



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

Center for Healthcare Regulatory Insight



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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 generic version of EpiPen](#) and a [first-of-its-kind targeted RNA-based therapy](#) for nerve damage caused by peripheral nerve disease...FDA draft [guidance would](#) expedite the clinical development of cancer drugs through [multiple expansion cohort trial designs](#)... FDA Commissioner Scott Gottlieb and NIH Director Francis Collins [announced plans](#) to streamline oversight for gene therapy trials.

HHS [awarded \\$125 million](#) in Quality Improvement grants to 1,352 community health centers...

CMS [provided an update on Medicaid state plan amendments](#) and announced section 1915 waiver process improvements... OMB [completed review of a proposed rule](#) to ease [excessive burdens](#) on Medicare providers and suppliers.

OIG [estimated that CMS](#) authorized \$434.4 million in improper ACA financial assistance payments in 2014; OIG also [reported that CMS](#) spent 24 times more on compounded topical drugs in 2016 than in 2010, suggesting potential fraud, waste, and abuse.



Healthcare law and policy news

President Trump [would like the Justice Department to file a federal lawsuit against](#) opioid manufacturers and urged DOJ to crack down on synthetic opioids from China and Mexico; meanwhile CDC [reported that nearly 72,000 Americans](#) died of opioid overdoses in 2017, up 6.6% from 2016.

CMS [approved New Jersey's 1332 waiver](#) to establish a five-year ACA reinsurance program... New Mexico Health Connections [asked a federal judge](#) to throw out CMS' new risk adjustment proposed rule... Advocacy groups in Arkansas [sued to block the state](#) from enforcing new work requirements, while the state announced that [5,400 individuals failed to report work hours](#) for two straight months and could lose coverage.

North Carolina is [accepting bids from insurers](#) to participate in its managed Medicaid program... Louisiana is exploring a ["subscription-based" payment model for hepatitis C](#) treatments for its Medicaid and prison populations... Ohio's Medicaid Department [ordered the state's five managed care plans](#) to cancel contracts with PBMs engaging in "spread pricing;" CVS [announced plans to "restructure"](#) its contracts to meet new "pass-through" pricing requirements.

Oscar Health [received \\$375 million](#) from Alphabet, and plans to launch Medicare Advantage plans in 2020... Major technology companies [pledged to collaborate](#) to remove barriers to adoption of interoperable health technologies... Best Buy [will acquire GreatCall](#), a manufacturer of mobile devices for senior citizens.





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



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