



LEGISLATIVE AND REGULATORY UPDATE May 31, 2016

Week in Brief

House Ways & Means Committee <u>Approves H.R. 5273</u>, Helping Hospitals Improve Patient Care Act of 2016.

White House <u>Issues</u> the Final Data Security Policy Prinicples and Framework for the Precision Medicine Initiative.

LEGISLATIVE UPDATE

May 17

House <u>Announces</u> Full List of Conferees in the House and Senate Conference Commmittee on Opioid Legislation; Senate Has Yet to Nominate Conferees.

May 20

House Energy & Commerce Committee Chairman Fred Upton (R-MI) and House Ways & Means Committee Chairman Kevin Brady (R-TX) <u>Sent</u> Letters to the Department of the Treasury, HHS, and OMB Requesting the Production of Information on the ACA's Cost Sharing Reduction Program.

Senate Homeland Security & Governmental Affairs Committee Chairman Ron Johnson (R-WI) and Senator Dan Coats (R-IN) <u>Sent</u> a Letter to FDA Commissioner Robert Califf Expressing Disappointment in the Peripheral and Central Nervous System Drugs Advisory Committee's Vote Against the New Drug Application for a Treatment of Duchenne Muscular Dystrophy and Urging Consideration in Making a Final Determination.

May 23

House Committee on Veterans' Affairs Chairman Jeff Miller (R-Fl) <u>Issues</u> Statement on the House Passage of Veteran-Related Bills: <u>H.R. 3956</u>, the *VA Health Center Management Stability and Improvement Act*; <u>H.R. 3989</u>, the *Support our Military Caregivers Act*; and <u>H.R. 2460</u>, a bill to improve the provision of adult day health care services for veterans.

Senate Committee on Veterans' Affairs Chairman <u>Johnny Isakson</u> (R-GA), Senate Committee on Homeland Security & Governmental Reform Chairman <u>Ron Johnson</u> (R-WI), and House Committee on Veterans' Affairs Chairman <u>Jeff Miller</u> (R-FL) Issue Statements Regarding VA

Secretary Robert McDonald's Comments Comparing the VA's Health Care Wait Times to the Wait Times at Disney Theme Park.

House Energy & Commerce Committee <u>Highlights</u> Legal Opinion on the Use of Funds Collected Under the Transitional Reinsurance Program.

15 Senators <u>Sent</u> a Letter to Senate Committee on Veterans Affairs Chairman Johnny Isakson (R-GA) and Ranking Member Richard Blumenthal (D-CT) Urging Action to Authorize the VA Major Medical Facility Leases Pending Before Congress.

Senate Committee on Veterans' Affairs Chairman Johnny Isakson (R-GA) <u>Authors</u> Op-Ed on the *Veterans First Act*.

House Energy & Commerce Democrats <u>Release</u> Report, *The National Football Leagues' Attempt to Influence Funding Decisions at the National Institutes of Health*.

May 24

House Ways & Means Committee Chairman Kevin Brady (R-TX) <u>Delivers</u> Opening Statement at the Markup of H.R. 5273, *Helping Hospitals Improve Patient Care Act of 2016*.

Senate Committee on Veterans' Affairs Chairman Johnny Isakson (R-GA) <u>Urges</u> VA Secretary Robert McDonald to Apologize for Health Care Wait Time Comments.

House Energy & Commerce Committee Members Kick Off the Pediatric Trauma Caucus.

May 25

House Energy & Commerce Committee, Subcommittee on Health <u>Holds</u> Hearing to Examine Cybersecurity Efforts at HHS.

May 26

House <u>Votes</u> to Go to Conference with Senate Regarding the Zika Funding Packages.

House Energy & Commerce Chairman Fred Upton (R-MI) and Subcommittee on Health Chairman Joseph Pitts (R-PA) <u>Write</u> HHS Secretary Sylvia Burwell to Express Concerns Regarding HHS's Position on the FDA Regualtion of Medical Product Manufacturer Communications.

LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>S. 2998</u>	A bill to ensure prompt coverage of breakthrough devices under the Medicare program.	Sen. Coats [R-IN]	Finance	Introduced 5/26/2016
<u>S. 2980</u>	Health Savings Account Expansion Act of 2016	Sens. Flake [R-AZ] and Vitter [R-LA]	Finance	Introduced 5/25/2016
<u>S. 2981</u>	To add standards for drug compendia for physician use for purposes of Medicaid payment for certain drugs.	Sens. Grassley [R-IA] and Casey [D-PA]	Finance	Introduced 5/25/2016
S. 2977	A bill to establish an excise tax on the production and importation of opioid pain relievers.	Sens. Manchin [D-WV]; Klobuchar [D-MN]; Shaheen [D-NH]; King [I-ME]; Heitkamp [D-ND]; Baldwin [D-WI]; Nelson [D-FL]; Warren [D-MA]; Schatz [D-HI]; and Heinrich [D-NM]	Finance	Introduced 5/24/2016
S. 2049	To establish in the VA a continuing medical education program for non-Department medical professionals who treat veterans and their family members to increase knowledge and recognition of medical conditions common to veterans and their family members.	Sen. Brown [D-OH]	Senate Veterans' Affairs	Full committee hearing 5/24/2016
S. 2487 / H.R. 2915	Female Veteran Suicide Prevention Act	Sens. Boxer [D-CA]; Ernst [R-IA]; Blumenthal [D-CT]; Brown [D-OH];	Senate Veterans' Affairs	Full committee hearing 5/24/2016
H.R. 4460 / S. 2508	Youth Sports Concussion Act	Reps. Pascrell [D-NJ-9] and Rooney [R-FL-17]	Energy & Commerce	Subcommittee on Commerce,

S. 2520 S. 2679 / H.R. 2237 S. 2883 / H.R. 5091	Newborn Care Improvement Act Helping Veterans Exposed to Burn Pits Act Appropriate Care for Disabled Veterans Act of 2016	Sens. Klobuchar [D-MN] and Tillis [R-NC] Sens. Klobuchar [D-MN] and Tillis [R-NC] Sens. Brown [D-OH]; Toomey [R-PA]; Sanders [I-VT]; Murray [D-WA]; and Casey [D-PA]	Senate Veterans' Affairs Senate Veterans' Affairs Senate Veterans' Affairs	Manufacturing, and Trade hearing 5/24/2016 Full committee hearing 5/24/2016 Full committee hearing 5/24/2016 Full committee hearing 5/24/2016 Full committee hearing 5/24/2016
<u>S. 2896</u>	Care Veterans Deserve Act of 2016	Sens. McCain [R-AZ]; Graham [R-SC]; Flake [R-AZ]; Tillis [R-NC]; Cornyn [R-TX]; Ayotte [R-NH]; Ernst [R-IA]; and Cruz [R-TX]	Senate Veterans' Affairs	Full committee hearing 5/24/2016
H.R. 5273/ H.R. 441/ H.R. 672/ H.R. 2506/ H.R. 2580/ H.R. 3291/ H.R. 5268/ S. 202/ S. 607	Helping Hospitals Improve Patient Care Act of 2016	Reps. Tiberi [R-OH-12] and McDermott [D- WA-7]	Ways & Means; Energy & Commerce	Passed Ways & Means Committee 5/24/2016
H.R. 5343	A bill to require increased reporting regarding certain scheduled surgeries at medical facilities of the VA.	Reps. Dingell [D-MI-12] and Walberg [R-MI-7]	House Veterans' Affairs	Introduced 5/26/2016
H.R. 5344	Organ Donation Clarification Act of 2016	Rep. Cartwright [D-PA-17]; Grijalva [D-AZ-3]; Honda [D-CA-17]; Johnson [D-TX-30], Polis [D-CO-2]; Rangel [D-NY-13]; Young [R-AK]; Marino [R-PA-10], Posey [R-FL-8]	Energy & Commerce	Introduced 5/26/2016
H.R. 5362	A bill to provide a higher Federal matching rate for increased expenditures under Medicaid for mental	Rep. Kennedy [D-MA-4]	Energy & Commerce	Introduced 5/26/2016

	and behavioral health services.			
H.R. 5327	To reauthorize and improve programs related to mental health and substance use disorders.	Reps. Kuster [D-NH-2] and Mooney [R-WV-2]	Energy & Commerce	Introduced 5/25/2016
H.R. 5331	To provide for behavioral health infrastructure improvements under the Medicaid program.	Reps. B. Lujan [D-NM-3]; Kennedy [D-MA-4]; M. Lujan [D-NM-1]; Napolitano [D-CA-32]; and Clarke [D-NY-9]	Energy & Commerce	Introduced 5/25/2016
H.R. 3956	VA Health Center Management Stability and Improvement Act	Reps. Bost [R-IL-12]; Costa [D-CA-16]; Davis [R-IL-13]; and Swalwell [D-CA-15]	House Veterans' Affairs; Senate Veterans' Affairs	Passed House and referred to Senate Committee on Veterans' Affairs 5/24/2016
H.R. 3989	Support Our Military Caregivers Act	Rep. Stefanik [R-NY-21]	House Veterans' Affairs; Senate Veterans' Affairs	Passed House and referred to Senate Committee on Veterans' Affairs 5/24/2016
H.R. 2460	To improve the provision of adult day health care services for veterans.	Rep. Zeldin [R-NY-1]	House Veterans' Affairs; Senate Veterans' Affairs	Passed House and referred to Senate Committee on Veterans' Affairs 5/24/2016

REGULATORY UPDATE

DEPARTMENT OF HEALTH AND HUMAN SERVICES May 20

OIG Releases Reports

- Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented.
- *Medicaid: Vulnerabilities Related to Provider Enrollment and Ownership Disclosure.*

May 23

VA Secretary Robert McDonald <u>Compares</u> the VA Health Care Wait Times to the Wait Times at Disney Theme Parks.

HHS Secretary Sylvia Burwell <u>Details</u> Plan to Use the Nonrecurring Expenses Fund for Certain Investments in a Letter to Subcommittee on Labor, Health and Humans Services, Education, and Related Agencies Chairman Tom Cole (R-OK).

May 24

CMS Releases 2013 Medicare Current Beneficiary Survey Public Use File.

CDC <u>Solicits</u> Nominations for Membership on the Advisory Committee on Immunization Practices.

AHRQ <u>Issues</u> the Patient Safety and Quality Improvement Act of 2005—Guidance Regarding Patient Safety Work Product and Providers' External Obligations.

May 24

CMS Acting Principal Deputy Administrator and Chief Medical Officer Patrick Conway <u>Blogs</u> on the Release of a Request for Proposal for Hospital Improvement and Innovation Networks.

CMS Acting Administrator Andy Slavitt <u>Participates</u> in a Forum on Bringing Technological Advances to Medicaid.

May 26

NIH to <u>Award</u> \$142 Million to Establish World's Largest Research-Cohort Biobank as Part of the Precision Medicine Initiative.

OTHER UPDATE

May 24

GAO Releases Report, <u>Medicare Program: Continued Action Required to Address Weaknesses in Provider and Supplier Enrollment Controls.</u>

14 Attorneys General Sent a Letter Urging Congress to Remove the Annual Rider in the Appropriations Bill Barring the Use of CDC Funds to Advocate or Promote Gun Control, and to Provide CDC Funding to Study Gun-Related Injuries and Death.

UPCOMING EVENTS

CONGRESSIONAL HEARINGS/MARKUPS

SENATE

Military Construction, Veterans' Affairs & Related Agencies

Review of the VA Electronic Health Record Network (VistA)

• June 8| 10:30 a.m. 124 Dirksen Senate Office Building

DEPARTMENT OF HEALTH AND HUMAN SERVICES

<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

Advisory Commission on Childhood Vaccines Meeting

Updates from The Division of Injury Compensation Programs, Department of Justice, National Vaccine Program Office, Immunization Safety Office, National Institute of Allergy and Infectious Diseases and Center for Biologics, Evaluation and Research.

June 3 | 9 a.m. – 12:30 p.m.
 Fishers Lane Conference Center
 Conference Room o8SWo1
 5600 Fishers Lane
 Rockville, MD 20857

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

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

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 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> <u>Committee Meeting</u>

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.

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

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

<u>Public Meeting for the Laboratory Payment</u> <u>for New Clinical Test Codes for 2017</u>

The Panel will gather information regarding new and reconsidered Clinical Laboratory Fee Schedule services, and make preliminarily recommendations.

July 18 | TBD
 CMS Main Auditorium
 Central Building
 7500 Security Boulevard
 Baltimore, MD 21244

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

OTHER

<u>Value Assessment 2.0: The Next Generation</u> of Tools to Address the Patient Perspective

Registration required.

• June 1 | 4 p.m. – 5 p.m. Webinar

E-Cigarettes and Public Health: What's Next After the FDA Rule?

• June 2 | 10 a.m. – 12 p.m. American Enterprise Institute 1150 17th Street, NW Washington, DC 20036

<u>Preventing the Next Pandemic: A</u> Conversation with the World Bank President

Discussion on what additional investments in global health are essential to better protect the world from the spread of pandemics and promote stable economies, including the launch of a Pandemic Emergency Financing Facility in late May at the G7 Summit in Japan.

June 2 | 11 a.m. - 12 p.m.
 CSIS Headquarters
 1616 Rhode Island Ave., NW
 Washington, DC 20036