

LEGISLATIVE AND REGULATORY UPDATE

April 18, 2016

Week in Brief

CMS [Announces](#) the Comprehensive Primary Care Plus (CPC+), a Five-Year Advanced Primary Care Medical Home Model.

Senate Appropriations Committee [Discloses](#) 302(b) Spending Allocations Allowing 12 Subcommittees to Begin Drafting Individual Spending Bills; Labor-HHS-Education Allocation Is \$161.9 Billion.

LEGISLATIVE UPDATE

April 11

60 Senators [Sent](#) Bipartisan Letter to CMS Requesting a Delay in the Release of the Hospital Compare Star Ratings.

April 12

Senate HELP Ranking Member Patty Murray (D-WA) and Senators Al Franken (D-MN) and Michael Bennet (D-CO) [Sent](#) a Letter to HHS and DOJ Demanding Higher Quality Health Care and Better Access to Supportive Services for Survivors of Sexual Assault.

Senate HELP Chairman Lamar Alexander (R-TN) [Releases](#) Statement in Praise of Congressional Passage of S. 2512, the *Adding Zika Virus to the FDA Priority Review Voucher Program Act*; Bill Headed to President's Desk for Signature into Law.

House Energy & Commerce Committee [Lauds](#) Passage of S. 2512, the *Adding Zika Virus to the FDA Priority Review Voucher Program Act*.

April 13

Senate Special Committee on Aging [Schedules](#) April 18 Deposition for Valeant CEO, Michael Pearson, to Testify on Price Spikes of Decades Old Prescription Drugs; Pearson Under Subpoena to Appear Before Committee.

April 14

Senate Appropriations Committee [Approves](#) FY2017 Appropriations Measure to Fund Military Personnel, Infrastructure, and Veterans Affairs Including Providing a Record-Level of Funding for Veterans' Health Care and Benefits.

April 14

House Ways & Means Chairman Kevin Brady (R-TX) [Comments](#) on Committee Efforts to Modernize Tax Code and Advance 21st Century Health Care Options.

April 15

Senate Judiciary Chairman Charles Grassley (R-IA) and Senator Dianne Feinstein (D-CA) [Sent](#) a Letter to CMS Requesting Administrative Action to Reduce the Misuse and Abuse of Prescription Opioids.

House Energy & Commerce Subcommittee on Health [Plans](#) to Markup Opioid Bills Next Week.

LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
S. 2758 / H.R. 4499	<i>Promoting Responsible Opioid Prescribing (PROP) Act of 2016</i>	Sens. Johnson [R-WI]; Manchin [D-WV]; Barrasso [R-WY]; and Blumenthal [D-CT]	Finance	Introduced 4/7/2016
S. 2765 / H.R. 1706	<i>Real Education for Healthy Youth Act of 2016</i>	Sen. Booker [D-NJ] and 11 co-sponsors	HELP	Introduced 4/7/2016
S. 2771	To expand the qualifications for licensed mental health counselors of the Department of Veterans Affairs.	Sen. Inhofe [R-OK]	Veterans' Affairs	Introduced 4/11/2016
S. 2772	To eliminate the requirement that veterans pay a copayment to the Department of Veterans Affairs to receive opioid antagonists or education on the use of opioid antagonists.	Sens. Baldwin [D-WI] and Moran [R-KS]	Veterans' Affairs	Introduced 4/11/2016
S. 2782 / H.R. 1859	<i>Ensuring Children's Access to Specialty Care Act of 2016</i>	Sens. Blunt [R-MO] and Reed [D-RI]	HELP	Introduced 4/12/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>S. 2784</u>	To ensure that Federal science agencies and institutions of higher education receiving Federal research and development funding are fully engaging the entire national talent pool, and for other purposes.	Sen. Hirono [D-HI] and 10 co-sponsors	HELP	Introduced 4/12/2016
<u>S. 2786</u>	To provide for payments for certain rural health clinic and Federally qualified health center services furnished to hospice patients under the Medicare program.	Sens. Capito [R-WV] and Shaheen [D-NH]	Finance	Introduced 4/13/2016
<u>S. 192</u>	<i>Older Americans Act Reauthorization Act of 2016</i>	Sens. Alexander [R-TN]; Murray [D-WA]; Burr [R-NC]; and Sanders [I-VT]	HELP / Education & the Workforce	Measure presented to the President 4/13/2016
<u>S. 2512 / H.R. 4400</u>	<i>Adding Zika Virus to the FDA Priority Review Voucher Program Act</i>	Sens. Franken [D-MN]; Nelson [D-FL]; Isakson [R-GA]; Brown and [D-OH]	HELP / Energy & Commerce	Measure presented to the President 4/14/2016
<u>S. 483/ H.R. 471</u>	<i>Ensuring Patient Access and Effective Drug Enforcement Act of 2016</i>	Sens. Hatch [R-UT] and Whitehouse [D-RI]	Judiciary / Energy & Commerce; Judiciary	Measure presented to the President 4/14/2016
<u>S. 2799</u>	To require the Secretary of Health and Human Services to develop a voluntary patient registry to collect data on cancer incidence among firefighters.	Sen. Menendez [D-NJ] and 13 co-sponsors	HELP	Introduced 4/14/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>S. 2803</u>	To require the Secretary of Health and Human Services to deposit certain funds into the general fund of the Treasury in accordance with provisions of Federal law with regard to the Patient Protection and Affordable Care Act's Transitional Reinsurance Program.	Sen. Sasse [R-NE]	HELP	Introduced 4/14/2016
<u>H.R. 4892</u>	To pay special compensation to certain veterans with the loss or loss of use of creative organs.	Rep. Miller [R-FL-1]	Veterans' Affairs	Introduced 4/11/2016
<u>H.R. 4916</u>	To reauthorize the program of the Department of Veterans Affairs under which the Secretary of Veterans Affairs provides health services to veterans through qualifying non-Department health care providers.	Reps. Poliquin [R-ME-2] and Pingree [D-ME-1]	Veterans' Affairs	Introduced 4/12/2016
<u>H.R. 4918</u>	To direct the Secretary of Health and Human Services to issue guidance for the safe prescribing of opioids for the treatment of acute pain.	Reps. Slaughter [D-NY-25] and Katko [R-NY-24]	Energy & Commerce	Introduced 4/12/2016

BILL NUMBER/ RELATED BILLS	<i>TITLE or SHORT SUMMARY</i>	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>H.R. 4931</u>	To direct the Attorney General to establish a national pharmaceutical stewardship program to facilitate the collection and disposal of prescription medications.	Rep. Slaughter [D-NY-25]	Energy & Commerce	Introduced 4/13/2016
<u>H.R. 4959</u>	To direct the Secretary of Health and Human Services to conduct a study on the designation of surgical health professional shortage areas.	Reps. Bucshon [R-IN-8] and Bera [D-CA-7]	Energy & Commerce	Introduced 4/15/2016
<u>H.R. 4965</u>	To enhance medical device communications and ensure device cleanliness.	Rep. Lieu [D-CA-33]	Energy & Commerce	Introduced 4/15/2016
<u>H.R. 4966</u>	To establish requirements for reusable medical devices relating to cleaning instructions and validation data, and for other purposes.	Reps. Lieu [D-CA-33] and Roskam [R-IL-6]	Energy & Commerce	Introduced 4/15/2016
<u>H.R. 4969</u>	To direct the CDC to provide for informational materials to educate and prevent addiction in teenagers and adolescents who are injured playing youth sports and subsequently prescribed an opioid.	Reps. Meehan [R-PA-7]; Kind [D-WI-3]; Rooney [R-FL-17]; and Veasey [D-TX-33]	Energy & Commerce	Introduced 4/15/2016

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

April 12

OIG [Issues](#) the April 2016 Edition of the *Compendium of Unimplemented Recommendations*.

April 13

CMS [Posts](#) the Second Year Evaluation Report of the Comprehensive Primary Care Initiative.

AHRQ [Opens](#) Public Comment Period for Proposed Information Collection Project: *AHRQ ACTION III—Measurement for Performance Improvement in Physician Practices*; Comment Deadline June 13, 2016.

NEJM [Publishes](#) CDC Study Finding Causal Relationship Between the Zika Virus and Microcephaly and Other Serious Brain Defects in Infants.

April 15

HRSA [Seeks](#) Nomination for Membership on the Advisory Committee on Heritable Disorders in Newborns and Children.

April 18

Dr. Patrick Conway, Acting Principal Deputy Administrator and Chief Medical Officer, [Blogs](#) on Extending Bundled Payments for Care Improvement (BPCI) Initiative Participation.

FDA [Issues](#) Final Order Reclassifying External Pacemaker Pulse Generator Devices.

OIG [Releases](#) Report: *Inconsistencies in State Implementation of Correct Coding Edits May Allow Improper Medicaid Payments*.

OIG [Issues](#) Revised Policy Statement on Exclusion Authority.

NIH [Begins](#) Research Initiative to Reduce Health Disparities in Surgical Outcomes.

OTHER NEWS

GAO Releases Reports

- [Opportunities Exist to Recover Potential Overpayments to Providers with Criminal Backgrounds](#). (Apr. 13)

- Government Efficiency and Effectiveness: Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits. (Apr. 13).
- NIH Chimpanzee Management Program: Consolidation Should Achieve Cost Savings, but a Clear Implementation Plan is Needed. (Apr. 14).
- Workplace Safety and Health: Additional Efforts Needed to Help Protect Health Care Workers from Workplace Violence. (Apr. 14).

April 13

NEJM [Publishes](#) Article on the Early Performance of ACOs in Medicare.

UPCOMING EVENTS

CONGRESSIONAL HEARINGS/MARKUPS

SENATE

Special Committee on Aging Prescription Drug Price Spikes

- April 27 | Time TBD
Location TBD

HOUSE

Energy & Commerce

Medicare Access and CHIP Reauthorization Act of 2015: Examining Physician Efforts to Prepare for Medicare Payment Reforms

- April 19 | 10:15 a.m.
2322 Rayburn House Office Building

Veterans' Affairs

A Continued Assessment of Delays in Veterans' Access to Health Care

- April 19 | 10:30 a.m.
334 Cannon House Office Building

Hearing on H.R. 2460; H.R. 3956; H.R. 3974; H.R. 3989; Draft Legislation to Ensure that Each VA Medical Facility Complies with Requirements Relating to Scheduling Veterans for Health Care Appointments and to Improve the Uniform Application of Directives; and, Draft Legislation to Direct VA to Establish a List of Drugs that Require an Increased Level of Informed Consent

- April 20 | 10 a.m.
334 Cannon House Office Building

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

National Institute of Mental Health's Interagency Autism Coordinating Committee

Discussion on updates and issues related to autism spectrum disorder research and services, and the IACC Strategic Plan.

- April 19 | 9 a.m. – 5 p.m.
NIH
Conference Room 10
Building 31, C Wing, 6th Floor
31 Center Drive
Bethesda, MD 20892

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

Agenda will be posted.

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

Medicare Shared Savings Program ACO Application Process Call

Discussion on how to complete the Medicare Shared Savings Program applications.

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

CMS Hospital/Quality Initiative Open Door Forum

Discussion on the Self-Identified Overpayment Final Rule and upcoming IMPACT Act stakeholder engagement.

- April 19 | 2 p.m. – 3 p.m.
via teleconference

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 AHRQ

Update on AHRQ's current research, programs, and initiatives; presentation on AHRQ's work in Primary Care; and discussion on possible new research ideas.

- April 20 | 8:30 a.m. – 2:45 p.m.
AHRQ
5600 Fishers Lane
Rockville, Maryland 20857

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

2016 PQRS Reporting: Avoiding 2018 Negative Payment Adjustments Call

Overview of the 2016 PQRS; presentation on how eligible professionals and PQRS group practices can commence, report/participate, and avoid the 2018 PQRS negative payment adjustment.

- April 21 | 3 p.m. – 4:30 p.m.
National Provider Call

Meeting of the Big Data to Knowledge
Multi-Council Working Group

Discussion on Big Data to Knowledge activities and newly proposed initiatives.

- April 25 | 11 a.m. – 12:30 p.m.
Teleconference

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 webcast

Meeting of the Muscular Dystrophy
Coordinating Committee

Update on process relevant to the Action Plan for the Muscular Dystrophies, coordinate activities, and discuss gaps.

- 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 Advisory Council on
Alzheimer's Research, Care, and Services

Consideration of recommendations of subcommittees for updates to the 2016 National Plan and presentations on the Dementia Friendly America campaign, among other things.

- April 29 | 9 a.m. – 5 p.m.
Hubert H. Humphrey Building
Room 800
200 Independence Ave. SW
Washington, DC 20201

Meeting of the National Advisory Board on
Medical Rehabilitation Research

Discussion on the NICHD and NCMRR Director's reports, NICHD training activities, review of Cerebral Palsy workshop, operationalizing NIH rehabilitation research plan, common data elements in rehabilitation research, and promoting rehabilitation research grant applications.

- May 2 | 9 a.m. – 5 p.m.
- May 3 | 8:30 a.m. – 12 p.m.
Bethesda Marriott Suites
6711 Democracy Boulevard
Bethesda, MD 20817

National Advisory Council on Drug Abuse

Discussion on announcements and reports of administrative, legislative, and program developments in the drug abuse field

- May 4 | 8:30 a.m. – 4 p.m.
NIH
Neuroscience Center
6001 Executive Boulevard
Rockville, MD 20852

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

Discussion on the evolving role of national bioethics advisory bodies and their contributions to health policy as well as perspectives about similar bodies and the future of the Commission.

- May 3 | 9 a.m. – 5 p.m.
Grand Hyatt Washington Hotel
1000 H Street NW
Washington, DC 20001

Office of Global Affairs: Stakeholder Listening Session in Preparation for the 69th World Health Assembly

An informal Stakeholder Listening Session to assist the HHS Office of Global Affairs prepare the U.S. delegation for the World Health Assembly.

- May 6 | 10:30 a.m. – 12 p.m.
Hubert H. Humphrey Building
Room 505A
200 Independence Ave. SW
Washington, DC 20201
RSVP required

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

Presentations and discussions on newborn screening, long-term follow-up, the Newborn Sequencing in Genomic Medicine and Public Health projects, screening for lysosomal storage disorders, and prenatal education regarding newborn screening bloodspots, among others.

- May 9 | 9 a.m. – 5 p.m.
- May 10 | 9 a.m. – 3 p.m.
Fishers Lane Conference Center
Terrace Level
5635 Fishers Lane
Rockville, MD 20852
and via webcast

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 Frederick National Laboratory Advisory Committee to the National Cancer Institute

Discussion on ongoing and new activities.

- May 11 | 8 a.m. – 5 p.m.
National Cancer Institute
Shady Grove
Conference Room TE406
9609 Medical Center Drive
Rockville, MD 20850
and via videocast

Understanding the IMPACT Act-Patient and Family Focused for Informed Decision Making

Discussion on the IMPACT act

- May 12 | 2 p.m. – 3 p.m.
Teleconference

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

National Diabetes and Digestive and Kidney Diseases Advisory Council Meeting

Presentation on the Director's Report and other scientific presentations.

- May 18 | 8:30 a.m. – 12 p.m.
NIH
Room 10, Conference Center
6th Floor, Building 31, C Wing
31 Center Drive
Bethesda, MD 20892

National Advisory Council on Migrant Health

Discussion on the services and issues related to the health of migratory and seasonal agricultural workers and their families and formulation of recommendations.

- May 17 | 8:30 a.m. – 5 p.m.
- May 18 | 8:30 a.m. – 5 p.m.
Hyatt Regency Bethesda
7400 Wisconsin Avenue
Bethesda, MD 20814

2015 Mid-Year QRURs Webcast

Overview of the 2015 MYQRURs and explanation of how to interpret and use the information.

- May 19 | 1:30 p.m. – 3 p.m.
via webcast

Meeting of the National Advisory Council for Biomedical Imaging and Bioengineering

Discussion on the report from the Institute Director, presentation of task force reports, and scientific presentation.

- May 19 | 9 a.m. – 12:30 p.m.
The William F. Bolger Center
Franklin Building
Classroom 15/16
9600 Newbridge Drive
Potomac, MD 20854

Council of Councils Meeting

Agenda includes NIH updates, Undiagnosed Disease Network, Zika virus, updates from NHGRI, NIH Precision Medicine Initiative Cohort Program; input on the Office of Behavioral and Social Sciences Research Strategic Plan; update on Common Fund Program.

- May 20 | 8:15 a.m. – 11:15 a.m.
- May 20 | 2 p.m. – 4:10 p.m.
NIH
Conference Room 19
6th Floor
Building 31, C Wing
45 Center Drive
Bethesda, MD 20892

Meeting of the National Advisory General Medical Sciences Council

Discussion of program policies and issues and the report of the Director, NIGMS.

- May 20 | 8:30 a.m. – 12 p.m.
NIH
Conference Rooms E1 & E2
Natcher Building
45 Center Drive
Bethesda, MD 20892
and via videocast

Meeting of the National Institute of Aging Board of Scientific Counselors

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

Meeting of the Presidential Advisory Council on HIV/AIDS

Discussions of Health System Transformations, the Updated National HIV/AIDS Strategy, and food as medicine.

- May 24 | 9 a.m. – 5 p.m.
- May 25 | 9 a.m. – 12 p.m.
Hubert H. Humphrey Building
Room 800
200 Independence Ave. SW
Washington, DC 20201

Meeting of the National Institute of Neurological Disorders and Stroke

Report by NINDS Director, report by the Associate Director for Extramural Research, administrative and program developments, and overview of NINDS Intramural Program.

- May 26 | 8 a.m. – 2:30 p.m.
NIH
Room 10
Building 31, C-Wing, 6th Floor
31 Center Drive
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
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

DEPARTMENT OF VETERANS AFFAIRS

Commission on Care Meeting Notice

- April 18 | 8:30 a.m. – 6 p.m.
- April 19 | 8:30 a.m. – 4 p.m.
J.W. Marriott Jr.
ASAE Conference Center
1575 I St. NW
Washington, DC 20005
and via teleconference

Veterans Rural Health Advisory Committee Meeting

Updates from the Chairman and Director of the Veterans Health Administration Office of Rural Health, among other things.

- May 3-4 | 8:30 a.m. – 5 p.m.
Building 40, Room 225
2815 N. Assembly Street
Spokane, Washington

Special Medical Advisory Group Meeting

Review the potential policy requiring physicians provide a 90 day notification when they leave the VA, *Pay for Performance*, and *best practice dissemination project*.

- May 25 | 8 a.m. – 3:30 p.m.
Department of Veterans Affairs
Central Office
Room 230
810 Vermont Ave. NW.
Washington, DC 20420

OTHER

Precision Medicine: The Promise, the Journey, the Future

- April 18 | 12 p.m. - 1:30 p.m.
The Aspen Institute
Suite 700
One Dupont Circle, NW
Washington, DC 20036

30+ Years of Person-Centric Care: Innovations in Hospice and the Future of End-of-Life Care

- April 19 | 2:30 p.m. - 4 p.m.
G-11 Dirksen Senate Office Building

The National Hospice and Palliative Care Organization: 31st Management and Leadership Conference

- April 21- 23 | 9 a.m. - 5 p.m.
Gaylord National Resort and Convention Center
201 Water Street
National Harbor, MD 20745

Trust but Verify: The Crisis in Biomedicine

- April 21 | 11 a.m. - 12:30 p.m.
New America
740 15th Street NW
Suite 900
Washington, DC 20005