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## Health Care Update

- **21<sup>st</sup> Century Cures Remains Top Bi-Partisan Priority for 2015:** House Energy and Commerce Committee Chairman Fred Upton (R-MI) reiterated his intent to push for a bi-partisan 21<sup>st</sup> Century Cures Initiative bill in early 2015. Rep. Upton recently remarked that the bill(s) would be on the House floor for a vote before Memorial Day and on the President's desk by the end of next year. Upton's timeline includes outreach to the Senate in December and a discussion draft introduced as early as January in the new Congress. Foreshadowing components of the legislation, Upton said the bill could contain additional research funding for the National Institutes of Health (NIH), provisions to further drug and device development, and structural changes for the FDA.
- **Senate Passes Critical Access Hospital Direct Supervision Bill:** On November 20<sup>th</sup>, the Senate passed H.R. 4067, a bill to delay Medicare's enforcement of critical access hospital (CAH) direct supervision rules for outpatient services in 2014. The bill, which was already passed by the House in September, now heads to the President's desk. The legislation, sponsored by Representative Lynn Jenkins (R-KS) in the House and Senator Jerry Moran (R-KS), exempts CAHs from requirements that a supervising physician must be present in a department whenever a Medicare beneficiary is receiving outpatient services. While the legislation only extends the exemption through the end of 2014, Senator Moran has also introduced legislation—S. 1143, the Protecting Access to Rural Therapy Services (PARTS) Act—which would create a permanent fix. In addition, the discussion draft floated last week by House Ways and Means Subcommittee on Health Chairman Kevin Brady (R-TX) includes language to delay direct supervision requirements for an additional year.

## Implementation of the Affordable Care Act

**OPM Releases Multi-State Plan Rule:** The Office of Personnel Management (OPM) released a [proposed rule](#) to implement modifications to the multi-state plan (MSP) program to accommodate lessons learned from the program to date. The proposal revises MSP requirements and requirements for the insurance companies who offer the plans.

**HHS Releases 2016 Benefit and Payment Parameters:** The Department of Health and Human Services (HHS) issued its Notice of Benefit and Payment Parameters for 2016 [proposed rule](#). The proposal implements ACA provisions on payment parameters for issuers and Marketplaces, addresses risk corridors, user fees for the Health Insurance Marketplace, and essential health benefits and network adequacy. In addition, the proposal states that the Open Enrollment period beginning in 2016 would begin in October 1<sup>st</sup> and run through December 15<sup>th</sup> of the year prior to the benefit year.

## Other Federal Regulatory Initiatives

**CBO: \$144 Billion Price Tag for SGR Repeal:** The Congressional Budget Office (CBO) [found](#) that the Senate and House proposals for permanent doc fix replacement bills would cost \$144 billion over 10 years. If Congress were to freeze current payment rates through 2024, the cost would drop to \$118.9 billion.

**CMS Announces New Chief Data Officer:** The Centers for Medicare & Medicaid Services (CMS) [announced](#) the formation of the Office of Enterprise Data and Analytics (OEDA), which will be led by Niall Brennan, the agency's first Chief Data Officer (CDO). The office will be tasked with overseeing improvements in data collection and dissemination as the agency strives to be more transparent.

**HHS Proposes Rules on Clinical Trials:** HHS [issued](#) a notice of proposed rulemaking on reporting requirements for clinical trials. The proposed rule seeks to clarify requirements regarding registration for clinical trials and the submission of summary trial results to ClinicalTrials.gov. The rule also seeks to enlarge the scope of clinical trials that submit trial results to include trials of unapproved, unlicensed, and uncleared products.

**OIG Targets HIT as 2014 Challenge:** The HHS Office of Inspector General (OIG) [released](#) FY 2014 top management and performance challenges. Among the challenges identified, the agency found that "a lack of data exchange and incompatibility across systems presents challenges to achieving the benefits promised by EHRs and other health IT and could undermine the goals of some reform initiatives."

**First Round of ICD-10 Testing Begins:** Testing for the submission of ICD-10 coded claims to CMS will [begin](#) this week. It will last two more non-consecutive weeks, one in March and one in June.

**Medicaid, CHIP Enrollment Up:** CMS announced Medicaid and CHIP [added](#) 9.1 million enrollees since last fall. The increase comes mainly from states that expanded Medicaid, where enrollment is up 23 percent; in states that opted of expansion, enrollment is up 6 percent. As of September, CMS said 68 million people were enrolled in the two programs, which may be an underestimate, as many states have yet to report.

**CMS Announces Region IX Director:** HHS Secretary Burwell announced that Melissa Stafford will be Region IX Regional Director. The Region IX office is based in San Francisco, and works with officials in Arizona, California, Hawaii, Nevada, Guam, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Republic of Marshall Islands and the Republic of Palau.

## Congressional Initiatives

**House Energy and Commerce Leadership Solidified:** Representative Frank Pallone (D-NJ) will become Ranking Member of the House Energy and Commerce Committee. In addition, Chairman Fred Upton [announced](#) that Representative Joe Pitts (R-PA) will continue as Health Subcommittee Chairman and Representative Tim Murphy will serve as Oversight Subcommittee Chairman.

**House Presses CMS on Medicare Advantage:** A bipartisan group of House Members, led by Representatives Diane Black (R-TN) and Earl Blumenauer (D-OR), [wrote](#) to CMS Administrator Tavenner urging the agency to factor in socioeconomic and other characteristics of dual eligible beneficiaries when evaluating Medicare Advantage (MA) payment systems.

**Lawmakers Oppose Rural Hospital Provisions:** Twenty-seven bipartisan Senators [wrote](#) to President Obama in opposition to provisions in the Administrations FY2015 budget that would reduce payments to critical access hospitals and remove CAH special designation for facilities located within 10 miles of another hospital.

**Senators Ask to Prioritize Heart Disease:** Ten bipartisan women Senators [wrote](#) to HHS Secretary Burwell requesting that the agency pay closer attention to women's heart disease. The letter notes that women's heart treatment has largely been based on medical research on men; while 42 percent of women who have a heart attack die within a year compared to 24 percent of men.

**Republicans Write to Burwell on ACA Funds:** Senators Orrin Hatch (R-UT), Chuck Grassley (R-IA), and John Barrasso (R-WY) [wrote](#) to HHS Secretary Burwell with questions concerning recoupment of federal funds spent on failed state ACA exchanges.

**House E&C Leaders On Cures Panel:** Representatives Fred Upton (R-MI) and Diana DeGette (D-CO), leaders of the 21<sup>st</sup> Century Cures Initiative, participated on a panel of medical innovators and researchers at the 2014 [Partnering for Cures](#) event hosted by Faster Cures.

**House Oversight on ACA Enrollment Numbers:** Following press reports that HHS had inflated enrollment numbers in the ACA, the House Oversight and Government Reform [released](#) an analysis of enrollment data. The analysis shows that the agency included enrollment in dental plans in addition to medical plans in the advertised 7.3 million total. CMS publically announced that "individuals who had both Marketplace medical and dental coverage were erroneously counted in our recent announcements."

**House Ways and Means Draft Hospital Bill:** The House Ways and Means Committee released a [discussion draft](#) championed by Representative Kevin Brady. Collectively titled the Hospital Improvements for Payment (HIP) Act of 2014, the bill includes provisions related to hospital pay policies, health IT and data analytics, EHRs, Representative Paul Ryan's Expanding the Availability of Medicare Data Act, and bundled payments for hospitals. A section-by-section is available [here](#).

### Ongoing Ebola Response

**Senate HELP Passes Ebola Bill:** The Senate Health, Education, Labor, and Pensions Committee [passed](#) legislation to add Ebola to the FDA's Priority Review Voucher Program Act. A similar bill has been introduced in the House by Representatives Marsha Blackburn (R-TN) and Gene Green (D-TX).

**Health Subcommittee on Medical Development and Ebola:** The House Energy and Commerce Subcommittee on Health held a [hearing](#) to address efforts underway at the Biomedical Advanced Research and Development Authority (BARDA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) to develop medical products for diagnosis, prevention, and treatment of Ebola and how the Administration's \$6.18 billion emergency funding request would support these efforts.

**House E&C Subcommittee on Public Health and Ebola:** The House Energy and Commerce Subcommittee on Oversight and Investigations convened a [hearing](#) to discuss the U.S. public health response to the Ebola outbreak. The hearing, with witnesses from the CDC, HHS, the University of Nebraska Medical Center, and the Texas Department of State Health Services hearing focused on the Administration's emergency request for funding to respond to the Ebola outbreak in West Africa.

**Republican Lawmakers Introduce Visa Bills:** Senate and House Republicans [introduced](#) legislation that would put a temporary visa ban on residents or nationals of a country that is experiencing "widespread transmission of Ebola." The legislation is being sponsored by Senators Marco Rubio (R-FL), Chuck Grassley (R-IA), Pat Roberts (R-KS), John Thune (R-SD), and Mark Kirk (R-IL) and Representative Mike Kelly (R-PA).

### Other Health Care News

**Money Prize for Antibiotics Test:** The U.K foundation [Nesta](#) has announced that it will award its Longitude Prize, worth \$15.7 million, to a developer(s) of a cheap and efficient test that would indicate when to take an antibiotic(s) and which would work best.

**More Patients Reading Doctor Reviews:** This year, there was a twenty-percent [increase](#) (22% to 42%) in the number of patients who read online reviews while they research doctors, according to a [Software Advice](#) survey.

**Three Companies Partner on Data Exchange:** HIMSS, Integrating the Health Enterprise USA, and the EHR/HIE Interoperability Work Group plan to partner to ease data exchange. Their goal is to ensure a seamless transfer of data between and among state governments and organizations, which they hope to accomplish by assessing and certifying EHRs and health information exchanges.

**Doctors Increase Use of Health IT, Despite Privacy Concerns:** Doctors and health care workers have integrated health IT into their practices, per a PwC [survey](#). Health professionals are increasingly using electronic medical records, prescriptions, images, and mobile technologies, which they consider efficient and inexpensive.

**Health Care Orgs Oppose FDA on LDTs:** A coalition of more than 50 health care organizations [wrote](#) to FDA Commissioner Margaret Hamburg to urge the agency to wait before regulating laboratory-developed tests and requested that regulations be conducted through the standard rulemaking process. The FDA has sought to bypass that process through its “draft guidance” proposal, which would treat LDTs like other medical devices that must receive pre-market approval.

### **Upcoming Congressional Hearings**

*The Senate and House are in recess.*

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