



# LEGISLATIVE AND REGULATORY UPDATE April 4, 2016

### Week in Brief

CMS <u>Issues</u> Medicaid and CHIP Mental Health and Substance Use Disorder Parity Rule.

Senate Returns from Spring Recess on April 4; House Continues Recess until April 12.

## WHITE HOUSE UPDATE

### March 29

President Obama <u>Addresses</u> the National Rx Drug Abuse & Heroin Summit in Atlanta; Announces Actions to Combat the Prescription Opioid Abuse and Heroin Epidemic.

White House <u>Releases</u> Memorandum on the Mental Health and Substance Use Disorder Parity Task Force.

### LEGISLATIVE UPDATE

### March 28

Senate Special Committee on Aging Chair Susan Collins (R-ME) and Ranking Member Claire McCaskill (D-MO) <u>Announce</u> 3<sup>rd</sup> Hearing on Price Spikes of Decades-Old Rx Drugs; CEO of Valeant Pharmaceuticals Expected to Testify.

### March 29

Senate Finance Chairman Orrin Hatch (R-UT), House Energy & Commerce Chairman Fred Upton (R-MI) and House Energy & Commerce Subcommittee on Health Chairman Joseph Pitts (R-PA) <u>Sent</u> Follow-up Letter to MACPAC on Conflict of Interest Policies.

Senate HELP Chairman Lamar Alexander (R-TN) <u>Releases</u> Statement on Recent Hacking of MedStar Health and the Need for HHS to Implement Cybersecurity Legislation to Protect Patient Health Information.

Senate HELP Ranking Member Patty Murray (D-WA) <u>Lauds</u> Administration Announcement of Measures to Tackle Opioid Epidemic.

House Energy & Commerce Chairman Fred Upton (R-MI) <u>Releases</u> Statement on Administration's Opioid Initiatives.

House Energy & Commerce Chairman Fred Upton (R-MI) and Oversight & Investigations Subcommittee Chairman Tim Murphy (R-PA) <u>Sent</u> Letter to HHS Questioning Zika Response and Insufficient Diagnostic Testing.

House Energy & Commerce and Ways & Means Committees <u>Subpoena</u> HHS for Information on the Administration's Funding of the Basic Health Program without a Congressional Appropriation.

House Ways & Means Health Subcommittee Chairman Pat Tiberi (R-OH) and 25 Additional Members of the Ways & Means Committee Sent Letter to CMS Urging Delay of Changes to Medicare's Clinical Laboratory Fee Schedule.

### March 30

Senate Finance Ranking Member Ron Wyden (D-OR) <u>Welcomes</u> Beth Vrabel as Senior Health Counsel on Medicare (Including Part B) for the Finance Committee Minority Staff.

House Energy & Commerce Select Investigative Panel on Infant Lives <u>Subpoena</u> Biomedical Researchers for April 11 Hearing.

House Ways & Means <u>Posts</u> Blog on HHS Announcement of Health Care Marketplace Enrollment Numbers Falling Short of Expectations.

### March 31

Senate HELP Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) Plan to <u>Introduce</u>, *the Promoting Biomedical Research and Public Health for Patients Act*, a Bill to Let NIH "Spend More Time on Life-Saving Treatments and Cures," for Consideration at the April 6 HELP Committee Executive Session.

Senate HELP Ranking Member Patty Murray (D-WA) <u>Releases</u> Statement Against House Republican Subpoenas of Biomedical Researchers for Upcoming Energy & Commerce Hearing that Continues the Investigation of Planned Parenthood.

House Veterans' Affairs Chairman Jeff Miller (R-FL) and Senator Marco Rubio (R-FL), Sponsors of the House and Senate Versions of the *VA Accountability Act*, <u>Urge</u> Senate Veterans' Affairs Chairman Johnny Isakson (R-GA) and Rest of Senate to Address VA's Accountability Crisis.

### April 1

Senate Finance Chairman Orrin Hatch (R-UT), House Energy & Commerce Chairman Fred Upton (R-MI) and House Energy & Commerce Subcommittee on Health Chairman Joseph Pitts (R-PA) <u>Send</u> Letter to CMS Highlighting the Importance of Incentivizing Abuse-Deterrent Drug Formulations.

Senate Special Committee on Aging Chair Susan Collins (R-ME) and Ranking Member Claire McCaskill (D-MO) <u>Announce</u> April 6 Hearing on Alzheimer's: "Finding a Cure: Assessing Progress Toward the Goal of Ending Alzheimer's by 2025."

## JUDICIAL UPDATE

### March 29

Supreme Court Requests Supplemental Briefs in Case Concerning Contraceptive Coverage.

## **REGULATORY UPDATE**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES March 28

ASPE Releases Report on the Benefits of Medicaid Expansion for Behavioral Health.

### March 30

HHS <u>Publishes</u> Proposed Rule Expanding Access to Medication-Assisted Treatment by Authorizing Practitioners to Request Approval to Treat Up to 200 Patients Under the Controlled Substances Act.

CMS <u>Invites</u> QIN-QIOs to Partner with Providers to Compete for 28 Special Innovation Project Awards Falling Within Two Topic Categories.

AHRQ Seeks Nominations for Public Members of National Advisory Council.

### March 31

HHS OIG <u>Releases</u> Report: Hospices Inappropriately Billed Medicare over \$250 Million for General Inpatient Care.

### April 1

CMS <u>Launches</u> the Comprehensive Care for Joint Replacement Model.

### **April 4**

AHRQ Seeks Nominations for New Members of the U.S. Preventive Services Task Force.

NIH <u>Announces</u> Blue Ribbon Panel to Help Guide Vice President Biden's National Cancer Moonshot Initiative.

NIH Director Dr. Francis Collins and National Cancer Institute Acting Director Dr. Doug Lowy Author New England Journal of Medicine Article on the National Cancer Moonshot.

OASH Requests Nominations to Fill Chronic Fatigue Syndrome Advisory Committee Positions.

## OTHER NEWS

### March 29

CBO Releases Cost Estimate Report Analyzing the President's FY 2017 Budget.

### March 30

Johns Hopkins Performs First Liver and Kidney Transplants between HIV-Positive Patients.

### March 31 - April 1

MACPAC <u>Holds</u> Public Meeting on the Draft Chapters for the June Report, the IMD Exclusion, Children's Coverage, 1332 and 1115 Waivers, Reductions in Adult Eligibility Post-ACA, and Long-Term Care.

### **UPCOMING EVENTS**

### **CONGRESSIONAL HEARINGS/MARKUPS**

#### **SENATE**

#### **HELP**

Executive Session: S. 2700, FDA and NIH
Workforce Authorities Modernization Act;
S. 185, Promise for Antibiotics and
Therapeutics for Health Act; S. 2713,
Advancing Precision Medicine Act of 2016; S.
\_\_\_\_, NIH Strategic Plan and Inclusion in
Clinical Research; S. \_\_\_\_, Promoting
Biomedical Research and Public Health for
Patients Act

• April 6 | 10 a.m. 216 Hart Senate Office Building

### **Special Committee on Aging**

Finding a Cure: Assessing Progress Toward the Goal of Ending Alzheimer's by 2025

• April 6 | 2:30 p.m. 106 Dirksen Senate Office Building

<u>Third Hearing on Price Spikes of Decades</u>-Old Rx Drugs

• April 27 | 2:30 p.m. TBA

### Appropriations

Hearing to Review the FY 2017 Budget
Request and Funding Justification for NIH

• April 7 | 10 a.m. 138 Dirksen Senate Office Building

### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

## 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 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 how to complete Medicare Shared Savings Program applications.

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

## Meeting of the Interagency Autism Coordinating Committee

Information on the National Autism Awareness Month activities and discussion on the 2016 update of 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

## 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 web conference

### Meeting of the Muscular Dystrophy Coordinating Committee

Update on process relevant to the Action Plan for the Muscular Dystophies, 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 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 other things.

- 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 at the Frederick National Laboratory for Cancer Research.

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

### <u>Healthcare Common Procedure Coding</u> <u>System Public Meeting</u>

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 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

## 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

## 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

# 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

### **OTHER EVENTS**

Health Affairs: April 2016 Issue Briefing on Patients' and Consumers' Use of Evidence

April 7 | 9 a.m. - 1 p.m.
 W Hotel Washington
 515 15th Street NW
 Great Room, Lower Level
 Metro Center
 Washington, DC 20004

U.S. Chamber of Commerce Forum on "Innovations in Workplace and Community Wellness: Bridging Personal and Population Health."

April 7 | 8:30 a.m. – 12:30 p.m.
 U.S. Chamber of Commerce
 1615 H Street NW
 Briefing Center
 Washington, D.C.
 Registration Required.