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Health Care Update

House Energy and Commerce Continues 21st Century Cures Progress: Following the release of new draft [legislation](#) for the 21st Century Cures Initiative, the House Energy and Commerce Subcommittee on Health met to solicit feedback from witnesses from the National Institutes of Health (NIH) and the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH).

At the hearing, lawmakers on both sides of the aisle lauded the increased funding for the NIH, additional tools for breakthrough pathways for medical devices and drugs, antibiotic and antibiotic resistance provisions, streamlined clinical trials, and a focus on precision medicine and biomarkers. One item of note from the hearing was the need to resolve ongoing questions in the draft bill regarding interoperability and telemedicine, which now appear in the bill only as placeholders for further discussion among lawmakers and staff. Several members—including Health Subcommittee Chairman Joe Pitts (R-PA) Representative Doris Matsui (D-CA)—made note of the fact these items were left out and expressed a desire to continue work on these areas.

The bill does still tackle some aspects of health IT and it includes a new version of the Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act—championed by Representative Marsha Blackburn (R-TN)—which would create a definition of “health software” products that would be exempt from FDA regulation except for instances in which the agency determines the product “poses a significant risk to patient safety.” While many stakeholders believe interoperability and telehealth will eventually be folded into the bill, inclusion of provisions such as the SOFTWARE Act seems to reflect the Committee's dedication to streamlining current regulatory practices.

Pioneer ACO Program to be Expanded: Department of Health and Human Services (HHS) Secretary Sylvia Burwell has formalized the Obama Administration's intention to expand the Pioneer ACO demonstration program, the first and arguably most aggressive alternative payment model being tested by the Medicare program. At an American Hospital Association (AHA) conference this morning, Burwell noted that the Pioneer ACO program was the first to meet the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary's approval for expansion, a critical benchmark necessary to scale models under authority granted by the ACA. Central to the ultimate success of the Pioneer ACO program will be what additional changes are made to give providers more flexibility around Medicare rules and also the next iteration of shared savings and quality measures.

Federal Regulatory Initiatives

CMS Released Part D Data: CMS [announced the availability](#) of on Medicare Part D prescription drugs prescribed by physicians and other health care professionals in 2013—detailing \$103 billion in drug spending. The data shows what drugs were prescribed, how many patients were prescribed to, and the costs of the drugs.

CMS Updates 2016 Hospice Benefit Rates: CMS released a proposed [rule](#) to update FY 2016 Medicare payment rates and the wage index for hospices serving Medicare beneficiaries.

FDA Releases Final Biosimilar Guidances: The FDA released three documents, [scientific considerations](#), [quality considerations](#) and [biosimilars Q&A](#) to provide guidance to drug manufacturers.

Burwell Joins Roundtable Discussion on Opioid Abuse: HHS Secretary Burwell [travelled](#) to Massachusetts to join Governor Charlie Baker to participate in a roundtable discussion with Baker's Opioid Addiction Working Group and Massachusetts HHS Secretary Marylou Sudders on opioid abuse.

NIH Names New Head of Minority Health: NIH Director Francis Collins [announced](#) that Eliseo J. Pérez-Stable, M.D., will serve as Director of the National Institute on Minority Health and Health Disparities (NIMHD).

ONC Webinar on Certification: The Office of the National Coordinator for Health IT (ONC) held a [webinar](#) on the agency's proposed rule to implement the ONC Health IT Certification Program and outline the 2015 Edition Health IT Certification Criteria.

Congressional Initiatives

Bicameral Committee Leadership Writes to MACPAC: – House Energy and Commerce Committee Chairman Fred Upton (R-MI), Health Subcommittee Chairman Joe Pitts (R-PA), Senate Finance Committee Chairman Orrin Hatch (R-UT), and Senate Committee on Health, Education, Labor, and Pensions Chairman Lamar Alexander (R-TN) [wrote](#) to the Commissioners of the Medicaid and CHIP Payment and Access Commission (MACPAC) soliciting ideas for strengthening Medicaid as the program turns 50 years old.

Bipartisan MEDTECH Bill Introduced: Senators Michael Bennet (D-CO) and Orrin Hatch (R-UT) [reintroduced](#) the Medical Electronic Data Technology for Consumers' Health (MEDTECH) Act, which would exempt low-risk medical software and mobile apps from Food and Drug Administration (FDA) oversight.

Rep. Courtney Introduces Cadillac Tax Bill: Representative Joe Courtney (D-CT) [introduced](#) the Middle Class Health Benefits Tax Repeal Act, which would repeal the 40 percent excise tax—known as the Cadillac Tax—on high-cost health insurance plans scheduled to go into effect in 2018.

Bipartisan Bill Targets Small-Group Expansion: Senators Tim Scott (R-SC) and Jeanne Shaheen (D-NH) introduced [S. 1099](#), a bill that would amend the ACA to give states flexibility in implementing the small-group market expansion. The bill gives states discretion in determining the size of employers in the small-group market.

Lawmakers Introduce Menu Labeling Bill: Representatives Cathy McMorris Rodgers (R-WA) and Loretta Sanchez (D-CA) reintroduced the Common Sense Nutrition Disclosure Act, which would exempt grocery and convenience stores from the calorie menu labeling rule the FDA issued last year.

Lawmakers Press FDA on Generic Labeling: Forty-seven Democrats from the Senate and House wrote to the FDA urging the agency to finalize a proposal to require generic drug makers to update their labeling to include new safety measures.

Rep. Eshoo Introduced Medical Research Bill: Representative Anna Eshoo (D-CA) introduced [legislation](#) that would fund agencies pursuing medical research—including the NIH, Centers for Disease Control (CDC), Department of Defense health programs, and the Veterans Medical and Prosthetic Research Program, at the rate of inflation plus 5 percent per year.

House E&C Examines Microbeads: The House Energy and Commerce Subcommittee on Health met to [discuss](#) bipartisan legislation to address the issue of microbeads in cosmetic products polluting bodies of water.

Senate Finance Hearing on Medicare Appeals: The Senate Finance Committee held a hearing on [reforming Medicare's appeal process](#) and discussed new ways to make the process more efficient and address the problems

associated with audits and appeals.

Senate HELP Continues Innovation Hearings: The Senate Health, Education, Labor, and Pensions Committee [met](#) to examine the question of how to improve and hasten the drug and medical device approval process. Panelists from the FDA and NIH described their agencies' innovative processes and medical breakthroughs, and addressed the funding and collaborative challenges they face.

House E&C Meets on Opioids: The House Energy and Commerce Oversight and Investigations Subcommittee [hearing](#) entitled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic." Lawmakers discussed treatment options for the management of chronic pain other than opioids and the federal response to the opioid crisis.

Other Health Care News

IOM Changes Name: The [Institute of Medicine](#) (IOM) announced at the 152nd annual meeting of the National Academy of Sciences (NAS) that it will change its name to the National Academy of Medicine. The Institute said in a release that this change "is an acknowledgement of the importance of medicine and related health sciences to today's global research enterprise."

Kaiser Study on Individual Market Progress: The Kaiser Family Foundation released a [study](#) on how the individual insurance market changed under the ACA. The study found that the market grew to 15.5 million people in 2014, 46 percent increase since the launch of the ACA.

S&P Report on ACA Risk Corridors: A [report](#) by Standard & Poor's found that the ACA's risk corridor pool is likely to be "significantly underfunded" in 2014 if funding for the program is only provided by insurers.

U.S. health data hurt by poor quality clinical registries: Most U.S. clinical registries that collect data on patient outcomes are not useful and lack good standards, according to a [study](#) in the Journal for Healthcare Quality today. Less than a quarter of the registries adjusted results for disease complexity, and less than a fifth of the registries had independently entered data.

Upcoming Congressional Hearings

Senate

On Tuesday, May 5th, the Senate Health, Education, Labor, and Pensions Committee will hold a [hearing](#) titled "Continuing America's Leadership: Realizing the Promise of Precision Medicine for Patients."

On Wednesday, May 6th, the Senate Appropriations Subcommittee on State, Foreign Operations, and Related Programs will hold a [hearing](#) on global health programs.

On Thursday, May 7th, the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies will hold a [hearing](#) on rural health.

House

The House will be in Recess.

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