



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

The [2019 Medicare Shared Savings Program \(MSSP\) proposed rule](#) would overhaul the ACO program with [a basic track](#) requiring two-sided risk assumption after 2 years (1 year for current participants), and an enhanced track that begins in two-sided risk... CMS [proposed rule](#) would adopt the ACA risk adjustment program it previously established for the 2018 benefit year... OMB is reviewing a [proposed rule](#) impacting Medicaid and CHIP managed care provider enrollment and terminations.

CMS [guidance encourages](#) “unloaded silver plans” outside the Exchange in some states... a Medicaid Rebate Program [notice](#) provides calculation guidance impacting drug manufacturer rebate liability for line extensions... FDA [draft guidance](#) establishes new endpoints for demonstrating effectiveness of medication-assisted treatment for opioid use disorder... FDA approved the first [generic drug under the Competitive Generic Therapy](#) designation; FDA [approved or tentatively approved](#) a record number of generics in July (126).

President Trump [told business leaders](#) an announcement is coming next week to get drug prices down “really, really substantially”... CMS [will allow Medicare Advantage plans](#) to use step therapy for Part B drugs in 2019... the [FDA and FTC are partnering](#) to address rising drug prices.



Healthcare law and policy news

AMA [urged the Justice Department](#) to block the proposed CVS-Aetna merger; Rite Aid and Albertson [terminated](#) their proposed \$24B merger... [Express Scripts will stop covering](#) 48 brand-name drugs next year, saving more than \$3B... Humana [sued dozens of generic drug manufacturers](#) for alleged price-fixing that increased drug prices as much as 8,000%.

[Memorial Sloan Kettering researchers](#) concluded that the US spent \$480 billion (nearly 15% of total healthcare spending) on prescription drugs in 2016, when gross profits of intermediaries such as PBMs are included... [CVS argued](#) that there is little relationship between the size of a drug rebate and list price increases, deflecting assertions that [PBMs are responsible](#) for increasing costs.

Altarum [reported that health spending grew](#) 5.2% over the past year, up from 4.2% the previous year... National Business Group on Health [projected that employers will spend](#) \$14,800 per employee on health coverage next year, up 5% from this year... Henry Ford Health System will [contract directly with General Motors](#) to offer new health plan options for 3,000 employees in 2019.



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