



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



[December 14, 2018 | Issue 50](#)

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.

In order to continue receiving ATW 360 in future weeks, you will need to subscribe to our mailing list [here](#). Please share this email with colleagues and other interested individuals.

[Subscribe here](#)



Healthcare regulatory news

HHS [requested comments](#) on modifying HIPAA privacy rules to better promote coordinated care... OMB is reviewing [advance notices](#) for CY2020 Medicare Advantage and Part D program changes.

FDA [guidance](#) would [reclassify insulin](#), growth hormones, and [other living cell substances](#) as biological products to encourage generic competition... an FDA [proposed rule](#) amends the definition of "biological product" and [revised guidance](#) addresses biosimilar development questions.

FDA [withdrew](#) a generic drug labeling proposed rule and [announced changes](#) to generic cancer drug labels... FDA [guidance](#) documents aim to [relax current good marketing practice](#) (CGMP) requirements for drug compounding facilities and clarify the [role of data integrity](#) in CGMP... FDA will [increase pharmaceutical enforcement](#) actions and improve inspection assessments, including through a new inspection protocol for sterile generic drugs.

OIG [released its semiannual](#) report to Congress and [reported that Medicare improperly paid](#) \$34 million from 2015 through 2017 for inpatient durable medical equipment, prosthetics, orthotics, and other supplies.



Healthcare law and policy news

ACA open enrollment ends tomorrow; as of December 8th, [4.1 million individuals had enrolled](#), 11.7% behind last year's pace; CMS [extended enrollment](#) for call-center customers who called before December 15.

The Supreme Court [will hear oral arguments](#) on whether state-law failure-to-warn claims are preempted by FDA action... A [federal appeals court ruled](#) that Blue Cross Blue Shield companies must defend against antitrust class action claims... Washington Post [reported that 16 generic manufacturers](#) and over 300 drugs are implicated in a lawsuit alleging "cartel"-like behavior, including price fixing.

California and New York [approved the Cigna-Express Scripts merger](#) with conditions... Walmart and Express Scripts [extended](#) their network agreement [by three years](#)... Walgreens and FedEx [will launch](#) next-day prescription deliveries... Kaleo will [introduce a generic](#) version of naloxone.

The House passed [the IMPROVE Act](#), which would [crack down](#) on pharmaceutical manufacturers knowingly misclassifying branded products as generics in Medicaid; the Senate anticipates passing its own version.

An [NPR-IBM poll](#) found that 34% of individuals under 35 years old delayed care due to costs, compared to 19% of those between 35 and 64, and 8% of those above 65... Healthcare [hiring](#) (32,000) exceeded all other sector hiring in November; TheKnowledgeAcademy.com [projects](#) more than 1.1 million new healthcare jobs by 2026.



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



[Privacy](#) | [Legal](#)

You have received this message from KPMG LLP. If you wish to unsubscribe from Around the world of U.S. healthcare in 360 words or less, please [click here](#). If you wish to unsubscribe from all KPMG communications, please [click here](#).

KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2018 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 698390

The KPMG name and logo are registered trademarks or trademarks of KPMG International.