



Health Policy Briefing

May 18, 2015

21st Century Cures Legislation Advances

Bill to Be Considered by Full Energy and Commerce Committee This Week

The House Energy and Commerce Health Subcommittee favorable reported out the 21st Century Cures draft bill to the full Committee for consideration by a voice vote with no amendments. The Subcommittee marked up the bipartisan medical innovation bill last week, following the release of an updated draft that reflects the most recent bipartisan negotiations on previously unresolved issues such as telemedicine and interoperability of electronic health records. Updates to the bill would allow the U.S. Department of Health and Human Services inspector general to investigate possible information blocking. The latest draft dropped a provision to grant longer exclusivity periods for manufacturers of dormant therapies for unmet medical needs, and will no longer provide U.S. generic drug manufacturers longer periods of protection from global competition. These exclusivity periods would prevent competitors from selling the same drugs. Instead, the bill marked up by the Subcommittee includes a six-month extension of market exclusivity for drugs that treat rare diseases. Some Democrats expressed concerns that this provision will hinder patient access to the treatments. Republicans fought for its inclusion, arguing that the incentive will encourage more investment in the development of “orphan drugs,” which the Food and Drug Administration (FDA) defines as treatments for diseases affecting fewer than 200,000 Americans. Orphan drug status can also be granted to companies whose products will not be profitable within seven years of FDA approval. The latest 21st Century Cures Act legislation includes the addition of a seven-year reauthorization of the rare pediatric disease priority review voucher program. The program gives manufacturers of a rare pediatric disease drug a voucher for faster FDA review of another product. Manufactures are allowed to sell the vouchers to another company. During the markup, members from both sides of the aisle expressed support for the bill but stressed that the draft is not final and that more work remains to be done. Funding for the FDA continues to be a point of contention. While the bill includes \$10 billion over five years in mandatory spending for the National

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Institutes of Health (NIH), as well as yearly increases to boost the NIH's budget by an additional \$5 billion by 2018, no additional funding is included for the FDA. Democrats are pushing for the inclusion of additional FDA resources to enable the agency to meet its new obligations as a result of 21st Century Cures and to approve new cures in a safe and timely manner. How the bill will be offset is still unknown. Energy and Commerce Committee Chairman Fred Upton (R-Mich.) has stated that the bill will be fully offset, though it may be possible that leadership will be left to negotiate pay-fors after the bill clears the Committee. The full Energy and Commerce Committee will consider the legislation this week. Chairman Upton has reiterated his hopes to have the bill on the House floor by June and enacted into law later this year. Meanwhile, the Senate's parallel "Healthier Americans" initiative is on a much slower track. While the chamber plans to produce its own bill, Health, Education, Labor, and Pensions Committee Chairman Lamar Alexander (R-Tenn.) has said that he does not expect to bring a bill to the floor before early 2016.

Trade Deal Would Lengthen Biologics Exclusivity

Congress is currently considering a trade bill that would include 12 years of data exclusivity on biologics. The Trans-Pacific Partnership (TPP) is a priority of the President and would set the terms of trade between the United States and 11 other countries. Opponents of the provision fear that this significant period of exclusivity will make medicines unaffordable in poor nations. The pharmaceutical industry argues that this length of time is necessary to recover investment in biologic discovery and development. Compared to market exclusivity, data exclusivity prevents competitors from even starting to develop a drug. In its budgets, the Obama Administration has proposed cutting biologic exclusivity to seven years, citing a potential of \$4.4 billion in Medicare program savings. Senate Majority Leader Mitch McConnell (R-Ky.) has stated that he would like to pass the legislation before the end of this week.

Affordable Care Act Update

Cassidy, Price Reveal Plans to Repeal and Replace the ACA

Rep. Tom Price (R-Ga.) and Sen. Bill Cassidy (R-La.) are the latest Republicans to offer plans for the repeal and replacement of the Affordable Care Act (ACA) in the time leading up to the Supreme Court's decision in the *King v. Burwell* case. House Budget Committee Chairman Tom Price's plan is based on his Empowering Patients First Act, previously introduced during the 113th Congress. His proposal would permanently repeal the ACA, while providing refundable tax credits for the purchase of health insurance following the elimination of federal subsidies. The credits would be based on the recipient's age and would take into account whether the recipient has children. Individuals would also be provided with a \$1,000 tax credit for the purpose of establishing a health savings account (HSA). The contribution limit of HSAs would be raised to match that of individual retirement arrangements (IRAs). Grants to states would aid in the coverage of those with pre-existing conditions through the establishment of high-risk pools. Individuals would also be allowed to opt out of Medicare, Medicaid, and the VA, and instead use tax credits to purchase private insurance. Under Rep. Price's bill, small business would be able to purchase insurance across state lines. The plan also includes medical liability reform, changing the burden of proof based on physicians following clinical guidelines. Rep. Price has expressed opposition to proposals from Senate Republican leadership to temporarily extend federal subsidies should the Supreme Court rule against the Administration and invalidate that section of the health care law. Sen. Bill Cassidy plans to introduce the Patient Freedom Act later this month, as a part of a two-part Senate Republican response to the *King v. Burwell* case. After Republicans settle upon how to temporarily assist the 7.5 million federal marketplace enrollees who could lose their subsidies for purchasing health insurance, Sen. Cassidy's proposal would allow states to receive tax credits for HSAs if they opt out of ACA mandates. The Court's ruling is expected in late June. The budget resolution sets a deadline of July 24 for each chamber's Budget Committee to submit a contingency plan in preparation for the Court's ruling.

Affordable Care Act Update cont.

House Democrats Urge Medical Device Tax Repeal

Eighteen House Democrats have sent a **letter** to Speaker John Boehner (R-Ohio) and Minority Leader Nancy Pelosi (D-Calif.) urging advancement of a bill that repeals the ACA's medical device tax before Memorial Day. Led by Rep. Scott Peters (D-Calif.), the letter warns that the 2.3 percent tax on manufacturers and importers of medical devices is causing companies to cut their research and development budgets, which "jeopardizes advancements in patient care that have the potential to improve outcomes, lower costs, and offer a better quality of life for millions of patients." Repeal of the tax would cost \$26 billion between 2015 and 2024. H.R. 160, the Protect Medical Innovation Act, currently has 277 bipartisan cosponsors.

Medicare & Medicaid News

Super Users Responsible for Half of Medicaid Spending

The top five percent of Medicaid beneficiary spenders account for almost half of the program's expenditures, according to a new **analysis** released by the Government Accountability Office (GAO). In contrast, in each fiscal year from 2009 through 2011, the least expensive half of Medicaid beneficiaries accounted for less than eight percent of program spending.

Upcoming Congressional Meetings and Hearings

House Ways and Means Health Subcommittee: hearing on "Improving Competition in Medicare: Removing Moratoria and Expanding Access;" 10:00 a.m., 1100 Longworth Bldg.; May 19

Senate Budget Committee: hearing on oversight of the Congressional Budget Office; 10:30 a.m., 608 Dirksen Bldg.; May 19

House Energy and Commerce Committee: opening statements on markup to consider the 21st Century Cures Act; 5:00 p.m., 2123 Rayburn Bldg.; May 19

House Energy and Commerce Committee: markup to consider the 21st Century Cures Act; 10:00 a.m., 2123 Rayburn Bldg.; May 20

House Ways and Means Oversight Subcommittee: hearing titled "Examining the Use of Administrative Actions in the Implementation of the Affordable Care Act;" 10:00 a.m., 1100 Longworth Bldg.; May 20

Senate Special Aging Committee: hearing titled "Challenging the Status Quo: Solutions to the Hospital Observation Stay Crisis;" 2:15 p.m., 562 Dirksen Bldg.; May 20

House Energy and Commerce Oversight Subcommittee: hearing on opioid abuse issues; 10:15 a.m., 2322 Rayburn Bldg.; May 21

Health Legislation Recently Introduced

H.R. 2247 (ICD-10), to require the Secretary of Health and Human Services to provide for transparent testing to assess the transition under the Medicare fee-for-service claims processing system from the ICD-9 to the ICD-10 standard, and for other purposes; BLACK; jointly, to the committees on Energy and Commerce and Ways and Means; May 12

H.R. 2248 (VA), to provide that service of the members of the organization known as the United States Cadet Nurse Corps during World War II constituted active military service for purposes of laws administered by the Secretary of Veterans Affairs; LOWEY; jointly, to the committees on Veterans' Affairs and Armed Services; May 12

H.R. 2249 (MEDICAID), to amend title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 to restore Medicaid coverage for citizens of the Freely Associated States lawfully residing in the United States under the Compacts of Free Association between the Government of the United States and the Governments of the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau; GABBARD; to the House Committee on Energy and Commerce; May 12

H.R. 2253 (PRIMARY CARE), to amend title XIX of the Social Security Act to extend the application of the Medicare payment rate floor to primary care services furnished under Medicaid and to apply the rate floor to additional providers of primary care services; CASTOR; to the House Committee on Energy and Commerce; May 12

H.R.2256 (VA), to amend title 38, United States Code, to direct the Secretary of Veterans Affairs to submit an annual report on the Veterans Health Administration and the furnishing of hospital care, medical services, and nursing home care by the Department of Veterans Affairs; BENISHEK; to the House Committee on Veterans' Affairs; May 12

H.J.RES.50 (HEALTH CARE COMPACT), granting the consent of Congress to the Health Care Compact; COLLINS; to the House Committee on the Judiciary; May 12

H.RES.256 (STROKE), expressing support for designation of May as Stroke Awareness Month; BEATTY; to the House Committee on Energy and Commerce; May 12

H.RES.257 (NURSING), supporting the goals and ideals of National Nurses Week on May 6, 2015, through May 12, 2015; BERNICE JOHNSON; to the House Committee on Energy and Commerce; May 12

H.RES.259 (BRAIN ANEURYSM), expressing support for designation of September 2015 as "National Brain Aneurysm Awareness Month"; TIBERI; to the House Committee on Energy and Commerce; May 12

S. 1287 (VIRAL HEPATITIS), to amend the Public Health Service Act to revise and extend the program for viral hepatitis surveillance, education, and testing in order to prevent deaths from chronic liver disease and liver cancer, and for other purposes; KIRK; to the Committee on Health, Education, Labor, and Pensions; May 12

S. 1290 (TRICARE), to ensure the ability of covered beneficiaries under the TRICARE program to access care under a health plan under such program in each TRICARE program region, and for other purposes; ROUNDS; to the Committee on Armed Services; May 12

S.RES.178 (NURSING), supporting the goals and ideals of National Nurses Week from May 6, 2015, through May 12, 2015; MERKLEY; to the Committee on Health, Education, Labor, and Pensions; May 12

H.R. 2292 (REHABILITATION), to amend title XVIII of the Social Security Act to preserve access to rehabilitation innovation centers under the Medicare program; OLSON; jointly, to the committees on Ways and Means and Energy and Commerce; May 13

H.R. 2298 (DRUG ABUSE), to amend title XVIII of the Social Security Act to provide for programs to prevent prescription drug abuse under parts C and D of the Medicare program; BILIRAKIS; jointly, to the committees on Energy and Commerce and Ways and Means; May 13

Health Legislation Recently Introduced cont.

H.R. 2299 (MEDICARE), to amend title XVIII of the Social Security Act to provide for site-of-service price transparency under the Medicare program; BILIRAKIS; jointly, to the committees on Energy and Commerce and Ways and Means; May 13

H.R. 2300 (INSURANCE), to provide for incentives to encourage health insurance coverage, and for other purposes; PRICE; jointly, to the committees on Energy and Commerce, Ways and Means, Education and the Workforce, the Judiciary, Natural Resources, House Administration, Rules, Appropriations, and Oversight and Government Reform; May 13

H.R. 2311 (NIH), to expand the research activities of the National Institutes of Health with respect to functional gastrointestinal and motility disorders, and for other purposes; SENSENBRENNER; to the Committee on Energy and Commerce; May 13

H.R. 2313 (HYDROCEPHALUS), to amend the Public Health Service Act to enhance and expand infrastructure and activities to track the epidemiology of hydrocephalus, and for other purposes; SMITH; to the Committee on Energy and Commerce; May 13

S. 1313 (TRICARE), to expand eligibility for reimbursement for smoking cessation services to include copayments for such services paid after fiscal year 2009 by covered beneficiaries under the TRICARE program who are eligible for Medicare; BROWN; to the Committee on Armed Services; May 13

S. 1327 (CONTROLLED SUBSTANCES), to amend the Controlled Substances Act relating to controlled substance analogues; KLOBUCHAR; to the Committee on the Judiciary; May 13

H.R.2325 (MEDICARE), to amend title XVIII of the Social Security Act to provide for a pharmaceutical and technology ombudsman under the Medicare program; BROOKES; jointly, to the committees on Ways and Means and Energy and Commerce; May 14

H.R.2335 (DRUG ABUSE), to amend the Federal Food, Drug, and Cosmetic Act to incentivize the development of abuse-deterrent drugs; KEATING; to the House Committee on Energy and Commerce; May 14

H.R.2337 (BREAKTHROUGH DEVICES), to amend the Federal Food, Drug, and Cosmetic Act to authorize priority review for breakthrough devices; PITTS; to the House Committee on Energy and Commerce; May 14

H.R.2338 (PATIENT EXPERIENCE DATA), to amend the Federal Food, Drug, and Cosmetic Act to provide for the development and use of patient experience data to enhance the structured risk-benefit assessment framework, and for other purposes; PITTS; to the House Committee on Energy and Commerce; May 14

H.R. 2342 (NHSC), to amend the Public Health Service Act to provide for the participation of physical therapists in the National Health Service Corps Loan Repayment Program, and for other purposes; SHIMKUS; to the House Committee on Energy and Commerce; May 14

H.CON.RES.46 (NIH), expressing the sense of the Congress that the National Institutes of Health should encourage a global pediatric clinical trial network, and for other purposes; PITTS; to the House Committee on Energy and Commerce; May 14

S. 1345 (DIABETES), to amend title XVIII of the Social Security Act to improve access to diabetes self-management training by authorizing certified diabetes educators to provide diabetes self-management training services, including as part of telehealth services, under part B of the Medicare program; SHAHEEN; to the Committee on Finance; May 14

S. 1347 (EHR), to amend title XVIII of the Social Security Act with respect to the treatment of patient encounters in ambulatory surgical centers in determining meaningful EHR use, and for other purposes; ISAKSON; to the Committee on Finance; May 14

S. 1349 (OBSERVATION STATUS), to amend title XVIII of the Social Security Act to require hospitals to provide certain notifications to individuals classified by such hospitals under observation status rather than admitted as inpatients of such hospitals; CARDIN; to the Committee on Finance; May 14

Health Legislation Recently Introduced cont.

S. 1354 (PHYSICIAN ASSISTANTS), to amend title XVIII of the Social Security Act to provide for recognition of attending physician assistants as attending physicians to serve hospice patients, and for other purposes; ENZI; to the Committee on Finance; May 14

H.R. 2348 (MEDICAID), to amend titles XI and XIX of the Social Security Act to promote program integrity with respect to the enrollment of certain immigrants in State plans under Medicaid, and for other purposes; FLORES; to the Committee on Energy and Commerce; May 15

H.R. 2349 (INSURANCE), to ensure receipt of all health insurance benefits to which a member of a union is entitled; GRAYSON; to the Committee on Education and the Workforce; May 15

H.R. 2355 (WOMEN'S HEALTH), to provide for a national public outreach and education campaign to raise public awareness of women's preventive health, and for other purposes; BERA; to the Committee on Energy and Commerce; May 15

H.R. 2362 (MEDICAL DEBT), to exclude from consumer credit reports certain medical debt that is less than 180 days delinquent or that has been in collection and has been fully paid or settled, to amend the Fair Debt Collection Practices Act to provide for a timetable for verification of medical debt and to increase the efficiency of credit markets with more perfect information, and for other purposes; CARNEY; to the Committee on Financial Services; May 15

H.R. 2366 (EMERGENCY MEDICINE), to provide for improvement of field emergency medical services, and for other purposes; BUCSHON; jointly, to the committees on Energy and Commerce and Ways and Means; May 15

H.R. 2373 (MEDICAL MARIJUANA), to provide for the legitimate use of medicinal marijuana in accordance with the laws of the various States; GRIFFITH; to the Committee on Energy and Commerce; May 15

H.RES. 265 (AIDS), recognizing the importance of a continued commitment to ending pediatric AIDS worldwide; LEE; jointly, to the committees on Foreign Affairs and Energy and Commerce; May 15

H.RES. 268 (UTERINE FIBROIDS), Supporting the designation of July 2015 as Uterine Fibroids Awareness Month; SCOTT; to the Committee on Energy and Commerce; May 15