

Alexander Hecht, AHecht@mlstrategies.com Andrew Shin, AJShin@mlstrategies.com Abby Matousek, AMatousek@mlstrategies.com

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ML Strategies, LLC 701 Pennsylvania Avenue, N.W. Washington, DC 20004 USA 202 434 7300 202 434 7400 fax www.mlstrategies.com

April 27, 2015 **Health Care Update**

House E&C Proceeds with Cures Initiative this Week: At the end of last week, the House Energy and Commerce Committee announced it will release in the coming days a new draft version of the 21st Century Cures Initiative legislation. As part of the unveiling, the Committee said it will hold a hearing on April 30th to hear testimony from National Institute of Health (NIH) and Food and Drug Administration (FDA) officials on the draft proposal. Dr. Kathy Hudson, Deputy Director for Science, Outreach, and Policy at the National Institutes of Health, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the Food and Drug Administration, and Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health at the FDA, will testify.

Speaking earlier in the week, Representative Diana DeGette (D-CO), who is working closely with Chairman Fred Upton (R-MI) on the initiative, said that the Committee and staff have been working closely with the FDA on various aspects of the legislation, including over democratic and industry concerns over certain clinical trial language. Chairman Upton has praised the initiative and has said he hopes to have legislation on the House floor by June.

As the House prepares for work on the new 21st Century Cures draft, on Friday a bipartisan group of Senators introduced legislation in the Senate which touches on portions of the 21st Century Cures Initiative. Senators Michael Bennet (D-CO), Richard Burr (R-NC), and Orrin Hatch (R-UT) introduced the Advancing Breakthrough Devices for Patients Act, which builds on legislation passed by the same group in 2012 and which provides for expedited review of breakthrough medical devices and products.

Congress Continues Budget Considerations; Health Care Playing Leading Role: Even as Committees continue to meet on portions of the FY 2016 budget—with Senate Appropriations convening this week to consider the NIH budget—the Senate Budget Committee and the House Budget Committee met for a FY 2016 Budget Conference last week. Health care issues topped the agenda at the hearing, with lawmakers debating budget proposals that could cut Medicare and Medicaid. Additionally, some lawmakers brought up a potential strategy to use reconciliation to defund the ACA—an issue that very much remains in play, notwithstanding the fact that President Obama would veto any such legislation. Interestingly, Senate Republicans rejected a GOP House proposal that would transition Medicare into a voucher program while they remained open to decreasing spending on Medicaid and food stamp programs in the first round of negotiations.

Implementation of the Affordable Care Act

CMS Updates Coverage Numbers After Tax Season: After the tax season special enrollment period, the Centers for Medicare and Medicaid Services (CMS) announced that over 68,000 Americans enrolled for health care coverage through April 13th.

Other Federal Regulatory Initiatives

CMS Guidance on 2016 Exchange Eligibility: CMS released guidance for exchange eligibility redeterminations and re-enrollments for the 2016 plan year.

CMS Releases 2016 Payments for Inpatient Rehabilitation Facilities: CMS issued a proposed rule outlining proposed FY 2016 Medicare payment policies and rates for the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS) and the IRF Quality Reporting Program (IRF QRP). According to the Administration, the rule increases payments for these facilities by 1.7 percent in 2016.

CMS 2016 Payments Policies for Inpatient Psychiatric: CMS issues a proposed rule to govern the FY 2016 Medicare payment policies and rates for the Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS). According to the Administration, the proposal would increase payment to psychiatric hospitals by \$80 million.

CMS Evaluated eRx Participation: CMS announced in a blog post that it paid out over \$168 million in incentives to more than 377,000 eligible professionals for electronic prescribing in 2013.

CMS Extends Protections to Ebola Drugs: CMS published a notice of declaration in the federal register that would "provide liability protection for activities related to Ebola Virus Disease Therapeutics." The declaration, specifically dealing with ZMapp, lasts 12 months.

Murthy Sworn in as Surgeon General: Vice President Biden presided over a swearing in ceremony for Dr. Vivek Murthy to serve as the U.S. Surgeon General. In his remarks, Murthy outlined three important goals during his time as surgeon general: combatting misinformation, shifting from a culture of treatment to one of prevention, and curbing dangerous habits to one's health such as smoking.

GAO Report on Medicare Smart Cards: A new Government Accountability Office (GAO) report found that CMS could use electronically readable cards in Medicare for a number of different purposes, including: authenticating beneficiary and provider presence at the point of care, electronically exchanging beneficiary medical information, and electronically conveying beneficiary identity and insurance information to providers.

HHS OIG Recommendations Could Have Saved Millions: A new report from the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that CMS could have reduced Medicare spending on infusion drugs by \$251 million over 18 months by implementing recommendations made by the OIG in a February 2013 report.

CDC Report on Expanding Naloxone Use: The Centers for Disease Control (CDC) released a report finding that allowing more basic emergency medical service (EMS) staff to administer naloxone could reduce drug overdose deaths that involve opioids

VA Creates Health Advisory Group: The Department of Veterans Affairs announced a new eleven member Special Medical Advisory Group (SMAG) composed of leading medical experts to assist the VA in health care delivery to veterans.

ONC Blog Post on Health IT Efforts: The head of the Office of the National Coordinator for Health IT (ONC) Karen DeSalvo wrote a blog post detailing her perspective on the national health IT landscape. DeSalvo writes about incentivizing interoperability, standardization, and creating expectations for data security and privacy.

Congressional Initiatives

Upton and DeGette on 21st **Century Cures:** Chairman Fred Upton (R-MI) and Representative Diana DeGette (D-CO) met with patient advocacy groups, medical students and faculty, and innovators in Michigan to discuss the 21st Century Cures initiative.

House Approves Prescription Drug Bill: The House approved H.R. 471, the Ensuring Patient Access and Effective Drug Enforcement Act of 2015, which would clarify the Controlled Substances Act "to establish clear and consistent enforcement standards and promotes collaboration among government agencies, patients, and industry stakeholders to ensure patients have access to medications."

Senate Commerce Committee on Telehealth: The Senate Commerce Subcommittee on Communications, Technology, Innovation, and the Internet met to consider testimony from industry groups, stakeholders, and regulators on advancing telehealth through connectivity. Notably, Chairman Wicker said he and Senator Cochran would be reintroducing the Telehealth Enhancement Act, which would expand the use of Telehealth technology to improve health care for seniors and other patients in underserved areas.

Senate Finance Probes Device Tax: The Senate Finance Subcommittee on Health Care held a hearing to consider the effects of the 2.3 percent tax on medical devices that was included in the ACA. Republican lawmakers have long been opposed to the tax, which is expected to raise approximately \$30 billion over ten years.

House E&C Subcommittee on Opioid Abuse: The House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing to consider the perspectives of professional and academic experts on opioid abuse—including hearing testimony on treatment options, emerging treatment practices, and support for those who become addicted.

Senate Appropriations Hearing on HHS Budget: The Senate Appropriations Subcommittee on Labor, Health And Human Services, Education, and Related Agencies Subcommittee met to review the fiscal year 2016 funding request and budget justification for HHS. During the hearing, Senate Health, Education, Labor, and Pensions Committee Chairman Lamar Alexander (R-TN) announced that he and Ranking Member Patty Murray (D-WA) have formed a bipartisan working group on electronic health record use.

Senate Small Business Votes on ACA Subpoena Request: The Senate Small Business Committee voted down a request by Chairman David Vitter (R-LA) to subpoena documents related to congressional staff health insurance under the ACA.

Senate Approves Home Care Demo Bill: The Senate approved S. 971, the Independence at Home Act, a bipartisan two-year extension of a demonstration project to deliver care to chronically ill seniors in their homes.

Senator Bennet Pushed FDA on LDT Regulations: In a letter to the Acting FDA Commissioner Stephen Ostroff, Senator Michael Bennet (D-CO) said, as the agency moves forward with regulating laboratory developed tests (LDTs), he urges "the Administration to evaluate and clearly articulate the effect this ruling might have on both medical innovation and patient access."

Other Health Care News

Poll on Public Health Priorities: According to a poll conducted by the Kaiser Family Foundation, favorable opinions of the ACA slightly exceeded negative opinions, with 43 percent of the U.S. in favor of the law and 42 percent against it.

Industry Groups write Congress on Medicare Cuts: The American Hospital Association, the American Medical Association, the American Health Care Association and the National Association for Home Care and Hospice wrote to the House and Senate in opposition to extending Medicare sequestration to 2024 in order to pay for the Trade Adjustment Assistance (TAA) program.

PCORI Announces Research Grants: The Patient-Centered Outcomes Research Institute (PCORI) Board of Governors announced the approval of over \$120 million to fund 34 patient-centered clinical comparative clinical effectiveness research (CER) studies on a range of conditions and patient populations.

White Paper on Health of Children in Need: A white paper put together by Samsung Innovation Center at Children's Health Fund examines the health gap for children that live in poverty. The paper also provides an overview of technologies that can help improve care and access to care.

Report on Food Stamp Enrollment: The Associated Press released an analysis of the ACA's effect on food stamp

enrollment. The report found that streamlined enrollment as a result of the ACA caused food stamp demand to increase in 11 states between 2013 and 2014.

Upcoming Congressional Hearings

Senate

On Tuesday, April 28th, the Senate Health, Education, Labor and Pensions Committee will hold a hearing titled "Continuing America's Leadership: The Future of Medical Innovation for Patients."

On Tuesday, April 28th, the Senate Finance Committee will hold a hearing titled "Creating a More Efficient and Level Playing Field: Audit and Appeals Issues in Medicare."

On Wednesday, April 29th, the Senate Small Business and Entrepreneurship Committee will hold a hearing titled "King vs Burwell Supreme Court Case and Congressional Action that can be taken to Protect Small Businesses and their Employees"

On Wednesday, April 29th, the Senate Committee on Veterans' Affairs will hold a hearing titled, "GAO's High Risk List and the Veterans Health Administration."

On Thursday, April 30^{th} , the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies will hold a hearing on the NIH budget request.

House

On Wednesday, April 29th, the House Education and the Workforce Subcommittee on Health, Employment, Labor and Pensions will hold a hearing titled, "Examining Reforms to Modernize the Multiemployer Pension System."

On Thursday, April 30^{th} , the House Energy and Commerce Subcommittee on Health will hold a legislative hearing on 21^{st} Century Cures.

On Thursday, April 30^{th} , the House Veterans' Affairs Committee will hold a hearing titled, "Examining Access and Quality of Care and Services for Women Veterans."

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