



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

An [FDA proposed rule](#) would streamline and clarify the process for evaluating low and moderate-risk medical devices... [FDA approved](#) Editas Medicine to test a CRISPR-based therapy on patients with a genetic blindness disorder... An FDA and World Health Organization [pilot program](#) aims to expedite HIV drug application reviews.

GAO [found that 69% of approved orphan drug applications](#) in late 2017 were deficient... [GAO reported](#) that CMS could pay billions

more than necessary for clinical lab tests through 2020 if it does not gather more complete private payer payment rate data; meanwhile [ACLA filed an appeal](#) challenging the payment policy.

CMS released the [2018 ACA risk adjustment methodology](#) final rule... CMS [announced that more than 55% of hospitals](#) will receive incentive payments in 2019 under the Value-based Purchasing Program, down from 57% in FY2018... CMS [announced oversight](#) of nursing home safety, including assuring adequate facility staffing... CMS [reported that 48.74%](#) of Medicare Advantage provider directories have at least one inaccuracy.

[OIG found](#) that more than 20% of Medicare patients receiving treatment in long-term care facilities have experienced serious harm... OMB is [reviewing a final rule](#) to improve the Medicare provider enrollment process.



Healthcare law and policy news

HHS released a [report on improving “choice and competition”](#) in healthcare markets... HHS Secretary Alex Azar [named John O’Brien](#) his new senior adviser on drug pricing.

[CMS reported](#) that national health spending grew 3.9% in 2017, 1% slower than 2016... Just under [3.2 million individuals](#) have enrolled in healthcare.gov plans, down from [3.6 million](#) last year.

AHA and AAMC [sued HHS](#) to stop the [site-neutral payment policy](#)... A US District Court Judge [ordered CVS and Aetna](#) to provide justification for their merger by December 14th for a hearing on December 18th... 13 Attorneys General [sued two health IT companies](#) for data breaches resulting in theft of medical information from 4 million patients.

Pfizer [agreed to delay](#) launch of its biosimilar for Abbvie’s Humira by five years... GlaxoSmithKline [will acquire Tesaro](#) for \$5.1 billion... Takeda [shareholders approved](#) its acquisition of Shire... Actelion Pharmaceuticals [will pay \\$360 million](#) to settle a charity co-pay investigation.

[HIMSS Analytics found](#) that fewer than 15% of 159 healthcare organizations consider themselves “well prepared” for blockchain.



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



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