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Health Care Update

Changes Ahead for Health Policy In 2015: Last week ended with an announcement that Centers for Medicare & Medicaid Services (CMS) Administrator Marilyn Tavenner will leave the agency in February. Tavenner has served at the agency for over six years as Administrator.

Current Department of Health and Human Services (HHS) Deputy Administrator Andy Slavitt will take over Tavenner's role at CMS. Slavitt, who joined HHS after 20 years of private sector experience, including at UnitedHealth Group and Optum, will take charge of the agency as it is faced with a number of key challenges—including a Republican Congress which will much more aggressively pursue changes to the ACA and the upcoming Supreme Court ruling in *King v. Burwell*—which could potentially have a tremendous impact on ACA subsidies. ML Strategies and Mintz Levin have described the implications of *King v. Burwell* in greater detail in our alert, [On the Verge of Melt-Down: Core of ACA at Risk and Remedial Options Scant If Supreme Court Rules Against Government in King v. Burwell](#).

The Tavenner announcement follows several other high-profile departures that have played prominent roles in implementing the ACA and other health policy initiatives for the past six years. Looking ahead towards 2015, additional personnel changes and policy initiatives, especially from the new Congress, are sure to keep stakeholders on their toes.

In a special 114th Congressional [Outlook](#), the [health care and life sciences team at ML Strategies](#) takes an in-depth look at some of these issues, including Congress' approach to the ACA and the implications of *King v. Burwell*.

With Republicans controlling both Chambers of Congress for the first time since passage of the Affordable Care Act (ACA), health care priorities in the 114th Congress will likely reflect this new majority. We predict a focus on changes to the health law—some of which could very well be bipartisan—another run at sustainable growth rate (SGR) reform, the continuation of the 21st Century Cures Initiative, payment and delivery system reform, and telehealth, health IT, and promoting the role of innovative health care technology.

The full Outlook piece can be viewed [here](#). In addition to health and life sciences issues, the ML Strategies team forecasts issues related to appropriations, defense and national security, energy and the environment, financial services, telecommunications, trade, and more.

Implementation of the Affordable Care Act

HHS Reports 6.8 Million Enrolled through ACA: HHS [announced](#) that 6.8 million people selected a plan or were automatically re-enrolled in the Federally Facilitated Marketplace since the beginning of Open Enrollment on November 15th.

Burwell Speech on Health Policy: Secretary Burwell [delivered a speech](#) focusing on “common values, interests and priorities with Congress to deliver impact on health care for the American people.”

Other Federal Regulatory Initiatives

ONC Meets on Standards Implementation: The Office of the National Coordinator for Health IT (ONC) [met](#) for a meeting titled, “Standards: Implementation, Certification and Testing Workgroup.” The meeting included consideration of Congressional provisions for health IT.

CDC Finds Hospital Acquired Infection (HAI) Progress: The Centers for Disease Control (CDC) [released](#) the *National and State Healthcare-Associated Infections Progress Report*. The report found reductions at the national level for 2013 for nearly all infections.

FDA Guidance on Wellness Products and Devices: The FDA released [guidance](#) saying it does not plan to regulate general wellness IT products “designed to maintain or encourage a general state of health.” Separate [guidance](#) was also released outlining a certain amount of regulatory authority for accessories that work with such medical devices. An accessory is defined as “a device that is intended to support, supplement, and/or augment the performance” of a larger device.

Congressional Initiatives

Upton and DeGette Cures Op-Ed: House Energy and Commerce Chairman Fred Upton (R-MI) and Representative Diana DeGette (D-CO), leaders of the 21st Century Cures Initiative, published an [op-ed](#) outlining the findings and goals of the initiative’s review so far, including: modernizing clinical trials, integrating patients into the regulatory process, promoting access to and sharing of information, investing in science, and incentivizing new drugs and devices for unmet needs.

House E&C Members Float Telehealth Draft: Eight members of the House Energy and Commerce Committee—Representatives Gregg Harper (R-MS), Peter Welch (D-VT), Bob Latta (R-OH), Greg Walden (D-OR), Doris Matsui (D-CA), Bill Johnson (R-OH), and Chairman Fred Upton (R-MI) and Ranking Member Frank Pallone (D-NJ)—floated a discussion draft of legislation, “Advancing Telehealth Opportunities in Medicare.” The text aims to ease Medicare restrictions on telemedicine payments as long as the services meet certain requirements, such as servicing unmet needs or reducing costs.

Hatch Introduced Medical Device Bill: Senator Orrin Hatch (R-UT), Chairman of the Senate Finance Committee, introduced legislation to repeal the ACA’s medical device tax. Senators Pat Toomey (R-PA), Richard Burr (R-NC), Rob Portman (R-OH), Dan Coats (R-IN), Amy Klobuchar (D-MN), Joe Donnelly (D-IN), Al Franken (D-MN), Bob Casey (D-PA), and Jeanne Shaheen (D-NH) cosponsored the legislation.

Ellmers Reintroduced Flex-IT Act: Representative Renee Ellmers (R-NC) [reintroduced](#) the Flexibility in Health IT Reporting (Flex-IT) Act of 2015. The bill allows providers the option to choose any three-month quarter for an EHR reporting period to qualify for the Meaningful Use Program in 2015, as opposed to a full year.

House Passed Firefighter Exemption Bill: The House [passed](#) the Protecting Volunteer Firefighters and Emergency Responders Act, a bill which would exempt emergency-service personnel from consideration as full-time employees under the employer mandate.

McDermott on End-of-Life Issues: Representative Jim McDermott (D-WA) gave a [TED Talk](#) on end-of-life issues. The talk, “Don’t Take Death Lying Down,” focused on advanced directives and reimbursement for end-of-life discussions.

Cassidy Introduces Two Obamacare Repeal Bills: On January 13th, Senator Bill Cassidy (R-LA) introduced two bills ([S. 157](#) and [S. 158](#)) that would repeal provisions of the ACA, including the medical device tax, employer mandate, and individual mandate, and would also allow plans currently in the group market to be offered through 2018.

Other Health Care News

Ebola Vaccines Approach West Africa Trials: The World Health Organization (WHO) [announced](#) that two Ebola vaccines being developed have been deemed appropriate for clinical trial testing in West Africa. One vaccine has been developed by GlaxoSmithKline working with the National Institutes of Health, the other vaccine by Merck and NewLink Genetics.

Tennessee Continues Telehealth Work: The Tennessee Board of Medical Examiners [met](#) to continue the state's review of its telemedicine practice rules.

Paper on U.S. Influence on Medical Research: A [paper](#) published in the Journal of the American Medical Association found that reductions in scientific investments in the United States have led to less influence in scientific discoveries and innovations.

IOM urges sharing of clinical trial data: In a [report](#), the Institute of Medicine (IOM) urged researchers to release clinical trial data within six months of publication, citing the issue that withholding data slows research efforts. The IOM also says that measures to protect IP and grant proper academic credit will be important to encourage data sharing.

Upcoming Congressional Hearings

Senate

On January 22nd, the Senate Health, Education, Labor, and Pensions (HELP) Committee will hold a [hearing](#) titled, "Examining Job-Based Health Insurance and Defining Full-Time Work."

House

On January 21st and 22nd, The House Energy and Commerce Subcommittee on Health will hold a two-day [hearing](#) to discuss how to bring Sustainable Growth Rate (SGR) reform to the President's desk before the current patch expires at the end of March 2015.

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