



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 [final guidance](#) details application of [least burdensome provisions](#) to medical device reviews... FDA [draft guidance](#) lays out principles for [combination product premarket review](#)... FDA will hold a [public workshop](#) to examine barriers to generic drug development... FDA [took enforcement action](#) against Walgreens for alleged tobacco sales to minors.

CMS and CDC [proposed updates](#) to laboratory proficiency testing under CLIA... OMB is [reviewing a final rule to reverse the ban](#) on nursing home pre-dispute arbitration agreements... OCR [announced a record year](#) for HIPAA enforcement penalties.



Healthcare law and policy news

During his [State of the Union](#) address, President Trump announced [a strategy](#) to end the HIV epidemic and \$500 million for childhood cancer research, and urged Congress to address global “freeloading” impacting drug costs.

HHS Secretary Alex Azar [urged hospitals](#) to better inform patients about treatment costs; [suggested new models for rural healthcare](#) outside of the hospital; and discussed FDA efforts to promote [generic drug competition](#) through harmonization with peer nations.

Seven [pharmaceutical company CEOs](#) will [testify before the Senate Finance Committee](#) on drug pricing... [CMS Actuary estimated](#) that the rebate safe harbor proposed rule could increase federal spending by \$196 billion over a decade; [Eli Lilly](#) and [Novartis](#) expressed support for the proposed rule.... Beginning in March, Johnson & Johnson will [include](#) the list price and typical out-of-pocket cost for Xarelto.

North Carolina [selected five plans](#) to participate in its Managed Medicaid program... Four states [moved to join](#) 17 other states as defendants in *Texas v. U.S.* and defendants [requested](#) an expedited appeal... Pennsylvania’s [Attorney General told UPMC](#) to keep its network open to Highmark.

Healthcare [added 41,600 jobs](#) in January, up almost 20,000 from January 2018... Baylor Scott & White and Memorial Hermann [ended their merger](#)... Aetna, Anthem, HCSC, PNC, and IBM [will collaborate](#) to design a blockchain ecosystem for improving transparency and interoperability.

Premier [estimated that unnecessary ED visits](#) for chronic condition patients cost \$8.3 billion in excessive 2017 healthcare spending... *Health Affairs* studies found that inpatient hospital prices [rose 42% between 2007 and 2014](#), while physician services

prices rose 18%; and that [half of the Medicare spending slowdown](#) between 1999 and 2012 is attributable to slower spending growth for cardiovascular diseases.



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



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

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