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July 13, 2015 **Health Care Update**

Recent Mandatory APMs Signal Evolution in Delivery Reform Efforts: Although the beltway media has been largely focused on the fate of the health insurance exchanges and years of repeal votes or other activity around the coverage provisions of the Affordable Care Act (ACA), health policy insiders have long viewed delivery system reform as the issue that would transcend ACA politics.

Current and former GOP and Democratic lawmakers, economic and health care executive branch officials, and policy experts have for the large part, supported various delivery system reform initiatives that have aimed to lower costs while maintaining or even improving the quality of health care. The work of the Center for Medicare and Medicaid Innovation (CMMI) has undergone an evolution since its inception out of the ACA in 2011. With over two dozen alternative payment models (APMs) in its current portfolio, the number of providers participating in at least one Medicare APM is over 60,000 and touches approximately 2.5 million Medicare beneficiaries.

With last week's announcement of two mandatory APMs implementing a home health value-based purchasing model and an orthopedic bundled payment for lower extremity joint replacement, the Obama Administration has unveiled the next iteration of APMs that may be mandatory in order to ultimately scale up as a permanent part of the Medicare program.

The Home Health Value-Based Purchasing model will hold all certified home health agencies in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee and Washington accountable for a series of quality measures for up to eight percent of their total annual payments.

The Comprehensive Care for Joint Replacement (CCJR) model is a bundled payment that includes all Medicare Part A and B costs from a hospital admission through recovery until 90 days following discharge. All hospitals in 75 geographic areas will be required to participate; however, providers testing similar hip and knee bundled payments in CMMI's Bundled Payment for Care Improvement initiative are exempt. Providers will be subject to a cost target that is likely to represent a two percent discount on the expected costs for the bundle of services.

Both models are expected to last five years and are open for comment until September 4th and 8th respectively. To read more about HH-VBP and the CCJR, please see our latest blog entries on *Health Law and Policy Matters*.—including a telehealth roundup, which highlights, among other things, favorable telemedicine provisions in the CCJR rule that could facilitate Medicare reimbursement for those services.

Implementation of the Affordable Care Act

HHS Releases New Contraception Mandate Rule: The Obama Administration announced a new reporting system for private companies and religious-affiliated organizations that object to the ACA's birth control coverage requirements. Under the new system, those entities can notify the administration that they have a religious-based objection to providing contraception to their employees. The Administration can then notify their insurers, which would provide the contraception directly to the employees.

Federal Regulatory Initiatives

HHS Report Finds Lapses with Reporting Medicaid Managed Care Data: A report produced by the Department of Health and Human Services (HHS) Inspector General (OIG) found that not all states are reporting crucial data on Medicaid managed care to a national database, and Centers for Medicare & Medicaid Services (CMS) should use its authority to withhold federal funding until they comply. Eight of 38 states reviewed by OIG did not report data from any managed care entities by the required deadline, and another 11 states did not report data for all managed care organizations. Accurate "encounter data," which includes information about services provided to beneficiaries, is necessary for appropriate Medicaid oversight and to prevent fraud and abuse.

HHS Awards Grants To Prevent Teen Pregnancies: HHS announced roughly \$86 million in teen pregnancy prevention grants for 81 organizations, including nonprofits, school districts, and universities. The funding will support expansion of evidence-based teen pregnancy prevention programs in communities where teen birth rates remain high, fill knowledge gaps on what can prevent such pregnancies and test new approaches. The grants cover the first year of funding for a five-year period.

HHS Awards Funding for Emergency Preparedness: As part of a cooperative agreement to improve emergency preparedness, HHS awarded state and local health departments with \$228 million from the Hospital Preparedness Program and \$611 million from the Public Health Emergency Preparedness programs.

Obama Nominates Slavitt as Permanent CMS Admin: Since former CMS Administrator Marilyn Tavenner left the agency in January, Andy Slavitt has been serving in an acting capacity. Last week, the White House announced the nomination of Slavitt to serve as permanent CMS Administrator.

CMS Expanding Bundled Payments: CMS announced it would be expanding its Medicare bundled payment initiative to hip and knee replacement surgeries. Additionally, the agency is waiving telemedicine originating site restrictions for bundled payments.

CMS Begins Implementation Of Key Payment Legislation: CMS released the first proposed update to the physician payment schedule since the repeal of the Sustainable Growth Rate through the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The proposal includes a number of provisions focused on person-centered care, and continues the Administration's commitment to transform the Medicare program to a system based on quality and healthy outcomes.

CMS Announces New Initiative to Promote Value-Based Home Health Care: CMS announced a proposal to launch a new the Home Health Value-Based Purchasing model designed to support greater quality of care among Medicare beneficiaries. Included in the CY 2016 Home Health Prospective Payment System proposed rule, the model updates payments and requirements for home health agencies under the Medicare program, and would test whether incentives for better care can improve outcomes in the delivery of home health services.

CMS Accepting Applications for Participation in Million Hearts®: Cardiovascular Disease (CVD) Risk Reduction Model: CMS is offering health care professionals the opportunity to design sustainable models of care that help reduce 10-year atherosclerotic cardiovascular disease (ASCVD) risk and prevent heart attacks and strokes for tens of thousands of eligible Medicare beneficiaries. Letters of Intent (LOI) and applications (PDF) from health care professionals who plan to participate in the Million Hearts®: CVD Risk Reduction Model are currently being accepted.

OIG Finds CMS Not Getting Enough Medicaid Managed Care Claims Data: According to an OIG report, thirteen states studied are either submitting no data on Medicaid Managed Claims, or very flawed data, giving the agency little visibility into the status of the program. Managed care plans are supposed to send claims data on to states, who pass the data on to CMS.

White House Articulates Precision Medicine Principles: The White House released a set of principles for its Precision Medicine Initiative, expressing hopes for a new type of research study that is more public, transparent and

patient-centered than in the past. The report is focused on ensuring that patients participate as partners, rather than mere subjects of scientists' curiosity. It states that patients need to be updated about the project's prospects; need to be asked for their consent, and periodically allowed to re-evaluate their preferences; and need to sit on the governance committees guiding the various cohorts.

AHRQ Releases Health IT-Workflow Report: In a report studying the impact of implementing health IT at six ambulatory primary care clinics in the Vanderbilt Medical Group in Tennessee, the AHRQ found that, even when implanted uniformly in a single health system, health IT systems can produce wildly different impacts on care coordination from practice to practice depending on the specific task, technology and user.

FDA Delays Enforcement of "Track and Trace" for Pharmacies: The Food and Drug Administration (FDA) gave pharmacies four additional months come in to compliance with the part of the Drug Supply Chain Security Act that requires pharmacies to only accept shipments of prescription drugs if they're given certain tracking information with the products, and requires that the pharmacies store this data upon receipt. Track and trace was supposed to take effect July 1 but now won't be enforced by the agency until November 1. FDA issued a guidance document announcing the enforcement change and plans to have a number of stakeholder calls in the coming weeks.

GAO Report on the 340B Program: the Government Accountability Office (GAO) released a report finding that consumers at Disproportionate Share Hospitals (DSH) are either prescribed more outpatient drugs or more expensive drugs than at non-340B facilities. The report cites numbers from the 2012 Medicare Part B spending at 340B DSH hospitals.

CDC Finds Heroin Overdoses on the Rise: A joint report by the Centers for Disease Control (CDC) and the FDA found that, from 2002 to 2013, heroin use increased 63 percent and the rate of deaths from overdoses has nearly tripled.

Congressional Initiatives

House E&C Requests Review of Select Agent Program: Bipartisan leaders of the House Energy and Commerce Committee wrote to the HHS Office of the Inspector General requesting the agency review the federal select agent program and federal laboratory guidelines. The letter comes in the wake of findings that live anthrax was accidently shipped by the government.

House E&C Hearing on Medicaid Anniversary: The House Energy and Commerce Subcommittee on Health, coinciding with the 50th anniversary of Medicaid, held a hearing to review the program at its semi centennial. Witnesses from CMS, GAO, and the Medicaid and CHIP Payment and Access Commission (MACPAC) discussed recent changes to the program and its legacy.

Senate HELP Examines Small Business Heath Care: The Senate Health, Education, Labor, and Pensions Subcommittee on Primary Health and Retirement Security met to consider small business health care challenges and opportunities, hearing testimony from industry and academia. Among the topics discussed was the Small Business Health Options Program (SHOP) Marketplace.

Bipartisan Members Press FDA on Opioids: Following a request by House Energy and Commerce Democrats to the FDA regarding the agency's response to the opioid epidemic, bipartisan Committee leaders sent a letter to the FDA questioning why the agency does not require additional warning labels for painkillers and if FDA's risk-management strategies for the medicines are effective.

GAO Update on HealthCare.gov Improvement: GAO information security expert Gregory Wilshusen testified before a House Science Subcommittee following the OPM breach that he is not aware of any efforts by CMS to act on that recommendation from a fall GAO report finding weaknesses in information security at HealthCare.gov.

House Democrats Push for Full-Year Birth Control Coverage: A group of House Democrats wrote a letter to HHS, urging the agency to require insurers to cover a year's supply of birth control without cost-sharing after recent legislation in Oregon and the District of Columbia. "We urge the Department to address this significant barrier that prevents women from accessing birth control in a timely and effective manner," wrote the 55 Democrats, led by Reps. Jackie Speier (D-CA) and Suzanne Bonamici (D-OR).

Rep. Thompson Reintroduces Telehealth Bill: Representative Mike Thompson (D-CA) reintroduced the Medicare Telehealth Parity Act, which would gradually move telehealth services under Medicare toward parity with in-person health care services. The bill is cosponsored by Representatives Gregg Harper (R-MS), Diane Black (R-TN), and Peter Welch (D-VT).

Bipartisan Small Business Health Bill Reintroduced: Senators Chuck Grassley (R-IA) and Heidi Heitkamp (D-ND) and Representatives Charles Boustany (R-LA) and Mike Thompson (D-CA) reintroduced the Small Business Healthcare Relief Act. The bill would also small businesses to maintain Health Reimbursement Arrangements to pay for employees' health-related expenses.

Democratic Senators Push Chamber to Stop Tobacco Advocacy: Senators Richard Blumenthal (D-CT), Dick Durbin (D-IL), and several of their Democratic colleagues sent a letter to U.S. Chamber of Commerce President Tom Donahue, asking him to reevaluate the Chamber's support of the tobacco industry. "Countries seeking to preserve the health and safety of their citizens and reduce tobacco-related deaths should not be stymied or intimidated by an outside lobbying force — especially one that represents many American businesses."

Upcoming Congressional Hearings

Senate

On July $14^{\rm th}$, the Senate Commerce, Science and Transportation Committee will hold a hearing titled, "Unlocking the Cures for America's Most Deadly Diseases."

On July 15th, the Senate Special Aging Committee will hold a hearing titled, "Diabetes Research: Improving Lives on the Path to a Cure."

On July 16th, the Senate Finance Committee will hold a hearing titled, "Reviewing HealthCare.gov Controls."

House

On July 14th, the House Energy and Commerce Committee on Oversight will hold a hearing titled, ""Medicare Part D: Measures Needed to Strengthen Program Integrity."

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