



## Health Policy Briefing

January 25, 2016

### Snow Week for the House of Representatives



*(Photo by Alex Wong/Getty Images)*

The House of Representatives will be out of session this week due to the winter storm that took place this weekend in the D.C. area. The House was already scheduled for a short week due to Democratic lawmakers attending their legislative retreat in Baltimore from Wednesday to Friday. Previously, the House had scheduled a vote for Tuesday to override the president's veto on repealing the Affordable Care Act (ACA) and defunding Planned Parenthood. The vote will almost certainly fail, as two-thirds of the House and Senate are required to override a presidential veto. Votes will recommence on February 1. The Senate has not revised its schedule at this point, and is currently scheduled to meet on Tuesday. Federal government offices in D.C. will be closed on Monday, January 25 due to inclement weather.

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## ***CBO Budget and Economic Outlook***

Last week, the Congressional Budget Office (CBO) released a **summary** of its annual Budget and Economic Outlook. The report is a 10-year forecast analyzing the impact of new laws and economic developments on economic growth. According to the analysis, the federal budget deficit will increase to \$544 billion this year, \$105 billion more than last year. This amounts to 2.9 percent of the gross domestic product (GDP), and the first time since 2009 that the deficit has risen as a share of the economy. The new baseline projects that the deficit will continue to go up after this year – reaching \$561 billion in fiscal year (FY) 2017 and \$1 trillion by 2022. CBO notes that these deficit predictions would increase debt held by the public to 86 percent of GDP by the end of the budget window, which is more than twice the average over the past five decades. The agency predicts that the 2015 budget deal and omnibus-tax extenders package passed by Congress in December will boost real GDP slightly both this year and next. CBO estimates that real GDP will grow by 2.7 percent in calendar year (CY) 2016, by 2.5 percent in 2017, and then slow by an average rate of growth of 2 percent between 2018 and 2026. CBO projects \$51.4 trillion in spending and \$42 trillion in revenue over the next decade. Additionally, spending for mandatory programs such as Social Security, Medicare, Medicaid, and health insurance subsidies are expected to rise from 13.1 percent of GDP to 15 percent of GDP by 2026. Discretionary spending will fall from 6.5 percent of GDP to 5.2 percent in 2026. The full Budget and Economic Outlook will be released today. Updated projections will be issued in March, and will include feedback effects – the impact of economic growth on revenue and spending. The House Budget Committee will hold a hearing on the report, which will inform congressional work on a budget resolution.

## ***Senate HELP Announces Schedule for Consideration of Biomedical Innovation Bills***

Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee Lamar Alexander (R-Tenn.) announced that HELP will not be working on a Senate version of the House's 21st Century Cures Act, but will instead vote separately on a range of medical innovation bills. Chairman Alexander announced three scheduled markups to consider legislation: February 9, March 9 and April 6. The Committee will consider at least seven bipartisan bills during its first markup in February:

- Bipartisan HELP Committee legislation to improve electronic health records. (The draft was released last week and as explained below comments are requested to the committee no later than January 29.)
- ***The FDA Device Accountability Act of 2015 (S.1622)***, sponsored by Sens. Burr (R-N.C.) and Franken (D-Minn.);
- ***The Advancing Targeted Therapies for Rare Diseases Act of 2015 (S.2030)***, sponsored by Sens. Bennet (D-Colo.), Burr (R-N.C.), Warren (D-Mass.), and Hatch (R-Utah);
- ***The Advancing Research for Neurological Diseases Act of 2015 (S.849)***, sponsored by Sens. Isakson (R-Ga.) and Murphy (D-Conn.);
- ***The Next Generation Researchers Act (S.2014)***, sponsored by Sens. Baldwin (D-Wisc.) and Collins (R-Maine);
- ***The Enhancing the Stature and Visibility of Medical Rehabilitation Research at the NIH Act (S. 800)***, sponsored by Sens. Kirk (R-Ill.), Bennet (D-Colo.), Hatch (R-Utah), Murkowski (R-Alaska), Isakson (R-Ga.), and Collins (R-Maine); and
- Legislation regarding Food and Drug Administration (FDA) regulation of duodenoscopes.

Additional bipartisan bills to modernize the FDA and the National Institutes of Health (NIH) and provide congressional support for the president's Precision Medicine Initiative will be considered by the Committee in March:

- ***The Advancing Hope Act of 2015 (S. 1878)***, sponsored by Sens. Casey (D-Pa.), Isakson (R-Ga.), Brown (D-Ohio) and Kirk (R-Ill.);
- ***The Medical Electronic Data Technology Enhancement for Consumer's Health (MEDTECH) Act (S. 1101)***, sponsored by Sens. Bennet (D-Colo.) and Hatch (R-Utah);
- ***The Medical Countermeasures Innovation Act of 2015 (S. 2055)***, sponsored by Sens. Burr (R-N.C.), Casey (D-Pa.), Isakson (R-Ga.), and Roberts (R-Kan.);
- ***The Combination Products Innovation Act of 2015 (S.1767)***, sponsored by Sens. Isakson (R-Ga.), Casey (D-Pa.), Roberts (R-Kan.) and Donnelly (D-Ind.);

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- *The Advancing Breakthrough Medical Devices for Patients Act of 2015 (S. 1077)*, sponsored by Sens. Burr (R-N.C.), Bennet (D-Colo.), Hatch (R-Utah), and Donnelly (D-Ind.); and
- Legislation to support the president's Precision Medicine Initiative and ensure that the NIH has the tools it needs to research treatments that are individualized for patients.

A final markup in April is planned for the Committee to complete its work on the Innovations Initiative. The House's medical innovation bill, *the 21st Century Cures Act (H.R. 6)*, passed the chamber in July by a 344 - 77 vote.

### ***HELP Releases HIT Interoperability Draft Bill***

The Senate Health, Education, Labor, and Pensions (HELP) Committee released a staff discussion **draft** of bipartisan legislation to improve health information technology (HIT). The draft is result of the work of the committee's HIT working group convened in April 2015. The legislation focuses on decreasing unnecessary physician documentation; enabling patients to have easier access to their own health records; and making electronic health records (EHRs) more accessible to the entire health care team, such as nurses. The bill would allow non-physician members of health care teams document information in EHRs on behalf of physicians. It establishes an unbiased rating system for HIT to help providers choose products. It also gives the U.S. Department of Health and Humans Services (HHS) Office of the Inspector General (OIG) the authority to investigate and establish deterrents to information blocking practices. The draft would establish an initial set of common data elements, such as standard formatting for entering a patient's date of birth. It also includes a measure to support the certification and development of patient-centered EHR technology so that patients can access their information through secure software. The Committee identifies stopping information blocking – or intentional interference with access to personal health information, ensuring the government's certification of a records system means what it says it does, and improving standards as the most critical steps to developing systems that achieve interoperability. Comments are due on the draft legislation no later than January 29 to [HealthIT@help.senate.gov](mailto:HealthIT@help.senate.gov). The bill will be considered during the Committee's first Innovation markup on February 9. A summary of the draft is available [HERE](#).

### ***Shkreli Subpoenaed Over Drug Price Increases***

The House Oversight Committee has issued a subpoena to Martin Shkreli, the ex-CEO of Turing Pharmaceuticals who became notorious last year by increasing the cost of Daraprim by 5,000 percent overnight. Committee Chairman Jason Chaffetz (R-Utah) wrote to Shkreli last week demanding financial information and profits from the sale of this drug. Shkreli's lawyer has told Rep. Chaffetz that the former executive will plead the Fifth Amendment and remain silent if he is forced to appear before the committee. Other hearing witnesses include Howard Schiller, the interim CEO of Valeant Pharmaceuticals. Valeant has also been accused of price gouging. The Director of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) will also testify, in addition to Mark Merritt, president of the Pharmaceutical Care Management Association.

## **FDA News**

### ***Hold Placed on Califf's FDA Nomination***

Sen. Ed Markey (D-Mass.) has placed a hold on Robert Califf's nomination to be Commissioner of the Food and Drug Administration (FDA) because of the agency's policies for evaluating prescription opioids. Specifically, Sen. Markey is concerned about the FDA's approval of OxyContin for pediatric use in 2015. Sen. Markey has requested that the FDA convene an advisory panel of outside experts when making approval decisions on opioid painkillers. He also wants the agency to weigh the risks of abuse and addiction before approving an opioid drug. The hold follows Sen. Lisa Murkowski's (R-Alaska) announcement that she would block a floor vote on Dr. Califf's nomination until she receives more information about the agency's decision surrounding genetically engineered salmon. Presidential candidate Bernie Sanders (D-Vt.) has also threatened to place a hold on the nomination because of the Dr. Califf's previous relationships with the pharmaceutical industry.

***Data Book on Dual Eligibles Released***

The Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) have released the third edition of the joint data book titled **Beneficiaries Dually Eligible for Medicare and Medicaid**. The data book is a part of an ongoing effort by both groups to better understand the characteristics of dually eligible beneficiaries and their use of health care services. This edition includes 2011 data and 2007-2011 trends in the population's composition, associated service use, and spending. The data book is meant to inform Congress as well as each commission's discussions about the policy issues surrounding the dual eligible population.

***Federal Spending on Medicaid Managed Care Reaches \$107 Billion***

Federal spending on Medicaid managed care accounted for one-third of total federal Medicaid spending in fiscal year (FY) 2014, according to a new Government Accountability Office (GAO) **report**. The agency finds that states are increasingly using managed care as they expand their Medicaid programs under the Affordable Care Act (ACA). Federal spending on managed care rose from \$27 billion in FY 2004 to \$107 billion in FY 2014.

**Upcoming Congressional Meetings and Hearings**

**Senate Special Aging Committee field hearing:** *"Fighting Against a Growing Epidemic: Opioid Misuse and Abuse Among Older Americans;"*, 21170 Ashby Ponds Boulevard, Ashburn, Va.; January 25, time tbd (originally scheduled for 10:30 a.m.)

**POSTPONED:** *House Energy and Commerce Health Subcommittee hearing: "Examining Medicaid and CHIP's Federal Medical Assistance Percentage;"* 10:00 a.m., 2322 Rayburn Bldg.; January 26

**POSTPONED:** *House Oversight and Government Reform Committee hearing: "Developments in the Prescription Drug Market: Oversight;"* 2:00 p.m., 2154 Rayburn Bldg.; January 26

**Senate Health, Education, Labor and Pensions Committee hearing:** *"Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs;"* 10:00 a.m., 430 Dirksen Bldg.; January 28

**House Veterans' Affairs Health Subcommittee: hearing on** *"Choice Consolidation: Evaluating Eligibility Requirements for Care in the Community;"* 10:00 a.m., 334 Cannon Bldg.; February 2

**House Energy and Commerce Committee hearing on** *biosimilars, details TBD;* February 4

**Senate Health, Education, Labor and Pensions Committee markup:** *S.1622, the "FDA Device Accountability Act of 2015"; S.2030, the "Advancing Targeted Therapies for Rare Diseases Act of 2015"; S.849, the "Advancing Research for Neurological Diseases Act of 2015"; S.2014, the "Next Generation Researchers Act"; S.800, the "Enhancing the Stature and Visibility of Medical Rehabilitation Research at the NIH Act"; and legislation regarding health IT and FDA regulation of duodenoscopes; time TBA;* 430 Dirksen Bldg.; February 9

**House Veterans' Affairs Health Subcommittee: hearing on** *"Choice Consolidation: Improving VA Community Care Billing and Reimbursement;"* 10:00 a.m., 334 Cannon Bldg.; February 11

**Senate Health, Education, Labor and Pensions Committee executive session on the innovation agenda; time and place** TBA; March 9

**Senate Health, Education, Labor and Pensions Committee final markup on innovation agenda; time and place** TBA; April 6