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Editor's note

This note is produced by the KPMG Center for Healthcare Regulatory Insight and is intended to be short and succinct, less than 360 words, to provide a digestible bite of news relevant to our clients and practices. Links are provided to source material (proposed and final regulations, agency guidance and press releases, reports, research, etc.) when available.

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Healthcare regulatory news

FDA approved the first direct-to-consumer genetic test for cancer risk… OMB began review of the final Medicare Advantage and Part D rule for FY2019… CMS announced $30 million in grants to develop and improve performance measures for the Quality Payment Program.

CMS informed Idaho officials that it would likely have to take enforcement action based on Idaho's current plan to allow the sale of noncompliant ACA plans… CMS approved an 1115 waiver allowing Arkansas to impose a work requirement for some Medicaid enrollees, but did not accept Arkansas' proposal to cap

program eligibility for the ACA expansion population at the federal poverty line.

Healthcare law and policy news

HHS Secretary Alex Azar laid out HHS priorities for allowing patient access to medical records, increasing transparency, driving value-based payment reforms, and reducing government burdens; CMS Administrator Seema Verma announced the MyHealthEData initiative to allow better patient access to their health data; FDA Commissioner Scott Gottlieb blasted the "rigged" payment system that allows drug supply chain stakeholders to profit at the expense of patients and cheaper treatment alternatives, particularly biosimilars.

Cigna has agreed to acquire Express Scripts for $67 billion; while Atrium Health suspended merger talks with UNC Healthcare… United announced it would start passing some rebates it gets from drug manufacturers along to roughly 7.5 million consumers.

The upcoming federal spending bill could reverse recent changes to the Medicare Part D "donut hole" and include the CREATES Act to address delays on generic drug introductions… The DC Court of Appeals requested additional information about the deal reached between the House of Representatives, Trump Administration, and states to end the challenge to the constitutionality of unappropriated funding for cost-sharing reduction (CSR) subsidies… Covered California projected that repeal of the ACA individual mandate and shortening of open enrollment periods, would result in marketplace premium increases ranging from 35% to 90% over three years.

A study in *JAMA* concluded that larger and non-profit hospitals were more likely than other hospitals to succeed financially under mandatory bundled payment models… Researchers at Tufts estimated that it takes 31 weeks for a clinical trial to begin after a drug manufacturers commits to testing a drug, a month longer than 10 years ago.

Questions or comments, please send to us-hcinsight@kpmg.com