



Health Policy Briefing

April 27, 2015

Movement on 21st Century Cures Initiative Continues

Updated Discussion Draft to be Released this Week

House Energy and Commerce Committee Chairman Fred Upton (R-Mich.) and Rep. Diana DeGette (D-Colo.) are close to the completion of a new discussion draft for the 21st Century Cures Initiative. The bipartisan Initiative spearheaded by Rep. Upton and Rep. DeGette is aimed at accelerating the pace at which medical treatments and devices are discovered, developed, and delivered to patients. The first Cures discussion draft was released by Chairman Upton in January of this year and focused on potential improvements to the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). Since release of the first draft, Rep. Upton and Rep. DeGette have met with other members of the Energy and Commerce Committee, including Ranking Member Frank Pallone (D-N.J.), Health Subcommittee Chairman Joe Pitts (R-Pa.), and Health Subcommittee Ranking Member Gene Green (D-Texas), to help advance the legislation. The first Cures discussion draft was not endorsed by either Rep. Pallone or Rep. DeGette. The latest draft will be released prior to the 21st Century Cures Initiative hearing scheduled for Thursday of this week, exactly one year since the launch of the Initiative. Dr. Kathy Hudson, Deputy Director for Science, Outreach, and Policy at the NIH, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at FDA, and Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health (CDRH) at the FDA will testify. The latest draft will not be a completed bill, but rather an indication of the provisions that could be included in a final bill. The draft will be indicative of whether or not further action on the Initiative will be possible within the Chairman's projected timeline. Rep. Upton has expressed hopes for passage of final legislation before Memorial Day. Acting Commissioner of the FDA Stephen Ostroff, M.D. commented that the 21st Century Cures package could be complementary to user fee discussions at his agency that will begin in June. Dr. Ostroff noted that the FDA approved a record 52 medicines last year, but new unfunded mandates from Congress through the 21st Century Cures Initiative could slow this progress.

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USPSTF Maintains Mammogram Recommendations

The U.S. Preventive Services Task Force (USPSTF) has decided to **reiterate** its 2009 recommendation that women under the age of 50 should wait to start getting mammograms, while women aged 50-74 should only be screened every two years. The Task Force's reasoning points to evidence that the benefits of such testing do not outweigh the risks – citing false positives and overdiagnosis associated with mammograms in younger women. The recommendations are subject to public comment before they are finalized. The Affordable Care Act (ACA) requires insurers to offer without copays USPSTF “A” or “B” grade recommendations. These grades indicate an endorsement for routine use of a procedure by the Task Force. This year's draft mammography recommendation for women 50-74 received a “B” grade, while the Task Force's draft recommendation for women in their 40s received a “C” grade, indicating that the USPSTF is not encouraging doctors to provide the screening. However, the ACA also requires women to be able to access annual mammograms without cost sharing. In a **letter** to the U.S. Department of Health and Human Services (HHS), Sen. Barbara Mikulski (D-Md.) expressed concerns that the Task Force's recommendations could obstruct this part of the law. “Should the draft recommendation be finalized,” Mikulski writes, “I will actively and aggressively pursue all legislative options available to ensure that women aged 40 and older are able to continue receiving free annual mammograms.” Sen. Mikulski also urged the Secretary to take a public stance against the recommendations. The USPSTF's announcement arrived the same week that the National Cancer Institute (NCI) released estimates that the number of breast cancers suffered by American women will increase by about 50 percent by 2030. Breast cancers are already the most common form of cancer in the U.S.

House Passes Bill to Decrease Drug Abuse

H.R. 471, the Ensuring Patient Access and Effective Drug Enforcement Act, passed the House early last week. The bipartisan bill would establish clear and consistent enforcement standards and promote collaboration among government agencies, patients, and industry stakeholders to ensure patients have access to controlled substances. The Secretary of HHS, in coordination with the head of the Drug Enforcement Administration (DEA), would be required to submit a report to Congress identifying obstacles to legitimate patient access to these medications, issues with diversion of controlled substances, and how collaboration between agencies and stakeholders can benefit patients and prevent prescription drug abuse. H.R. 471 was authored by Energy and Commerce Committee Vice Chairman Marsha Blackburn (R-Tenn.) and Representatives Tom Marino (R-Pa.), Peter Welch (D-Vt.), and Judy Chu (D-Calif.).

PCORI Awards \$120 Million in Grants

The Patient Centered Outcomes Research Institute (PCORI) **announced** the approval of \$120 million in grants for 34 comparative effectiveness research (CER) studies. \$58.5 million will go towards five projects comparing practical clinical treatments, while \$61.6 million in funds will be provided to 29 studies examining options for improving outcomes for various conditions. This is the second round of awards to be made through PCORI's initiative to fund pragmatic clinical studies. Conditions awarded projects are studying include cancer, cardiovascular health, kidney disease, liver disease, mental/behavioral health, multiple/co-morbid chronic conditions, muscular and skeletal disorders, neurological disorders, nutritional and metabolic disorders, rare diseases, and trauma/injury. Since funding its first research grants in 2012, PCORI has spent \$854.6 million on 399 outcomes research projects.

House Appropriations Approves Top Line Spending Levels

Last week, the House Appropriations Committee voted to adopt top-line allocations for the 12 Appropriations Subcommittees, effectively locking in sequester level spending amounts. These funding levels will provide a starting point as subcommittees work on their spending bills. The Committee allocated the Labor, HHS, and Education Subcommittee \$153.1 billion in discretionary funding. While the current funding level is \$156 billion, this amount represents a much smaller reduction than the more than \$30 billion cut that was previously proposed. The Appropriations Committee also went on to approve the first two fiscal year 2016 spending bills, Energy-Water and Military Construction-Veterans Affairs (VA). The House spending bill on veterans health programs would provide \$64.8 billion for the Veterans Health Administration, which is more than the \$59.5 billion provided in last year's spending package but less than the \$65.2 billion requested in the President's budget. Secretary of Veterans Affairs Robert McDonald has indicated that the funding in the House spending bill will not be adequate to meet the demands for medical care at the VA. In 2016, the VA is expected to handle at least 101 million outpatient visits, an increase of 2.8 million from 2015. While Democrats continue to push for another bipartisan budget deal, appropriators continue working under the spending caps set by sequestration. The President has promised not to sign any spending bills that continue the use of statutory sequester spending limits. Movement on a bipartisan budget agreement is unlikely to begin before the conference committee tasked with reconciling the House and Senate budget resolution adjourns. The conference committee is expected to conclude negotiations in the near future. Senate Budget Chairman Michael Enzi (R-Wyo.) has confirmed that the conference language will call for the repeal of the sustainable growth rate (SGR) to be fully offset, but at some unspecified point in the future. Repeal of the Medicare reimbursement formula included \$141 billion in unpaid costs. The conference plan will also outline how reconciliation legislation will be developed, with much consideration given to alternatives to repealing and replacing the ACA. Last week, the Republican Study Committee Chairman Rep. Bill Flores (R-Texas) and Senate Steering Committee Chairman Sen. Mike Lee (R-Utah) expressed support for the conference committee's use of narrow reconciliation language focused on the full repeal of the ACA.

Medicare & Medicaid News

Trade Bill Includes Cuts to Medicare Program

The Trade Adjustment Assistance (TAA) bill advanced by the House and Senate last week is offset in part with cuts to the Medicare program. The TAA provides a tax credit to help workers displaced by trade purchase health insurance. The bill includes a six-month extension of the Medicare sequester, which would entail a 0.25 percent cut in Medicare payments in fiscal year 2024. This provision amounts to a \$700 million cut, according to the Congressional Budget Office (CBO). The House Ways and Means Committee cleared the measure by voice vote but without recommendation. The Senate Finance Committee also advanced a similar package. Many Democrats opposed the use of offsets from the Medicare program, and House Ways and Means Chairman Paul Ryan (R-Wis.) has indicated that an alternative pay-for could be found in the development of a final package.

Republicans Continue Work on King v. Burwell Contingency Plans

Sen. Ron Johnson (R-Wis.) introduced the most recent Republican legislation in preparation for the *King v. Burwell* Supreme Court decision. The **Preserving Freedom and Choice in Health Care Act** (S. 1016) would allow people to temporarily keep their health care exchange plans if the Court rules against the Administration and invalidates the ACA's use of federal subsidies. Under S. 1016, people could keep their health plan and their subsidies until August 2017. At this point, there could be a Republican president in office, allowing the ACA to be repealed in its entirety and replaced with a Republican alternative. The bill would also repeal the law's individual and employer mandates. This bill is the latest in more than half a dozen Republican contingency plans which would help maintain coverage for the 7.5 million Federally Facilitated Marketplace enrollees in at least 34 states in the aftermath of a Supreme Court decision in favor of the plaintiffs. Sen. Johnson's bill has 31 Republican cosponsors, including Majority Leader Mitch McConnell (R-Ky.). A ruling is expected in the *King v. Burwell* case by the end of June.

Upcoming Congressional Meetings and Hearings

Senate Caucus on International Narcotics Control: hearing on the quota system used to manage controlled substances; rescheduled time and place TBD (postponed from April 14)

Senate Finance Committee: hearing titled "Creating a More Efficient and Level Playing Field: Audit and Appeals Issues in Medicare;" 10:00 a.m., 215 Dirksen Bldg., April 28

Senate Health, Education, Labor and Pensions Committee: hearing titled "Continuing America's Leadership: The Future of Medical Innovation for Patients;" 10:00 a.m., 430 Dirksen Bldg., April 28

House Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee: Public and Outside Witness Hearing; 8:30 a.m., 2359-C Rayburn Bldg.; April 29

House Energy and Commerce Subcommittee on Health: hearing titled "Legislative Hearing on 21st Century Cures;" 10:00 a.m., 2123 Rayburn Bldg.; April 30

House Veterans' Affairs Committee: hearing titled "Examining Access and Quality of Care and Services for Women Veterans;" 10:30 a.m., 334 Cannon Bldg.; April 30

House Veterans' Affairs Committee: hearing titled "Assessing the Promise and Progress of the Choice Program;" 10:30 a.m., 334 Cannon Bldg.; May 13

Health Legislation Recently Introduced

S. 1013 (REHABILITATION), to amend title XVIII of the Social Security Act to provide for coverage and payment for complex rehabilitation technology items under the Medicare program, and for other purposes; COCHRAN; to the Committee on Finance; April 20

S. 1014 (COSMETICS), to amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of cosmetics; FEINSTEIN; to the Committee on Health, Education, Labor, and Pensions; April 20

S. 1016 (PPACA), to preserve freedom and choice in health care; JOHNSON; to the Committee on Finance; April 20

H.R. 1906(RECREATIONAL THERAPY), to amend title XVIII of the Social Security Act to include recreational therapy among the therapy modalities that constitute an intensive rehabilitation therapy program in an inpatient rehabilitation hospital or unit; THOMPSON; to the Committee on Ways and Means; April 21

H.R. 1909 (VA); to require the Secretary of Veterans Affairs to use existing authorities to furnish health care at non-Department of Veterans Affairs facilities to veterans who live more than 40 miles driving distance from the closest medical facility of the Department that furnishes the care sought by the veteran; CULBERSON; to the Committee on Veterans' Affairs; April 21

H.R. 1919 (EYE TRACKING ACCESSORIES), to amend title XVIII of the Social Security Act to provide Medicare beneficiary access to eye tracking accessories for speech generating devices and to remove the rental cap for durable medical equipment under the Medicare Program with respect to speech generating devices; MCMORRIS RODGERS; jointly, to the committees on Energy and Commerce and Ways and Means; April 21

S. 1020 (DIAGNOSTIC IMAGING), to amend title XVIII of the Social Security Act to ensure the continued access of Medicare beneficiaries to diagnostic imaging services, and for other purposes; VITTER; to the Committee on Finance; April 21

H.R. 1934 (ONCOLOGY), to amend title XVIII of the Social Security Act to establish a national Oncology Medical Home Demonstration Project under the Medicare program for the purpose of changing the Medicare payment for cancer care in order to enhance the quality of care and to improve cost efficiency, and for other purposes; MCMORRIS RODGERS; jointly, to the committees on Energy and Commerce and Ways and Means; April 22

H.R. 1936 (DISABILITIES), to amend title II of the Social Security Act to exclude certain medical sources of evidence in making disability determinations; JOHNSON; to the Committee on Ways and Means; April 22

H.R. 1953 (PPACA), to require members of Congress and congressional staff to abide by the Patient Protection and Affordable Care Act with respect to health insurance coverage, and for other purposes; DESANTIS; jointly, to the committees on Oversight and Government Reform, and House Administration, Ways and Means, and Energy and Commerce; April 22

H.R. 1974 (ACCESS), to expand access to health care services, including sexual, reproductive, and maternal health services, for immigrant women, men, and families by removing legal barriers to health insurance coverage, and for other purposes; LUJAN GRISHAM; jointly, to the committees on Energy and Commerce and Ways and Means; April 22

S. 1051 (NHSC), to include county and municipal correctional facilities among medical facilities that qualify for designation as health professional shortage areas for purposes of the National Health Service Corps; DURBIN; to the Committee on Health, Education, Labor, and Pensions; April 22

H.R. 1988 (MEDICAID), to provide for the waiver of the Medicaid IMD limitation in order to permit Medicaid coverage for substance use disorder treatment services furnished to certain individuals in a community-based institution for mental diseases; FUDGE; to the Committee on Energy and Commerce; April 23

Health Legislation Recently Introduced cont.

H.R. 2005 (DRUG REBATES), to amend title XVIII of the Social Security Act to require drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals under the Medicare prescription drug benefit program; CASTOR; jointly, to the committees on Energy and Commerce and Ways and Means; April 23

S. 1064 (ASTHMA), to amend the Public Health Service Act with regard to research on asthma, and for other purposes; GILLIBRAND; to the Committee on Health, Education, Labor, and Pensions; April 23

S. 1065 (ASTHMA), to amend title IV of the Elementary and Secondary Education Act of 1965 to provide grants for the development of asthma management plans and the purchase of asthma inhalers and spacers for emergency use, as necessary; GILLIBRAND; to the Committee on Health, Education, Labor, and Pensions; April 23

S. 1066 (PART D), to amend title XVIII of the Social Security Act to provide for coverage, as supplies associated with the injection of insulin, of containment, removal, decontamination and disposal of home-generated needles, syringes, and other sharps through a sharps container, decontamination/ destruction device, or sharps-by-mail program or similar program under part D of the Medicare program; ISAKSON; to the Committee on Finance; April 23

S. 1077 (BREAKTHROUGH DEVICES), to provide for expedited development of and priority review for breakthrough devices; BURR; to the Committee on Health, Education, Labor, and Pensions; April 23

S. 1079 (COLORECTAL CANCER), to amend titles XI and XVIII of the Social Security Act and title XXVII of the Public Health Service Act to improve coverage for colorectal screening tests under Medicare and private health insurance coverage, and for other purposes; CARDIN; to the Committee on Finance; April 23

S. 1083 (DRUG REBATES), to amend title XVIII of the Social Security Act to require drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals under the Medicare prescription drug benefit program; NELSON; to the Committee on Finance; April 23