HHS

Hart Health Strategies Inc.



Ith Policy Briefing

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Innovations Could See Movement Before July

During a floor speech last week, Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee Lamar Alexander (R-Tenn.) said that he hopes to see a floor vote on his committee's biomedical innovation legislation before July. Lawmakers are still trying to resolve the issue of funding for the National Institutes of Health (NIH). While Sen. Alexander has expressed support for an innovation fund aimed at specific projects, Democrats hold that they will only support the biomedical innovation package if it includes a mandatory funding stream. They are also pushing to direct funding to the Food and Drug Administration (FDA). Determining how much funding to provide and how to offset the cost are also obstacles that will have to be overcome before the package heads to the floor. The Senate is in session until May 27, before both chambers adjourn for Memorial Day recess. There are two short sessions of Congress in June and July before the party conventions and August recess.

Lawmakers Continue to Press CMS on Part B Drug Payment Model

Medicare and Medicaid Services (CMS) regarding the agency's proposed Part B drug payment model. Sen. Heidi Heitkamp (D-N.D.) led a letter signed by eight other democrats urging CMS not to move forward with the demonstration until concerns about the size and scope of the model, as well as beneficiary access to physician-administered drugs, are resolved. Rep. Diana DeGette (D-Colo.) and 12 other democratic members of the House Energy and Commerce Committee wrote to express concerns about medication access and the impact of the proposal on small practices and providers in rural and underserved areas, but they do not ask CMS to pause or withdraw the model. The DeGette letter encourages CMS "to tailor the demonstration to an appropriate size capable of gathering meaningful data." Also, it states their preference that CMS "plan to prevent ... problems on the front-end rather than as problems arise." Similarly, Rep. Richard Neal (D-Mass.) led a letter signed by

more than 50 democrats asking for resolution to 11 questions, on topics ranging from beneficiary and physician impact to potential shifts in sites of service and emphasizes that "these questions require careful and detailed resolution before CMS moves forward with either

continued on page 2

Inside

House Passes Package of Legislation to Combat Opioid
Abuse2
Zika Update
LeadersinHealthITConveneforDatapalooza3
Senate Hotlines Mental Health Bill
Health Reform Task Force Holds Briefing on White
Paper
Upcoming Congressional Meetings and Hearings4
RecentlyIntroducedHealthLegislation4

continued from page 1

phase of the demonstration." Rep. Jan Schakowsky (D-Ill.) and 19 other House Democrats wrote to the administration defending the demonstration project, explaining that they believe the proposal will "not only help to fix the current and flawed status quo but will also help combat the increasingly unaffordable prices that drug companies are charging for their products." The House Energy and Commerce Health Subcommittee will hold a hearing on the Part B demo this Tuesday. The hearing will consider the experiment as well as H.R. 5122, legislation introduced by Rep. Larry Bucshon (R-Ind.) that would block the proposal from advancing. Witnesses for the hearing include Dr. Michael Schweitz (on behalf of the Coalition of State Rheumatology Organizations and the Alliance of Specialty Medicine); Marcia Boyle (on behalf of the Immune Deficiency Foundation); Dr. Debra Patt (on behalf of Texas Oncology, The US Oncology Network, the Community Oncology Alliance (COA) and the American Society of Clinical Oncology (ASCO)); and others. The hearing will be webcast and may be viewed at http://energycommerce.house.gov/.

House Passes Package of Legislation to Combat Opioid Abuse

Last week, the House of Representatives passed a package of legislation aimed at combating the prescription drug and heroin abuse epidemic. The chamber began by advancing H.R. 4641, a bipartisan bill offered by Energy and Commerce Committee members Susan Brooks (R-Ind.) and Joseph Kennedy (D-Mass.). The legislation would establish an inter-agency task force to review, modify, and update best practices for pain management and how pain medication is prescribed. It was agreed to by a vote of 412-4. The House also passed an additional 10 bills under suspension of the rules:

- H.R. 4978 NAS Healthy Babies Act
- H.R. 3680 Co-Prescribing to Reduce Overdoses Act of 2016
- H.R. 3691 Improving Treatment for Pregnant and Postpartum Women Act of 2016
- H.R. 1818 Veteran Emergency Medical Technician Support Act of 2016
- H.R. 4969 John Thomas Decker Act of 2016
- H.R. 4586 Lali's Law
- H.R. 4599 Reducing Unused Medications Act of 2016
- H.R. 4976 Opioid Review Modernization Act of 2016
- H.R. 4982 Examining Opioid Treatment Infrastructure Act of 2016
- H.R. 4981 Opioid Use Disorder Treatment Expansion and Modernization Act

These bills would address a wide array of issues surrounding the drug abuse crisis, such as neonatal abstinence syndrome, access to addiction treatment, and disposal of unused medications. H.R. 5046, the Comprehensive Opioid Abuse Reduction Act of 2016, was passed later in the week. This bill would award \$100 million in grants to state and local governments to provide opioid abuse services, and would help increase collaboration between criminal justice and substance abuse agencies. Finally, the House considered S. 524, the Comprehensive Addiction and Recovery Act of 2016 (CARA) before adjourning for the weekend. CARA is a wide-ranging bill that would help states prevent drug abuse, treat addiction, and reduce overdose deaths. The House passed the legislation by a vote of 400-5. It was previously passed by the Senate in March. The House will next vote on conferencing with the Senate to resolve the differences between the packages of bills each chamber passed to address the addiction epidemic. The legislation is likely to be signed into law by President Obama, despite some objection that the bills do not include sufficient funding to address the problem of opioid abuse. Also last week, the president of the American Medical Association (AMA) encouraged doctors to avoid beginning new patients with chronic non-cancer pain on opioids, and to limit the amount of opioids prescribed in post-operative and acute settings to the lowest effective dose for the shortest period of time necessary. This is the first time the AMA has made a statement in preference of non-drug or non-opioid pain treatments.

Zika Update

This week, the Senate will vote on a \$1.1 billion funding measure to combat the Zika virus. The compromise was struck by Sen. Patty Murray (D-Wash.) and Sen. Roy Blunt (R-Mo.). The funding will be attached to a package that combines the transportation and military construction/Veterans Administration appropriations bills. Senators will actually have the chance to vote on three Zika amendments. In addition to the Murray/Blunt compromise, an amendment will be offered that fulfills the \$1.9 billion requested by the administration, as well as one that fully offsets the \$1.1 billion package by eliminating the Affordable Care Act's (ACA) Prevention and Public Health Fund. House Appropriations Chairman Harold Rogers (R-Ky.) is expected to release a standalone Zika package this week with funding levels below what was negotiated in the Senate.

Leaders in Health IT Convene for Datapalooza

Health care systems, technology companies, designers, and developers gathered for the 7th annual Health Datapalooza in Washington, D.C. last week. During the event, U.S. Department of Health and Human Services (HHS) Secretary Sylvia Mathews Burwell kicked off the "A Bill You Can Better Understand" contest. It will award \$5,000 to winners who design a clearer and simpler medical bill from the perspective of the patient. National Coordinator for Health IT Karen DeSalvo announced \$1.7 million in awards to improve data access. The funding will focus on improving medication management, care coordination standards, and laboratory data exchange. Vice President Joe Biden was also in attendance, and spoke about the importance of data sharing between clinicians and researchers.

Senate Hotlines Mental Health Bill

Senate leadership has decided to use a fast-track measure known as "hotlining" to gauge the ability of considering S. 1945, the Mental Health Reform Act of 2015, introduced by Sen. Bill Cassidy (R-La.) and Sen. Christopher Murphy (D-Ct.) last year. The bill has not seen movement since it was approved by the Senate Health, Education, Labor and Pensions (HELP) Committee in March. There remain several obstacles to be overcome, including disagreements about funding and gun control. The "hotline" will help identify those senators with concerns about the legislation and hopefully encourage issues to be worked out to have the bill ready for floor debate sometime between Memorial Day and the July Fourth recess. Sen. Murphy and Sen. Cassidy announced that they will hold a mental health summit in support of their legislation. The summit is scheduled for 8:00 a.m. to 1:20 p.m. on May 26 in 902 Hart Senate Office Building.

Health Reform Task Force Holds Briefing on White Paper

Last week, the Republican task force charged with developing an alternative to replace the Affordable Care Act (ACA) briefed and accepted feedback from their colleagues on the details of their plan. Instead of framing their proposal as legislation, the task force decided to use the form of a white paper. The blueprint is expected to be released in the coming weeks, and is said to include proposals such as the establishment of health savings accounts, high-risk pools, and allowing insurers to sell across state lines. It is also likely to include reforms to the Medicare and Medicaid programs, such as a "per capita cap" on federal Medicaid payments and instituting the use of Medicare vouchers for the purchasing of private insurance.

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Upcoming Congressional Meetings and Hearings

House Ways and Means Health Subcommittee hearing on "Tax-Related Proposals to Improve Health Care;" 10:00 a.m., 1100 Longworth Bldg.; May 17

House Energy and Commerce Health Subcommittee hearing on "The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective;" 10:00 a.m., 2123 Rayburn Bldg.; May 17

Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Business meeting to markup an original bill entitled, "Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act, 2017;" 4:00 p.m., 124 Dirksen Senate Bldg.; May 17

Senate Small Business and Entrepreneurship Committee hearing to examine small business and the Affordable Care Act; 2:00 p.m., 428A Russell Bldg.; May 18

House Ways and Means Human Resources Subcommittee hearing on "The Heroin Epidemic and Parental Substance Abuse: Using Evidence and Data to Protect Kids from Harm;" 2:00 p.m., 1100 Longworth Bldg.; May 18

House Energy and Commerce Health Subcommittee hearing on "Examining H.R. 3299, Strengthening Public Health Emergency Response Act;" 10:00 a.m., 2123 Rayburn Bldg.; May 19

House Appropriations Committee Business meeting to markup an original bill entitled, "Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2017", and an original bill entitled, "Legislative Branch Appropriations Act, 2017;" 10:30 a.m., 106 Dirksen Bldg.; May 19

House Veterans' Affairs Oversight and Investigations Subcommittee Field Hearing on "Assessing VA Oversight of Drug Prescription Practices and Proper Use of Medical Facilities;" 9:30 a.m. (local time), Old Supreme Court Chambers, State Capital Building, Room 200, 200 East Colfax Avenue, Denver, CO 80203; May 20

Recently Introduced Health Legislation

H.R. 5182 (introduced by Rep. Long): A bill to promote the development of safe drugs for neonates; to the Committee on Energy and Commerce; May 10

H. Res. 719 (introduced by Rep. Veasey): A resolution expressing support for designation of May 2016 as ``Health and Fitness Month'; to the Committee on Energy and Commerce; May 10

H. Res. 721 (introduced by Rep. Israel): A resolution expressing support for the designation of May 8, 2016, through May 14, 2016, as Food Allergy Awareness Week; to the Committee on Energy and Commerce; May 10

H.R. 5188 (introduced by Rep. Love): A bill to amend title XVIII of the Social Security Act to promote physician training in newly recognized primary medical specialties, and for other purposes; to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; May 11

H.R. 5189 (introduced by Rep. Kuster): A bill to address the opioid abuse crisis; to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Veterans' Affairs, Education and the Workforce, Ways and Means, Armed Services, and Natural Resources, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; May 11

H.R. 5194 (introduced by Rep. Blumenauer): A bill to amend the Internal Revenue Code of 1986 to allow a credit against tax for costs incurred by certain businesses for drug disposal programs; to the Committee on Ways and Means; May 11

- H.R. 5195 (introduced by Rep. DeLauro): A bill to require that health plans provide coverage for a minimum hospital stay for mastectomies, lumpectomies, and lymph node dissection for the treatment of breast cancer and coverage for secondary consultations; to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; May 11
- H. Res. 724 (introduced by Rep. Eddie Bernice Johnson of Texas): A resolution supporting the goals and ideals of National Nurses Week on May 6, 2016, through May 12, 2016; to the Committee on Energy and Commerce; May 11
- H.R. 5210 (introduced by Rep. Byrne): A bill to improve access to durable medical equipment for Medicare beneficiaries under the Medicare program, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; May 12
- H.R. 5216 (introduced by Rep. Ben Ray Luján of New Mexico): A bill to provide funding for opioid and heroin abuse prevention and treatment, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, and the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; May 12
- H.R. 5234 (introduced by Rep. Judy Chu of California):. A bill to amend the Public Health Service Act to provide for behavioral and mental health outreach and education strategies to reduce stigma associated with mental health among the Asian American, Native Hawaiian, and Pacific Islander population; to the Committee on Energy and Commerce; May 13
- H.R. 5241 (introduced by Rep. Ruiz): A bill to amend title XVIII of the Social Security Act to distribute additional information to Medicare beneficiaries to prevent health care fraud, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; May 13
- H. Res. 730 (introduced by Rep. Black): A resolution expressing the sense of the House of Representatives regarding the important role of the health care industry in identifying victims of sex trafficking; to the Committee on Energy and Commerce; May 13
- S.RES.459 (introduced by Sen. Dianne Feinstein): A resolution recognizing the importance of cancer research and the vital contributions of scientists, clinicians, cancer survivors, and other patient advocates across the United States who are dedicated to finding a cure for cancer, and designating May 2016, as "National Cancer Research Month"; to the Committee on the Judiciary; May 9
- S. 2912 (introduced by Sen. Johnson): A bill to authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, and for other purposes; to the Committee on Health, Education, Labor, and Pensions; May 10
- S.2922 (introduced by Sen. Whitehouse): A bill to amend title 38, United States Code, to provide for partnerships and contracts between the Secretary of Veterans Affairs and eligible academic affiliates for the mutually beneficial coordination, use, or exchange of health-care resources, and for other purposes; to the Committee on Veterans' Affairs; May 11
- S.2921 (introduced by Sen. Isakson): A bill to amend title 38, United States Code, to improve the accountability of employees of the Department of Veterans Affairs, to improve health care and benefits for veterans, and for other purposes; to the Committee on Veterans' Affairs; May 11

S. 2927 (introduced by Sen. Lankford): A bill to prevent governmental discrimination against providers of health services who decline involvement in abortion, and for other purposes; to the Committee on Health, Education, Labor, and Pensions; May 12