

LEGISLATIVE AND REGULATORY UPDATE

March 8, 2016

Week in Brief

House [Passes](#) Bipartisan Legislation, [H.R. 3716](#), Which Strengthens Medicaid by Reducing Fraud and Increasing Access to Care.

WHITE HOUSE UPDATE

March 1

The Administration [Expresses](#) Concerns with [S. 524](#), *Comprehensive Addiction and Recovery Act of 2016*.

The Administration [Announces](#) Support of [H.R. 3716](#), *Ensuring Access to Quality Medicaid Providers Act*.

March 3

President Obama [Proclaims](#) March 2016 as National Colorectal Cancer Awareness Month.

Administration Officials [Announce](#) Early Attainment of Medicare Payment Goal.

LEGISLATIVE UPDATE

March 1

Senate Republicans [Send](#) Letter to CMS Seeking Answers Regarding the Administration of the Federally Facilitated Marketplace's Special Enrollment Periods.

House Members [Urge](#) House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agency to Provide at Least \$1.2 Billion for Telehealth Services for Veterans.

March 2

Senate HELP Ranking Member Patty Murray [Issues](#) Statement Following Oral Arguments in Supreme Court Case, *Whole Woman's Health v. Hellerstedt*.

March 3

House Energy & Commerce Chairman Upton [Speaks](#) at Milken Institute Panel Discussion on Public Health.

March 3

Senate HELP Democrats [Introduce](#) the *National Biomedical Research Act* Regarding Biomedical Research Funding.

Senate [Votes](#) on Series of Amendments to Opioid Legislation, S. 524, *Comprehensive Addiction and Recovery Act of 2016*.

March 4

House Ways & Means Committee Leaders [Express](#) Concerns About the Proposed 2017 Medicare Advantage Payment Policies.

March 7

Senate HELP Committee [Releases](#) Draft Mental Health Bill.

LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
S. 524	<i>Comprehensive Addiction and Recovery Act of 2016</i>	Sens. Whitehouse [D-RI], and 42 cosponsors	Judiciary	Senate Floor Consideration on 3/2/2016 & 3/3/2016; Amendments offered
S. 2614	Reauthorizes Missing Alzheimer's Disease Patient Alert Program and promotes initiatives that will reduce the risk of injury and death relating to wandering characteristics of some children with autism.	Sens. Schumer [D-NY], Grassley [R-IA], and Tillis [R-NC]	Judiciary	Introduced 3/1/2016
S. 2615	<i>A bill to increase competition in the pharmaceutical industry</i>	Sens. Collins [R-ME] and McCaskill [D-MO]	HELP	Introduced 3/1/2016
S. 2605	<i>Medicaid Coverage for Addiction Recovery Expansion Act</i>	Sens. Durbin [D-IL] and King [I-ME]	Finance	Introduced on 2/29/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>S. 2562</u>	<i>Heroin and Prescription Drug Abuse Prevention and Reduction Act</i>	Sens. Brown [D-OH] and Baldwin [D-WI]	HELP	Introduced on 2/22/2016
<u>H.R. 4669</u>	<i>Advancing Standards in Regenerative Medicine Act</i>	Rep. Foster [D-IL-11]	Energy & Commerce	Introduced on 3/2/2016
<u>H.R. 3716</u>	<i>Ensuring Access to Quality Medicaid Providers Act</i>	Reps. Buchson [R-IN-8]; Welch [D-VT]; and Butterfield [D-NC-1]	House Energy & Commerce; Senate Finance	Passed by House on 3/2/2016
<u>H.R. 4650</u>	<i>Preserving Patient Access to Post-Acute Hospital Care Act of 2016</i>	Reps. Buchanan [R-FL-16] and Pascrell [D-NJ-9]	Ways & Means	Introduced on 2/29/2016
<u>H.R. 4640</u>	<i>Veteran Suicide Prevention Act</i>	Reps. Jolly [R-FL-13]; Titus [D-NV-1]; Abraham [R-LA-5]; and Gabbard [D-HI-2]	Veterans' Affairs	Introduced 2/26/2016
<u>H.R. 4642</u>	<i>Diabetic Eye Disease Prevention Act of 2016</i>	Reps. Collins [R-NY-27] and McNerney [D-CA-9]	Energy & Commerce; Ways & Means	Introduced 2/26/2016
<u>H.R. 4641</u>	<i>To provide for the establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication, and for other purposes.</i>	Reps. Brooks [R-IN-5] and Kennedy [D-MA-4]	Energy & Commerce	Introduced 2/26/2016
<u>H.R. 4627</u>	<i>Medicaid Expansion Parity Act of 2016</i>	Rep. Lewis [D-GA-5]	Energy & Commerce	Introduced 2/25/2016

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

February 26

CMS [Issues](#) Update in Payment Policy Affecting Federal Funding for Services Received Through an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives.

February 29

CMS [Releases](#) Notice of Benefit and Payment Parameters for 2017 and Accompanying [Fact Sheet](#).

CMS [Publishes](#) 2017 Letter to Issuers in the Federally-Facilitated Marketplaces.

CMS [Provides](#) a Frequently Asked Questions Document on the 2017 Moratorium on the Health Insurance Provider Fee.

CMS [Issues](#) Final Federal Funding Methodology for Program Years 2017 and 2018 to States that Elect to Establish a Basic Health Program.

March 1

HHS [Announces](#) Formation of the Congressionally Mandated Health Care Industry Cybersecurity Task Force; Requests Nominations by March 9.

CMS [Delays](#) Enforcement of the Part D Prescriber Enrollment Requirements Until Feb. 1, 2017.

March 2

ONC [Issues](#) Notice of Proposed Rulemaking Announcing Modifications and New Requirements under the ONC Health IT Certification Program.

FDA [Releases](#) Donor Screening Recommendations to Reduce Zika Virus Transmission by Human Tissues, Cells, and Tissue and Cellular/Tissue-Based Products.

The Secretary of HHS [Issues](#) Notice on Determination that Concerning Emergency Use of *In Vitro* Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection.

March 3

ONC [Announces](#) Requirements and Registration for “Consumer Health Data Aggregator Challenge.”

ONC [Announces](#) Requirements and Registration for “Provider User-Experience Challenge.”

March 4

SAMHSA [Announces](#) Requirements and Registration for the “Opioid Overdose Prevention Challenge.”

March 5

CMS [Announces](#) Next Generation ACO Model Second Application Cycle

DEPARTMENT OF VETERANS AFFAIRS

February 29

VA OIG [Begins](#) Roll-Out of Administrative Summaries of Wait Time Investigations Concerning VA Medical Facilities.

JUDICIAL UPDATE

March 2

Supreme Court [Hears](#) Oral Arguments in *Whole Woman’s Health v. Hellerstedt* on Texas Abortion Measure.

March 4

Supreme Court Temporarily [Blocks](#) Enforcement of Louisiana Abortion Law in *June Medical Services, LLC v. Gee*.

OTHER NEWS

GAO Releases Several Reports

- [*Federal Health Care Center: VA and DOD Need to Address Ongoing Difficulties and Better Prepare for Future Integrations.*](#) (Feb. 29)
- [*Emerging Infectious Diseases: Preliminary Observations on the Zika Virus Outbreak.*](#) (Mar. 2)
- [*Rare Diseases: Too Early to Gauge Effectiveness of FDA’s Pediatric Voucher Program.*](#) (Mar. 2)

CRS Publishes Reports

- [*Health Care for Veterans: Suicide Prevention.*](#) (Feb. 23)
- [*Prescription Drug Abuse.*](#) (Feb. 23)
- [*Prescription Drug Monitoring Programs.*](#) (Feb. 23)
- [*Medicaid Financial Eligibility for Long-Term Services and Supports.*](#) (Feb. 24)
- [*The Use of Modified Adjusted Gross Income \(MAGI\) in Federal Health Programs.*](#) (Feb. 25)
- [*Implementation of the FDA Food Safety Modernization Act \(FSMA, P.L. 111-353\).*](#) (Feb. 25)
- [*Synthetic Drugs: Overview and Issues for Congress.*](#) (Feb. 26)

March 3-4

MedPAC [Meets](#) to Discuss Part B Drug Payment Policy Issues, Medicare Part D, Oncology Care in Fee-for-Service Medicare, Telehealth Services, a Unified Payment System for Post-Acute Care, and Competitive Pricing to Set Beneficiary Premiums in the Fee-for-Service and Medicare Advantage Programs.

MedPAC [Contemplates](#) Eliminating Two Medicare Part D Protected Drug Classes.

UPCOMING EVENTS

CONGRESSIONAL HEARINGS/MARKUPS

SENATE

HELP

[Executive Session: Biomedical Innovation Bills](#)

[S. 1878](#), The Advancing Hope Act of 2015
[S. 1077](#), The Advancing Breakthrough Devices for Patients Act of 2015;
[S. 1101](#), MEDTECH Act; [S. 2055](#), The Medical Countermeasures Innovation Act of 2015;
[S. 1767](#), The Combination Products Innovation Act of 2015; [S. 1597](#), Patient-Focused Impact Assessment Act of 2015; and
[S. 2512](#), Adding Zika Virus to the FDA Priority Review Voucher Program Act.

- March 9 | 10 a.m.
106 Dirksen Senate Office Building

[Third Executive Session Considering Biomedical Innovation Bills](#)

- April 6 | Time/Location TBA

Finance

[HealthCare.gov: A Review of Operations and Enrollment](#)

- March 10 | 10 a.m.
215 Dirksen Senate Office Building

Homeland Security & Governmental Affairs

[Review of the Affordable Care Act Health Insurance CO-OP Program](#)

- March 10 | 9:30 a.m.
342 Dirksen Senate Office Building

SENATE (Continued):

Appropriations

[Review FY 2017 Budget Request and Funding Justification for the Indian Health Service.](#)

- March 9 | 10 a.m.
124 Dirksen Senate Office Building

[Review FY 2017 Budget Request and Funding Justification for the Defense Health Program](#)

- March 9 | 10:30 a.m.
192 Dirksen Senate Office Building

HOUSE

Energy & Commerce

[Broad Review of Concussions: Initial Roundtable](#)

- March 14 | 2 p.m.
2123 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

[Choice Consolidation: Leveraging Provider Networks to Increase Veteran Access](#)

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CMS Hospital & Hospital Quality Initiative Open Door Forum

Updates and announcements on the FY 2017 IPPS wage index timeline, upcoming stakeholder engagement opportunities, IRF and LTCH dry run readmissions reports, and public reporting of hospital overall quality star rating.

- March 8 | 2 p.m. – 3 p.m.
via Conference Call

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 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.
Conference call

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

Examine 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
Shady Grove
9609 Medical Center Drive
Rockville, MD 20850
Or Conference Call

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.
- March 30 | 8:30 a.m. – 12 p.m.
NIH
31 Center Drive
Building 31, C-Wing, 6th Floor
Room 10
Bethesda, MD 20892
Or Webcast

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.
U.S. Department of Health & Human
Services
Hubert H. Humphrey Building
Great Hall
200 Independence Ave., SW
Washington, DC 20201
Or webcast
Pre-register 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.

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 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
Or webcast

Meeting of the Medicare Evidence Development & Coverage Advisory Committee

Meeting to obtain the MEDCAC's 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

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

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

DEPARTMENT OF VETERANS AFFAIRS

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, among other things.

- April 19 | 8:30 a.m. – 5 p.m.
- April 20 | 8 a.m. – 12 p.m.
VA
810 Vermont Ave., NW
Room 730
Washington, DC 20420

OTHER EVENTS

Health Affairs Discussion: "The Evolving Landscape of Physician Practice"

- March 8 | 9 a.m. – 10:30 a.m.
National Press Club
529 14th Street, NW
13th Floor, Metro Center
Washington, DC 20045

AHIP 2016 National Health Policy Conference

- March 9 | 9 a.m. – 6:15 p.m.
- March 10 | 9 a.m. – 12:30 p.m.
The Ritz-Carlton Washington
1150 22nd Street, NW
Washington, DC 20037

Healthcare Leadership Council Briefing: "Breaking the Boundaries of Health: Enhancing Patient Well-Being Through Coordinated Care"

- March 9 | 12 p.m.
B-318 Rayburn House Office Building
RSVP required.

Annual Meeting: Pharmaceutical Research
and Manufacturers of America

- March 9 – 10
Washington Marriott,
Wardman Park
2660 Woodley Road, NW
Washington, DC 20008
 - Invite-only for onsite
attendance;
 - Events of the day will be live-
streamed at the link above.

Panel Discussion: "U.S. Response to Zika:
Engagement with International Partners."

Held by The Bipartisan Policy Center.

- March 11 | 11 a.m.
U.S. Capitol Visitor Center
Room 216 HVC
First St NE
Washington, DC 20001