



# LEGISLATIVE AND REGULATORY UPDATE March 14, 2016

#### Week in Brief

Senate <u>Passes</u> the *Comprehensive Addiction and Recovery Act* (S. 524), Authorizing Grants for States to Address National Prescription Opioid and Heroin Addiction Epidemics.

Senate HELP Committee Passes Seven Bipartisan Bills in Biomedical Innovation Agenda.

Brain Injury Awareness Day Occurs on March 16; Part of Brain Awareness Week (March 14 – 18).

CMS Releases Proposed Rule on Testing New Medicare Part B Prescription Drug Models.

#### LEGISLATIVE UPDATE

#### March 7

House Committee Leaders <u>Send</u> Letter to CMS Regarding Proposed Changes to the Medicare Advantage and Part D Programs Payment and Policies for CY 2017.

Senate HELP Committee Leaders <u>Release</u> Discussion Draft of Mental Health Crisis in America and Schedule Markup of Bill for March 16.

#### March 8

House Energy & Commerce Committee <u>Announces</u> Participants for March 14 Concussion Roundtable.

Senate Finance Chairman Orrin Hatch and Senator Marco Rubio <u>Question</u> Administration on Reinsurance Program Created under the ACA.

#### March 9

House Energy & Commerce Republican Leaders <u>Send</u> Letters to AHIP and 6 Major Insurers on Reinsurance Payments from CMS.

House and Senate Republican Committee Leaders <u>Release</u> Statement on the Administration's Proposed Changes to the Medicare Part B Drug Payment Model.

Senate Republicans <u>Send</u> Letter to CMS to Halt Medicare Advantage Program Cuts.

Senate HELP Chairman Lamar Alexander <u>Lauds</u> Biomedical Innovation Package as Most Important Bill of 2016.

HELP Committee Holds 2<sup>nd</sup> Markup of Biomedical Bills on March 9; 3<sup>rd</sup> Markup Scheduled for March 16.

Bipartisan Bicameral Letter Sent to HHS Requesting More Guidance on Mobile Health Apps.

#### March 10

House Committee on Veterans' Affairs Chairman Jeff Miller <u>Announces</u> Retirement at End of Current Term and Senate Committee on Veterans' Affairs Chairman Johnny Isakson <u>Releases</u> Statement Praising Miller's Years of Service.

House Energy and Commerce Committee Schedules March 17 MACRA Implementation Hearing.

Senate Permanent Subcommittee on Investigations Majority Staff Releases Report: Failure of the Affordable Care Act Health Insurance CO-OPs.

Senate HELP Leaders <u>Release</u> Statement on Senate Actions to Combat Opioid Abuse and <u>Call</u> for Continued Work.

Senate Committee on Veterans' Affairs Ranking Member Richard Blumenthal <u>Requests</u> VA Expand List of Medical Conditions Qualifying Veterans for Presumptive Agent Orange Exposure.

#### March 11

House Energy & Commerce Chairman Fred Upton Pens Op-Ed on Strengthening Medicaid for the Most Vulnerable.

#### March 14

House Energy and Commerce Committee Markup the Common Sense Savings Act of 2016 (H.R. 4725), a Bill Reforming Health Entitlement Programs.

House Energy & Commerce Oversight & Investigations Subcommittee <u>Hosts</u> Initial Roundtable Discussion on Concussions.

#### LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>S. 2618</u>	Medicaid Directory of Caregivers Act	Sen. Grassley [R-IA]	Finance	Introduced 3/2/2016
<u>S. 2633</u>	Improving Veterans Access to Care in the Community Act	Sens. Tester [D-MT], Blumenthal [D-CT], Bennet [D-CO], Udall [D-NM], Brown [D-OH], Heitkamp [D-ND]	Veterans' Affairs	Introduced 3/3/2016
<u>S. 2646</u>	Veterans Choice Improvement Act of 2016	Sen. Burr [R-NC] and 7 original cosponsors	Veterans' Affairs	Introduced 3/7/2016
<u>S. 2647</u>	Behavioral Health Coverage Transparency Act of 2016	Sens. Warren [D-MA], Brown [D-OH], Franken [D- MN], Blumenthal [D-CT], Baldwin [D-WI]	HELP	Introduced 3/7/2016
<u>S. 2649</u>	Veterans Choice Equal Cost for Care Act of 2016	Sen. Rounds [R-SD]	Veterans' Affairs	Introduced 3/8/2016
<u>S. 524</u>	Comprehensive Addiction and Recovery Act (CARA)	Sens. Whitehouse [D-RI], Portman [R-OH], Klobuchar [D-MN], Ayotte [R-NH], Coons [D-DE], Kirk [R-IL]	Judiciary	Passed 3/10/2016; Message on Senate action sent to the House
<u>S. 1878</u>	Advancing Hope Act of 2015	Sens. Casey [D-PA] and Isakson [R-GA]	HELP	Reported out of Committee 3/8/2016
S. 1077	Advancing Breakthrough Medical Devices for Patients Act of 2015	Sens. Burr [R-NC], Bennet [D-CO], Hatch [R-UT]	HELP	Reported out of Committee 3/8/2016
<u>S. 1101</u>	Medical Electronic Data Technology Enhancement for Consumers Health Act	Sen. Bennet [D-CO]	HELP	Reported out of Committee 3/8/2016
S. 2055	Medical Countermeasures Innovation Act of 2015	Sens. Burr [R-NC] and Hatch [R-UT]	HELP	Reported out of Committee 3/8/2016
S. 1767	Combination Products Innovation Act of 2015	Sens. Isakson [R-GA], Casey [D-PA], Roberts [R-KS]	HELP	Reported out of Committee 3/8/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
S. 1597	Patient Focused Impact Assessment Act of 2016	Sens. Wicker [R-MS], Klobuchar [D-MN], Collins [R-ME], Franken [D-MN], Isakson [R-GA], Bennet [D- CO]	HELP	Reported out of Committee 3/8/2016
S. 2512	Adding Zika Virus to the FDA Priority Review Voucher Program Act	Sens. Franken [D-MN], Nelson [D-FL], Isakson [R- GA], Brown [D-OH]	HELP	Reported out of Committee 3/8/2016
<u>S. 2660</u>	Veterans Health Administration Spending Transparency and Oversight Act of 2016	Sen. Rounds [R-SD]	Veterans' Affairs	Introduced 3/10/2016
H.R. 4714	Removing Barriers to Clinical Research Act of 2016	Reps Young [R-IN-9] and Peters [D-CA-52]	Energy & Commerce; Ways & Means	Introduced 3/3/2016
H.R. 4689	Timely Payment for Veterans' Emergency Care Act	Rep. Boustany [R-LA-3]	Veterans' Affairs	Introduced 3/3/2016
H.R. 4695	Quality Care for Moms and Babies Act	Reps. Eliot [D-NY-16], Stivers [R-OH-15] and 12 original cosponsors	Energy & Commerce; Ways & Means	Introduced 3/3/2016
H.R. 4697	Prevent Drug Addiction Act of 2016	Reps. Esty [D-CT-5], Costello [R-PA-6], and Knight [R-CA-25]	Energy & Commerce; Ways & Means; Judiciary	Introduced 3/3/2016
H.R. 3796	Ensuring Access to Quality Medicaid Providers Act	Reps. Bucshon [R-IN-8], Welch [D-VT-At Large], Butterfield [D-NC-1]	Energy & Commerce; Senate Finance	Passed House 3/2/2016 Referred to Senate Finance Committee 3/3/2016
H.R. 4556	Expedited Hiring for VA Trained Psychiatrists Act of 2016	Rep. Cartwright [D-PA-17] and 14 original cosponsors	Veterans' Affairs	Referred to Subcommittee on Health 3/7/2016
H.R. 4725	Common Sense Savings Act of 2016	Rep. Pitts [R-PA-16]	Energy & Commerce	Introduced 3/10/2016

### REGULATORY UPDATE

## DEPARTMENT OF HEALTH AND HUMAN SERVICES March 8

#### **ASPE Releases Reports**

- <u>Observations on Trends in Prescription Drug Spending</u>, Which Finds that Expenditures on Prescription Drugs Are Rising.
- <u>Medicare Part B Drugs: Pricing and Incentives</u>, Which Finds that the Part B Payment Model Provides Weak Incentives for Physicians to Choose the Lowest Cost Therapy to Effectively Treat Patients.

CMS <u>Corrects</u> Errors Appearing in the Final Rule, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY* 2016.

HRSA <u>Seeks</u> Comments on an Information Collection Concerning the Telehealth Resource Center Performance Measurement Tool.

#### March 9

CMS <u>Issues</u> the Skilled Nursing Facility Utilization and Payment Public Use File Data.

CMS <u>Suspends</u> Policy Providing Automatic Reduction of Star Ratings for Medicare Advantage and Part D Contracts.

FDA <u>Publishes</u> Notification of Public Hearing and Requests Comment on Generic Drug User Fee Amendments.

IHS Publishes Medicare and Medicaid Reimbursement Rates for CY 2016.

NIH <u>Releases</u> Summary of Substance Abuse Prevention Research on Early Childhood Risk and Protective Factors.

#### March 10

FDA <u>Solicits</u> Comment on Information Collection for Industry and FDA Staff Guidance, *Dear Health Care Provider Letters: Improving Communication of Important Safety Information*.

#### March 11

CMS Announces March 14 Departure of Communications Director Lori Lodes.

HHS <u>Awards</u> \$94 Million to Health Centers Nation-Wide to Help Treat Prescription Opioid Abuse and Heroin Epidemic.

NIH Celebrates Brain Awareness Week with Outreach to Students Planned for March 14 -18.

#### March 14

CMS <u>Seeks</u> Comment on Information Collection for Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients Data System Revision.

#### OTHER NEWS

#### **CRS** Releases Reports

- <u>Patient Protection and Affordable Care Act (ACA): Resources for Frequently Asked Questions.</u> (Mar. 3)
- <u>Health Care for Dependents and Survivors of Veterans</u>. (Mar. 3)

#### **GAO** Releases Reports

- <u>Provider Networks: Comparison of Child-Focused Network Adequacy Standards between CHIP and Private Health Plans</u>. (Mar. 7)
- <u>Medicaid: Federal Guidance Needed to Address Concerns about Distribution of Supplemental Payments</u>. (Mar. 7)
- <u>National Institutes of Health: Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency</u>. (Mar. 10)

#### March 9

In Recent Study, Doctors Successfully <u>Alter</u> Patients' Immune Systems to Allow Kidney Transplants from Any Donor.

#### **UPCOMING EVENTS**

#### **CONGRESSIONAL HEARINGS/MARKUPS**

#### **SENATE**

#### Veterans' Affairs

<u>Hearing and Discussion on Pending</u> <u>Legislation:</u> Senate Bills 2646, 2633, and 2473

March 15 | 2:15 p.m.
 418 Russell Senate Office Building

### Joint Hearing of Senate and House Veterans' Affairs Committees

To Receive the Legislative Presentations from FRA, TREA, NASDVA, MOAA, AFSA, AXPOW, NCOA, JWV, and IAVA

March 16 | 10 a.m.
 50 Senate Dirksen Office Building

#### HELP

#### **Executive Session and Hearing**

#### Agenda:

- S. \_\_, Mental Health Reform Act of 2016
- S. 1455, The Recovery Enhancement for Addiction Treatment Act
- S. 2256, Co-Prescribing Saves Lives Act of 2015
- S. 480, National All Schedules
   Prescription Electronic Reporting (NASPER)
- S. \_\_, Plan of Safe Care Improvement Act
- March 16 | 10 a.m.
   106 Dirksen Senate Office Building

## Third Executive Session Considering Biomedical Innovation Bills

• April 6 | Time/Location TBA

#### **Environment and Public Works**

The 2016 Water Resources Development Act—Policies and Projects

March 16 | 10 a.m.
 406 Dirksen Senate Office Building

#### **Special Committee on Aging**

<u>Sudden Price Spikes in Decades-Old RX</u> <u>Drugs</u>

March 17 | 10 a.m.
 562 Dirksen Senate Office Building

#### **Judiciary**

<u>Late-Term Abortion: Protecting Babies Born</u> <u>Alive and Capable of Feeling Pain</u>

March 15 | 10 a.m.
 226 Dirksen Senate Office Building

Preventing America's Looming Fiscal Crisis:
The Need for a Balanced Budget
Amendment to the Constitution

March 16 | 2 p.m.
 226 Dirksen Senate Office Building

#### **Executive Business Meeting**

March 17 | 10 a.m.
 226 Dirksen Senate Office Building

#### **Finance**

<u>HealthCare.gov: A Review of Operations and Enrollment</u>

• March 17 | 10 a.m. Location TBA

#### **HOUSE**

#### **Energy & Commerce**

Broad Review of Concussions: Initial Roundtable

March 14 | 2 p.m.
 2123 Rayburn House Office Building

Medicare Access and CHIP Reauthorization
Act of 2015: Examining Implementation of
Medicare Payment Reforms

March 17 | 10 a.m.
 2123 Rayburn House Office Building

#### **Judiciary**

Executive Overreach in Domestic Affairs
Part I - Health Care and Immigration

March 15 | 10 a.m.
 2141 Rayburn House Office Building

#### **Education and Workforce**

Examining the Policies and Priorities of the U.S. Department of Health and Human Services.

**HHS Secretary Burwell Testifies** 

March 15 | 10 a.m.
 2175 Rayburn House Office Building

#### **Ways & Means**

Preserving and Strengthening Medicare

 March 16 | 10 a.m.
 1100 Longworth House Office Building

#### **Appropriations**

**Budget Hearing-National Institute of Health** 

March 16 | 10 a.m.
 2358 Rayburn House Office Building

#### Oversight and Government Reform

<u>Examining Federal Administration of the</u> <u>Safe Drinking Water Act in Flint, Michigan</u>

- March 15 | 10 a.m.
- March 17 | 9 a.m.
   2154 Rayburn House Office Building

Accountability and Transparency Reform at the Office of Information and Regulatory Affairs

March 15 | 2 p.m.
 2154 Rayburn House Office Building

#### **Veterans' Affairs**

Hearing on Draft Legislation to Improve the Authority of the VA Secretary to Hire and Retain Physicians and Other VA Employees

March 16 | 2 p.m.
 334 Cannon House Office Building

#### <u>Choice Consolidation: Leveraging Provider</u> Networks to Increase Veteran Access

March 22 | 10 a.m.
 334 Cannon House Office Building

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### CMS Open Payments Question and Answer Session

Conference call and webinar

March 15 | 1 p.m. - 2 p.m.
 <u>Register</u> to submit a question or view presentation.

Meeting of the Board of Scientific
Counselors, National Center for
Environmental Health/Agency for Toxic
Substances and Disease Registry

Discussion on NCEH/ATSDR support for the public health emergency in Flint, Michigan.

March 21 | 3 p.m. - 5 p.m.
 via Teleconference

## Meeting of the Advisory Panel on Outreach and Education

Listening session with CMS leadership, recap of previous meeting, discussion on ACA initiatives, and opportunity for public comment.

 March 23 | 8:30 a.m. – 4 p.m.
 Hubert H. Humphrey Building Room 425A, Conference Room 200 Independence Ave., SW Washington, DC 20201

## Meeting of the National Cancer Advisory Board

Examining global cancer research outline for presentation at the June 2016 Joint BSA and NCAB meeting.

March 23 | 2 p.m. – 3 p.m.
 National Cancer Institute
 9609 Medical Center Drive
 Rockville, MD 20850
 and via Teleconference

#### Meeting of the Board of Scientific Counselors, Office of Infectious Diseases

Agenda: Administrative/budget issues, current emerging infectious disease outbreak responses. <u>Agenda and supplementary materials</u> will be available.

• March 28 | 2 p.m. – 4 p.m. via Teleconference

#### Meeting of the National Cancer Institute Board of Scientific Advisors

Discussion of the Director's report, reports of program review group(s), budget presentations, and reports of special initiatives, among other things.

March 29 | 8:30 a.m. - 5 p.m.

NIH
31 Center Drive
Building 31, C-Wing, 6<sup>th</sup> Floor
Room 10
Bethesda, MD 20892
and via Webcast

## Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Agenda to be <u>posted</u> when available.

- March 30 | 10 a.m. 5 p.m.
  - March 31 | 9 a.m. 4 p.m.
    U.S. Department of Health & Human
    Services
    Hubert H. Humphrey Building
    Great Hall

200 Independence Ave., SW Washington, DC 20201 and via Webcast

<u>Pre-register</u> by March 21.

#### Meeting of the Healthcare Infection Control Practices Advisory Committee

Updates on antimicrobial stewardship, Draft Guideline for Prevention of Infections in Healthcare Personnel, and CDC activities for prevention of HAIs, among other things.

- March 31 | 9 a.m. 5 p.m.
- April 1 | 9 a.m. 12 p.m.

CDC Global Communications Center Building 19, Auditorium B 1600 Clifton Road, NE

Atlanta, Georgia 30333

#### FDA Public Workshop: Proposed Pilot Projects under the Drug Supply Chain Security Act

Focusing on projects that will explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

- April 5 | 9 a.m. 5 p.m.
- April 6 | 9 a.m. 12:15 p.m.
   FDA White Oak Campus
   Building 31, Conference Center
   Great Room (Rm. 1503)
   Sections B & C
   10903 New Hampshire Ave.
   Silver Spring, MD 20993-0002
   Registration requested.

# Meeting of the Advisory Committee to the Director (ACD), CDC State, Tribal, Local and Territorial Subcommittee

Discussion of implementation of ACDadopted recommendations, and how CDC may best support STLT health departments.

• April 8 | 11:30 a.m. – 1 p.m. via Teleconference

#### Meeting of CDC Board of Scientific Counselors, Office of Public Health Preparedness and Response

- April 11 | 10 a.m. 5:30 p.m.
- April 12 | 8:30 a.m. -3:30 p.m.
   CDC
   Global Communications Center
   Building 19, Auditorium B3

1600 Clifton Road NE Atlanta, Georgia 30333 Pre-register by email to attend.

## Meeting of the Clinical laboratory Improvement Advisory Committee

Agency updates from CDC, CMS, FDA; presentations and discussion on lab interoperability, among other things.

- April 13 | 8:30 a.m. 5 p.m.
- April 14 | 8:30 a.m. 12 p.m.

CDC

1600 Clifton Road NE
Tom Harkin Global Communications
Center
Building 19, Auditorium B
Atlanta, Georgia 30333
and via Webcast

#### Meeting of the Sleep Disorders Research Advisory Board

April 14 – 15 | 1 p.m. – 3 p.m.
 National Institutes of Health
 Two Rockledge Center
 6701 Rockledge Drive
 Conference Room 9100/9104
 Bethesda, MD 20892-7952

#### Meeting of the Muscular Dystrophy Coordinating Committee

Agenda to be <u>posted</u> prior to meeting.

April 27 | 8:30 a.m. – 4:30 p.m.
 Neuroscience Center
 Conference Room C/D
 6001 Executive Boulevard
 Bethesda, Maryland 20892
 and via Webcast

#### Meeting of the Medicare Evidence Development & Coverage Advisory Committee

Recommendations on the definition of TRD and to advise CMS on the use of the definition of TRD in the context of coverage.

April 27 | 7:30 a.m. – 4:30 p.m.
 CMS Main Auditorium
 7500 Security Boulevard
 Baltimore, MD 21244

#### Meeting of the Board of Scientific Counselors, National Center for Biotechnology Information

May 10 | 8:30 a.m. - 12 p.m.; 2 - 3 p.m.
 National Library of Medicine
 Building 38, 2nd Floor
 The Lindberg Room
 8600 Rockville Pike
 Bethesda, MD 20892

## FDA Regulatory Sciences Initiatives Public Meeting

Agenda: Generic Drug Regulation.

May 20 | 9 a.m.
 FDA White Oak Campus
 Building 31, Conference Center
 Great Room (Rm. 1503)
 Sections B & C
 10903 New Hampshire Ave.
 Silver Spring, MD 20993-0002
 and via Webcast
 Registration Required by April 29.

## NIH Meeting of the National Institute of Neurological Disorders and Stroke

Agenda: Report by Director, Administrative and Program Developments, Overview of NINDS Intramural Program.

May 26 | 8 a.m. to 2:30 p.m.
 NIH
 31 Center Drive
 Building 31, C-Wing, 6<sup>th</sup> Floor
 Room 10
 Bethesda, MD 20892
 and via Webcast

#### <u>Healthcare Common Procedure Coding</u> <u>System Public Meeting</u>

Discussion on preliminary coding and payment determinations for new public requests for HCPCS revisions.

- May 17 | 9 a.m. 5 p.m.
- May 18 | 9 a.m. 5 p.m.
- May 19 | 9 a.m. 5 p.m.
- June 1 | 9 a.m. 5 p.m.
- June 2 | 9 a.m. 5 p.m.
   CMS Main Auditorium
   Central Building
   7500 Security Boulevard
   Baltimore, MD 21244

## Meeting of the PubMed Central National Advisory Committee

Meeting to review and analyze systems.

June 7 | 9:30 a.m. - 3 p.m.
 National Library of Medicine
 Building 38, 2nd Floor
 The Lindberg Room
 8600 Rockville Pike
 Bethesda, MD 20892

#### **DEPARTMENT OF VETERANS AFFAIRS**

#### Meeting of the Commission on Care

- March 21 | 1 p.m. 5 p.m.
- March 22 | 8:30 a.m. 5 p.m.
- March 23 | 8:30 a.m. 5 p.m.
   Conference Center
   20 F Street, NW
   Washington, DC 20001

## Meeting of the Genomic Medicine Program Advisory Committee.

Focus on interagency collaborations, development of IT and informatics infrastructure, quality control of genomic data, and data access for the Million Veteran Program.

April 12 | 9 a.m. - 5 p.m.
 U.S. Access Board
 1331 F Street NW, Suite 1000
 Washington, DC 20004

#### Meeting of the Geriatrics and Gerontology Advisory Committee

Presentations and discussion of VA's geriatrics and extended care programs.

- April 19 | 8:30 a.m. 5 p.m.
- April 20 | 8 a.m. 12 p.m.
   U.S. Department of Veterans' Affairs 810 Vermont Ave., NW
   Room 730
   Washington, DC 20420

#### **OTHER EVENTS**

#### 2016 Comparative Effectiveness Research and the Environment for Health Care Decision-Making

March 14 | 2 p.m. - 3 p.m.
 Register to attend via webinar.

## ACA at Five Years: Do Americans have Better Access to Quality Care?

Discussion held by Health Affairs and Abt Associates.

March 15 | 9 a.m. – 12 p.m.
 Newseum
 Knight Conference Room
 555 Pennsylvania Ave, NW
 Washington, DC 20001
 Register to attend.

#### Resistance: The Antibiotics Challenge

Panel discussion and breakfast hosted by *The Atlantic*.

March 16 | 8 - 10:30 a.m.
 Newseum
 Knight Broadcast Studio
 555 Pennsylvania Avenue, NW
 Washington, DC 20001
 Register to attend.

#### Summit on Mental Health and Addiction

Panel discussion and breakfast hosted by *The Atlantic.* 

April 12 | 8:30a.m. – 12 p.m.
 1777 F Street, NW
 Washington, DC 20006
 <u>Register</u> to attend.