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May 26, 2015 Health Care Update

House Energy and Commerce Unanimously Advances 21st Century Cures Legislation: Despite a delay in the markup of the 21st Century Cures Act (H.R. 6) caused by ongoing negotiations over offsets and other controversial issues, the House Energy and Commerce Committee advanced the legislation to the House Floor in a 51-0 roll call vote.

As in previous hearings on the bill, Committee members largely used opening statements to praise the Committee's effort and the bipartisan nature of the legislation. In bringing up the Manager's amendment, Chairman Upton highlighted that the amendment would provide the Food and Drug Administration (FDA) with the funding it needs to implement the legislation, including creating an annual Cures Innovation Fund and exempting certain FDA user fees from sequestration. The manager's amendment contained \$13 billion in pay fors which drew from programs across the Committee's jurisdiction including selling oil from the Strategic Petroleum Reserve, limiting the federal Medicaid match for durable medical equipment to Medicare rates, instituting payment penalties for the use of outdated X-ray technology, and cutting the amount of time that private Medicare Part D drug plans receive reinsurance funds from the government before the money is spent on medical care.

While the Committee passed the bill with much praise, segments of industry are poised for a fight over offsets used in the legislation. For example, pharmaceutical organizations remain opposed to Medicare Part D cuts now contained in the bill and AdvaMed has cited concerns about provisions dealing with Durable Medical Equipment competitive bidding. In addition, America's Health Insurance Plans (AHIP) has been vocal in its opposition to an offset that would target reinsurance payments to Medicare Part D plans.

On the House side, the Ways and Means, Appropriations, Budget, and Rules Committees must now evaluate the merits of the 21st Century Cures Act. Chairman Upton has said he envisions a House floor vote in "the third week or so" of June. Stakeholder focus will increasingly shift to the Senate, which is not expected to follow the House's aggressive timeline for legislation. Senate Health, Education, Labor, and Pensions Committee Chairman Lamar Alexander (R-TN) has said he does not plan to bring his own legislation to the floor before "early next year."

In the coming weeks and months, stakeholders will also likely continue work in both chambers on standalone opportunities, such as telehealth reimbursement, the Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act, provisions dealing with dormant therapies for diseases such as ALS, Alzheimer's, and Parkinson's, and the Advancing Care for Exceptional Kids Act of 2015 (ACE Kids Act), that were ultimately not included in the 21st Century Cures Act.

Implementation of the Affordable Care Act

ACA's Special Enrollment Period Extends Health Insurance to 147,000 People: The Department of Health and Human Services (HHS) [announced](#) that the Affordable Care Act gained around 147,000 enrollees during the special enrollment period that coincided with tax season. The period allowed people who had not enrolled but want to avoid the law's penalty for not having insurance to sign up for coverage through HealthCare.gov between March 15th and April 30th.

CMS Begins Its Push to Clarify Proposed Rates for ACA Plans: The Centers for Medicare and Medicaid Services (CMS) began [reviewing](#) insurers' applications to sell individual and small group health plans on federal-run exchanges in 2016. These insurers must submit their proposed rates to the Center for Consumer Information and Insurance Oversight (CCIIO) and the state departments of insurance (DOI).

Federal Regulatory Initiatives

CDC: Health Professionals Saved Lives from Meningitis: Public health officials and clinicians' containment of the fungal meningitis outbreak prevented 124 deaths and 153 strokes or additional infections, according to the Centers for Disease Control ([CDC](#)). Experts attribute the outbreak to contaminated steroid injections from a now-defunct pharmacy in New England. They said that because of the outbreak, 64 people died and 750 people contracted illnesses in 2012 and 2013.

FDA Hearing on Opioid Issues: The FDA [released](#) a notice of a public meeting and request for comment on increasing the use of naloxone to reduce the incidence of opioid drug overdose fatalities. The agency will accept comments on the issue leading up to the July 1st meeting. The deadline to comment is September 1, 2015.

ONC Adjusts Standards Committee Structure: In a [blog post](#), the Office of the National Coordinator for Health IT's (ONC) Jon White, Acting Deputy National Coordinator, and Steven Posnack, ONC's Director Of Standards And Technology, announced that the agency will sunset five working groups and replace them with "targeted, time-limited task forces."

HHS Report on IT's Role in Public Health: HHS's Office of the Assistant Secretary for Planning and Evaluation released a [report](#) titled, "Public Health IT to Support Chronic Disease Control." The report found that while "clinical data exchange between public health and health care providers may ultimately improve chronic disease control," there are significant barriers to implementing such tools and procedures.

HHS Study on Uninsured Rates: CDC's National Health Interview [Survey](#) found that states which expanded Medicaid lowered the rate of uninsured among low-income adults when compared to non-expansion states. The survey found uninsured rates fell from 20.4 percent in 2013 to 15.9 percent in April-September 2014.

GAO Study on Physician Payments and Price Accuracy: According to a [study](#) by the Government Accountability Office (GAO), Medicare pays \$70 billion a year to 7,000 physicians with rates set primarily on the basis of relative value assigned to each service. GAO recommended CMS better document its process for establishing relative values and develop a process to inform the public of potentially misvalued services identified by the Relative Value Scale Update Committee (RUC).

Congressional Initiatives

Bipartisan Group of Senators to FDA: Wait to Enforce Menu Labeling Rules: Senators Lamar Alexander and Patty Murray, the Chair and Ranking Member, respectively, of the Senate Health, Education, Labor, and Pensions (HELP) Committee, led a bipartisan [letter](#) signed by 30 other senators to the FDA urging it extend the deadline to comply with its menu labeling rules. The senators argued that restaurants, grocery stores, and convenience stores needed more guidance from the FDA for the labeling rules to work as intended.

CBO Director Discusses Dynamic Scoring, ACA on the Hill: Before the Senate Budget Committee, new CBO Director Keith Hall said his agency would clarify how it calculates legislations' macroeconomic impacts. He even expressed openness to "dynamic scoring," which forecasts effects of economic reactions to policy changes. Republicans have long supported dynamic scoring because they claim it reinforces the multiplier effect of tax cuts. Hall also said the CBO will further examine the budgetary effects of the Affordable Care Act.

E&C Committee Heads Inquiry on Biosafety Assessments of Health Agencies: Republican leaders of the House

Energy and Commerce Committee sent a [letter](#) to GAO requesting it assess CDC, NIH, and FDA's biosafety and biosecurity. They cited incidents of the agencies violating safety protocols, such as the NIH's storage of dangerous pathogens, some of which carried live smallpox, on its Bethesda site.

W&M Subcommittee Addresses Medicare Competition: The House Ways and Means Subcommittee on Health held a [hearing](#) to examine market solutions to foster competition in Medicare. Testifying at the hearing were witnesses from the American Hospital Association, Methodist McKinney Hospital, the American Association for Homecare, and the American Enterprise Institute.

Durbin, Graham Form NIH Caucus: Senators Dick Durbin (D-IL) and Lindsey Graham (R-SC) held an inaugural ceremony for the Senate National Institute of Health caucus. The ceremony, which NIH director Francis Collins attended, showcased the agency's research.

Senate Aging Committee Tackles Hospitals' "Observation Statuses:" The Senate Aging Committee held a [hearing](#) to examine a new trend of hospitals conferring patients "observation status" rather than admitting them. CMS's Sean Cavanaugh, MedPAC's Mark Miller and several industry representatives testified. They explained the impact of this trend on patients and whether the trend stems from hospitals seeking to evade penalties for readmissions.

Sens. McConnell and Markey Press HHS on Opioids: Senate Majority Leader Mitch McConnell (R-KY) and Senator Ed Markey (D-MA) [wrote](#) to HHS asking that the agency conduct a surgeon general's report in order to raise awareness about the growing opioid abuse epidemic. The pair also requests the agency share how it plans to measure progress on initiatives aimed at decreasing overdose deaths.

Senator Markey Introduces Opioid Bill: Senator Ed Markey (D-MA) introduced the [Safer Prescribing of Controlled Substances Act](#), which would require providers which prescribe opioid pain medications to undergo training on safe prescribing.

House E&C Examines State Response to Opioid Crisis: The House Energy and Commerce Oversight and Investigations Subcommittee [met](#) to consider the state government response to opioid abuse. Republicans on the committee attributed the epidemic partially to federal policy, over-prescriptions, and doctor-shopping while Democrats focused on funding and the root of the public health crisis as a result of inadequate health infrastructure for substance abuse.

Rep. Ellmers Introduces Biomedical Education Bill: Representative Renee Ellmers (R-NC) introduced [legislation](#) that would make education more affordable for students pursuing biomedical and public health degrees in one of four NIH programs: minority health disparities research, general research for NIH grantees, clinical research and pediatric research.

Sen. Murray Writes Colleagues on Public Health: Senate HELP Committee Ranking Member Patty Murray (D-WA), joined by 13 Democratic Senators, [wrote](#) to their Senate colleagues highlighting the benefits of wellness and prevention programs and praising the ACA's Prevention and Public Health Fund.

Other Health Care News

Patients Groups to CMS: Bring Back Meaningful Use Requirements: Twelve patient advocacy groups [called on](#) CMS to add meaningful use quality measures to Next Generation accountable cares organizations. They said that addition, which was in place up until this year, would help patients learn if their doctors are meaningful users and if they have electronic access to their own health records.

Upcoming Congressional Hearings

Congress is in Recess

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