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Around the world of U.S. healthcare in 360 words or less

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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

CMS updated the Medicare local coverage determination (LCD) process to improve beneficiaries' access to therapies and devices... A CMS proposed rule streamlines the appeal process for coverage determinations under Medicare Parts A, B, and D... CMS announced a multi-year e-Medicare initiative to improve the user experience for Medicare beneficiaries...CMS plans to increase oversight and transparency of Medicare's Accrediting Organizations.

FDA announced program pilots to evaluate proposed changes to the Special 510(k) Program to expedite medical device design and labeling changes… FDA draft guidance on adaptive trials and master protocols aim to lower the cost of drug development and spur competition… FDA guidance cracks down on citizen petitions including alerting the FTC if it suspects a brand manufacturer petition is being used to delay generic competitors… FDA announced new steps to strengthen the agency's medical device cybersecurity program.

OIG estimated that Medicare made $5.7 billion in unnecessary payments to inpatient rehabilitation facilities in 2013.

Healthcare law and policy news

Congress passed opioid legislation, which resident Trump is expected to sign.

GAO reported that rural hospital closures from 2013 to 2017 more than doubled (64) over the previous five-year period (31)… Baylor Scott & White and Memorial Hermann signed a letter of intent to merge and create the largest health system in Texas (68 hospitals)… Pitchbook found that investment in healthcare startups is 70% greater than a year ago, driven by larger deals… DaVita Medical Holdings agreed to pay $270 million for False Claims Act liabilities from improper MA billing practices.

California enacted a bill requiring PBMs to register and disclose conflicts of interest, rebates, and other incentives to purchasers; meanwhile, PhRMA refiled a lawsuit challenging (subscription required) California's drug price transparency law requiring manufacturers to provide advance notice of price increases.

Kaiser Family Foundation reported that average premiums for employer-sponsored family health coverage rose 5% this year to $19,616; individual coverage increased 3% to $6,896… A Health Affairs analysis found that 60% of the population lives in a county with at least three ACA insurers, down from 93% in 2016… Pew reported that one of out of five patients may not be accurately matched to their individual electronic health record at facilities they have previously visited.

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