



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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Healthcare regulatory news

CMS released several fee schedule final rules: The [physician fee schedule rule](#) implements [new evaluation and management billing](#) for 2021; expands payment for “virtual” care; and reduces the ASP add-on for Part B drugs in the first quarter of sales from 6% to 3%. The rule also [finalizes 2019 QPP policies](#), including allowing low-volume clinicians to opt into MIPS participation. The [hospital outpatient rule](#) phases in [site-neutral payments](#) for clinic visits and updates and streamlines quality measures for outpatient departments and ASCs. The [DME and ESRD rule revises the competitive bidding program](#) and encourages innovative therapies for ESRD. The CMS [home health rule](#) expands [access to remote](#)

[patient monitoring technology](#), updates payments with a new case-mix system, and begins a new home infusion therapy benefit.

A CMS [MA and Part D policy proposed rule for 2020](#) would [provide more flexibility](#) for plans to cover telehealth, streamline benefits, and update the risk adjustment data validation (RADV) audit process... OMB began [review of a proposed “drug pricing” rule](#) for Part D and MA... A [HRSA proposed rule](#) would move up enforcement of 340B ceiling prices and manufacturer civil monetary penalties to January 1... A federal judge [ordered HHS](#) to eliminate its Medicare hospital appeals [backlog by 2022](#).

FDA [approved Novartis’ biosimilar](#) of Abbvie’s Humira and [authorized](#) the first direct-to-consumer DNA test to help determine individual effectiveness of certain medications, while also [warning about potential false claims](#) about their utility... OIG [reported that FDA](#) post-market medical device cybersecurity plans and procedures do not go far enough to protect public health.



Healthcare law and policy news

A [Clearwater survey](#) found that only 29% of health systems have implemented a comprehensive cybersecurity program.

ACA open enrollment began on Thursday with less [CMS funding for “navigators”](#)... CMS [approved Wisconsin’s 1115 Medicaid waiver](#) to [impose work requirements](#) and add new copays and premiums... MACPAC [urged HHS](#) to [pause Medicaid work requirements](#); warned that the immigration [public charge proposed rule could depress Medicaid](#) enrollment; and explored [methods to rebase DSH](#) allotments.

A [Politico/Morning Consult poll](#) found 65% of respondents support Medicaid expansion in their state... Avalere estimated that [2.7 million Americans could gain access to Medicaid](#) as a result of the midterm elections.





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



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