



House of Representatives Passes the 21st Century Cures Act

H.R. 6 Heads to the Senate

Health Policy Briefing

July 13, 2015

The House of Representatives passed H.R. 6, the 21st Century Cures Act, with strong bipartisan support last week. With 230 bipartisan cosponsors, the bill passed comfortably by a roll call vote of 344-77. Seven Democrats joined 70 Republicans in voting against the bill. The bill had previously experienced delays due to disagreements regarding how to pay for the legislation, which will cost \$9.23 billion over the next decade but will cut federal spending by \$470 million through 2025, according to the Congressional Budget Office (CBO). The bill's original \$10 billion in funding over the next five years for the National Institutes of Health (NIH) was reduced to \$8.75 billion during debate about offsets. Many Cures supporters would like to see this funding restored when the bill is conferenced with the Senate. 21st Century Cures will be paid for through mandatory funding instead of discretionary funding. This means that the funds will not be subject to spending caps and will not be revisited each year during the appropriations process. \$7 billion in offsets comes from selling oil from the Strategic Petroleum Reserve, while limiting Medicaid payments for durable medical equipment to Medicare rates will save an additional \$2.5 billion. Prior to passage, lawmakers considered six amendments to the bill, including one from freshman Representative Dave Brat (R-Va.) which would have converted the bill's \$8.75 billion in mandatory funding for the NIH and \$550 million for the Food and Drug Administration (FDA) into discretionary spending. If passed, the amendment would have jeopardized Democratic support for the bill. The amendment failed by a vote of 141-281. The House did adopt amendments to authorize NIH to establish a medical innovation prize for breakthrough science and another amendment to support young women and minority scientists. The legislation received backing from the White House, who expressed support for provisions advancing the President's precision medicine initiative as well as measures dealing with electronic health records (EHRs) and improvements to the clinical trial process. The White House also praised policies to incorporate the patient perspective into the drug development process and the development of biomarkers. The Administration did outline concerns regarding the

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wisdom of providing the NIH with additional funding without considering the preexisting budgetary implications of sequestration. The White House's statement went on to question whether the FDA will have the necessary resources to successfully execute the new responsibilities contained in 21st Century Cures while maintaining current performance levels. Finally, the Administration expressed concerns about the impact of patent exclusivity exemptions on drug costs, and whether policies to bring drugs to market faster will negatively impact regulatory standards. H.R. 6 is not expected to reach the Senate until later this fall, at the earliest. The Senate has held its own series of hearings on its **Innovations for Healthier Americans**, but legislative language for the initiative is not expected until later in the year. House leadership hopes to bring 21st Century Cures to conference and send to the President's desk by the end of the year.

Out of Pocket Costs Experience Modest Rise

The total amount of money spent per patient per physician visit increased by 3.5 percent over the last year, according to a new **study** from the Robert Wood Johnson Foundation. Deductibles for every type of physician visit also increased across the board. The report included data from 15,000 physicians, and found that primary care physicians saw slightly higher reimbursement rate increases when compared to other doctors. The study indicates that reimbursements for specialty care dropped substantially in 2014.

Medicare and Medicaid News

Slavitt Nominated as CMS Administrator

President Obama has nominated Andy Slavitt to the permanent position of Administrator of the Centers for Medicare and Medicaid Services (CMS). Slavitt has been serving as the acting administrator since January, when Marilyn Tavenner resigned from the position. Before joining CMS last year as principal deputy administrator, Slavitt worked in the private sector, most recently as an executive at Optum, a health care technology firm that was partially responsible for the launch of HealthCare.gov. His involvement in the difficult launch of the website has caused some legislators, including members of the Senate Finance Committee which will hold his confirmation hearing, to raise concerns about his nomination.

GAO Releases Report on 340B Drugs

The Government Accountability Office (GAO) has released a **report** on the Medicare program designed to offset drug costs at hospitals serving the poor, finding that the 340B drug program is incentivizing doctors to overprescribe drugs to their patients. The 340B program requires drug manufacturers to discount outpatient drugs dispensed at disproportionate share hospitals (DSH), while Medicare Part B payments to these hospitals remain the same regardless of whether a drug is discounted. GAO's report indicates that hospitals participating in the 340B Drug Pricing Program are either prescribing more drugs or more expensive drugs to their patients compared to hospitals that don't qualify for the program. 340B hospitals spend nearly 2.5 times more than hospitals outside the program, \$144 per beneficiary as compared to \$60 per beneficiary. The report notes that these differences cannot alone be explained by differences in the health status of the patient populations. GAO notes that unnecessary spending has negative implications for the Medicare program as well as for beneficiaries, who may be liable for higher copayments resulting from more drugs or more expensive drugs. The GAO also outlines concerns about the health implications of potentially inappropriate care. The report urges Congress to take actions to change 340B program incentives, an action which is outside the power of the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA).

FDA Update***Energy and Commerce Members Criticize FDA Opioid Policies***

Bipartisan leaders of the House Energy and Commerce Committee have **written** to Dr. Stephen Ostroff, Acting Commissioner of the Food and Drug Administration (FDA), posing questions regarding the agency's efforts to combat the opioid abuse epidemic. Chairman Fred Upton (R-Mich.), Ranking Member Frank Pallone, Jr. (D-N.J.), Oversight and Investigations Subcommittee Chairman Tim Murphy (R-Pa.) and Ranking Member Diana DeGette (D-Colo.) press Dr. Ostroff to explain why immediate-release opioid labels are not required to include the same warnings regarding potential abuse as long-acting versions of the same painkillers. "Experts have raised concerns with staff about the basis and effectiveness of...FDA labeling and risk-management strategies, and a recent review on opioid use for chronic pain by the Agency for Healthcare Research and Quality (AHRQ) found no evidence that risk mitigation strategies were effective," the letter says. This letter follows a letter to the FDA signed by Democrats only posing the same concerns.

Upcoming Congressional Meetings and Hearings

House Veterans' Affairs Committee: hearing on: "H.R. 272; H.R. 353; H.R. 359; H.R. 421; H.R. 423; H.R. 1356; H.R. 1688; H.R. 1862; H.R. 2464; H.R. 2914; H.R. 2915; draft legislation to clarify the role of podiatrists in VA; and, draft legislation to authorize VA major medical facility construction projects for FY 2015 and to make certain improvements in the administration of VA medical facility construction projects;" 10:00 a.m.; 334 Cannon Bldg.; July 14

House Energy and Commerce Oversight and Investigations Subcommittee: hearing titled "Medicare Part D: Measures Needed to Strengthen Program Integrity;" 2:00 p.m., 2322 Rayburn Bldg.; July 14

Senate Special Aging Committee hearing titled "Diabetes Research: Improving Lives on the Path to a Cure;" 2:15 p.m., G-50 Dirksen Bldg.; July 15

Senate Finance Committee: hearing to review HealthCare.gov controls; 10:00 a.m., 215 Dirksen Bldg.; July 16

Health Legislation Recently Introduced

H.R. 2948 (TELEHEALTH), to amend title XVIII of the Social Security Act to provide for an incremental expansion of telehealth coverage under the Medicare program; THOMPSON; jointly, to the committees on Energy and Commerce and on Ways and Means; July 7

H.R. 2974 (VA), to amend the Veterans Access, Choice, and Accountability Act of 2014 to increase the duration of follow-up care provided under the Veterans Choice Program; BROWNLEY; to the House Committee on Veterans' Affairs; July 8

S. 1718 (PPACA), to provide for the repeal of certain provisions of the Patient Protection and Affordable Care Act that have the effect of rationing health care; ROBERTS; to the Committee on Finance; July 8

S. 1721 (VA), to require the Secretary of Defense and the Secretary of Veterans Affairs to establish a joint uniform formulary with respect to systemic pain and psychotropic drugs that are critical for the transition of an individual from receiving health care services furnished by the Secretary of Defense to health care services furnished by the Secretary of Veterans Affairs, and for other purposes; BLUMENTHAL; to the Committee on Veterans' Affairs; July 8

H.R.3006 (HSA), to amend the Internal Revenue Code of 1986 to improve health savings accounts, and for other purposes; FLEMING; to the House Committee on Ways and Means; July 9

H.R.3012 (TERMINAL ILLNESS), to authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, and for other purposes; SALMON; jointly, to the committees on Energy and Commerce and the Judiciary; July 9

H.R.3014 (CONTROLLED SUBSTANCES), to amend the Controlled Substances Act to authorize physicians, pursuant to an agreement with the Attorney General, to transport controlled substances from a practice setting to another practice setting or to a disaster area; SESSIONS; jointly, to the committees on Energy and Commerce and the Judiciary; July 9

H.R. 3016 (VA), to amend title 38, United States Code, to clarify the role of podiatrists in the Department of Veterans Affairs; WENSTRUP; to the House Committee on Veterans' Affairs; July 9

H.R. 3018 (ICD-10), to provide for a safe harbor period for the transition from the ICD-9 to the ICD-10 standard for health care claims; BLACKBURN; jointly, to the committees on Energy and Commerce and Ways and Means; July 10

H.R. 3019 (VA), to amend title 38, United States Code, to direct the Secretary of Veterans Affairs to furnish, at the request of an eligible veteran, nursing home care and hospital care at State licensed or certified residential care facilities; DELAURO; to the Committee on Veterans' Affairs; July 10

H.R. 3024 (DSH), to amend title XVIII of the Social Security Act to permit review of certain Medicare payment determinations for disproportionate share hospitals, and for other purposes; BOUSTANY; to the Committee on Ways and Means; July 10