

Regulatory Issues Facing Genetic Testing

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ABSTRACT: With the mapping of the human genome and new technological developments, great advances in the field of genetic testing are possible. As with any new technology, however, the growth of genetic testing has presented new challenges, especially in the areas of pre-market approval, coverage, and payment. This article discusses the role of the U.S. Food and Drug Administration in regulating genetic tests, many of which are performed as Laboratory Developed Tests typically not subject to enforcement. It also examines the role of the Centers for Medicare & Medicaid Services, which oversees the quality assurance requirements set forth in the Clinical Laboratory Improvement Amendments of 1988. The article examines how laboratories performing genetic testing obtain coverage for their tests, either under local or national coverage decision processes. Finally, the article addresses the various issues related to payment, including coding new tests, billing issues, and pricing.

KEYWORDS: Analyte specific reagents (ASRs), CLIA, Clinical Laboratories, Cross-Walking, FDA, 14-day Rule, Gap-Filling, Genetic Testing, Hospital Bundling, In Vitro Diagnostic, In Vitro Diagnostic Multivariate Index Assays (IVDMIAs), Laboratory Developed Tests (LDTs), Medical Devices, Medicare Coverage

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