



LEGISLATIVE AND REGULATORY UPDATE June 6, 2016

Week in Brief

HHS OIG's Semiannual Report to Congress Reveals OIG Reported Expected Recoveries of More than \$2.77 Billion During the First Half of FY 2016.

Both House and Senate in Recess; Senate in Session Starting Monday and House in Session Starting Tuesday.

LEGISLATIVE UPDATE

May 31

House Ways & Means Committee Chairman Kevin Brady (R-TX) and Energy & Commerce Committee Chairman Fred Upton (R-MI) Write HHS Secretary Sylvia Burwell Regarding the Production of Documents Related to Basic Health Program Funding.

Senator Claire McCaskill (D-MO) <u>Releases</u> Report Detailing Mistreatment of World War II Veterans Exposed to Chemical Weapons.

Senator Ron Johnson (R-WI), Chairman of the Senate Homeland Security & Governmental Affairs Committee, Releases Report Detailing Failures at the Veterans Affairs Medical Center in Tomah, Wisconsin.

June 1

22 Senators <u>Urge</u> HHS to Increase Access to Medication Assisted Treatment for Opioid Use Disorders.

June 2

Senators Michael Bennet (D-CO) and Orrin Hatch (R-UT) Will <u>Introduce</u> the *PATH Act* to Support the Development of New Antibiotics.

June 3

House Energy & Commerce Committee Circulates Draft Proposed <u>Amendment</u> in the Nature of a Substitute to the *Helping Families in Mental Health Crisis Act of* 2016, H.R. 2646.

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

May 26

MedPAC <u>Submits</u> Comments on CMS's Proposed Rule Entitled *Medicare Program*; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Report Requirements.

May 27

CMS <u>Clarifies</u> that Primary Care Practices Participating in Track 1, 2, or 3 of the Medicare Shared Savings Program May Also Participate in Comprehensive Primary Care Plus.

May 31

CDC <u>Issues</u> Interim Guidance on Zika Virus Antibody Test Result Interpretation.

MedPAC <u>Submits</u> Comments on CMS's Proposed Rule and Interim Final Rule, Which Would Revise the Hospital IPPS, the Long-Term Care Hospital Payment System, and Quality Reporting Requirements for Certain Providers.

NIH Announces the Establishment of the NIH Clinical Center Research Hospital Board.

June 1

CDC Issues Vital Statistics Rapid Release, <u>Crude and Age-Adjusted Death Rates for All Causes:</u> <u>2014-Quarter 4</u>, <u>2015</u>.

NIH, CDC, and Other Federal Agencies <u>Launch</u> a Three-Year, \$9 Million Program to Train First Responders and Hazardous Waste Workers on Infectious Disease Safety.

June 2

FDA <u>Issues</u> Guidance on Form FDA 3926, Individual Patient Expanded Access Investigational New Drug Application (IND).

OTHER UPDATE

June 1

GAO Releases Report, <u>Medicare: Utilization and Expenditures for Complex Wheelchair</u> <u>Accessories.</u>

June 2

GAO <u>Announces</u> Appointment of Five New Members and Reappointment of One Current Member to MedPAC.

UPCOMING EVENTS

CONGRESSIONAL HEARINGS/MARKUPS

HOUSE

Ways & Means

<u>Legislation to Improve and Sustain the</u> Medicare Program

 June 8| 2 p.m.
 1100 Longworth House Office Building

Energy & Commerce

Health Subcommittee Vote on H.R. 3299 and H.R. 921

June 7 | 5 p.m.
 2123 Rayburn House Office Building

Health Subcommittee Reconvenes Markup

• June 8| 2 p.m. 2123 Rayburn House Office Building

Advancing Patient Solutions for Lower Costs and Better Care

• June 10 | 9:15 a.m. 2322 Rayburn House Office Building

SENATE

Judiciary

<u>Deadly Synthetic Drugs: The Need to Stay</u> Ahead of the Poison Peddlers

June 7 | 10 a.m.
 226 Dirksen Senate Office Building

Appropriations

Markup of the Labor, Health and Human Services, Education, and Related Agencies Appropriations Act for Fiscal Year 2017

- June 7 | 10:30 a.m.
 138 Dirksen Senate Office Building
- June 9| 10:30 a.m. 106 Dirksen Senate Office Building

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

Discussions on the barriers and scientific challenges to the development of new and improved vaccines, a presentation from the NVAC Maternal Immunization Working Group, and an update on immunization priorities at the local level, among other things. Pre-registration is required.

- June 7 | TBD
- June 8 | TBD

Hubert H. Humphrey Building The Great Hall 200 Independence Ave., SW Washington, DC 20201

National Advisory Council on Minority Health and Health Disparities Meeting

Discussion of administrative matters, Director's report, NIH Health Disparities update, and other business of the Council.

 June 7 | 8 a.m. – adjournment NIH
 Conference Room 6
 Building 31
 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 Arthritis and Musculoskeletal and Skin Diseases Advisory Council Meeting

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 10
 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

Meeting of the National Center for
Advancing Translational Sciences Advisory
Council and Meeting of the Cures
Acceleration Network Review Board

Report from the Institute Director and other staff.

• June 13 | 12 p.m. – 2 p.m. Virtual Meeting

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

Discussion on syphilis among MSM and congenital syphilis; update on CDC's Medical Monitoring Project; discussion on infectious diseases prevention for PWID; findings of the Institute of Medicine Committee on a National Strategy for the Elimination of Hepatitis B and C; and updates from workgroups.

- June 14 | 8:30 a.m. 5:30 p.m.
- June 15 | 8:30 a.m. 3 p.m.
 CDC Corporate Square
 Conference Room 1-ABC
 Building 8, 8 Corporate Boulevard
 Atlanta, Georgia 30329
 And via teleconference

National Committee on Vital and Health Statistics Meeting

Presentations and discussions on several health data policy topics, among other things.

- June 14 | 9 a.m. 5:40 p.m.
- June 15 | 8 a.m. 2:25 p.m.
- June 16 | 8:30 a.m. 5 p.m.
 Hubert H. Humphrey Building Room 705-A
 200 Independence Ave. SW.
 Washington, DC 20024
- June 17 | 8:15 a.m. 4 p.m.
 Wilbur J. Cohen Building
 Snow Room, #5051
 330 Independence Ave. SW
 Washington, DC 20201

Special Open Door Forum: Inpatient Rehabilitation Facility Tier Comorbidity Updates- Soliciting Stakeholder Input

CMS will host a forum for inpatient rehabilitation facilities and other stakeholders to provide suggestions regarding updates to the tier comorbidity portion of payments.

• June 16 | 2 p.m. – 3:30 p.m. Conference call

National Heart, Lung, and Blood Advisory Council Meeting

Discussion of program policies and issues.

• June 15 | 8 a.m. – 12:30 p.m.

NIH

Porter Neuroscience Research Center Building 35A Convent Drive Bethesda, MD 20892

Intramural Research at the NIH with the Chairpersons of the Boards of Scientific Counselors Meeting

Discussion of policies and procedures that apply to the regular review of NIH intramural scientists and their work.

June 17 | 10 a.m. - 2 p.m.
 NIH
 Room 7
 Building 31, C-Wing, 6th Floor
 31 Center Drive

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

Bethesda, MD 20892

Meeting will 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 Advisory Committee on Minority Health

Discussion on strategies to improve the health of ethnic and racial minority populations through health policies and programs that will help eliminate health disparities. Registration is required.

- June 20 | 9 a.m. 5 p.m.
- June 21 | 9 a.m. 1 p.m.
 Doubletree by Hilton Hotel Bethesda 8120 Wisconsin Ave.
 Bethesda, MD 20814

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

Presentations on topics related to incentives for the development of vaccines, diagnostics, and therapeutics; discussions on environment and antibiotic-resistance; and a presentation on a new guidance from the FDA. Registration is required.

- June 21 | 10 a.m. 5 p.m.
- June 22 | 9 a.m. 4 p.m.

HHS
Hubert H. Humphrey Building
Great Hall
200 Independence Ave. SW.
Washington, DC 20201
And via webcast

Meeting of the Advisory Panel on Outreach and Education

Discussion on Affordable Care Act initiatives and an opportunity for public comment.

 June 22 | 8:30 a.m. – 4 p.m.
 Hubert H. Humphrey Building Room 425A 200 Independence Ave. SW. Washington, DC 20201

National Advisory Council on the National Health Service Corps

The Council will refine top priorities for the NHSC and will continue to work on recommendations to submit to HHS and HRSA.

June 22 | 11 a.m. - 5 p.m.
 HRSA
 Conference Room #5E29
 5600 Fishers Lane
 Rockville, MD 20857
 And via webinar and conference call

Meeting of the Advisory Committee on Immunization Practices

Discussions on meningococcal vaccines, HPV vaccines, influenza, cholera vaccine, hepatitis vaccines, safety of maternal Tdap vaccination, child/adolescent immunization schedule, RSV and vaccine supply; a recommendation vote for meningococcal vaccines and cholera vaccine; and a VFC vote for meningococcal vaccines.

- June 22 | 8 a.m. 6 p.m.
- June 23 | 8 a.m. 5 p.m.

CDC
Kent "Oz" Nelson Auditorium
Tom Harkin Global Communications
Center
Building 19
1600 Clifton Road, NE.
Atlanta, Georgia 30329
And via webcast

DEPARTMENT OF VETERANS AFFAIRS

Commission on Care

Registration required.

- June 7 | 9 a.m. 6 p.m.
- June 8 | 8:30 a.m. 4 p.m.

 J.W. Marriott

 Jr. ASAE Conference Center

 1575 I St. NW.

 Washington, DC 20005

 And via teleconference

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 a.m.
- American Association of Airport Executives
 601 Madison Street

Alexandria, VA 22314