Health Law Vitals - A Healthcare Newsletter from Haynes and Boone, March 2018

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PRACTICES Healthcare Transactions and Regulatory, FDA Regulatory and Compliance, Healthcare and Life Sciences

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FDA Draft Guidance Proposes Risk-Based Regulatory Scheme for Drug Products Labeled as Homeopathic

More than two and a half years after the U.S. Food and Drug Administration (FDA) announced that it was re-evaluating its regulatory framework for homeopathic products, the FDA released its Draft Guidance on Drug Products Labeled as Homeopathic. The Draft Guidance summarizes the FDA's current enforcement perspective on homeopathic products and provides a list of the FDA's enforcement priorities.
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The Extension of the Texas 1115 Waiver – What is Next?

With only nine days left before the expiration of the existing 1115 Waiver, in late December 2017, the Centers for Medicare & Medicaid Services (CMS) approved another extension of the 1115(a) demonstration project, "Texas Healthcare Transformation and Quality Improvement Program" (2017 Waiver) for an additional five-year term from October 2017 to September 2022. The 2017 Waiver extension will allow the state to maintain its use of capitated Medicaid managed care model to continue to improve the delivery of healthcare to Texans. The 2017 Waiver is still funded by supplemental payments and managed care savings, but it should be noted that, at an estimated $25 billion over five years, it will receive $2 billion less in funding than the previous 1115 Waiver. According to the Texas Health and Human Services Commission (HHSC) Executive Commissioner, Charles Smith, the renewal "preserves critical support for the state's hospital safety-net" by providing needed funding through the Uncompensated Care (UC) pool, without which, hospitals serving vulnerable patient populations would face potentially insurmountable financial struggles. Whether the renewal ultimately lives up to the Executive Commissioner's lofty expectations remains to be seen; the 2017 Waiver comes with new requirements and potentially far-reaching modifications.
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The New Framework for Characterizing the Deductibility of FCA Settlement Payments

In addition to its certain impact within the general realm of finance and business, the December 2017 passage of the Tax Cuts and Jobs Act may have somewhat less obvious, but equally important, implications for the delivery of healthcare and the industry as a whole. Some of the new law's key healthcare policy changes relate to the individual mandate, medical expense deductions, and the Orphan Drug Tax Credit; however, the particular implications of these changes are largely speculative at this time. On the other hand, the change to the deductibility of settlements with government agencies under Internal Revenue Code (Code) § 162(f), though not specifically aimed

at healthcare, may nonetheless have the most immediate impact on industry operations.
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How Should Restaurants Handle and Declare Major Food Allergens?

Although many restaurants are not in states that require food allergens to be declared on menus, the declaration (or labeling) and handling of food allergens is a growing concern for restaurants, due to the significant risks of liability and poor public relations, if handled incorrectly. Restaurants should create careful plans to address food allergens, from ensuring that food product suppliers provide comprehensive allergen checklists to training food handlers in methods to prevent cross-contact among food products that contain major food allergens and those that do not.
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