

LEGISLATIVE AND REGULATORY UPDATE February 16, 2016

Week in Brief

Supreme Court Justice Antonin Scalia [Dies](#) at the Age of 79. President Obama Will [Nominate](#) a Replacement. Senate Majority Leader McConnell [Releases](#) Statement that the Senate Should Not Confirm Scalia's Replacement until after the Presidential Election. (*Feb. 13*)

Congress is Out of Session This Week; Will Return to Washington the Week of February 22nd.

WHITE HOUSE UPDATE

February 9

President Obama [Releases](#) Fiscal Year (FY) 2017 Budget Request.

LEGISLATIVE UPDATE

February 8

Senate Finance Chronic Care Working Group [Releases](#) Submissions Responding to Policy Options Paper.

Senate Finance Ranking Member Wyden [Offers](#) Support for the Proposed CDC Opioid Prescription Guidelines.

Senate Finance Chairman Hatch and House Energy & Commerce Leaders Submit [Letter](#) to OIG Regarding Medicaid Payments for Deceased Beneficiaries.

February 9

Senate Finance Chairman Hatch [Issues](#) Statement on President's FY 2017 Budget Request.

House Ways & Means Chairman Brady [Issues](#) Statement on President's FY 2017 Budget Request.

Senate HELP Ranking Member Murray [Releases](#) Statement on President's FY 2017 Budget Request Concerning Mental Illness and Substance Abuse.

Senate HELP Committee [Passes](#) Seven Biomedical Innovation Bills with Bipartisan Support; Biomedical Innovation Agenda to Continue March 9. House Energy & Commerce Leaders [Applaud](#) the Passage of Biomedical Innovation Bills; Call for Continuing Momentum.

Senator Warren [Urges](#) CDC to Finalize Prescription Guidelines for Opioids.

February 10

House Ways & Means Chairman Brady [Delivers](#) Opening Statement at FY 2017 Budget Hearing; HHS Secretary Burwell Testifies.

House Energy & Commerce Subcommittee on Health [Examines](#) Federal Matching for Medicaid and CHIP at Hearing.

February 11

HELP Ranking Member Murray [Calls](#) for Emergency Zika Virus Funds for States and Local Communities.

LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
S. 2519	<i>Empowering Patients First Act of 2015</i>	Sens. McCain [R-AZ] and Perdue [R-GA]	Finance	Introduced 2/9/2016
S. 2525	<i>Expand Excellence in Mental Health Act</i>	Sens. Stabenow [D-MI] and Blunt [R-MO]	Finance	Introduced 2/9/2016
S. 2520	<i>Newborn Care Improvement Act</i>	Sens. Klobuchar [D-MN] and Tillis [R-NC]	Veterans' Affairs	Introduced 2/9/2016
S. 2030	<i>Advancing Targeted Therapies for Rare Diseases Act of 2015</i>	Sens. Bennet [D-CO], Burr [R-NC], Warren [D-MA], and Hatch [R-UT]	HELP	Reported out of Committee 2/9/2016
S. 1622	<i>FDA Device Accountability Act of 2015</i>	Sens. Burr [R-NC] and Franken [D-MN]	HELP	Reported out of Committee 2/9/2016
S. 2014	<i>Next Generation Researchers Act</i>	Sens. Baldwin [D-WI] and Collins [R-ME]	HELP	Reported out of Committee 2/9/2016
S. 800	<i>Enhancing the Stature and Visibility of Medical Rehabilitation Research at NIH Act</i>	Sens. Kirk [R-IL], Bennet [D-CO], Hatch [R-UT], and Murkowski [R-AK]	HELP	Reported out of Committee 2/9/2016

<u>S. 849</u>	<i>Advancing Research for Neurological Diseases Act of 2015</i>	Sens. Isakson [R-GA], Murphy [D-CT], Vitter [R-LA], and Casey [D-PA]	HELP	Reported out of Committee 2/9/2016
<u>S. 2503</u>	<i>Preventing Superbugs and Protecting Patients Act</i>	Sen. Murray [D-WA]	HELP	Reported out of Committee 2/9/2016
<u>S. 2511</u>	<i>Improving Health Information Technology Act</i>	Sens. Alexander [R-TN], Murray [D-WA], Cassidy [R-LA], Whitehouse [D-RI], Hatch [R-UT], and Bennet [D-CO]	HELP	Reported out of Committee 2/9/2016
<u>S. 483</u>	<i>Ensuring Patient Access and Effective Drug Enforcement Act of 2015</i>	Sens. Hatch [R-UT] and Whitehouse [D-RI]	Judiciary	Reported out of Committee 2/12/2016
<u>S. 524</u>	<i>Comprehensive Addiction and Recovery Act of 2015</i>	Sens. Whitehouse [D-RI], Portman [R-OH], Klobuchar [D-MN], Ayotte [R-NH], Coons [D-DE], and Kirk [R-IL]	Judiciary	Reported out of Committee 2/12/2016
<u>H.R. 4506</u>	To help health care consumers comparison shop for medical services based on quality and cost.	Rep. Fortenberry [R-NE-1]	Energy & Commerce	Introduced 2/9/2016
<u>H.R. 4499</u>	<i>Promoting Responsible Opioid Prescribing (PROP) Act of 2016</i>	Rep. Mooney [R-WV-2], Rogers [R-KY-5], Kuster [D-NH-2], Comstock [R-VA-10], Ryan [D-OH-13], Guinta [R-NH-1], and Lynch [D-MA-8].	Ways & Means	Introduced 2/9/2016

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

February 5

HHS Prematurely [Posts](#) Notice to Contractors on Testing New Payment Methods for Medicare Part B Drugs.

February 8

CDC [Seeks](#) Comments on Proposed Vaccine Information Materials for Hepatitis A and B Vaccines.

CMS [Announces](#) More than 10 Million Medicare Beneficiaries Have Received Discounts Over \$20 Billion on Prescription Drugs Since the Enactment of the ACA.

February 9

HHS [Publishes](#) Overview of the President's FY 2017 Budget Request for HHS.

NIH Director [Provides](#) a Presentation on the President's FY 2017 Budget Request.

February 10

CMS [Extends](#) Deadline for 2015 PQRS EHR Submissions to March 11, 2016.

AHRQ [Publishes](#) *Request for Measures Assessing Health Care Organization Quality Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self-Management.*

HRSA [Requests](#) Comments on Proposed Data Collection on the Rural Opioid Overdose Reversal Grant Program.

February 11

CMS [Issues](#) Notice of Seven Membership Appointments to the Advisory Panel on Hospital Outpatient Payment.

CMS [Extends](#) Attestation Deadline for 2015 EHR to March 11, 2016.

CMS [Sends](#) Letter to State Medicaid Directors Providing Guidance on the Implementation of the Covered Outpatient Drug Final Regulation Provisions Concerning Reimbursement for Covered Outpatient Drugs in the Medicaid Program.

CDC [Seeks](#) Comments Concerning Proposed Information Collection on Congenital Heart Defects.

CMS [Extends](#) Deadline for Comment on MACRA Episode Groups to March 1, 2016.

February 12

CMS [Publishes](#) Final Rule on Medicare Reporting and Returning of Overpayments.

DEPARTMENT OF VETERANS AFFAIRS

February 8

VA [Seeks](#) Comments on the Proposed Information Collection on the Evaluation of the Department's Mental Health Services.

February 9

VA [Provides](#) Fact Sheet on the President's FY 2017 Budget Regarding Medical Care.

UPCOMING EVENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Committee on Vital and Health Statistics, Subcommittee on Standards

Meeting to gather input regarding proposed operating rules for certain HIPAA transactions and proposed Claim Attachment standards and code sets.

- February 16 | 9 a.m. – 5 p.m.
Hubert H. Humphrey Building
Room 705-A
200 Independence Ave., SW
Washington DC 20024

Meeting of the Cellular, Tissue and Gene Therapies Advisory Committee

Updates on research programs in Tumor Vaccines and Biotechnology Branch and the Cellular and Tissue Therapy Branch.

- February 16 | 1 p.m. – 3:55 p.m.
FDA's White Oak Campus
Bldg. 31 Conference Ctr.,
The Great Room (Rm. 1503)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Meetings of the National Committee on Vital and Health Statistics

Discussion on several health data policy topics.

- February 17 | 8:30 a.m. – 5:40 p.m.
- February 18 | 8:10 a.m. – 12 p.m.
Hubert H. Humphrey Building
Room 705-A
200 Independence Ave., SW
Washington DC 20024

Medicare Quality Reporting Programs Webinar: What Eligible Providers Need to Know in 2016

Topics will include MACRA preview, 2016 incentive payments and 2018 payment adjustments, 2016 PQRS updates, 2018 VM policies, Physician Compare updates for 2016, and meaningful use of CEHRT in 2016.

- February 17 | 11:30 a.m. – 1 p.m.

SAMHSA Webinar: Confidentiality of Alcohol and Drug Abuse Patient

Records. Provides an overview of HHS proposed revisions [published](#) in the Federal Register.

- February 19 | 1 p.m. – 2 p.m.

Meeting of the Community Preventive Services Task Force

Discussion of proposed methods for increasing number of Task Force Findings that are produced in a given time period.

- February 22, 2016 | 11 a.m. - 4:30 p.m.
[Register](#) for webinar by 5 p.m. EST on Monday, February 22.

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 | 9a.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.
(Same location as above.)

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 phone/web conference

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

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
Bldg. 31 Conference Ctr.
The Great Room (Rm. 1503)
10903 New Hampshire Ave.
Silver Spring, MD 20993

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

- March 3 | 8 a.m. – 5 p.m.
FDA White Oak Campus
10903 New Hampshire Avenue
Bldg. 31, Room 1503 (the Great Room)
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. to 4 p.m. EST
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

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 Ctr.
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

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 20892

DEPARTMENT OF VETERANS AFFAIRS

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

National Academies of Sciences, Engineering, and Medicine workshop on Research Priorities to Inform Public Health and Medical Practice for Domestic Zika Virus

- February 16 | 8:30 a.m.
National Academy of Sciences
Building Auditorium
2101 Constitution Ave NW
Washington, DC 20418

America's Health Insurance Plans (AHIP) holds a briefing on "Medicare Advantage: Delivering Value for Beneficiaries through Innovation"

- February 17 | 12 p.m.
485 Senate Russell Building

Pew Charitable Trusts Panel Discussion: "Confronting America's Opioid and Heroin Addiction Crisis"

- February 19 | 11 a.m.
901 E St. NW
Washington, DC 20004
and via live webcast

UPCOMING CONGRESSIONAL HEARINGS/MARKUPS

SENATE

Committee on Armed Services

Defense Health Care Reform

- February 23 | 2:30 p.m.
SD-G50 Dirksen Senate Office
Building

HELP Committee

Hearing on Zika Virus

- February 24 | 10 a.m.
Location TBA

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

HOUSE

Veterans' Affairs

Persian Gulf War: An Assessment of Health Outcomes on the 25th Anniversary

- February 23 | 4:30 p.m.
334 Cannon House Office Building