

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

Center for Healthcare Regulatory Insight

January 5, 2018 | Issue 1

Editor's note

Around the World (ATW) 360 is produced every Friday by the KPMG Center for Healthcare Regulatory Insight and is intended to be short and succinct (no more than 360 words) to provide a digestible bite of news relevant to our clients. Links are provided to source material (proposed and final regulations, agency guidance and press releases, reports, research, etc.) when available.

In order to continue receiving ATW 360 in future weeks, you will need to subscribe to our mailing list <u>here</u>.





Healthcare regulatory news

A <u>Department of Labor proposed rule</u> would allow certain small businesses and trade groups to form "association health plans" to purchase health insurance outside the ACA marketplace... A <u>Substance</u> <u>Abuse and Mental Health Services Administration</u> (SAMHSA) final rule updates standards on how and when insurance companies and providers can share information about substance abuse patients with third parties providing and paying for treatment...The FDA <u>proposed a</u> <u>program</u> allowing for voluntary quarterly reporting of medical device malfunctions...The FDA also <u>released draft guidance</u> on best practices to cut approval time for generic drugs applications and a <u>new</u> <u>framework</u> to streamline the generic review process. HHS is requesting information on potential reforms to increase competition and choice in healthcare markets... CMS <u>released data</u> on rebates paid to employers and individuals in 2016 as a result of ACA medical loss ratio requirements... CMS released proposed changes to the Medicare Advantage and Part D <u>risk adjustment model</u>... Beginning next year, CMS will <u>review Medicare Advantage plan provider</u> <u>networks</u> on <u>three-year cycles</u>, rather than only when a plan is approved or expanded.





Healthcare law and policy news

The <u>Senate Finance Committee will hold a confirmation hearing</u> for HHS Secretary-nominee Alex Azar on January 9th... A <u>federal judge</u> <u>refused to enjoin</u> CMS from proceeding with \$1.6 billion in cuts to 340B drug payments, finding that the hospitals lacked standing... a 2.3% <u>excise tax on medical device manufacturers</u> went back into effect January 1, following a two-year pause... <u>Spark Therapeutics announced</u> its genetic treatment for an inherited form of blindness will cost \$425,000 per eye.

HHS <u>OIG is seeking recommendations</u> for new or amended safe harbors from the anti-kickback statute to promote value-based payment models and care coordination efforts... The <u>OIG reported</u> that the New York State Department of Health may have misallocated nearly \$19.6 million in federal grants to create its ACA insurance exchange... CMS <u>approved a \$25 billion</u>, five-year extension of a Medicaid 1115 waiver in Texas to support its Delivery System Reform Incentive Payment (DSRIP) program and uncompensated care pool for safety-net hospitals and Medicaid providers... CMS <u>reported that more</u> <u>than 8.7 million</u> individuals were enrolled in 2018 ACA plans through Healthcare.gov as of December 23.



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