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HEALTH CARE UPDATE November 25, 2013

- **Final Medicare Payment Rules.** CMS released two important final payment rules late on Friday afternoon, setting Medicare reimbursement in 2014 for Home Health and End Stage Renal Disease (ESRD) providers. Home Health providers received little relief from the proposed payment rule issued this summer, as CMS instituted the fullest cut possible under the law, although it was slightly moderated from the proposed cut due to a technical correction. The proposed rule incorrectly applied a 3.5 percent cut to 2013 payment rates as opposed to 2010 rates, as required by the ACA, which CMS corrected in the final rule. Therefore, while the overall dollar amount was slightly moderated, CMS maintained the maximum allowable 3.5 percent annual cut, resulting in a total rebasing cut of 14 percent over 4 years. For ESRD, CMS cut reimbursement for dialysis services by 9.4 percent, or about \$29 per treatment, phased in over three to four years. The cut is moderated by an increase in pay for training for home dialysis patients, essentially keeping reimbursement flat over the next two years. **Stakeholder groups in both the home health and dialysis industries are likely to increase their advocacy efforts over the next year to try and reverse the cuts that they believe reimburse below the cost of delivering care and could negatively affect access.** Industry analysts are also awaiting additional payment rules for physicians and hospitals to be released as early as this week.
- **FDA Issues Warning Letter to Genetic Testing Innovation Leader:** Last Friday, DNA testing start-up, 23andMe received a starkly worded warning from the FDA to immediately stop marketing their Saliva Collection Kit and Personal Genome Service (PGS). As these tests determine genetic risk, the FDA considers the product a medical device. As one of the most recognizable names in the field of direct to consumer DNA testing, 23andMe allows consumers to assess their risk, and that of their offspring of genetic, inherited diseases. Citing the aggressive marketing in which the company has been engaged, the FDA expressed concern about the accuracy of the tests and how consumers will interpret test results and impact their decision-making on current and future treatments. The company has acknowledged the warning letter and has stated that they are actively working with the Agency to address their concerns. **The warning issued by the FDA is likely to add pressure to 23andMe competitors as they are all likely to have to validate tests in controlled studies.** Further, as the US market for these DNA testing services grow in the billions, the **accuracy of these tests will face greater scrutiny** due to the increased utilization and increased costs.

Implementation of the Affordable Care Act

2014 Deadline Delayed: CMS announced that the deadline for consumers to purchase coverage beginning on January 1 through the online health insurance marketplace will be pushed back from December 15 to December 23.

2015 ACA Enrollment Delayed: The Department of Health and Human Services Secretary (HHS) announced that the Affordable Care Act's (ACA) 2015 enrollment period will be delayed by one month. It will now begin on November 15, 2014 and end January 15, 2015. The move is expected to give insurers more time to assess the first year of enrollment and adjust premium rates accordingly.

State Insurance Commissioners Meet With White House: A bipartisan delegation from the National Association of Insurance Commissioners met on Wednesday with President Barack Obama, HHS Secretary Kathleen Sebelius, and other advisors to discuss the President's proposal to allow insurers to reinstate cancelled policies.

States Accept, Reject President's Proposal: California and Indiana have rejected the President's proposal to reinstate cancelled health insurance policies. However, Michigan will be allowing insurers to reinstate cancelled policies.

Chao Testifies Before Energy and Commerce: Centers for Medicare and Medicaid Services (CMS) Deputy Chief Information Officer Henry Chao testified before the Energy and Commerce Oversight and Investigations Subcommittee that 30 to 40% of the infrastructure of healthcare.gov remains to be built.

Oversight Releases Administration Emails: The House Oversight and Government Reform Committee released two email chains between Deputy Chief Information Officer Henry Chao and other CMS staff showing the White House and CMS' concerns about possible technical problems before the launch of healthcare.gov. White House Eric Schultz has criticized the committee for cherry-picking emails that reveal no new information.

Negative Exchange Experiences: A Gallup poll found that that 63% of Americans who have visited an online health insurance marketplace have described their experience as "negative" or "very negative," and 40% weren't sure if they'd visited a state or federal marketplace.

Public Opinion on ACA Grows Worse: A Kaiser Family Foundation poll found that 49% of Americans have an unfavorable opinion of the ACA, while only 33% had a favorable opinion. The gap in public opinion has only been this large in October 2011, during the Republican presidential primary.

Ways and Means Questions Income Verification: Republican members of the House Ways and Means Committee sent a letter to HHS Secretary Sebelius citing recent news reports that the income verification system in the online health insurance marketplace is malfunctioning and asked her to provide information about the system and its errors.

Begich Introduces "Copper Plan": Senator Mark Begich (D-AK) introduced a bill to create "copper plans" in the ACA. These copper plans would cover the ACA's essential health benefits, but would allow consumers to pay lower premiums if they were willing to pay more for out-of-pocket costs.

Cassidy Introduces Employee Health Plan Bill: Representative Bill Cassidy (R-LA) [introduced](#) the Employee Health Care Protection Act, allowing insurers to continue offering health plans currently in the group market.

Republicans Oppose Union Exemption: Eleven Senate Republicans [introduced](#) a bill which would prevent union health insurance plans, frequently called “Taft-Hartley” plans, from receiving an exemption from the ACA reinsurance tax.

Republican Concern Over Co-Ops: Five House Republicans [sent a letter](#) to HHS Secretary Sebelius, asking her to explain what she is doing to ensure that Consumer Operated and Oriented Plans repay the \$2 billion that was loaned to them.

Oversight Announces Field Hearings: House Oversight and Government Reform Committee Chairman Darrell Issa (R-CA) [announced](#) that the Committee will hold four field hearings about the ACA in North Carolina, Georgia, Arizona, and Texas.

Other HHS and Federal Regulatory Initiatives

President Signs HOPE Act: On November 21, President Obama [signed](#) the HIV Organ Policy Equity (HOPE) Act into law. The new law removes the research ban on organ transplants between individuals with HIV.

Other Congressional and State Initiatives

Senate Passes Compounding Bill: On November 18, the Senate [passed](#) the Drug Quality and Security Act by a voice vote. The bill now goes to the President for his signature.

Shaheen Introduces IT Bill: Citing the ongoing problems with healthcare.gov, Senator Jeanne Shaheen (D-NH) [introduced](#) the Federal Information Technology Reform Act as an amendment to the National Defense Authorization Act, which would clarify responsibility, authority, and accountability over IT acquisition, investment, and management within each federal agency.

SGR Markup Scheduled: The Senate Finance Committee [announced](#) that they will markup a bill to repeal the Sustainable Growth Rate (SGR) on December 12.

Senators Introduce Medicare Data Bill: Senators Tammy Baldwin (D-WI) and John Thune (R-SD) [introduced](#) the Quality Data, Quality Healthcare Act which will increase access to Medicare data by modernizing and reforming the Qualified Entity program.

Hearings and Mark-Ups Scheduled

The Senate will not be in session.

House

On Monday, November 25, the House Oversight and Government Reform Committee will hold a [field hearing](#) in Gainesville, Georgia titled “ObamaCare Implementation: High Costs, Few Choices for Rural America.”