



Health Policy Briefing

June 20, 2016

Energy and Commerce Advances Mental Health Reform Legislation

The House Energy and Commerce Committee unanimously approved Rep. Tim Murphy's (R-Pa.) legislation to reform the nation's mental health system. H.R. 2646, the Helping Families in Mental Health Crisis Act, was introduced three years ago following the mass shooting in Newtown, Conn. and advanced by the Health Subcommittee at the end of last year. Since then, the bill has been scaled back in scope to address concerns from lawmakers on both sides of the aisle. The bill is budget neutral, and has been stripped of costly provisions like repeal of Medicaid limits on psychiatric beds. Changes to the Health Insurance Portability and Accountability Act (HIPAA) were also removed before the full committee markup. During the markup, Democrats stressed that H.R. 2646 was not an adequate response to the problem of gun violence, and that gun control was needed in addition to mental health reform. Rep. Joe Kennedy III (D-Mass.) commented on the need for stronger mental health parity, and received assurances that the committee will hold a hearing on the subject before the end of the year. While Rep. Murphy hopes the bill will get a vote on the floor before the August recess, Energy and Commerce Chairman Fred Upton (R-Mich.) said that the bill is more likely to be considered in the full House during the fall. Mental health legislation has also been introduced in the Senate by Sen. Chris Murphy (D-Conn.) and Sen. Bill Cassidy (R-La.), but their bill faces Democratic opposition due to possible inclusion of gun related measures from Sen. John Cornyn (R-Texas).

Doctors Respond to Orlando Tragedy

During its annual meeting last week, the American Medical Association (AMA) voted for the first time to declare gun violence a public health crisis. The AMA will now begin to actively lobby in support of waiting periods and background checks for firearm purchases, as well as to allow federal research on guns. A policy has been in place for nearly two decades to effectively ban federally funded research to study gun violence. The AMA's vote took place only a few days after 49 people were killed in a mass shooting in Orlando, Fla. Congressional

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Republicans, including those in the GOP Doctors Caucus, have already expressed opposition to the AMA's decision. In related news, Democrats are working to reverse the blood donation ban for gay men in light of recent events. Rep. Mike Honda (D-Calif.) introduced the Deliver for Our Nation at Times of Emergency (DONATE) Act, which would allow for more flexibility when screening blood donors during an emergency. The Administration has responded that it has no plans to lift the current requirement that gay men remain celibate for one year before being cleared to donate blood.

Zika Update

Members of the congressional conference committee to resolve the differences between the House and Senate funding packages to combat the Zika virus convened for the first time last week. A compromise must be reached not only on a funding level – the House has proposed \$622 million, compared to the Senate's \$1.1 billion – but also on whether and how to offset the spending. House Appropriations Chairman Hal Rogers (R-Ky.) has said that the deal must be fully offset. While both Democratic and Republican appropriators seem hopeful that they will reach an agreement quickly, there is little time left for negotiations if a final package is to be complete before their target date of July 1. The House is scheduled to adjourn on Friday and won't return until July 5. Following its third emergency meeting on the Zika outbreak, the World Health Organization (WHO) has concluded that the Olympic games being held in Brazil this summer pose “a very low risk of further international spread” of the virus. WHO believes attendees' exposure to Zika will be minimal as a result of the Brazilian winter and precautionary measures being taken to reduce the chance of transmission. The Centers for Disease Control and Prevention (CDC) announced last week that three babies have been born in the United States with microcephaly as a result of the Zika virus. In three other cases, women have had miscarriages or terminated pregnancies due to the birth defect. All of the cases of Zika were contracted abroad.

Generics Bill introduced in the Senate

Chairman and Ranking Member of the Senate Judiciary Committee Chuck Grassley (R-Iowa) and Patrick Leahy (D-Vt.) have introduced the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. The legislation creates a cause of action in federal court for generic manufacturers who are facing issues obtaining access to reference products subject to a Risk Evaluation Mitigation Strategy with Elements to Assure Safe Use (REMS with ETASU) or a restricted distribution system self-imposed by the reference product manufacturer. The legislation creates some liability protection for a reference product manufacturer who makes product available to generic manufacturers. The Congressional Budget Office (CBO) estimates that the bill would save \$2 billion over 10 years. The Senate Judiciary Committee will hold a hearing on this legislation on Tuesday.

Republican ACA Replacement Coming This Week

Republicans in the House will release their white paper outlining an alternative to the Affordable Care Act (ACA) this week. Because the plan is not a complete piece of legislation, it has not been scored by the Congressional Budget Office (CBO). The white paper is expected to include the use of high-risk pools and health plans for small business collectives, Health Savings Accounts (HSAs), and tax benefits for purchasing health insurance coverage. It will also cap the tax benefits that employers get for providing health care coverage to their employees.

Senate Goes to Conference on Opioid Legislation

The Senate voted to go to conference with the House regarding opioid legislation last week. The conferees are the chairmen and ranking members of the Judiciary Committee; the Health, Education, Labor and Pensions (HELP) Committee; and the Finance Committee, as well as Sen. Jeff Sessions (R-Ala.). The chamber agreed to instruct the conferees that the final conference report should include an unspecified amount of funding for state and local efforts to prevent and treat opioid abuse. Conferees will also be instructed to include authorizations for prescription drug monitoring programs (PDMPs), consider the needs of rural communities, and raise the federal limit on the number of patients to whom a doctor can prescribe buprenorphine from 100 to 500.

AMA Considers Part B Demo, Opioids at Annual Meeting

While the American Medical Association (AMA) was already on record in support of the withdrawal of the Centers for Medicare and Medicaid Services (CMS) Part B Drug Payment Model demonstration, the organization approved a resolution to “support and actively work to advance Congressional action to block the proposed Part B Drug Payment Model” during their annual meeting last week. The AMA also adopted new policies in regard to opioid drugs. They will work to expand access to naloxone, and encourage doctors to co-prescribe the overdose reversal drug when prescribing opioid painkillers. Additionally, the AMA will encourage insurers to expand coverage of non-opioid and non-drug pain treatments, and will work to disconnect the link between Medicare payments and how patients feel their pain was managed.

GAO Reports Indicate Need for 21st Century Cures

The Government Accountability Office (GAO) released separate reports last week highlighting improvements that need to be made at the Food and Drug Administration (FDA). The **first report** finds that the agency is not measuring whether progress is being made in regulatory science, nor did it track the \$504 million spent on regulatory science between fiscal years (FY) 2010 and 2014. The GAO recommends developing and documenting measurable goals and the tracking of funding across the FDA’s regulatory science priorities. The **second report** reveals gaps in the agency’s strategic plan for oversight of new products. The GAO recommends engaging in strategic planning across each of the FDA’s medical product centers. The reports were highlighted by leadership on the House Energy and Commerce Committee and the Senate Health, Education, Labor and Pensions (HELP) Committee as indicative of the need for legislation like the 21st Century Cures Act/Senate Innovations package to help the FDA keep pace with medical innovation.

Upcoming Congressional Meetings and Hearings

House Veterans’ Affairs Subcommittee on Health field hearing titled “Access and Accountability: Examining Obstacles to High Quality Patient Care in Louisiana;” 3:00 p.m., Pineville City Council Chambers, Pineville City Hall, 910 Main Street, Pineville, LA 71360; June 20

Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights hearing “The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition;” 2:00 p.m. 226 Dirksen; June 21

Senate Special Aging Committee hearing titled “The Right Care at the Right Time: Ensuring Person-Centered Care for Individuals With Serious Illness;” 11:00 a.m., 562 Dirksen Bldg.; June 23

House Energy and Commerce Health Subcommittee hearing “Strengthening our National Trauma System;” 9:15 a.m., 2123 Rayburn Bldg.; June 24

Senate Appropriations Military Construction and Veterans Affairs, and Related Agencies Subcommittee hearing to examine a review of the Dept. of Veterans Affairs’ electronic health record (VistA), progress toward interoperability with the Department of Defense’s electronic health record, and plans for the future; 10:30 a.m., 124 Dirksen Bldg.; July 13

Recently Introduced Health Legislation

H.R. 5458 (introduced by Rep. Steward): A bill to provide for coordination between the TRICARE program and eligibility for making contributions to a health savings account, and for other purposes; to the Committee on Ways and Means, and in addition to the Committee on Armed Services, 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.; June 13

H.R. 5462 (introduced by Rep. Loeb sack): A bill to amend title XIX of the Social Security Act to provide for a State Medicaid option to enhance administrative matching funds to support statewide behavioral health access program activities for children under 21 years of age, and for other purposes; to the Committee on Energy and Commerce; June 13

H.R. 5463 (introduced by Rep. Murphy of Florida): A bill to support programs for mosquito-borne and other vector-borne disease surveillance and control; to the Committee on Energy and Commerce; June 13

H.R.5475 (introduced by Rep. Robin L. Kelly): A bill to improve the health of minority individuals, and for other purposes; to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Agriculture, Education and the Workforce, the Budget, the Judiciary, Veterans' Affairs, 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; June 14

H.R.5479 (introduced by Rep. Betty McCollum): A bill to provide for programs under the Department of Health and Human Services to improve newborn screening, evaluation, and intervention for critical congenital heart defect; to the House Committee on Energy and Commerce; June 14

H.R.5482 (introduced by Rep. Michael R. Turner): A bill to amend title XIX of the Social Security Act to provide States with the option of providing medical assistance at a residential pediatric recovery center to infants under 1 year of age with neonatal abstinence syndrome and their families; to the House Committee on Energy and Commerce; June 14

H.R.5492 (introduced by Rep. Patrick Murphy): A bill to support programs for mosquito-borne and other vector-borne disease surveillance and control; to the House Committee on Energy and Commerce; June 15

H.CON.RES.137 (introduced by Rep. Donald M. Payne, Jr.): A resolution supporting National Men's Health Week; to the House Committee on Oversight and Government Reform; June 15

H.R. 5497 (introduced by Rep. Lipinski): A bill to amend the Public Health Service Act to provide for the public disclosure of charges for certain hospital and ambulatory surgical center treatment episodes; to the Committee on Energy and Commerce; June 16

H.R. 5501 (introduced by Rep. O'Rourke): A bill to amend title 38, United States Code, to improve the recruitment of physicians in the Department of Veterans Affairs; to the Committee on Veterans' Affairs; June 16

H.R. 5506 (introduced by Rep. Young of Indiana): A bill to amend title XVIII of the Social Security Act to establish a demonstration program to provide integrated care for Medicare beneficiaries with end-stage renal disease, 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; June 16

H.R. 5514 (introduced by Rep. Honda): A bill to direct the Secretary of Health and Human Services to provide for increased flexibility in blood donor screening, while maintaining a safe blood donor pool, during times of national or local need; to the Committee on Energy and Commerce; June 16

H.R. 5526 (introduced by Rep. Wenstrup): A bill to improve the authority of the Secretary of Veterans Affairs to hire and retain physicians and other employees of the Department of Veterans Affairs, and for other purposes; to the Committee on Veterans' Affairs, and in addition to the Committee on Oversight and Government Reform, 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; June 16

S. 3052 (introduced by Sen. Kirk): A bill to amend title 38, United States Code, to authorize the Secretary of Veterans Affairs to provide for an operation on a live donor for purposes of conducting a transplant procedure for a veteran, and for other purposes; to the Committee on Veterans' Affairs; June 13

S.3056 (introduced by Sen. Patrick J. Leahy): A bill to provide for certain causes of action relating to delays of generic drugs and biosimilar biological products; to the Committee on the Judiciary; June 14

S. 3060 (introduced by Sen. Grassley): A bill to provide an exception from certain group health plan requirements for qualified small employer health reimbursement arrangements; to the Committee on Finance; June 16

S. 3075 (introduced by Sen. Durbin): A bill to establish programs related to prevention of prescription opioid misuse, and for other purposes; to the Committee on Finance; June 16