

LEGISLATIVE AND REGULATORY UPDATE

February 22, 2016

Week in Brief

President Obama [Responds](#) to Supreme Court Vacancy.

Congress Returns to Washington This Week After a Brief Recess.

LEGISLATIVE UPDATE

February 16

Senators [Object](#) to Medicare Advantage Program Cuts in Letter to CMS.

Senator McCain [Releases](#) Statement Regarding OIG [Report](#) on Mismanagement of VA Suicide Hotline.

February 17

House Members [Object](#) to Additional Medicare Advantage Program Cuts in Letter to CMS.

Senate Democrats [File](#) *Amicus* Brief with Supreme Court in Support of Access to Affordable Birth Control.

February 18

House Energy & Commerce Subcommittee on Health Leaders Continue [Efforts](#) to Strengthen Medicaid; Request Answers to Six Questions Regarding CMS Oversight of State Medicaid Programs' Use of Provider Taxes.

February 19

House Appropriators [Reject](#) President Obama's Request for \$1.8 Billion in Emergency Zika Funding and Push to Utilize Unused Ebola Funds Instead.

House Energy & Commerce Committee [Highlights](#) Washington Post Profile of U.S. Teenager with Ultra Rare Disease as Part of 21st Century Cures Initiative.

LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
S. 2543	To amend the FDA mission statement to consider dangers associated with prescription opioid medications.	Sen. Manchin [D-WV]	HELP	Introduced 2/11/2016
H.R. 4565	<i>Responsibility in Drug Advertising Act of 2016</i>	Rep. DeLauro [D-CT-3]	Energy & Commerce	Introduced 2/12/2016

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

February 16

CMS and America's Health Insurance Plans [Release](#) Seven Sets of Clinical Quality Measures.

CMS [Seeks](#) Nominations for IMPACT Act Technical Expert Panel; Nomination Period Closes February 26.

FDA [Releases](#) *Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus*; FDA Invites Comments on the Guidance.

CDC [Publishes](#) National Vital Statistics Report on Leading Causes of Deaths for 2013.

February 17

CMS [Releases](#) Final, Non-Exhaustive [List](#) of Essential Community Providers for Benefit Year 2017.

February 18

FDA Panel [Recommends](#) Extensive Monitoring of New Class of Pacemakers.

February 19

NIH [Seeks](#) Comments on Proposed Information Collection on NIH Loan Repayment Programs.

February 19

FDA [Releases](#) Summary [Report](#) of Public Comments on FDA Activities Under the FDASIA, Patient Participation in Medical Product Discussions.

CMS [Releases](#) Proposed Changes for the Medicare Advantage and Part D Prescription Drug Programs in 2017; Payment Rates Estimated to Increase By 1.35% on Average.

DEPARTMENT OF VETERANS AFFAIRS

February 17

Veterans Benefits Administration [Seeks](#) Comments on Proposed Information Collection Regarding Medical Form to Adjudicate Claims for VA Disability Benefits.

JUDICIAL UPDATE

February 17

DOJ [Reaches](#) Settlements with 51 Hospitals for More than \$23 Million Regarding Alleged False Claims for Cardiac Devices Implanted in Medicare Patients.

OTHER NEWS

CRS Releases Reports:

- [Provisions of the Senate Amendment to H.R. 3762](#) (Feb. 1)
- [Justice and Mental Health Collaboration Program: Fact Sheet](#) (Feb. 2)
- [Medicare Trigger](#) (Feb. 8)
- [Insight: Zika Virus: Global Health Considerations](#) (Feb. 9)
- [Medicaid's Federal Medical Assistance Percentage \(FMAP\)](#) (Feb. 9)
- [Private Health Insurance Market Reforms in the Patient Protection and Affordable Care Act \(ACA\)](#) (Feb. 10)
- [SAMHSA FY 2017 Budget Request and Funding History: A Fact Sheet](#) (Feb. 11)

February 16

WHO [Releases](#) Global Emergency Response Plan for Zika Outbreak.

GAO [Releases](#) Report on Medicaid: *Efforts to Exclude Nonemergency Transportation Not Widespread, but Raise Issues for Expanded Coverage.*

CBO [Estimates](#) that S. 2368, a Bill Aimed at Addressing the Medicare Appeals Backlog, Would Increase Direct Spending by About \$1.7 Billion from 2016 to 2026.

February 18

National Governors Association [Publishes](#) Recommendations to Address Opioid Epidemic.

UPCOMING EVENTS

WHITE HOUSE

Stakeholder Meeting on the Precision Medicine Initiative

- February 25 | Time and Location TBA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Physician Compare Public Reporting Information Sessions

Webinar on updates to and the future plans for the Physician Compare.

- February 23 | 12 p.m. - 1 p.m.;
- February 24 | 4 p.m. - 5 p.m.; or
- February 25 | 11 a.m. - 12 p.m.
Virtual Event via WebEx

Advisory Committee on Immunization Practices Meeting

Agenda includes discussions on various vaccines, a recommendation votes for influenza, and a VAC vote for certain vaccines.

- February 24 | 8 a.m. - 6 p.m.
CDC
Tom Harkin Global
Communications Center
Building 19
Kent "Oz" Nelson Auditorium
1600 Clifton Road, NE
Atlanta, GA 30329

Meeting of the Center for Substance Abuse Prevention

Discussion of aligning mental and substance use and misuse disorder prevention with health.

- February 24 | 9:30 a.m. - 4:30 p.m.
SAMHSA
5600 Fishers Lane
Room 5N76
Rockville, MD 20857;
Adobe Connect [webcast](#)

SAMHSA Advisory Committee for Women's Services

Discussion of U.S. Preventive Services Task Force Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services for Women.

- February 24 | 9 a.m. - 4:45 p.m.
SAMHSA
5600 Fishers Lane
Room 5E49
Rockville, MD 20857

SAMHSA Center for Substance Abuse Treatment

Agenda: Budget update, and presentations related to opiate use disorders, criminal justice reform, and other topics.

- February 24 | 9 a.m. – 5 p.m.
SAMHSA
5600 Fishers Lane
Room 5E49
Rockville, MD 20857

Meeting of the National Cancer Advisory Board

Topics will include the business of the Board, and program reports and presentations.

- February 24 | 1 p.m. – 2 p.m.
National Cancer Institute
Shady Grove
Room TE406
9609 Medical Center Dr.
Rockville, MD 20850

Joint Meeting of SAMHSA's Four National Advisory Councils

SAMHSA Administrator's report on priorities and updates. Several breakout groups on various topics.

- February 25 | 8:30 a.m. – 5 p.m.
Bethesda North Marriott and Conference Center
5701 Marinelli Road
Rockville, MD 20852
and via phoneweb conference

Webcast: "Using Technology to Enhance Addiction Treatment" Hosted by SAMHSA-HRSA Center for Integrated Health Solutions.

- February 25 | 3 p.m.

SAMHSA National Advisory Council

Agenda: Review of February 25 joint council meeting. Presentations on increasing engagement in quality care and subsequent discussion.

- February 26 | 8:30 a.m. – 1 p.m.
Bethesda North Marriott and Conference Center
5701 Marinelli Road
Rockville, MD 20852
and via phone/web conference

NIH Rare Disease Day Event

Event to raise awareness about rare disease.

- February 29 | 8:30 a.m. – 3:30 p.m.
NIH Clinical Center
(Building 10)
Masur Auditorium
10 Center Dr.
Bethesda, Maryland

Meeting of the Science Board to the FDA Advisory Committee

Agenda: Role of opioids in pain management, role FDA plays as part of larger Federal, State, and local response to challenges of providing appropriate treatment while reducing opioid abuse.

- March 1 | 8:30 a.m.
FDA White Oak Campus
10903 New Hampshire Ave.
Building 31 Conference Center
The Great Room
Silver Spring, MD 20993
and via [webcast](#)

Provider Enrollment Revalidation Call

Discussion on timing, improvements, and updates for the second round of revalidations.

- March 1 | 2 p.m. – 3:15 p.m.
National Provider Call

Public Workshop: Patient and Medical Professional Perspectives on the Return of Genetic Test Results

Discussion on better defining the specific information patients and providers prefer to receive.

- March 2 | 8 a.m. - 4 p.m.
FDA's White Oak Campus
Building 31, Conference Center
The Great Room (Rm. 1503)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Comparative Billing Report on Electrodiagnostic Testing Webinar

Discussion of the comparative billing report on Electrodiagnostic Testing.

- March 2 | 3 p.m. - 4:30 p.m.
Webinar

Advancing the Development of Biomarkers in Traumatic Brain Injury: FDA Workshop

- March 3 | 8 a.m. - 5 p.m.
FDA White Oak Campus
Building 31, Conference Center
The Great Room (Rm. 1503)
10903 New Hampshire Ave.
Silver Spring MD, 20993
and Webcast

Meeting of the Advisory Council on Blood Stem Cell Transplantation

Agenda: Hearing of work group report on cord blood and other topics.

- March 3 | 12 p.m. - 4 p.m.
Via Audio Conference Call and Adobe Connect Pro

Meeting of the Presidential Commission for the Study of Bioethical Issues

Discussion on the development of pedagogical materials to facilitate the integration of bioethics into education.

- March 3 | 2 p.m. - 4 p.m.
Teleconference

HRSA Advisory Commission on Childhood Vaccines

Agenda: Updates from Division of Injury Compensation Programs, Department of Justice, National Vaccine Program Office, Immunization Safety Office of the CDC, National Institute of Allergy and Infectious Diseases of the NIH and the Center for Biologics, Evaluation and Research of the FDA.

- March 3 | 10 a.m.
via Teleconference

Meeting of the Vaccines and Related Biological Products Advisory Committee

Meeting to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines.

- March 4 | 8:30 a.m. - 3 p.m.
FDA White Oak Campus
Building 31 Conference Center
The Great Room (Rm. 1503)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee

Discussion on NCI's clinical and translational research programs. Open session will be videocast and accessible.

- March 9 | 11 a.m. - 1 p.m.
NIH, Building 31,
C-Wing, 6th Floor
Room 10
9000 Rockville Pike
Bethesda, MD 20892

Kidney Interagency Coordinating Committee

Discussion of programmatic implications of U.S. Renal Data System to federal agencies.

- March 11 | 9 a.m. – 12 p.m.
NIH Natcher Conference Center
9000 Rockville Pike
Bethesda, MD 20894

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. [Registration](#) is requested by March 11.

- 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

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

Program discussion.

- 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

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 2089

DEPARTMENT OF VETERANS AFFAIRS

Meeting of the Commission on Care

- February 29 | 8:30 a.m. - 5 p.m.
- March 1 | 8:30 a.m. - 4 p.m.
Dallas VA Medical Center
4500 S. Lancaster Rd.
Dallas, TX 75216

Meeting of the National Research Advisory Council

To provide advice to the Under Secretary for Health and the VA Secretary on certain research and development.

- March 2 | 9 a.m. - 3:30 p.m.
810 Vermont Ave., NW,
Room 730
Washington, DC 20420

OTHER EVENTS

Atlantic Council Discussion: Cyber Risk Wednesday First, Do No Harm: Cybersafety of Medical Devices

- February 24 | 4 p.m.
Atlantic Council
1030 15th Street, NW
12th Floor (West Tower)
Washington, DC 20005

Values Based Lecture: The ACA After Five Years - The Importance of Values in a Dynamic Health Care Environment

- February 24 | 4 p.m.
Georgetown University
Leavey Salons ABC
3800 Reservoir Rd, NW
Washington, DC 20057

Bloomberg Webinar: Trends, Challenges and Insights: A Federal Perspective on the Health IT Industry

- February 25 | 2 p.m. – 3 p.m.
Webinar

American Medical Association 2016 National Advocacy Conference

- February 22-24
Grand Hyatt Washington
1000 H Street, NW
Washington, DC 20001

National Association of Health Underwriters 2016 Capitol Conference

- February 22 - 24
Hyatt Regency on Capitol Hill
400 New Jersey Ave., NW
Washington, DC 20001

UPCOMING CONGRESSIONAL HEARINGS/MARKUPS

SENATE

Finance

Examining the Opioid Epidemic: Challenges and Opportunities

- February 23 | 10 a.m.
215 Dirksen Senate Office Building

Special Committee On Aging Opioid Use Among Seniors - Issues and Emerging Trends

- February 24 | 2:30 p.m.
562 Dirksen Senate Office Building

HELP

Zika Virus: Addressing the Growing Public Health Threat

- February 24 | 10 a.m.
430 Dirksen Senate Office Building

Second Executive Session Considering Biomedical Innovation Bills

Committee will consider legislation to modernize the FDA and NIH and provide Congressional support for the Precision Medicine Initiative.

- March 9 | Time/Location TBA

Third Executive Session Considering Biomedical Innovation Bills

- April 6 | Time/Location TBA

Homeland Security & Governmental Affairs

Connecting Patients to New and Potential Life Saving Treatments

- February 25 | 10 a.m.
SD-342 Dirksen Senate Office Building

Veterans' Affairs

FY 2017 Budget for Veterans' Programs and FY 2018 Advance Appropriations Request

- February 23 | 10 a.m.
SR-418 Russell Senate Office Building

HOUSE

Appropriations

Budget Hearing – Indian Health Service

- February 25 | 9 a.m.
B-308 Rayburn House Office Building

Oversight Hearing - Veterans Affairs Office of Inspector General

- February 25 | 9:30 a.m.
2362-B Rayburn House Office
Building

Budget Hearing – Department of Health and Human Services

- February 25 | 10 a.m.
2358-C Rayburn House Office
Building

Budget Hearing - Food and Drug Administration

- February 25 | 10:30 a.m.
2362-A Rayburn House Office
Building

Oversight & Government Reform

The Zika Virus: Coordination of a Multi- Agency Response

- February 24 | 2 p.m.
2154 Rayburn House Office Building

Review of Obamacare Consumer Operated and Oriented Plans (CO-OPs)

- February 25 | 2 p.m.
2157 Rayburn House Office Building

Energy & Commerce

Broad Review of Concussions: Initial Roundtable

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

Veterans' Affairs

Addressing VA Opioid Prescription and Pain Management Practices

- March 4 | 10:30 a.m.
National Guard Headquarters
1 Minuteman Way
Concord, NH 03301