

# 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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CMS <u>1332 waiver guidance</u> allows <u>more consumer plan options</u>, including short-term policies; streamlines the waiver request process and provides <u>more flexibility</u> for states in meeting regulatory requirements... A CMS <u>proposed rule</u> seeks input on an "<u>International Pricing Index</u>" payment model to better align Part B drug prices with prices in other countries... CMS <u>announced that</u> <u>75,000 individuals</u>' files were improperly accessed on the ACA agents and brokers direct enrollment portal... CMS <u>announced</u> <u>release</u> of SNF Quality Reporting Program (QRP) data on Nursing Home Compare. An <u>IRS-Labor-HHS proposed rule</u> would expand the use of health reimbursement accounts (HRAs), allowing employers to provide subsidies for employees to purchase individual health coverage... OMB is <u>reviewing a HRSA proposed rule</u> to change the effective date of 340B ceiling prices and penalties from July 1 to January 1.

FDA <u>approved the first novel-mechanism flu drug</u> in almost 20 years... FDA, with international partners, <u>took action against 465</u> <u>online pharmacies</u> selling potentially dangerous and unapproved opioid, cancer, and antiviral drugs... FDA <u>draft guidance</u> clarifies verification system requirements for drug manufacturers to meet statutory changes for quarantine and investigation of suspect drugs, and disposal of illegitimate drugs... FDA <u>authorized</u> <u>"WideTrial" to charge patients</u> for participation in an experimental drug trial.



# Healthcare law and policy news

President Trump signed the <u>bipartisan opioid package</u>; a diverse group of private sector partners <u>pledged efforts</u> to help combat the opioid crisis... CMS announced the <u>Maternal Opioid Misuse</u> (<u>MOM</u>) model to help <u>align and coordinate care</u> of pregnant and postpartum Medicaid beneficiaries with opioid use disorder.

CMS <u>approved North Carolina's 1115 waiver</u> to transition Medicaid to managed care... A <u>KFF survey</u> found that Medicaid enrollment decreased 0.6% in FY18, while program spending grew 4.2%; <u>A2 Strategy Group</u> found that three-quarters of Medicaid beneficiaries (54.9 million) are enrolled in managed care... <u>KFF estimated</u> that ACA policy changes increased 2019 premiums, on average, by 6%.

Maryland <u>asked the Supreme Court</u> to <u>uphold the state's drug</u> <u>pricing gouging law</u>, while Arkansas <u>asked the Supreme Court</u> to overturn a federal appeals court decision <u>striking down its drug</u> <u>pricing law</u> regulating PBMs.

Amgen <u>cut the price</u> of its cholesterol medicine, Repatha, by 60%... Express Scripts <u>informed pharmacies</u> that networks will expand, including mail-order pharmacies in 2019.

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