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Investigational Device Exemption (IDE) and Humanitarian Device Exemption (HDE) Device Coverage & Billing: Compliance Insights

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- The key FDA and CMS regulations affecting IDE and HDE device use and coverage, and the corresponding roles and the responsibilities across a health system - including Compliance, Providers, IRB, Clinical Trials Office, Supply Chain, and Billing
- Tips for how Compliance departments can promote collaboration and successful partnerships across a health system (such as education and outreach, task forces, and policy review) to reduce regulatory risk and promote system-wide compliance
- Sample process for analyzing IDE and HDE devices as they enter a health system to help ensure compliant device usage and billing