019.

DELAYED RULE ON 340B PENALTIES FINALIZED

On November 29, the Health Resources and Services Administration ("HRSA") finalized a [long-delayed regulation](#) penalizing drug makers for overcharging providers in the 340B drug discount program. The regulation also outlines how ceiling prices in the 340B program are calculated. It will be effective January 1, 2019. In the final rule, HHS says it has determined that implementation of the 340B ceiling price and penalties rule in January won't interfere with the agency-wide comprehensive drug pricing strategy; therefore, a delay in the effective date is no longer necessary.

The regulation also indicates that stakeholders noted HRSA's previous statement on additional rulemaking for 340B, as some issues needed further consideration, but the agency never explained the conclusions it came to in those areas. HRSA responded that it is more efficient to implement the rule first, then continue separately with any additional rulemaking as needed. HHS said it believes the new civil monetary penalties will be used in "rare situations" because a manufacturer would have to "knowingly and intentionally" overcharge groups participating in the program.

HEALTH-RELATED BILLS INTRODUCED THIS WEEK

Sen. Orrin Hatch (R-UT) introduced [S.3693](#) to amend Title XVIII of the Social Security Act to provide for the treatment of certain cancer hospitals.

Sen. Todd Young (R-IN) introduced [S.3685](#) to amend the Public Health Service Act to expand the authority of the Secretary of Health and Human Services to permit nurses to practice in health care facilities with critical shortages of nurses through programs for loan repayment and scholarships for nurses.

Sen. Jeff Merkley (D-OR) introduced **S. 3680** to require the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of federal health programs.

Rep. Erik Paulsen (R-MN) introduced **H.R. 7177** to amend Title III of the Public Health Service Act and Titles XI and XVIII of the Social Security Act to accelerate the adoption of value-based payment and delivery arrangements among health care stakeholders intended to coordinate care, improve patient outcomes, share accountability or lower costs.

NEXT WEEK IN WASHINGTON

Congress is back next week working to avoid a partial government shutdown on December 7, 2018. The House is out Monday, which gives Congress four days in session to strike a deal on outstanding items such as funding a border wall or adding protections for special counsel Robert Mueller.

On December 5, the House Energy and Commerce Oversight and Investigations Subcommittee holds a hearing on "Examining the Availability of Safe Kits at Hospitals in the United States."

THIS WEEK IN WASHINGTON IN HISTORY

1963, 55 years ago today: President Lyndon B. Johnson appoints a special commission to investigate the assassination of President John F. Kennedy, which had occurred a week earlier.

1993, 25 years ago today: The Brady Bill, or the handgun-control bill was signed into law. The law requires a prospective handgun buyer to wait five business days while the authorities check on his or her background, during which time the sale is approved or prohibited based on an established set of criteria. In 1981, James Brady, Press Secretary for President Ronald Reagan, was shot in the head by John Hinckley, Jr. during an attempt on President Reagan's life outside a hotel in Washington, D.C. Brady, the most seriously injured in the attack, was momentarily pronounced dead at the hospital but survived.

For more information, please contact:

- **John Williams III** at (202) 370-9585 or jwilliams@hallrender.com;
- **Andrew Coats** at (202) 370-9587 or acoats@hallrender.com;
- **Abby Kaericher** at (202) 780-2989 or akaericher@hallrender.com; or
- Your regular Hall Render attorney.