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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

HHS is seeking public comment on drug pricing proposals announced by President Trump last week... In speeches this week, HHS Secretary Alex Azar promoted the drug pricing "blueprint"; encouraged manufacturers to work with the agency; and announced plans to launch a Part B drug competitive acquisition program... CMS released its updated drug pricing dashboard to provide information on companies raising prices and notified Part D plans to prohibit pharmacy gag clauses.

FDA Commissioner <u>Scott Gottlieb released</u> a list of drug manufacturers limiting access to branded product samples to slow

generic competition... FDA <u>published draft guidance</u> on waivers, exceptions, and exemptions to requirements for traceability and security of certain drugs... CMS initiated a <u>national coverage</u> <u>analysis</u> for CAR-T cell therapies.



Healthcare law and policy news

President Trump nominated acting VA Secretary, Robert Wilkie, to be VA Secretary... CMS Administrator Seema Verma emphasized that CMS would not approve state-proposed lifetime limits on Medicaid enrollment... CMS will consolidate several Medicare quality programs under a single contract worth up to \$25 billion... HHS OIG reported that 10.1% of Medicaid payments were improper in FY2017, short of its 9.57% reduction target; and that HHS failed to comply with the Improper Payments Elimination and Recovery Improvement Act of 2012.

The <u>Defense Department reported</u> that a pilot to replace its EHR system had 156 "critical" or "severe" incident reports between September and December 2017 that could lead to patient deaths; also, the <u>VA finalized its contract with Cerner</u> to modernize the VA health IT system... <u>HHS OIG told the Senate HELP Committee</u> that HRSA's oversight of the 340B program is inadequate.

CMS renewed and expanded Maryland's all-payer payment system through 2023... Vermont enacted legislation making it the first state to legalize importation of prescription drugs from Canada... Attorneys General from six states are filing lawsuits against Purdue Pharma, claiming deceptive marketing of OxyContin contributed to the opioid epidemic.

The <u>CMS Actuary estimated</u> that 0.8 million individuals would leave the ACA marketplace for short-term limited duration plans by 2022 resulting in premium increases 6% above baseline... <u>Kaiser Family Foundation found</u> that despite market uncertainty, ACA individual insurers are regaining profitability... UnitedHealth <u>estimates that Medicaid coverage</u> costs 43% less than ACA marketplace coverage.



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