January 18, 2024

FDA & CMS Double Down on Lab Developed Tests

CLIA Expansion Unlikely, FDA Likely to Finalize Pathway & Lawsuits Likely

Relevant Companies

Our Take & Next Up

Lab developed test (LDT) regulation is necessary, with home-brew diagnostic testing likely being regulated as medical devices. Today, FDA's Center for Devices and Radiological Health (CDRH) and the Center for Clinical Standards and Quality at Centers for Medicare & Medicaid Services (CMS) released a joint statement supporting the FDA's Laboratory Developed Tests (LDTs) proposed rule (here). We interpret the joint statement to mean that the agency will finalize its proposed pathway, in some form or shape, by April 2024 (the new regulatory deadline). In tandem, unrelated to LDTs, we believe CMS will finalize the TCET program, a way to expedite coverage of Breakthrough medical devices, likely lifting the cap on 5 per year as well as expanding to diagnostic testing.

Key Points

FDA reasserts the need to regulate LDTs due to impact on patients and the increasing complexity of tests. FDA points out that doctors rely heavily on laboratory tests to make patient care decisions. The agency has seen LDTs that could have led to patients being over- or under-treated for heart disease; patients with cancer being exposed to inappropriate therapies or not getting effective therapies; and resulted in incorrect diagnoses of rare diseases, autism, and Alzheimer's Disease. FDA also cites published literature and their recent experience regulating inaccurate COVID-19 LDT tests.

FDA is ready to defend LDT enforcement under the medical device pathway. The agency notes that inaccurate tests mislead the public, undermine legitimate competition and disincentivize responsible, science-based innovation. The agency is likely responding to the rhetoric on the negative impact to laboratory medicine innovation and looking towards the incoming litigation once the rule is finalized.

FDA proposed 4-year phase of LDT in pathway is likely to be finalized -- perhaps with tweaks -- this Spring. In September 2023, FDA released proposed guidance on how they plan to end general enforcement discretion for laboratory developed tests (LDTs) here.

- The general enforcement discretion approach plans to be phased-out during a 4-year period for all LDTs and instead be replaced with regulatory oversight under the agency's medical device authorities.
- FDA plans to regulate low-risk tests (class I devices), tests currently on the market, and tests for rare diseases under the same framework.

- Blood donor screening tests, tests intended for “emergencies,” and direct-to-consumer (DTC) tests are exempt.

CMS supports the FDA in their efforts to regulate LDTs because testing oversight is not in CMS's CLIA scope. CMS regulates laboratories through the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by establishing quality standards for all laboratory testing. This is distinct from ensuring that LDTs are clinically valid. CMS notes that: “some have suggested that concerns with LDTs should be addressed through expansion of CLIA. This is not the answer. As was stated in our 2015 testimony, CMS does not have the expertise to assure that tests work; the FDA does.”

CLIA expansion is not a viable solution. Currently, when a laboratory develops an LDT in-house without receiving FDA clearance or approval, CLIA prohibits the release of any test results until the laboratory establishes certain performance characteristics of analytical validity through a routine CLIA survey. The agencies note that expanding this authority to cover the clinical validity of the tests is duplicative and likely to lead to more inconsistencies in oversight.

An expanded TCET final rule (that includes diagnostic tests) is also expected in early 2024. We expect a more inclusive final rule that will lift the 5 Breakthrough device limit and expand eligibility to diagnostic tests. The proposed transitional coverage for emerging technologies (TCET) released in June 2023 (here) was very limited in scope, offering largely CED coverage for 5 Breakthrough devices a year. Devices will have to undergo an Evidence Preview (literature review), and an Evidence Development Plan (EDP) will have to be approved.

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