



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



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Editor's note

Due to the Labor Day holiday on Monday, September 2, the next issue of ATW will be published on Tuesday, September 3. Have a safe and enjoyable end of summer!

[This series](#) is produced by KPMG Healthcare and is intended to be short and succinct, less than 360 words, to provide a weekly digestible bite of healthcare regulatory, policy, and industry news relevant to our clients. Links are provided to source material (proposed and final regulations, agency guidance and press releases, reports, research, etc.) when available. Please share this email with colleagues and other interested individuals, and encourage them to [subscribe to our mailing list here](#).

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Healthcare regulatory news

HRSA [is allocating](#) \$1.4B to the Ryan White HIV/AIDS Program Fund for the AIDS Drug Assistance Program; without federal support, HIV antiretroviral treatment can cost individuals up to \$40K per year.

Two enhanced direct enrollment (EDE) sites, Benefitalign and Inshura, [have been temporarily blocked](#) from accessing enrollees' information through HealthCare.gov due to abnormal enrollment activity; both EDEs are facing legal scrutiny due to their alleged involvement in unauthorized enrollment practices.

A new [CMS data brief](#) shows that CMS has closed over 12,000 complaints pertaining to potential violations of the No Surprises Act (NSA) and the ACA; the agency provided approximately \$4.2M in relief to consumers and providers through remedial and corrective actions.

The Biomedical Advanced Research and Development Authority (BARDA) [awarded Walgreens](#) an additional \$100M over five years to expand BARDA's use of Walgreen's retail pharmacies as enrollment sites for clinical trials.

The FDA [granted](#) marketing authority to NOWDiagnostics for the first over-the-counter syphilis test amidst [a significant increase](#) in the incidence of syphilis cases between 2018 and 2022.



Healthcare law and policy news

An [OIG report](#) found that Medicare and some beneficiaries paid over 80% more for the popular immunosuppressant Stelara under Part D than under Part B... This report comes as [CMS released its negotiated price](#) for Stelara last Thursday that is significantly lower than the current cost under Part D.

The Association for Molecular Pathology [filed a lawsuit](#) against the FDA, alleging the agency lacks the authority to regulate lab-developed tests (LDTs) as a medical device; this is the second lawsuit challenging this provision, with the American Clinical Laboratory Association filing a similar lawsuit in May.

Humana [agreed to pay \\$90 million](#) to settle a [False Claims Act lawsuit](#) that claimed the insurer submitted fraudulent bids to the federal government to obtain Medicare Part D contracts from 2011-2017.

Sesame, an online marketplace, [announced](#) it will offer compounded semaglutide, a [non-FDA approved weight loss drug](#), for \$249 a month; prices for the same class of brand name weight loss drugs can cost consumers more than a \$1K per month.



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