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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 Commissioner Scott Gottlieb gave e-cigarette companies 60 days to submit plans for curbing youth vaping, warning that their products may be pulled from the market... FDA unveiled the agency's plan to combat antibiotic resistance...FDA issued a draft memorandum of understanding for state oversight of compounded medicines... FDA issued guidance for development of therapeutically equivalent generics to specific reference products...

<u>FDA approved</u> new Apple Watches to conduct electrocardiograms and <u>alert users</u> of potential atrial fibrillation.

A District Court <u>vacated the 2014 CMS rule</u> on Medicare Advantage Organization (MAO) overpayments...

OMB <u>began review</u> of the 2020 Medicare Advantage and Part D program <u>proposed rule</u>... CMS <u>guidance details</u> how individuals can claim a hardship exemption from the individual mandate tax penalty in 2018.





### Healthcare law and policy news

The Senate plans to <u>vote on an opioid package</u> on <u>Monday</u>... an industry alliance <u>launched a new private-sector alternative</u> <u>payment model</u> to address addiction recovery through patient-centered medical homes.

A <u>NAMD survey found</u> that delivery system reform, IT upgrades, and behavioral health are the most common priorities for state Medicaid directors... <u>California law</u> now gives state regulators more authority to impose conditions on "major" proposed insurance mergers... <u>Michigan submitted an 1115 waiver</u> to impose work requirements on Medicaid expansion beneficiaries... <u>Nebraska's Supreme Court struck down an appeal</u> to prevent a Medicaid expansion referendum... <u>Maryland sued HHS, DOJ, and IRS</u> to uphold the ACA's constitutionality.

An <u>industry study</u> found that MSSP ACOs saved Medicare \$542 million between 2013 and 2015, compared to CMS estimates of \$344 million in increased Medicare costs... The Physician-Focused Payment Model Technical Advisory Committee (PTAC) voted to <u>recommend one APM</u> for implementation and <u>two others</u> for limited scale testing.

The Census Bureau reported that 8.8% of Americans were uninsured in 2017, an insignificant change from 2016... CDC found that more than 35% of residents are obese in 7 states...A NORC-University of Chicago poll found that 77% of Americans believe drug prices are "unreasonable" and only 23% approved of President Trump's drug policy proposals... 85% of insured Amazon Prime members said they would purchase prescription drugs on the Amazon site... Navigant found no correlation

between higher hospital revenues and better operating margins between 2015 and 2017.



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