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Health Care Update

21st Century Cures Markup; Full Committee to Take Up this Week: The 21st Century Cures Initiative continues to heat up in the House with the House Energy and Commerce Committee last week advancing the measure to the full committee. As in previous hearings, lawmakers on both sides of the aisle were laudatory of the legislation. In particular, lawmakers applauded the increased funding for the National Institutes of Health (NIH), additional tools for breakthrough pathways for medical devices and drugs, antibiotic and antibiotic resistance provisions, streamlining of clinical trials, Medicare coverage for disposable medical technologies, and a focus on precision medicine and biomarkers.

While generally pleased with the effort, some lawmakers did raise concerns such as the fact that the additional NIH money which has been authorized still must be appropriated, the dropping of the Advancing Care for Exceptional Kids Act of 2015 (ACE Kids Act) from the bill, and the need for additional clarification of interoperability portions of the bill. Of note, Representative Doris Matsui (D-CA) addressed industry concerns regarding the limited telehealth portions of the legislation, saying that the provisions included in the 21st Century Cures Act targeting telehealth should be considered an “onramp.” Expect bipartisan work on telemedicine to continue in both the House and the Senate.

The full Committee will begin consideration of the legislation on Tuesday with opening statements and proceed to the markup Wednesday at 10am. Some key questions regarding about the bill remain—including how lawmakers will pay for the legislation. Negotiations reportedly continue over pay-fors, including how much the Food and Drug Administration (FDA) will receive in funding. Regardless, Chairman Fred Upton (R-MI) has said he hopes to bring the legislation to the House floor in June. Meanwhile, Senator Richard Burr (R-NC), in remarks last week, said that the Senate will likely proceed with its own version of the legislation and is unlikely to move as quickly as the House.

Senate Finance Committee Solicits Health Bills for Upcoming Markup: On Friday, the Senate Finance Committee closed a request by Chairman Orrin Hatch (R-UT) and Ranking Member Ron Wyden (D-OR) for miscellaneous health care legislation from Senators for a June markup. The Committee’s criteria for non-controversial health care bills included legislation: within the Committee’s jurisdiction, with strong bipartisan support, with little or no cost to offset, and which is not actively opposed by Senate leadership of the Administration. The Committee will now evaluate the legislation that was submitted and a markup is possible during the upcoming June work period.

Implementation of the Affordable Care Act

New Guidance on Preventative Services: The Obama Administration issued [guidance](#) clarifying the ACA's coverage of preventative services such as contraception. The guidance states that insurers must cover at least one type of contraception in each of the methods recognized by the FDA.

Data on Preventative Services Under ACA: [According](#) to the ASPE Data Point from the Department of Health and Human Services 137 million individuals, including 55 million women and 28 million children, have access to preventative services under the ACA without copays. This includes services such as: blood pressure screening, obesity screening, well-woman and well-baby visits, and flu and other vaccinations.

Treasury Report on ACA Taxes: A [report](#) from Treasury's Inspector General for Tax Administration found that the IRS is unable to assess the risk of premium tax credits (PTC) improper payments, estimate the improper payment rate, or establish corrective actions.

Federal Regulatory Initiatives

FDA Releases Biosimilar Guidance: The FDA released additional [guidance](#) for biosimilar manufacturers related to product development. The guidance includes information on conducting pediatric studies, how a company can demonstrate dosages relevant to the reference biologic, and how branded biologics can request exclusivity.

FDA Issues Developer Challenge: The FDA [issued](#) its first open FDA Developer Challenge, which makes available data sets so as to allow researchers to examine issues related to adverse drug events, product recalls and product labeling.

FDA Seeking to Include LOINC in Clinical Trials: The FDA is requesting comments on a [proposal](#) directing drug companies to provide Logical Observation Identifiers Names and Codes (LOINC) in the clinical trial results submitted to the agency.

GAO Report on Medicaid Spending: The Government Accountability Office (GAO) found that HHS has been unclear about the criteria that must be met to approve a Medicaid 1115 waiver. The [report](#) recommends that HHS "issue criteria for assessing whether expenditure authorities are likely to promote Medicaid objectives and document the use of these criteria in HHS's approvals of demonstrations."

ONC Releases Roadmap Comments: The Office of the National Coordinator for Health IT (ONC) [posted](#) close to 250 comments that it has received on its draft interoperability roadmap.

Congressional Initiatives

House Dems Join Device Tax Repeal Calls: Eighteen House Democrats, all newly elected to Congress, [wrote](#) to Speaker John Boehner (R-OH) and Minority Leader Nancy Pelosi (D-CA) requesting the House move to repeal the ACA's medical device tax before Memorial Day.

Sen. Sanders Pressing VA on Hep C Drugs: Senator Bernie Sanders (I-VT) [wrote](#) to Department of Veterans' Affairs Secretary Robert McDonald to request the agency use emergency powers to ensure veterans are able to receive expensive medicines — such as the Hepatitis C drug Sovaldi—at affordable prices.

Senators Seeking Menu Labeling Delay: Six bipartisan Senators [wrote](#) to HHS Secretary Sylvia Burwell requesting a one-year delay of the FDA's final menu labeling date of compliance. The letter also requests the agency provide guidance on what will be covered under the menu labeling "restaurant-type" food rule.

Senate Finance Convenes Chronic Care Reform Group: Chairman Orrin Hatch (R-UT) and Ranking Member Ron Wyden (D-OR) of the Senate Finance Committee announced the formation of a working group to explore ways in which to improve care for Medicare patients with chronic conditions. Senators Johnny Isakson (R-GA) and Mark Warner (D-VA) will head the group.

Senate PSI Investigation on ACA: The Senate Permanent Subcommittee on Investigations will begin an [examination](#) of "mismanagement" of the ACA exchanges. Chairman Rob Portman (R-OH) said in a statement that the "subsidy eligibility process is so complicated that many consumers believed they were receiving cheaper insurance coverage than they ultimately got."

Rep. Black Introduces ICD-10 Bill: Representative Diane Black (R-TN) introduced legislation ([H.R. 2247](#)) which would direct HHS to conduct “comprehensive, end-to-end testing” of its claims processing before the October transition to ICD-10.

Other Health Care News

Report on Super Drug Spending: According to an Express Scripts [report](#), the number of patients with “exceedingly high annual medication costs” is increasing rapidly. The report finds that the population of patients with costs of \$100,000 or more has nearly tripled since 2013.

Upcoming Congressional Hearings

Senate

No relevant Senate hearings.

House

On Tuesday, May 19th, the House Ways and Means Subcommittee on Health will hold a [hearing](#) titled, “Improving Competition in Medicare: Removing Moratoria and Expanding Access.”

On Wednesday, May 20th, the House Ways and Means Subcommittee on Oversight will hold a [hearing](#) titled “Examining the Use of Administrative Actions in the Implementation of the Affordable Care Act.”

On Thursday, May 21st, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a [hearing](#) titled, “What are the State Governments Doing to Combat the Opioid Abuse Epidemic?”

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