

## LEGISLATIVE AND REGULATORY UPDATE

June 13, 2016

### Week in Brief

CMS [Releases Final Rule](#) Addressing Modifications to the Medicare Shared Savings Program's Benchmarking Methodology, an Alternative Participation Option to Encourage ACOs to Enter Performance-Based Risk Arrangements Earlier, and Administrative Finality of Financial Calculations.

GAO [Releases](#) a Report Recommending that HHS Take Actions to Improve the Medicare Fee-for-Service Appeals Process.

## WHITE HOUSE UPDATE

### June 5

President Obama [Opposes](#) Privatizing the Department of Veterans Affairs, Claims It Would Delay Progress.

### June 6

Vice President Joe Biden [Addresses](#) the Cancer Moonshot Initiative at the American Society of Clinical Oncology Annual Meeting.

## LEGISLATIVE UPDATE

### June 6

Senate Special Committee on Aging Chairman Susan Collins (R-ME) and Ranking Member Claire McCaskill (D-MO) [Write](#) to Five Pharmaceutical Companies Seeking Information on Efforts to Preserve Access to Opioid Overdose Reversal Drug.

House Energy & Commerce Committee Chairman Fred Upton (R-MI) [Supports](#) the FDA's Simplification and Clarification of Compassionate Use Policies.

House Ways & Means Social Security Subcommittee Chairman Sam Johnson (R-TX) and Health Subcommittee Chairman Pat Tiberi (R-OH) [Sent](#) a Second Letter to Treasury Secretary Requesting Social Security and Medicare Annual Financial Status Reports.

## June 7

Senate Labor, Health and Human Services, and Education Appropriations Subcommittee Approves the \$161.9 Billion FY2017 Labor-HHS Appropriations Bill.

House Unanimously Passes the *Helping Hospitals Improve Patient Care Act* (H.R. 5273).

## June 8

Senate Agrees to Negotiate with House on Zika Virus Response Package.

Senate Finance Committee Considers Two Social Security and Medicare Trustee Nominations.

House Energy & Commerce Subcommittee on Health Advances the *Strengthening Public Health Emergency Response Act of 2015* (H.R. 3299) and the *Sports Medicine Licensure Clarity Act of 2015* (H.R. 921).

## June 9

House Energy & Commerce Committee Chairman Fred Upton (R-MI) and Ranking Member Frank Pallone, Jr. (D-NJ) Introduce the *FDA Cross-Center Collaboration Act of 2016* (H.R. 5414).

## June 10

House Energy & Commerce Subcommittee on Health Holds Hearing to Examine Ways to Advance Patient Solutions to Lower Costs and Strengthen Care.

## LEGISLATIVE TRACKING

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<u>S. 3019</u>	<i>TRICARE Expedited Evaluation and Treatment for Prenatal Surgery Act of 2016</i>	Sen. Rounds [R-SD]	Armed Services	Introduced 6/6/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<a href="#"><u>H.R. 5395</u></a>	<i>Expanding Capacity for Health Outcomes (ECHO) Act</i>	Reps. Burgess [R-TX-6] and Matsui [D-CA-6]	Energy & Commerce	Introduced 6/7/2016
<a href="#"><u>H.R. 5396</u></a>	<i>Medicare Dental, Vision, and Hearing Benefit Act of 2016</i>	Reps. McDermott [D-WA-7]; Conyers [D-MI-13]; Cummings [D-MD-7]; Dingell [D-MI-12]; Grayson [D-FL-9]; Schakowsky [D-IL-9]; Blumenauer [D-OR-3]; and Pingree [D-ME-1]	Ways & Means; Energy & Commerce	Introduced 6/7/2016
<a href="#"><u>H.R. 921 / S. 689</u></a>	<i>Sports Medicine Licensure Clarity Act of 2015</i>	Reps. Guthrie [R-Ky-2]; Richmond [D-LA-2]; and Womack [R-AR-3]	Energy & Commerce; Judiciary	House Energy & Commerce markup; Reported out with amendment in the nature of a substitute 6/8/2016
<a href="#"><u>H.R. 3299</u></a>	<i>Strengthening Public Health Emergency Response Act of 2015</i>	Reps. Brooks [R-IN-5] and Eshoo [D-CA-18]	Energy & Commerce	House Energy & Commerce markup; Reported out with amendment in the nature of a substitute 6/8/2016
<a href="#"><u>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</u></a>	<i>Helping Hospitals Improve Patient Care Act of 2016</i>	Reps. Tiberi [R-OH-12] and McDermott [D-WA-7]	Ways & Means; Energy & Commerce	Passed House and referred to Senate Committee on Finance 6/8/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<a href="#"><u>H.R. 5403</u></a>	A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to liability under State and local requirements respecting devices	Reps. Fitzpatrick [R-PA-8] and Slaughter [D-NY-25]	Energy & Commerce	Introduced 6/8/2016
<a href="#"><u>H.R. 5404</u></a>	A bill to amend the Federal Food, Drug, and Cosmetic Act to require physicians and physician's offices to be treated as covered device users required to report on certain adverse events involving medical devices, and for other purposes	Reps. Fitzpatrick [R-PA-8]; Slaughter [D-NY-25]; and Zinke [R-MT-At Large]	Energy & Commerce	Introduced 6/8/2016
<a href="#"><u>H.R. 5406</u></a>	A bill to amend the Indian Health Care Improvement Act to improve access to tribal health care by providing for systemic Indian Health Service workforce and funding allocation reforms, and for other purposes	Reps. Noem [R-SD-At Large]; Ashford [D-NE-2]; Smith [R-NE-3]; Fortenberry [R-NE-1]; Cramer [R-ND-At Large]; and McCollum [D-MN-4]	Natural Resources; Energy & Commerce; Ways & Means	Introduced 6/8/2016

BILL NUMBER/ RELATED BILLS	TITLE or SHORT SUMMARY	ORIGINAL SPONSOR(S)	COMMITTEES	LATEST ACTION
<a href="#"><u>H.R. 5411</u></a>	A bill to amend title XIX of the Social Security Act to provide under the State plan under the Medicaid program early and periodic screening, diagnostic, and treatment services to individuals under 21 who are receiving services in institutions for mental diseases	Reps. Kennedy [D-MA-4]; Schakowsky [D-IL-9]; Tonko [D-NY-20]; and Matsui [D-CA-6]	Energy & Commerce	Introduced 6/8/2016
<a href="#"><u>H.R. 5414</u></a>	A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for establishment of one or more Intercenter Institutes within the FDA for a major disease area or areas, and for other purposes	Reps. Upton [R-MI-6] and Pallone [D-NJ-6]	Energy & Commerce	Introduced 6/8/2016
<a href="#"><u>S. 3035</u></a>	A bill to require the Secretary of Veterans Affairs to carry out a pilot program to increase the use of medical scribes to maximize the efficiency of physicians at medical facilities of the VA	Sens. Heller [R-NV] and Tester [D-MT]	Veterans' Affairs	Introduced 6/8/2016
<a href="#"><u>H.R. 5431</u></a>	Expanding Care for Female Veterans Act	Reps. Israel [D-NY-3] and Zeldin [R-NY-1]	Veterans' Affairs	Introduced 6/9/2016

# REGULATORY UPDATE

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### June 1

The Center for Medicaid and CHIP Services (CMCS) [Issues](#) an Informational Bulletin on Medicaid Benefits Available for the Prevention, Detection, and Response to the Zika Virus.

### June 6

FDA [Announces](#) Opportunity for Public Comment on the Proposed Information Collection on Human Tissue Intended for Transplantation.

The National Cancer Institute [Launches](#) the Genomic Data Commons to Promote Sharing of Genomic and Clinical Data Between Researchers.

### June 7

OIG [Releases](#) Report, *Observations from Our Review of CMS's Administration of the First Performance Year of the Pioneer Accountable Care Organization Payment Model*.

### June 8

CMS [Implements](#) a New Pre-Claim Review Demonstration of Home Health Services in Five States.

### June 9

HHS [Releases](#) Proposed Semiannual Regulatory Agenda Presenting the Rulemaking Activities that HHS Expects to Undertake.

### June 10

ASPE [Releases](#) Issue Brief, *Impact of the Affordable Care Act Coverage Expansion on Rural and Urban Populations*.

CMS [Launches](#) Round Two of the Support and Alignment Networks Under the Transforming Clinical Practice Initiative to Help Clinicians Prepare for the Proposed Quality Payment Program.

HRSA [Seeks](#) Nominations for Appointment to the National Advisory Council on Migrant Health.

The Office of Minority Health [Seeks](#) Nominations for Appointment to the Advisory Committee on Minority Health.

## OTHER UPDATE

### GAO Releases Reports,

- [\*VA's Health Care Budget: In Response to a Projected Funding Gap in Fiscal Year 2015, VA Has Made Efforts to Better Manage Future Budgets.\*](#) (June 3)
- [\*VA Health Care: Improvements Needed for Management and Oversight of Sole-Source Affiliate Contract Development.\*](#) (June 6)

**June 12**

UnitedHealth Group [Announces](#) New Policy to Reimburse Travel Costs for Kidney Donors.

## UPCOMING EVENTS

### CONGRESSIONAL HEARINGS/MARKUPS

#### SENATE

##### **Homeland Security and Governmental Affairs**

##### [America's Insatiable Demand for Drugs: Examining Alternative Approaches](#)

- June 15 | 10 a.m.  
342, Dirksen Senate Office Building

#### HOUSE

##### **Energy & Commerce**

##### [Combating Superbugs: U.S. Public Health Responses to Antibiotic Resistance](#)

- June 14 | 10 a.m.  
2123 Rayburn House Office Building

##### [Helping Families in Mental Health Crisis Act \(H.R. 2646\) Markup](#)

- Opening Statements: June 14 | 5 p.m.  
2123 Rayburn House Office Building
- Full Markup: June 15 | 10 a.m.  
2123 Rayburn House Office Building

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### [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

##### [CMS Special Open Door Forum: Pre-Claim Review Demonstration for Home Health Services](#)

Opportunity for home health agencies, physicians, and other interested parties to learn about the demonstration.

- June 14 | 2 p.m. – 3 p.m.  
Via conference call

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 IOM Committee on a National Strategy for the Elimination of Hepatitis B and C; and workgroup updates.

- 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.

- 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

Forum for inpatient rehabilitation facilities and stakeholders to provide suggestions regarding updates to the tier comorbidity portion of IRF 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

Physician Compare Initiative Call

Opportunity to learn about the Physician Compare.

- June 16 | 1:30 p.m. – 3 p.m.  
Conference call

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, 6<sup>th</sup> Floor  
31 Center Drive  
Bethesda, MD 20892

Kidney Interagency Coordinating 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



## WHITE HOUSE

### White House Organ Summit

Discussion on future actions to continue to improve outcomes for individuals waiting for organ transplants and support for living donors.

- June 13 | 10:30 a.m. – 12:30 p.m.  
Via webcast

## OTHER

### Rethinking the Future: The Opportunities of Longevity

- June 14 | 9 a.m. – 12 p.m.  
Urban Institute  
2100 M Street, NW.  
5<sup>th</sup> Floor  
Washington, DC 20037

### Chronic Care: Getting its Complexity and Cost Under Control

- June 15 | 10 a.m. – 11 a.m.  
The Brookings Institute  
Falk Auditorium  
1775 Massachusetts Ave., NW  
Washington, DC 20036

### Global Health: Patient Safety, Cancer Care, Universal Health Coverage and Innovation

- June 14 | 9 a.m. – 12:30 p.m.  
National Press Club  
529 14<sup>th</sup> Street, NW.  
13<sup>th</sup> Floor  
Washington, DC 20045

### Patient Expectations and the Accountability Gap

- June 15 | 12:30 p.m. – 3:30 p.m.  
Kaiser Permanente Center for Total Health  
700 2<sup>nd</sup> Street, NE  
Washington, DC 20003