



LEGISLATIVE AND REGULATORY UPDATE May 9, 2016

Week in Brief

Congressional Recess during the Week of May 2; Senate Returns to Washington on May 9 and House Returns on May 10.

CMS <u>Issues</u> Final Rule to Update Certain Health Care Facilities' Fire Safety Standards.

WHITE HOUSE UPDATE

April 28

President Obama <u>Declares</u> May 2016 as National Mental Health Awareness Month.

May 3

White House <u>Releases</u> Fact Sheet, *Federal Support for the Flint Water Crisis Response and Recovery.*

LEGISLATIVE UPDATE

May 2

House Budget Chairman Tom Price (R-GA) and 241 Additional House Members <u>Sent</u> a Bipartisan Letter to CMS Requesting Withdrawal of the Proposed Part B Drug Payment Model.

May 3

House Ways and Means Social Security Subcommittee Chairman Sam Johnson (R-TX) and Health Subcommittee Chairman Pat Tiberi (R-OH) <u>Sent</u> a Letter to Treasury Secretary Jacob Lew Requesting Overdue Social Security and Medicare Trustee Reports.

May 4

Senate HELP Chairman Lamar Alexander (R-TN) <u>Calls</u> Biomedical Innovations Package "Most Important Legislation This Year."

House Energy & Commerce Chairman Fred Upton (R-MI) and House Ways & Means Chairman Kevin Brady (R-TX) <u>Issue</u> Subpoenas to HHS and OMB for ACA's Cost-Sharing Reduction Program Documents.

May 4

House Energy & Commerce Subcommittee on Oversight and Investigations <u>Announces</u> Continuation of Broad Review of Concussions at May 13 Hearing Examining Youth Sports.

May 6

Senator Marco Rubio (R-FL) <u>Calls</u> for Congress to Take Action against Zika Virus Before it becomes a Crisis in the U.S.

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES May 2

CMS Posts Final Quality Measure Development Plan.

Francis Collins, Director of NIH, <u>Discusses</u> the NIH PMI Cohort Program and the Cancer Moonshot Initiative at the Bloomberg Government Data Analytics Event.

OIG Releases April 2016 Monthly Update Podcast.

May 3

CDC <u>Releases</u> Report, Vital Signs: National and State-Specific Patterns of Attention Deficit/Hyperactivity Disorder Treatment among Insured Children Aged 2–5 Years — United States, 2008–2014.

CDC <u>Publishes</u> Study in *JAMA* Finding at Least 30 Percent of Prescribed Antibiotics are Unnecessary.

CMS Announces Requirements and Registration for the MIPS Mobile Challenge.

Andy Slavitt, Acting Administer of CMS, <u>Delivers</u> Speech at the American Hospital Association's Annual Membership Meeting.

National Institute of Nursing Research <u>Releases</u> New Resources for Families with Seriously Ill Children as Part of its Palliative Care: Conversations Matter Campaign.

SAMSHA <u>Declares</u> May 15-21 as National Prevention Week.

May 4

HHS <u>Awards</u> Over \$260 Million to 290 Health Centers Across the Country for Facility Renovation, Expansion, or Construction.

May 4

CDC <u>Releases</u> Report, Access to Care Among Adults Aged 18-64 With Serious Psychological Distress: Early Release of Estimates from the National Health Interview Survey, 2012- September 2015.

CDC Seeks Nominations for Candidates to Serve on the <u>Breast and Cervical Cancer Early</u> <u>Detection and Control Advisory Committee (BCCEDCAC)</u> and the <u>Healthcare Infection Control Practices Advisory Committee (HICPAC)</u>.

FDA Advisers Recommend Mandatory Training for Physicians Who Prescribe Opioid Painkillers.

Vivek Murthy, U.S. Surgeon General, <u>Calls</u> for More Comprehensive Training for Physicians Prescribing Opioids.

May 5

CMS Announces Flexibility to Revising Proposed Medicare Part B Drug Payment Changes.

CMS <u>Announces</u> Data Initiatives Updates Increased Medicare Program Transparency.

CMS <u>Issues</u> Report, Medicaid Managed Care Enrollment and Program Characteristics, 2014.

CMS <u>Releases</u> Physician and Other Supplier Utilization and Payment Public Use Data on Medicare Part B.

May 6

CMS <u>Issues</u> Final Rule, Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability.

CMS <u>Seeks</u> Comments on Information Collection Activities Concerning ESRD Network Semi-Annual Cost Report Forms and Supporting Regulations; Organ Procurement Organization's Health Insurance Benefits Agreement and Supporting Regulations; and CMS Innovation Partners Program Applications and Surveys.

May 8

Office of Women's Health Highlights National Women's Health Week; Begins on May 8.

OTHER UPDATE

CRS Releases Reports

- Health Care for Veterans: Answers to Frequently Asked Questions. (Apr. 21)
- Synthetic Drugs: Overview and Issues for Congress. (May 3)

GAO Releases Report

• <u>Medicaid Program Integrity: Improved Guidance Needed to Better Support Efforts to Screen Managed Care Providers</u>. (May 6)

UPCOMING EVENTS

CONGRESSIONAL HEARINGS/MARKUPS

SENATE

Finance

<u>Can Evidence Based Practices Improve</u> <u>Outcomes for Vulnerable Individuals and Families?</u>

May 10 | 2 p.m.
 215 Dirksen Senate Office Building

Hearing to Consider the Nominations of the Honorable Charles P. Blahous III and the Honorable Robert D. Reischauer

May 11 | 3 p.m.
 215 Dirksen Senate Office Building

HOUSE

Energy & Commerce

<u>Health Care Solutions: Increasing Patient</u> <u>Choice and Plan Innovation</u>

May 11 | 10 a.m.
 2322 Rayburn House Office Building

<u>Concussions in Youth Sports: Evaluating</u> Prevention and Research

May 13 | 9:30 a.m.
 2123 Rayburn House Office Building

Ways & Means

Implementation of Medicare Access & CHIP Reauthorization Act of 2015 (MACRA)

• May 11 | 2 p.m. 1100 Longworth House Office

Veterans' Affairs

<u>Combating the Crisis: Evaluating Efforts to Prevent Veteran Suicide</u>

• May 12 | 10 a.m. 334 Cannon House Office Building

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

Meeting description will be published closer to the meeting date.

- May 9 | 8:45 a.m. 5 p.m.
- May 10 | 8:45 a.m. 1 p.m.
 CDC Washington Office
 Room 9000
 395 E Street SW
 Washington, DC 20201
 and via teleconference

National Provider Call, MACRA Listening Session: Quality Payment Program Proposed Rule

An opportunity for stakeholders to provide CMS early feedback on proposed policy for the Quality Payment Program.

• May 10 | 2 p.m. – 3 p.m. via teleconference

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 of ongoing and new activities.

May 11 | 8:30 a.m. - 5:15 p.m.
 National Cancer Institute
 Shady Grove
 Conference Room TE406
 9609 Medical Center Drive
 Rockville, MD 20850
 and via webcast

<u>The Merit- Based Incentive Payment System</u> (MIPS) Overview

An opportunity for stakeholders to learn about MIPS and provide CMS with initial feedback on the proposed policy for the Quality Payment Program.

May 11 | 12 p.m. – 1 p.m.
 via teleconference

National Center for Advancing Translational Sciences Meeting

Report from the Institute Director and other staff.

May 12 | 8:30 a.m. – 2:45 p.m.
 NIH
 Conference Room 10
 Building 31, C Wing
 45 Center Drive
 Bethesda, MD 20892

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

<u>Chronic Fatigue Syndrome Advisory</u> <u>Committee Meeting</u>

Agenda will be posted on the CFSAC website.

- May 17 | 12 p.m. 5 p.m.
- May 18 | 12 p.m. 5 p.m. via webinar

<u>Healthcare Common Procedure Coding</u> 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 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

Can CER Help Answer Questions About Hepatitis C? A PCORI Stakeholder Workshop

Stakeholder discussion on additional PCORI investments.

• May 18 | 1 p.m. – 3 p.m. via webinar

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

Secretary's Advisory Committee on Human Research Protections Meeting

Presentation of a summary of public comment received on Federal Policy for the Protection of Human Subjects; draft work products, including considerations for single IRB review and minimal risk informed consent models; and recommendations on clustered randomized trials, the return of individual research results, and benchmarking.

- May 18 | 8:30 a.m. 5 p.m.
- May 19 | 8:30 a.m. 4:30 p.m.
 Fishers Lane Conference Center
 Terrace Level
 5635 Fishers Lane
 Rockville, MD 20852

2015 Mid-Year ORURs 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

PCORI Board of Governors Meeting

Location and agenda to be posted.

• May 23 | 10:15 a.m. – 5:30 p.m. and via teleconference/ webinar

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
 Select sessions open to the public.

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

National Committee on Vital and Health Statistics: Subcommittee on Privacy, Confidentiality & Security Meeting

Gather industry input on existing guidance and limitations of the de-identification methodologies of protected health information to make recommendations to the Secretary.

- May 24 | 9 a.m. 5:30 p.m.
- May 25 | 9 a.m. 5:15 p.m.
 Hubert H. Humphrey Building Room 705A
 200 Independence Ave. SW
 Washington, DC 20201

Advisory Committee on Interdisciplinary, Community- Based Linkages

Discussion on the next report on enhancing community-based clinical training.

- May 25 | 8:30 a.m. 5:30 p.m.
- May 26 | 8:30 a.m. 5:30 p.m. Location TBD and via webinar

National Advisory Mental Health Council Meeting

Presentation of the NIHM Director's Report and discussion of program and policy issues.

• May 26 | 9 a.m. - 1 p.m.

NIH

Neuroscience Center 6001 Executive Boulevard Rockville, MD 20852

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

<u>Eunice Kennedy Shriver National Institute of</u> <u>Child Health & Human Development</u> <u>Meeting</u>

Report from the Scientific Director, NICHD, on the status of the NICHD Division of Intramural Research, talks by various intramural scientists, and current organizational structure.

• June 3 | 8 a.m. – 11:30 a.m.

NIH

Conference Room 24A8

Building 31A

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

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Discussion of program policies.

• June 7 | 8:30 a.m. - 1:15 p.m.

NIH

Building 31, C-Wing, 6th Floor 31 Center Drive

Bethesda, MD 20892

Eunice Kennedy Shriver National Institute of Child Health & Human Development Meeting

Discuss administrative matters, Director's Report, Division of Extramural Research Report, and other business of the Council.

• June 9 | 8:30 a.m. - 12 p.m.

NIH

Conference Room 6

Building 31, C-Wing, 6th Floor

9000 Rockville Pike

Bethesda, MD 20892

Advisory Committee to the Director, NIH Meeting

Reports by NIH Director, ACD Working Group, IC Director.

- June 9 | 9 a.m. 5 p.m.
- June 10 | 9 a.m. adjournment

NIH

Room 6C6

Building 31, C-Wing, 6th Floor

31 Center Drive

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

<u>Kidney Interagency Coordinating</u> Committee Meeting

Discuss kidney programs in KICC member organizations and identify opportunities for collaboration; focus on improving access to kidney transplantation.

June 17 | 9 a.m. – 12 p.m.
 NIH
 Natcher Conference Center
 9000 Rockville Pike
 Bethesda, MD 20892

Meeting of the Medicare Evidence
Development and Coverage Advisory
Committee

The Committee will discuss recommendations regarding treatment strategies for patients with lower extremity chronic venous disease.

 July 20 | 7:30 a.m. - 4:30 p.m. CMS
 Main Auditorium
 7500 Security Boulevard
 Baltimore, MD 21244
 and via webcast

Patient-Focused Drug Development for Patients Who Have Received an Organ Transplant Meeting

Discussion of patient perspectives on impact of receiving an organ transplant and on treatment approaches as well as issues related to scientific challenges in developing drugs to manage organ transplantation.

September 27 | 9 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

DEPARTMENT OF VETERANS AFFAIRS

Commission of Care Meeting

- May 9 | 8:30 a.m. 6 p.m.
- May 10 | 8:30 a.m. 6 p.m.
- May 11 | 8:30 a.m. 4 p.m.
 J.W. Marriott,
 Jr. ASAE Conference Center
 1575 I Street NW
 Washington, DC 20005

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
 810 Vermont Ave. NW
 Room 230
 Washington, DC 20420

Clinical Science Research and Development Service Cooperative Studies Scientific Evaluation Committee Meeting

Discussion of administrative matters and the general status of the program.

June 29 | 8:30 a.m. – 10:15 p.m.
 American Association of Airport Executives
 601 Madison Street
 Alexandria, VA 22314

OTHER

<u>A New Era of Reform: Health Care Policy</u> <u>Solutions for 2017 and Beyond</u>

May 10 | 10:30 a.m. – 1:15 p.m.
 Cannon Caucus Room
 Cannon House Office Building
 27 Independence Ave., SE
 Washington, DC 20003

Educational Series on Affordable Medicines: Impact of Federal Policy on Innovation, Competition, and Costs

May 10 | 10 a.m. - 11:30 a.m.
 Bipartisan Policy Center
 1225 Eye Street, NW
 Washington, DC 20005

Outside, In: Unhealthy Hacking: Medical Privacy in the Age of Cyber Attacks

May 10 | 5:15 p.m.
 District Architecture Center
 421 7th Street, NW
 Washington, DC 20004

2016 Antitrust in Healthcare Conference

- May 12 | 7 a.m. 5 p.m.
- May 13 | 7 a.m. 4:45 p.m.
 Ritz Carlton Pentagon City
 1250 S. Hayes Street
 Arlington, VA 22202

A National Response to Hepatitis C
Treatment among the Hard to Reach, Hard
to Treat

Hepatitis Foundation International's Call to Action

May 18 | 9 a.m. – 4 p.m.
 Crowne Plaza
 The Hamilton
 1001 14th Street NW
 Washington, DC 20005