



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

Center for Healthcare Regulatory Insight



[April 20, 2018 | Issue 16](#)

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.

In order to continue receiving ATW 360 in future weeks, you will need to subscribe to our mailing list [here](#). Please share this email with colleagues and other interested individuals.

[Subscribe here](#)



Healthcare regulatory news

Attorney General [Jeff Sessions proposed](#) new regulations limiting production of addictive opioids through DEA-established quotas to hold manufacturers accountable for excessive drug distribution... OMB is reviewing the annual hospital [inpatient](#), hospital [outpatient](#), [SNF](#), and [physician](#) payment updates; the physician payment update [may include rules](#) for the Quality Payment Program 2019 performance year... HHS [proposed delaying](#) implementation of the "Common Rule" on human subjects research to January 2019.

CMS [released a set of interactive maps](#) and data showing market saturation of different providers... [CMS is appealing a February court decision](#) blocking its DSH payment changes from being enforced in Missouri; CMS has until May 7 to appeal a federal court decision halting national enforcement of its [2017 DSH rule](#).

[FDA announced a comprehensive plan](#) to enhance medical device safety... FDA issued [final guidance](#) on special protocol assessment (SPA) agreements to facilitate drug manufacturers and FDA [alignment](#) on the design and size of certain clinical trials to appropriately address scientific and regulatory requirements... An FDA [advisory panel recommended approval](#) of the first cannabidiol drug.



Healthcare law and policy news

President Trump [will announce plans](#) for addressing prescription drug prices on April 26, including ideas from his budget released earlier this year; OMB is [meanwhile reviewing an associated regulation](#), “HHS Strategy to Lower Drug Prices and Reduce Out-of-Pocket Costs.”

[OIG reported](#) that Medicare spending on telehealth increased from \$61,302 in 2011 to \$17.6 million in 2015; however 31% of the services in their audit did not comply with Medicare requirements... [OIG also reported CMS failed to prevent](#) improper drug benefit payments for dead beneficiaries, totaling \$1.1 million for more than 65,000 excess monthly payments.

Wisconsin Governor Scott Walker [formally requested a 1332 waiver](#) to establish a \$200M ACA reinsurance program... A federal appeals court [struck down](#) a Maryland [“price gouging” law](#) that allowed the state to sue generic drug manufacturers sharply increasing drug prices... Highmark Health announced [an outcomes-based contract](#) for AstraZeneca’s Symbicort... Amazon [abandoned plans](#) to sell pharmaceuticals and medical equipment to large healthcare practices and hospitals... A [study in the New England Journal of Medicine](#) concluded that just 37% of the 2017 QPP measures are “valid” for assessing physician performance.





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



[Privacy](#) | [Legal](#)

You have received this message from KPMG LLP. If you wish to unsubscribe from Around the world of U.S. healthcare in 360 words or less, please [click here](#). If you wish to unsubscribe from all KPMG communications, please [click here](#).

KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2018 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 698390

The KPMG name and logo are registered trademarks or trademarks of KPMG International.