



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FDA issued draft guidance to [boost transparency of regulatory decisions](#) on medical devices and announced initiatives to [speed decisions on low-risk devices](#) and [accelerate patient access](#)... FDA also released [draft guidance](#) on labeling dietary supplements containing microbes.

[Lewin Group](#) found that CJR reduced average Medicare episode payments by 3.3% in the program's first year... Meanwhile, studies in JAMA found that [mandatory CJR participation](#) reduced post-acute care after lower extremity joint replacements and that [BPCI hospital participants](#) did not significantly increase surgical volume

or change their case mix in response to program incentives... In a speech about HHS' [value-based care priorities](#), Secretary Alex Azar signaled openness to more mandatory models.



Healthcare law and policy news

House leaders [urged MedPAC to explore](#) implications of hospital consolidation on Medicare costs and whether 340B drug discount incentives prompt use of more expensive products... A [Health Affairs study](#) found that California hospital-employed physicians increased from 25% in 2010 to 40% in 2016, associated with a 12% increase in ACA premiums and price increases for specialist (9%) and primary-care (5%) services... [OIG found](#) that one-third of residents experienced harm from care provided in SNFs and more than half of the harm (adverse events) was preventable.

Two [preliminary analyses](#) of insurer filings concluded that average ACA premiums will increase less than 4% in 2019... A [federal court of appeals ruled](#) that HHS erred in withholding \$5 million in cost-sharing reduction payments from Montana Health Co-Op... Plaintiffs in the 20-state lawsuit challenging the ACA's constitutionality urged a district court to strike down the entire law; while [DOJ asked that any legal remedy](#) be delayed a year to prevent market "chaos."

Maine Governor [Paul LePage filed a Medicaid expansion plan](#), but [urged CMS to reject](#) it... [4,574 Arkansas residents lost Medicaid coverage](#) for failing to satisfy work requirements.

Seven large health systems launched [Civica Rx](#) to [manufacture generic drugs](#).... Hospital groups [filed another lawsuit](#) to reverse CMS' cut to Part B reimbursement for 340B drugs... [PhRMA-sponsored analysis](#) concluded that hospitals charge nearly 500% of their costs for drugs... Novartis [will sell](#) parts of Sandoz, its generic-drug business... WellCare Health Plans [completed its \\$2.5 billion acquisition](#) of MeridianRx and Meridian Health Plans in two states.





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

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