



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

Center for Healthcare Regulatory Insight



[June 1, 2018 | Issue 22](#)

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 [draft REMS guidance provides](#) general principles and recommendations to assist drug manufacturers in [developing Single System REMS programs](#) and situations in which [FDA will consider waiving](#) the single, shared system requirement... FDA is [gathering input](#) on the benefits and risks of [non-device medical software](#) products.

OMB is [reviewing a final rule](#) delaying penalties for drug manufacturers that overcharge hospitals for prescription drugs under the 340B Program... CMS is [seeking comments](#) on relaunching a demonstration for “developing improved procedures

for the identification, investigation, and prosecution” of home health agencies Medicare fraud.



Healthcare law and policy news

President Trump [appointed Peter O'Rourke](#) Acting VA Secretary, pending Robert Wilkie's confirmation... President Trump signed the [“right to try” bill](#) and suggested that drug manufacturers will [“announce voluntary massive drops in prices”](#) in two weeks.

U.S. [spending on cancer drugs](#) doubled in the last five years to \$50 billion annually, and will likely double again over the next five years, with 12-15% annual growth... [Health Care Cost Institute reported](#) that average ER spending for commercially-insured individuals increased 98% between 2009 and 2016 (\$125 to \$247); overall ER use remained the same, with prices nearly doubling for the highest severity visits..... Senator Bill Cassidy [released a white paper](#) with ideas to make healthcare more affordable.

[American Cancer Society recommended](#) screening for colorectal cancer begin at age 45, rather than 50... the [AMA reported](#) that the number of opioids prescribed last year dropped 9%, the fifth consecutive annual decline... CMS [announced that 91% of MIPS-eligible clinicians](#) participated in the first year of the QPP.

Virginia [passed legislation that will](#) expand Medicaid in the state, while advocates in Utah [collected enough signatures](#) to put expansion on the state's ballot this fall... New Jersey [enacted an individual health insurance mandate](#) to take effect January 1, 2019... Connecticut [enacted a bill](#) requiring drug manufacturers to justify price increases of 20% or more per year.

WellCare [will acquire Meridian's](#) PBM and health plans for \$2.5 billion... Nineteen Attorneys General [urged HHS to implement](#) reforms begun in 2016 to protect skilled nursing facility patients... the Community Oncology Alliance [sued HHS and OMB](#) to stop the 2% sequester of Medicare Part B drug reimbursement.





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



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