FDA Reverses Final Rule Regulating Laboratory Developed Tests

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PRACTICES FDA Regulatory and Compliance

The United States Food and Drug Administration (FDA) has officially rescinded its final rule proposing to regulate Laboratory Developed Tests (LDTs) as medical devices. On Sept. 19, 2025, FDA issued a new final rule reverting the text of the applicable device regulations to the version in-effect prior to the effective date of the May 2024 LDT rule. This action followed the Eastern District of Texas's decision to vacate the final rule earlier this year based on its finding that FDA exceeded its statutory authority when it issued the rule. For more information on the events leading up to FDA's formal rescission of the LDT rule, see our previous articles on the final rule and the court's decision.

Why Did FDA Initially Issue the Final Rule?

FDA explained that the final rule was intended to address technological advancements that have made for more complex LDTs capable of treating/diagnosing a larger portion of the population, as the historical LDT enforcement-discretion policy was intended to provide an exception for manually developed tests created and administered in the same clinical setting for a specific person(s). FDA cited concerns that today's version of LDTs pose safety and efficacy risks that require regulation.

What Did the Final Rule Propose?

The final rule proposed to phase out FDA's long-standing enforcement discretion policy for LDTs across five stages, meaning most LDTs would have to comply with the same regulatory requirements as medical devices by 2028. Most significantly, the final rule would have required LDTs to seek premarket clearance or approval before use.

As expected, the final rule was met with significant pushback. In particular, industry has long questioned FDA's authority to regulate LDTs, arguing that LDTs are not "devices" under the federal Food, Drug, & Cosmetic Act. Industry also maintained that Congress assigned sole regulatory authority over LDTs to CMS through the Clinical Laboratory Improvement Amendments (CLIA). This culminated in the American Clinical Laboratory Association and Association for Molecular Pathology successfully challenging the final rule in the Eastern District of Texas.

What Does the Official Revocation Mean?

The revocation is more of a technical formality following the district court's vacation of the rule and FDA's decision not to file an appeal. FDA will maintain the status quo, exercising enforcement discretion for LDTs and permitting the use of LDTs without 510(k) clearance or FDA approval.

Still, LDT manufacturers and developers should ensure that their tests satisfy the definition of an LDT. Specifically, LDTs are in vitro diagnostic (IVD) tests intended for clinical use that are **designed, manufactured and used** within a single laboratory. The LDT enforcement-discretion policy does not extend to IVDs that do not meet this narrow definition, which must be cleared or

approved by FDA before marketing and, otherwise, comply with all applicable medical device regulations.