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June 8, 2015

Health Care Update

CMS Finalizes ACO Program Rules; Scales Alternative Payment Model: On June 4th, the Centers for Medicare & Medicaid Services (CMS) released a [final rule](#) updating the Medicare Shared Savings Program (MSSP), addressing many industry concerns ranging from an extension of the one-sided risk track to changes to the beneficiary assignment methodology. The final rule also paved the way for the first expansion of a delivery reform pilot, known as the Pioneer ACO model, under authority granted to the Secretary of Health and Human Services (HHS) by the Affordable Care Act (ACA).

After releasing the initial MSSP regulations in 2011, CMS proposed certain refinements to the program by way of a proposed rule in December of 2014. The final rule released last week implements many of these refinements, while also addressing the over 250 comments that CMS received regarding the proposed rule. The final rule clarifies and codifies existing guidance in a number of areas, including:

1. Data-sharing requirements;
2. Eligibility and other requirements related to ACO participants and ACO providers/suppliers;
3. Clarifications and updates to application requirements;
4. Eligibility requirements related to the ACO's number of beneficiaries, required processes for coordinating care, the ACO's legal structure and governing body, and its leadership and management structure;
5. The beneficiary assignment methodology;
6. The methodology for determining ACO financial performance; and
7. Issues related to program integrity and transparency, such as public reporting, terminations, and reconsideration review.

Although the final rule has addressed some key areas of industry concern, stakeholders are likely to continue to press the Obama Administration to adopt additional Medicare payment waivers beyond just the 3-day stay Skilled Nursing Facility exception offered to some ACOs. Additionally, CMS indicated that they would publish future program changes affecting beneficiary attribution and benchmarking in the 2017 Physician Fee Schedule and a separate rule respectively.

As ACO models continues to evolve and the Obama Administration considers scaling additional alternative payment models, policymakers are likely to see increased activity from stakeholders as they fight to shape the delivery reform landscape that has been accelerated by this latest rule as well as Congressional efforts to shift payments to alternative payment models (APMs) such as the recently enacted Medicare Sustainable Growth Rate (SGR) replacement [law](#), Mintz Levin and ML Strategies analyzed [here](#).

Implementation of the Affordable Care Act

Coverage for 6.4 Million at Stake in King v. Burwell: The Obama Administration [warned](#) that if it lost in King v. Burwell then [HealthCare.gov](#) could no longer provide 6.4 million Americans a tax subsidy to buy health insurance. The subsidy, which, on average, is for \$272 per month, goes to enrollees in the 34 states have not implemented lack their own state-based health care exchange.

White House Touts 10.2 Million Payers of ACA Plans: The Obama Administration [reported](#) that by the end of March, 10.2 million Americans had signed up and paid for health insurance partially subsidized by the ACA. The figure beats the Administration's 9.1 million-target but, as expected, falls below the 11.7 million who had enrolled in a health plan through an ACA exchange.

NEC Report on Medicaid Expansion: People in twenty-two states that have not expanded Medicaid, at least yet, have lost out on important health and economic gains, according to the White National Economic Council (NEC). The gains include less financial hardship, fewer cases of depression, and fewer deaths.

Federal Regulatory Initiatives

HHS Reports Rate Requests to Increase Premiums: HHS has begun [listing](#) health plans whose rates insurers have requested to increase by at least 10 percent. As of now, the list is not exhaustive; only insurers who have to justify their rate hikes are required to post, and they have until October to do so.

HHS Inspector General to Study EHR Use: The HHS Office of Inspector General (OIG) will [examine](#) electronic health records (EHRs) use among ACOs that are part of the Medicare Shared Savings Program. The office's goal is to find best practices that promote (and possible challenges that threaten) interoperability.

Health Datapalooza Week: Speaking at Health Datapalooza, an annual conference focused on liberating health data, CMS Administrator Andy Slavitt [announced](#) a new policy that for the first time will allow innovators and entrepreneurs to access CMS data, such as Medicare claims.

Data on Hospital Payments and Physician Spending Released: CMS [posted](#) data on hospital payments and physician spending in 2013. The data pertain to Medicare Parts A and B, and they denote the amounts providers and hospitals have billed the program, not the amounts they have paid.

FDA to Hold Hearing on Generic Drug Initiatives: FDA will [hold](#) a public hearing Friday to examine the state of regulatory science initiatives for generic drugs and to hear from the public about research priorities in this field. FDA plans to factor the information into its FY 2016 Regulatory Science Plan.

GAO Report on CO-OP Enrollment Projections: GAO [found](#) that of 22 non-profit insurers, eight served 85 percent of consumer operated and oriented plan (CO-OP) program enrollees, around 385,000 people, during the ACA's first sign-up period. The other 14 insurers underperformed their enrollment projections.

NIH to Start MATCH Trial Next Month: The National Institutes of Health (NIH) National Cancer Institute [announced](#) it is to begin its Molecular Analysis for Therapy Choice (MATCH) trial next month, in which it will test FDA-approved and investigational drugs on tumors with unique genetic traits. The trial, which is a part of the President's Precision Medicine Initiative, seeks to yield treatments for cancers that traditional therapies have not cured.

NIH Shares Report on Health Disparities: The NIH highlighted a report, featuring commentary from the NIH and other federal agencies by the [American Journal of Public Health](#) finding that provides an assessment of the major factors contributing to the health status of Blacks, Hispanics, Asian Americans, Native Hawaiians, and Pacific Islanders, and American Indians and Alaska Natives and elevated minority health to the national stage.

Prize Competition Seeks Tests for Antibiotic Resistance: NIH and the Biomedical Advanced Research and Development Authority are funding a prize [competition](#) – with awards upwards of \$20 million – for tests detecting bacterial infections. The purpose of the competition is to incent the creation of diagnostics that can discover newly-formed bacterial infections. If effective, these diagnostics can then reduce the number of these infections that are drug-resistant.

White House Holds Forum on Superbugs: The White House hosted a forum on [antibiotic stewardship](#) in which it discussed how the overuse of antibiotics can create drug-resistant "superbugs" that endanger public health. The

forum attracted about 150 representatives from food companies, drugmakers, retailers, and other industries leading on this issue.

Congressional Initiatives

E&C Oversight Subcommittee Tackles Medicaid Fraud: The House Energy and Commerce Subcommittee on Oversight and Investigations held a [hearing](#) about waste, fraud, and abuse in Medicaid, at which GAO and CMS officials testified. The impetus for the hearing was a GAO report, the main findings of which were that millions of dollars were wasted on deceased beneficiaries, beneficiaries living in two or more states, and former providers now barred from medical practice.

E&C Subcommittee Hearing on Nutrition Disclosure: On June 4th, the House Energy and Commerce Subcommittee on Health held a [hearing](#) to look at the menu-labeling requirements as proposed by the FDA and H.R. 2017, the Common Sense Nutrition Disclosure Act, which would enable certain small institutions to avoid possible criminal prosecution.

Rep. Murphy Reintroduced Mental Health Bill: Representative Tim Murphy (R-PA) [reintroduced](#) a modified version of legislation he introduced in the wake of the Newtown, Connecticut school shootings which would extend the meaningful use program to behavioral health practitioners and institutions.

Other Health Care News

\$10 Billion in MA Excess Payments Due to Upcoding, not EHRs: According to [investigators](#) from University of Texas and Harvard Medical School, doctors and insurers have secured \$10 billion in excess payments from Medicare Advantage plans through "upcoding." "Upcoding" refers to the reporting of a wrong billing code to obtain a higher reimbursement.

Kaiser Quantifies Impact of a Pro-King ruling: The Kaiser Family Foundation released [estimates](#) for, among other things, the average premium increase and the number of people who would lose their subsidies through [HealthCare.gov](#) if the Supreme Court were to side against the Obama Administration in King v. Burwell. In ten states, Kaiser predicts that premiums will increase by at least threefold.

Upcoming Congressional Hearings

Senate

On June 10th, the Senate Health, Education, Labor and Pensions Committee will hold a [hearing](#) titled "Health Information Exchange: A Path Towards Improving the Quality and Value of Health Care for Patients."

House

On June 10th, the House Ways and Means Committee will hold a [hearing](#) on the 2010 health care law implementation and the fiscal 2016 budget request for the HHS.

On June 10th, the Oversight and Investigations Subcommittee of the House Veterans' Affairs Committee will hold a [hearing](#) titled "Prescription Mismanagement and the Risk of Veteran Suicide."

On June 11th, the Health, Employment, Labor and Pensions Subcommittee of the House Education and the Workforce Committee will hold a hearing on the James Zadroga 9/11 Health and Compensation Reauthorization Act.

On June 11th, the Subcommittee on Health of the House Energy and Commerce Committee will hold a [hearing](#) to discuss the James Zadroga 9/11 Health and Compensation Reauthorization Act.

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