



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

HHS published its [semiannual regulatory agenda](#)... A [CMS proposed rule](#) would require manufacturers to [disclose wholesale acquisition costs](#) for Medicare and Medicaid drugs in direct-to-consumer television advertisements; meanwhile [PhRMA announced that dozens of manufacturers](#) will direct patients to their websites for drug cost information.

FTC [took legal action](#) against two stem cell clinics for [deceptive advertising](#) of potential treatment benefits.

[FDA guidance](#) provides more clarity and direction to drug developers for pursuing next generation therapies and treatments, and [early stage development](#) of rare disease treatments... FDA [recommended development](#) of global standards for generic drugs... FDA and DHS [agreed](#) to collaborate on medical device cybersecurity... FDA's Oncologic Drugs Advisory Committee [unanimously recommended approval](#) of Celltrion and Teva's biosimilar to Genentech's Rituxan.



Healthcare law and policy news

CMS [announced](#) that average Part B premiums will increase \$1.50 next year to \$134, along with a \$2 increase in the deductible to \$185; the Part A deductible will increase \$20 to \$1,364... KFF reported that the average Medicare beneficiary will have [24 MA plans](#) and [27 Part D standalone plans](#) to choose from during open enrollment.

Mary Mayhew, former commissioner of the Maine Department of Health and Human Services, [was appointed](#) Deputy Administrator of CMS and Director of Medicaid and CHIP.

Virginia will [begin accepting applications](#) on November 1 from 400,000 newly eligible Medicaid expansion beneficiaries... Arkansas [will remove 4,109 more residents](#) from Medicaid for failing to meet work requirements... [GAO reported](#) that more low-income individuals in Medicaid non-expansion states (19.9%) had unmet medical needs in the past year than low-income individuals in expansion states (9.4%).

Anthem [will pay \\$16 million](#) to settle HIPAA data breaches in 2015 affecting nearly 79 million people... A [federal court](#) ordered HHS to pay Sanford Health Plan \$360,000 in cost-sharing reduction (CSR) payments owed for Q4 of 2017... Novartis [will acquire Endocyte](#) for \$2.1 billion.... UnitedHealthcare will [mandate "step therapy"](#) for at least three categories of drugs in some of its MA plans.

A [Commonwealth Fund-NYTimes-Harvard survey](#) found that 36% of seriously ill patients had used up all or most of their savings on care... A [BMJ study found](#) that accredited hospitals don't have significantly better mortality and readmission rates than non-accredited facilities.





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



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