



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

Center for Healthcare Regulatory Insight



[January 4, 2019 | Issue 52](#)

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 Commissioner Scott Gottlieb announced that he [has no plans to leave](#) the agency... meanwhile, [41% of FDA staff](#) (7,053 individuals) are furloughed as result of the government shutdown; Gottlieb [clarified which agency functions](#) continue during the shutdown.

FDA [guidance outlines](#) how stakeholders can develop and submit proposals for incorporating patient perspectives in drug development... FDA [updated its guidance](#) on endpoints for approval of oncology drugs and biologics.

Beginning January 1, [hospitals must post](#) their standard charges online in a [machine-readable format](#), and update them annually... also, Medicare Advantage and Part D plans [must reject payments](#) to providers or prescribers excluded from program participation ... CMS will [raise laboratory user fees](#) by 20% to sustain the Clinical Laboratory Improvement Amendments (CLIA) program through FY2021.



Healthcare law and policy news

A [notice of appeal](#) was filed in *Texas et al. v. United States et al.*; the ACA will [remain in place](#) pending outcome of the appeal ... The Democrat-controlled House passed a [rules package](#) allowing the House counsel to defend the ACA in court, and will [vote](#) next week on whether to formally intervene in the ACA lawsuit... A district court [found that HHS exceeded its authority and granted an injunction](#) to stop payment cuts for 340B drugs in Medicare Part B.

Next Generation ACOs [saved Medicare \\$129 million](#) in 2017; [32 of 44 participants](#) earned shared savings... HHS and industry partners [released ten “best practices”](#) to mitigate cybersecurity threats.

Final healthcare.gov enrollment [reached 8.4 million](#), down from 8.7 million last year... More than [200,000 Virginians](#) have enrolled in Medicaid expansion coverage... Maine’s new Governor [issued an executive order](#) to implement Medicaid expansion... CMS approved Medicaid work requirements in [Michigan](#) and [Maine](#).

Bristol-Myers Squibb [will acquire](#) Celgene for approximately \$74 billion... More than [30 pharmaceutical companies increased list prices](#) for hundreds of drugs, by an average of 6.3%, on January 1; President Trump [told his Cabinet](#) drug prices will drop this year.

AHA [data show](#) that hospital outpatient revenue nearly equals inpatient revenue in 2017 (\$472 vs. \$498 billion)... An AARP-University of Michigan [poll found](#) that 45% of 50 to 64 years olds aren’t confident they’ll be able to pay for health insurance when they retire.





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



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