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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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A partial government shutdown is looming in Washington as Congress and the President have until midnight tonight to reach agreement on a funding bill for about 25% of the federal agencies, including Departments of Justice, Homeland Security, Interior, State, Housing and Urban Development, and Agriculture (including FDA). The main sticking point is the level of funding for border security and the border wall, a priority of President Trump. Meanwhile, a lot happened this week in health care...



Healthcare regulatory news

<u>Part I</u> of the 2020 MA and Part D Advance Notice <u>updates the MA</u> <u>risk adjustment model</u> to account for the number of conditions an

individual may have... CMS released the MSSP <u>final rule</u> requiring ACOs to accelerate <u>moving to two-sided financial risk</u>, while also providing additional regulatory flexibility... A <u>CMS RFI</u> seeks comment on <u>financial relationships</u> between Accrediting Organizations and the healthcare facilities to which they provide consulting services.

An <u>FDA advisory panel recommended</u> that providers co-prescribe the opioid antidote naloxone with strong painkillers; <u>HHS guidance</u> recommended specific situations for naloxone prescribing... FDA <u>finalized details</u> of the Breakthrough Device Program and <u>announced plans</u> for the Safer Technologies Program, aiming to encourage development of safer medical devices.

CBO <u>provided options</u> to reduce the deficit, including adjusting MA risk scores and quality bonus payments, reducing federal Medicaid match rates, and raising the Medicare eligibility age to 67.





Healthcare law and policy news

A Texas <u>court ruled</u> that the ACA individual mandate is unconstitutional and inseverable from the rest of the law, striking down the entire law, which remains in effect pending appeal; Attorneys General from 16 states and DC will appeal the decision and <u>sought clarification</u> on what the decision means for ACA compliance in the interim.

The ACA enrollment period <u>closed with nearly 8.5 million</u> <u>enrollees</u>, down 4% from 8.8 million last year... Arkansas <u>removed 4,655 Medicaid enrollees</u> for failing to meet work requirements, bringing the total to more than 16,000 beneficiaries.

NIH found that 20.9% of surveyed high school seniors used ecigarettes in the last month, up from 11% last year... A Surgeon General public health advisory emphasized the growing vaping problem... meanwhile, Altria Group closed on a \$13 billion deal giving it 35% stake in Juul Labs.

<u>Cigna-Express Scripts</u> closed its merger... CVS and Aetna <u>agreed</u> to keep certain business operations separate while a judge considers final approval of its merger... 28 pharmaceutical manufacturers <u>plan to raise drug prices</u> as early as January 1... Pfizer and GlaxoSmithKline <u>plan to merge</u> their consumer health

units... Walgreens and Verily are <u>entering a partnership</u>, including to improve medication adherence... Novartis may <u>partner with reinsurance companies</u> to help pay for the cost of novel, personalized gene therapies.

Best Wishes for Happy Holidays and a healthy and prosperous new year! We will take a break next week... our next edition will be sent on January 4th.



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



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