



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

Center for Healthcare Regulatory Insight



[August 24, 2018](#) | [Issue 34](#)

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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Read our latest issue brief on the *Short-term, limited duration insurance final rule*, which you can access [here](#)



Healthcare regulatory news

OMB is reviewing a [drug pricing transparency proposed rule](#); meanwhile, the Senate [passed an HHS spending bill](#) that would require drug manufacturers to display drug prices in direct-to-consumer advertisements... OIG will soon publish a [request for information](#) on changes to the anti-kickback statute and beneficiary inducement monetary penalties... [OIG reported](#) that

CMS improperly paid hospitals nearly \$26 million for intensity-modulated radiation therapy planning services between 2013 and 2015.

FDA [extended by four months](#) the expiration date of some EpiPens to alleviate shortages... FDA [awarded a contract](#) to the National Academies of Sciences, Engineering, and Medicine to create new opioid prescribing guidelines for acute pain... an [FDA report addresses](#) under-representation of certain populations in clinical trials.

The Justice Department and [Drug Enforcement Administration proposed](#) reducing manufacturing quotas [by 10% in 2019](#) for the six most abused opioids; while the Justice Department [issued a first-of-its-kind restraining order](#) barring two physicians from prescribing medications while under investigation for illegal opioid prescribing.

[GAO urged](#) Congress to strengthen oversight of Medicaid providers and managed-care plans... [GAO said that CMS](#) needs to improve management of the federal ACA exchange after enrollment fell 5% (to 8.7 million) in 2018.



Healthcare law and policy news

HHS released [a 100-day recap of actions](#) taken to implement its drug pricing blueprint... CMS announced an Innovation Center (CMMI) model, [Integrated Care for Kids \(InCK\)](#) focusing on children in Medicaid and CHIP who [have physical and behavioral health needs](#), including substance use... CMMI is [seeking a small business](#) to support “medical bidding and price transparency services”... CMS [awarded \\$8.6 million](#) to 30 states and DC to support implementation of marketplace reforms and ACA consumer protections.

A [CMS State Medicaid Directors](#) letter affirms that Medicaid 1115 waivers must remain budget neutral... CMS approved [a Maryland 1332 waiver](#) to establish an ACA reinsurance program... A [district court ruled](#) that HHS and IRS must [repay six states \\$839 million](#) in ACA health insurer fees paid since 2014.

A [JAMA study estimated](#) that Medicare Part D could have reduced spending by \$952 million in 2016 by substituting 29 brand-name combination medications with generics... A [NBER](#)

[report](#) found that acquired hospitals save only 1.5% annually on supplies, devices, and other equipment.



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



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