



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

Center for Healthcare Regulatory Insight



[January 25, 2019 | Issue 55](#)

### 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

[FDA posted guidance documents on an expanded 510\(k\) device approval program](#) and for coordinating development of [antimicrobial drugs](#) and antimicrobial susceptibility test (AST) devices... FDA also released draft guidance documents for [amending tentative ANDAs for generic drug approval](#), assisting drug and biological product sponsors in conducting more efficient drug development programs for [treatment or](#)

[prevention of rare diseases](#), and providing [recommendations](#) for [conducting REMS assessment surveys](#).

FDA [approved the third biosimilar](#) of Roche's Herceptin and a [23andMe test](#) for detecting genetic variants associated with colorectal cancer... also, FDA [provided updates](#) on how its workforce is impacted by the shutdown, while 52 groups [warned that the shutdown](#) could jeopardize scientific discovery and innovation.



## Healthcare law and policy news

President Trump [vowed to crack down](#) on surprise medical bills.

MedPAC [recommended](#) CY2020 payment adjustments to Congress: increase [long-term care hospital](#) rates by 2%; reduce [home health](#) and [inpatient rehabilitation facilities](#) rates by 5% and [hospice providers](#) by 2%; eliminate payment updates for [skilled nursing facilities](#) and [ambulatory surgical centers](#); and increase [physician payments](#) by the amount specified in current law... [MACPAC recommended](#) that Congress slow down pending hospital DSH payment cuts.

The [Supreme Court upheld](#) a ruling prohibiting drug manufacturers [from obtaining patents](#) for products on sale for more than a year... 38 hospitals [sued HHS](#) over site-neutral payment changes... A US District Court [heard arguments](#) challenging the expansion of association health plans.

Walmart will [remain in CVS PBM networks](#)... Walgreens [agreed to pay \\$269 million](#) to settle two civil suits alleging False Claims Act violations for over-dispensing insulin pens... Civica Rx [plans to provide 20 generic drug products](#) to members this year and up to 100 in the next 3-5 years.

WHO [reported that cancer drug prices](#) are "impairing" access to treatment... [HCCI reported](#) that annual per person spending on insulin for type 1 diabetics increased from \$2,864 in 2012 to \$5,705 in 2016 (excluding discounts and rebates)... An ICER [tool will](#) assess "unsupported" prescription drug price increases.

Gallup found that [13.7% of Americans were uninsured](#) in Q4 2018, the highest level since Q1 2014... [BCBSA reported](#) increases

in the number of knee and hip replacements (17% and 33% respectively) between 2010 and 2017.



Questions or comments, please send to [us-hcinsight@kpmg.com](mailto: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

© 2019 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.