



LEGISLATIVE AND REGULATORY UPDATE May 23, 2016

Week in Brief

Supreme Court <u>Vacates</u> and Remands Contraceptive Mandate Cases.

House <u>Passes</u> H.R. 5243, the *Zika Response Appropriations Act*, a Bill Providing \$622.1 Million to Combat the Zika Virus.

House <u>Passes</u> H.R.4974, *Military Construction and Veterans Affairs and Related Agencies Appropriations Act for FY* 2017, Containing \$81.6 Billion in Funding.

EEOC <u>Issues</u> Final Rule to Amend Regulations Implementing Title II of the Genetic Information Nondiscrimination Act of 2008 as Related to Employer-Sponsored Wellness Programs.

WHITE HOUSE UPDATE

May 17

President Obama <u>Announces</u> Department of Labor Will Finalize Overtime Protections Rule.

May 18

President Obama <u>Declares</u> May 15th- May 21st as Emergency Medical Services Week.

LEGISLATIVE UPDATE

May 16

House Energy & Commerce Republican Leadership <u>Send</u> a Follow-up Letter to HHS and CMS Requesting Information on the ACA's Transitional Reinsurance Program.

May 17

Senate HELP Ranking Member Patty Murray (D-WA) and House Education & the Workforce Ranking Member Bobby Scott (D-VA) Praise Department of Labor Announcement of Final Overtime Rule; Expanded Overtime Benefits Will Impact 4 Million Employees in the U.S., Including Health Care Workers.

May 17

Senate Veterans' Affairs Chairman Johnny Isakson (R-GA) and Ranking Member Richard Blumenthal (D-CT) <u>Announce</u> Progress on S. 2921, the *Veterans First Act*, a Bill to Change the Culture at the VA and Improve Accountability.

House Conferees Announced for Effort to Finalize Opioid Package with Senate.

May 18

House Energy & Commerce Republican Leadership <u>Send</u> Letters to 11 CO-OPs Requesting Update Information.

House Ways & Means Health Subcommittee Chairman Pat Tiberi (R-OH) and Health Subcommittee Ranking Member Jim McDermott (D-WA) <u>Introduce</u> the *Helping Hospitals Improve Patient Care Act*, a Bill to Advance Hospital and Other Medicare Provider Reforms.

May 19

Senate Finance Ranking Member Ron Wyden (D-OR) and HELP Ranking Member Patty Murray (D-WA) <u>Send</u> a Letter to Labor Secretary Tom Perez and HHS Secretary Sylvia Mathews Burwell Urging Action to Improve Health Data Transparency.

LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
S. 2912/ H.R. 3012	A bill to authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, and for other purposes.	Sen. Johnson [R-WI]	HELP	Introduced 5/10/2016
S. 2922	Enhanced Veteran Healthcare Act of 2016	Sen. Whitehouse [D-RI]	Veterans' Affairs	Introduced 5/11/2016
S. 2921	Veterans First Act	Sens. Isakson [R-GA]; and 31 original cosponsors	Veterans' Affairs	Reported out of committee without amendment 5/16/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>S. 2932</u>	Protecting Patient Access to Emergency Medications Act of 2016	Sen. Cassidy [R-LA]	HELP	Introduced 5/16/2016
S. 2934/ H.R. 3411	Fix Gun Checks Act of 2016	Sens. Schumer [D-NY]; Blumenthal [D-CT]; Gillibrand [D-NY]; Murphy [D-CT]; Wyden [D-OR]; and Markey [D-MA]	Judiciary	Introduced 5/16/2016
S.	Survivors' Access to Supportive Care Act (SASCA)	Sen. Murray [D-WA]; Shaheen [D-NH]; McCaskill [D-MO]; Gillibrand [D-NY]; Baldwin [D-WI]; Blumenthal [D-CT]; and Boxer [D-CA]	HELP	Introduced 5/18/2016
H.R. 5182/ S. 2041	Promoting Life- Saving New Therapies for Neonates Act of 2016	Reps. Long [R-MO-7] and Lujan [D-NM-3]	Energy & Commerce	Introduced 5/10/2016
H.R. 5188	Enhancing Opportunities for Medical Doctors Act of 2016	Rep. Love [R-UT-4]	Ways & Means; Energy & Commerce	Introduced 5/11/2016
H.R. 5195	Breast Cancer Patient Protection Act of 2016	Reps. DeLauro [D-CT-3] and 38 original cosponsors	Energy & Commerce; Ways & Means; Education & the Workforce	Introduced 5/11/2016
H.R. 5219	Safe Medications for Moms and Babies Act of 2016	Reps. Herrera Beutler [R-WA-3] and Castor [D-FL-14]	Energy & Commerce	Introduced 5/12/2016
H.R. 5241	Protecting Seniors from Health Care Fraud Act of 2016	Rep. Ruiz [D-CA-36]	Energy & Commerce; Ways & Means	Introduced 5/13/2016
H.R. 5243	Zika Response Appropriations Act, 2016	Rep. Rogers [R-KY-5]	Appropriations; Budget	Introduced 5/16/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
H.R. 5249/ S. 2678	To direct the NIH to intensify and coordinate fundamental, translational, and clinical research with respect to the understanding of pain, the discovery and development of therapies for chronic pain, and the development of alternatives to opioids for effective pain treatments.	Reps. Capps [D-CA-24]; Ellmers [R-NC-2]; McKinley [R-WV-1]; and Matsui [D-CA-6]	Energy & Commerce	Introduced 5/16/2016
H.R. 5262	Care Veterans Deserve Act of 2016	Reps. Hudson [R-NC-8] and Ruppersberger [D-MD-2]	Energy & Commerce	Introduced 5/17/2016
H.R. 5268	Medicare Beneficiary Enrollment Improvement Act	Rep. McDermott [D-WA-7]	Ways & Means; Energy & Commerce	Introduced 5/17/2016
H.R. 5273	Helping Hospitals Improve Patient Care Act	Reps. Tiberi [R-OH-12] and McDermott [D-WA-7]	Energy & Commerce	Introduced 5/18/2016
H.R. 5284	To eliminate the individual and employer health coverage mandates under the Patient Protection and Affordable Care Act, to expand beyond that Act the choices in obtaining and financing affordable health insurance coverage, and for other purposes.	Rep. Sessions [R-TX-32]	Energy & Commerce; Ways & Means; Education & the Workforce	Introduced 5/19/2016

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES May 17

CDC <u>Issues</u> Report, Health Insurance Coverage: Early Release of Estimates from the National Health Interview Survey, 2015.

FDA <u>Announces</u> Availability of Draft Guidance, *Use of Electronic Health Record Data in Clinical Investigations*.

NIH Director Francis S. Collins and U.S. Secretary of Labor Thomas Perez <u>Post</u> Op-Ed on Revisions to the Fair Labor Standards Act as it Affects Postdoctoral Researchers.

NIH <u>Grants</u> \$15 Million to Support Research on Ethical, Legal, and Social Impact of Genomic Information.

May 18

NIH <u>Issues</u> Statement on HIV Vaccine Awareness Day.

NIH <u>Names</u> Maureen M. Goodenow, Ph.D., as Associate Director for AIDS Research and Director of the NIH Office of AIDS Research.

May 19

CDC Shares Resources and Information to Support Hepatitis Testing Day and Awareness Month.

NIH Director Dr. Francis Collins <u>Discusses</u> the Zika Virus Vaccine and the Importance of Funding Research.

NIH-Funded Study <u>Finds</u> the "Number of People with Visual Impairment or Blindness in the United States Is Expected to Double to More than 8 Million by 2050."

OTHER UPDATE

GAO Releases Reports

- Office of National Drug Control Policy: Progress Toward Some National Drug Control Strategy Goals, but None Have Been Fully Achieved. (May 17)
- <u>Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed</u>. (May 19)

May 13

CRS Releases Report, Active Opioid Legislation in the House: In Brief.

May 19

Health Affairs <u>Publishes</u> Article, Mental Disorders Top the List of the Most Costly Conditions in the United States: \$201 Billion.

MACPAC Unanimously <u>Passes</u> Policies on Financial Disclosure, Recusal, and Conflict of Interest.

UPCOMING EVENTS

CONGRESSIONAL HEARINGS/MARKUPS

HOUSE

Energy & Commerce

Medicare and Medicaid Program Integrity: Combating Improper Payments and Ineligible Providers

May 24 | 10:15 a.m.
 2322 Rayburn House Office Building

Examining Cybersecurity Responsibilities at HHS

May 25 | 10 a.m.
 2123 Rayburn House Office Building

Science, Space & Technology

Science of Zika: The DNA of an Epidemic

May 25 | 10:15 a.m.
 2318 Rayburn House Office Building

Ways & Means

Markup on Commonsense Proposals to Advance Hospital Reforms and Improve TANF

May 24 | 2 p.m.
 Longworth House Office Building

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 p.m.
- May 26 | 8:30 a.m. 3 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

Meeting of the National Institute of Neurological Disorders and Stroke

Rockville, MD 20852

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

Discussion on preliminary coding and payment determinations for new public requests for HCPCS revisions.

- 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

<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 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

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

Bethesda, MD 20892

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

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 Medicare Evidence Development and Coverage Advisory Committee

Discussion of 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

Advisory Panel on Hospital Outpatient Payment Meeting

Evaluating APC group structure, addressing procedures within an APC group, reviewing the packaging of OPPS services and costs, and other related topics.

- August 22 | 9 a.m. 5 p.m.
- August 23 | 9 a.m. 5 p.m.

CMS

Main Auditorium 7500 Security Boulevard Woodlawn, MD 21244 and via webcast and teleconference

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

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

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 a.m.
 American Association of Airport Executives
 601 Madison Street
 Alexandria, VA 22314

OTHER

Ten Guidelines for Real Health Care Reform

May 25 | 12 p.m. – 1:30 p.m.
 Hudson Institute
 1201 Pennsylvania Avenue, NW
 Suite 400
 Washington, DC 20004

12th Annual State of Personalized Medicine Luncheon Address

May 25 | 12 p.m. – 2 p.m.
 The National Press Club
 529 14th Street, NW
 Washington, DC 20045

National Health Law Program Health Equity Event

May 26 | 10 a.m. – 11:30 a.m.
 Kaiser Family Foundation
 Barbara Jordan Conference Center
 1330 G Street, NW
 Washington, DC 20005

NPC Luncheon with CDC Director Dr. Tom Frieden

May 26 | 10 a.m. – 11:30 a.m.
 The National Press Club
 Holeman Lounge
 529 14th Street, NW
 Washington, DC 20045