

## LEGISLATIVE AND REGULATORY UPDATE March 28, 2016

### Week in Brief

White House [Issues](#) Statement by the President on the 6<sup>th</sup> Anniversary of the ACA and [Touts](#) Health Care Accomplishments.

Congress is on Spring Recess This Week.

## WHITE HOUSE UPDATE

**March 22**

White House [Announces](#) President Obama Will Address the National Rx Drug Abuse & Heroin Summit in Atlanta on March 29; Administration Sends Letter to Governors Highlighting Best Practices to Prevent Overdoses and Expand Access to Care.

## LEGISLATIVE UPDATE

**March 21**

House Passes [S. 192](#), the *Older Americans Act Reauthorization Act of 2015*, as amended; Bill Previously Passed by Senate in July 2015.

House Ways & Means Website [Starts](#) Blog Questioning Administration's Implementation of the ACA.

**March 22**

House Appropriations Committee [Releases](#) Draft of Subcommittee Bill on Fiscal Year 2017 Military Construction and Veterans Affairs Appropriations.

House Veterans' Affairs Chairman Jeff Miller (R-FL) [Releases](#) Statement on Latest Failures of Accountability at the VA.

House Judiciary Committee [Postpones](#) Markup on H.R. 4771, a Medical Tort Reform Bill.

## March 23

Senate HELP Chairman Lamar Alexander (R-TN) [Releases](#) Statement on 6<sup>th</sup> Anniversary of the ACA Calling on the Next President to Work with Congress and Replace Law with Bipartisan Health Care Solutions.

Senate HELP Ranking Member Patty Murray (D-WA) [Releases](#) Statement on 6<sup>th</sup> Anniversary of the ACA Urging Continued Health Care Progress for Patients and Families.

Republican Senate and House Committee Leaders [Send](#) Letter to the Administration Seeking Information on 316 [HealthCare.gov](#) Security Breaches Detailed in Newly Released GAO Report.

Republican House Leaders [Send](#) Letter to CMS Asking for Reconsideration of Proposed Changes to the Medicare Advantage Employer Group Waiver Plans.

House Energy & Commerce Chairman Fed Upton (R-MI) and Ways & Means Chairman Kevin Brady (R-TX) [Send](#) Letter to CMS Opposing Reinsurance Payments Under the ACA.

House Ways & Means Website [Posts](#) Blog Highlighting Shortcomings of the ACA on the Law's 6<sup>th</sup> Anniversary.

## March 24

House Energy & Commerce Website [Posts](#) Blog on Reforming Medicaid and Shares a Series of Detailed Slides Overviewing the Program.

## LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<a href="#">S. 2689</a>	<i>Reliable and Effective Growth for Regenerative Health Options that Improve Wellness</i>	Sens. Kirk [R-IL], Manchin [D-WV], and Collins [R-ME]	HELP	Introduced 3/16/2016
<a href="#">S. 2701</a>	<i>Medicaid Program Integrity Enhancement Act of 2016</i>	Sens. Heinrich [D-NM] and Udall [D-NM]	Finance	Introduced 3/17/2016
<a href="#">S. 2713</a>	<i>Advancing Precision Medicine Act of 2016</i>	Sen. Alexander [R-TN]	HELP	Introduced 3/17/2016
<a href="#">S. 192</a>	<i>Older Americans Act Reauthorization Act of 2015</i>	Sens. Alexander [R-TN], Murray [D-WA], and Burr [R-NC]	HELP, Education & the Workforce	Measure, as amended, passed in the House by voice vote, under suspension of the rules 3/21/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<a href="#"><u>H.R. 4805</u></a>	<i>Ensuring Patient Access to Healthcare Records Act of 2016</i>	Reps. McMorris Rodgers [R-WA-5] and Byrne [R-AL-1]	Energy & Commerce; Ways & Means	Introduced 3/17/2016
<a href="#"><u>H.R. 4819</u></a>	To direct the HHS Secretary to establish a grant program for States that provide flexibility in licensing for health care providers who offer services on a volunteer basis.	Reps. Duncan [R-TN-2], Roe [R-TN-1], Fleischmann [R-TN-3], and DesJarlais [R-TN-4]	Energy & Commerce; Ways & Means	Introduced 3/21/2016
<a href="#"><u>H.R. _____</u></a>	Making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2017, and for other purposes.		Appropriations	Subcommittee draft released 3/22/2016
<a href="#"><u>H.Con.Res.125</u></a>	Establishing the congressional budget for the United States Government for fiscal year 2017 and setting forth the appropriate budgetary levels for fiscal years 2018 through 2026.	Rep. Price [R-GA-6]	Budget	Introduced and placed on the Union Calendar 3/23/2016
<a href="#"><u>H.R. 4878</u></a>	<i>Better Care, Lower Cost Act</i>	Reps. Paulsen [R-MN-3] and Welch [D-VT-At Large]	Energy & Commerce; Ways & Means	Introduced 03/23/2016
<a href="#"><u>H.R. 4876</u></a>	<i>Medicare Prescription Drug Abuse Prevention Act</i>	Reps. Meehan [R-PA-7] and Neal [D-MA-1]	Energy & Commerce; Ways & Means	Introduced 03/23/2016
<a href="#"><u>H.R. 4861</u></a>	<i>Access to Substance Abuse Treatment Act</i>	Rep. Delauro [D-CT-3]	Energy & Commerce	Introduced 03/23/2016
<a href="#"><u>H.R. 4853</u></a>	<i>Strengthening Accreditation For Everyone (SAFE) Act</i>	Rep. Roskam [R-IL-6]	Ways & Means	Introduced 03/23/2016
<a href="#"><u>H.R. 4841</u></a>	<i>Co-Prescribing Saves Lives Act</i>	Reps. Rothfus [R-PA-12] and Keating [D-MA-9]	Armed Services; Energy & Commerce; Natural Resources; Veterans' Affairs	Introduced 03/23/2016
<a href="#"><u>H.R. 4848</u></a>	<i>Healthy Inpatient Procedures (HIP) Act of 2016</i>	Reps. Price [R-GA-6] and Scott [D-GA-13]	Energy & Commerce; Ways & Means	Introduced 03/23/2016

## JUDICIAL UPDATE

**March 23**

Supreme Court [Hears](#) Oral Arguments in *Zubik v. Burwell*, a Case Challenging the ACA's Contraceptive-Coverage Mandate.

## REGULATORY UPDATE

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**March 21**

OCR [Commences](#) Phase 2 of HIPAA Audits.

HHS [Releases](#) Final Rule to Apply Medicare Payment Methodologies to Physician/Other Health Professional Services and Non-Hospital-Based Services Purchased by an IHS or Tribal Purchased/Referred Care Program, or Urban Indian Organizations.

**March 22**

ASPE [Issues](#) a Report Examining National Health Care Spending Growth.

FDA [Announces](#) New Labeling Requirements for Immediate-Release Opioid Pain Medications.

**March 23**

CDC [Announces](#) Availability of the 2016 Guideline for Prescribing Opioids for Chronic Pain.

CMS [Releases](#) Evaluation Report Summary of the Diabetes Prevention Program and [Announces](#) Expansion of the Program.

HHS [Releases](#) White Paper *March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting*.

**March 25**

FDA [Releases](#) a Notice of Availability for the General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drugs Products.

CMS [Announces](#) a Public Comment Period on CMS's Implementation of the Medicare Prescription Drug Plan (PDP) And Medicare Advantage (MA) Plan Disenrollment Reasons Survey

## OTHER NEWS

### March 22

CBO [Issues](#) Statement for the Record Regarding CBO's Appropriation Request for Fiscal Year 2017.

### March 23

GAO Releases Report, [Healthcare.Gov: Actions Needed to Enhance Information Security and Privacy Controls](#).

### March 24

CBO [Issues](#) Updated Budget Projections for 2016 Through 2026.

CBO [Issues](#) Report on Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2016 to 2026.

## UPCOMING EVENTS

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Administrative/budget issues, current emerging infectious disease outbreak responses. [Agenda and supplementary materials](#) will be available.

- March 28 | 2 p.m. – 4 p.m.  
via teleconference

#### Meeting of the National Institute of Allergy and Infectious Diseases

*Zika Virus in the Americas: An HHS Expert Consultation to Accelerate the Development of Countermeasures*

- March 28 | 12 p.m. – 5:50 p.m.
- March 29 | 8:30 a.m. – 4:50 p.m.  
Bethesda North Marriott Hotel and Conference Center  
North Bethesda, MD  
and via webcast

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

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

- 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

#### NIH's Pathways to Prevention Workshop

Workshop on research to prevent youth suicide.

- March 29 | 8:30 a.m. – 5 p.m.
- March 30 | 8:15 a.m. – 1 p.m.  
Masur Auditorium  
Building 10  
NIH main campus  
Bethesda, Maryland

### Open Door Forum: Next Generation ACO Model

Forum to provide an application overview for the 2017 Next Generation ACO Model

- March 29 | 4 p.m. – 5:30 p.m.  
via teleconference

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

Agenda to be posted when available.

- March 30 | 10 a.m. – 5 p.m.
- March 31 | 9 a.m. – 4 p.m.  
Hubert H. Humphrey Building  
Great Hall  
200 Independence Ave., SW  
Washington, DC 20201  
and via webcast

### 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, GA 30333

### Medicare Shared Savings Program ACO: Preparing to Apply for 2017 Call

Information on how to prepare for the Medicare Shared Savings Program application process.

- April 5 | 1:30 p.m. – 3 p.m.  
National Provider Call

### Open Door Forum: Next Generation ACO Model

Forum covering financial methodology for the 2017 Next Generation Model.

- April 5 | 4 p.m. – 5:30 p.m.  
via teleconference

### 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  
Registration requested.

### Meeting of the Office of AIDS Research Advisory Council

Discussions and presentations on “Next Steps in Microbicides and PrEP Research.”

- April 7 | 8:30 a.m. – 5 p.m.  
NIH  
5601 Fishers Lane  
1st Floor, Room 1D13  
Rockville, MD 20852

### Meeting of the Council on Graduate Medical Education (COGME)

Agenda will be available 2 days prior to the meeting on HRSA’s website.

- April 7 | 8:30 a.m. – 5 p.m.
- April 8 | 8:30 a.m. – 3 p.m.  
5600 Fishers Lane  
Room 5A02  
Rockville, MD 20857  
or via webinar

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

Discussion of implementation of ACD-adopted 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, GA 30333  
Pre-register by email to attend.

Open Payments 2016: Prepare to Review Reported Data Call

Discussion on the how to access the Open Payments system to review the accuracy of the data submitted

- April 12 | 2:30 p.m. -3:30 p.m.  
National Provider Call

Open Door Forum: Next Generation ACO Model

Forum covering participation provider lists for the 2017 Next Generation ACO Model.

- April 12 | 4 p.m. -5:30 p.m.  
via teleconference

Meeting of the Clinical Laboratory Improvement Advisory Committee

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

- April 13 | 8:30 a.m. – 5 p.m.
- April 14 | 8:30 a.m. – 12 p.m.  
CDC  
1600 Clifton Road NE  
Global Communications Center  
Building 19, Auditorium B3  
Atlanta, GA 30333  
and via webcast

IMPACT Act: Data Element Library Call

Discussion on the development of the Data Element Library.

- April 14 | 2 p.m. – 3 p.m.  
National Provider Call

Meeting of the National Advisory Committee on Rural Health and Human Services

Committee will examine issues of opioid abuse disorder in rural areas and alternatives for emergency care, conduct site visits, and summarize key findings.

- April 18 | 8:30 a.m. – 5 p.m.
- April 19 | 8:30 a.m. – 5:15 p.m.
- April 20 | 8:30 a.m. – 11 a.m.  
Keyserling Cancer Center  
1680b Ribaut Road  
Port Royal, SC 29935

Meeting of the Advisory Committee on Research on Women's Health

- April 19 | 9 a.m. – 4 p.m.  
National Institutes of Health  
31 Center Drive  
Building 31, Room 6C,  
Bethesda, MD 20892

Medicare Shared Savings Program ACO Application Process Call

Discussion on helpful tips to complete an application for the Medicare Shared Savings Program.

- April 19 | 1:30 p.m. – 3 p.m.  
National Provider Call

Open Door Forum: Next Generation ACO Model

Forum covering benefit enhancements for the 2017 Next Generation ACO Model.

- April 19 | 4 p.m. – 5:30 p.m.  
via teleconference

Meeting of the Advisory Committee to the Director

Updates from Subcommittees, Workgroups, and the CDC Director.

- April 21 | 8:30 a.m. – 3 p.m.  
CDC  
Global Communications Center  
Building 19, Auditorium B3  
1600 Clifton Road NE  
Atlanta, GA 30329  
or via webcast



### Meeting of the Advisory Council for the Elimination of Tuberculosis

Discussion on the recommendations of the USPSTF and on the draft of TB treatment guidelines, among other things.

- April 26 | 10 a.m. – 3:30 p.m.  
Via web conference

### Meeting of the Muscular Dystrophy Coordinating Committee

Update on process relevant to the Action Plan for the Muscular Dystrophies, coordinate activities, and discuss gaps and opportunities to better understand muscular dystrophies.

- 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. and 2 - 3 p.m.  
National Library of Medicine  
Building 38, 2nd Floor  
The Lindberg Room  
8600 Rockville Pike  
Bethesda, MD 20892

### Meeting of the National Institute of Aging Board of Scientific Counselors

- May 24 | 8:15 a.m. – 12:15 p.m.
- May 24 | 1:15 p.m. – 3:30 p.m.
- May 24 | 4:30 p.m. – 7 p.m.
- May 25 | 8:15 a.m. – 12:25 p.m.
- May 25 | 1:25 p.m. – 3 p.m.  
National Institute on Aging  
Biomedical Research Center  
3rd Floor Conference Room  
251 Bayview Boulevard  
Baltimore, MD 21224

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

Agenda: Report by Director, NINDS; Report by the Associate Director for Extramural Research; Administrative and Program Developments; and an Overview of NINDS Intramural Program.

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

### Healthcare Common Procedure Coding System Public Meeting

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  
The Lindberg Room  
Building 38, 2nd Floor  
8600 Rockville Pike  
Bethesda, MD 20892

Meeting of the President's Cancer Panel

Examination of the cancer drug cost and  
access landscape.

- June 10 | 9 a.m. - 4 p.m.  
New York Hilton Midtown  
1335 Avenue of the Americas  
New York, NY 10019