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Experts Say LDT Small-Business Compliance Guide Does Little To Persuade

by Elizabeth Orr

A new FDA lab-developed test compliance guide for small enterprises summarizes agency policy but fails to address clinical lab industry concerns about the LDT final rule.

The US Food and Drug Administration issued a *new compliance guide* on lab-developed tests for small enterprises on 26 June. But will the document be enough to allay clinical lab industry concerns about the potential costs and regulatory burdens of FDA oversight?

Stakeholders who spoke to *Medtech Insight* said it may not be. The compliance guide, they explained, is largely a condensed restatement of information that the FDA has already released in other forms. As such, it provides little practical reassurance for wary clinical labs.

While device industry groups like AdvaMed have signaled support for the LDT final rule, clinical labs have been hold-outs. Last month, the American Clinical Laboratory Association (ACLA) filed suit to block enforcement of the new policy on the grounds that the FDA does not have authority over LDTs. (Also see "*News We're Watching: ACLA Sues FDA; Philips Recall; New Funding In Women's Health; FDA Nods*" - Medtech Insight, 31 May, 2024.)

"The key issues of the final rule and its negative impact to small laboratories still remain," says Jonathan Genzen, Chief Medical Officer of ARUP Laboratories.

ARUP, a national reference lab, has been an active opponent of the FDA's expanded role in LDT regulation. In March, it released a survey finding that 71.6% of responding labs opposed the rule and 83.9% believed it would hurt their businesses. (Also see "*News We're Watching: LDT Survey Finds Concern, Abbott Recall, New Q-Sub Guidance*" - Medtech Insight, 15 Mar, 2024.)

Regulatory experts also appear skeptical.

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“I was looking for the substance and really didn’t see much,” Gail Javitt, a director at law firm Hyman, Phelps & McNamara, told *Medtech Insigh*t. “[The compliance guide] is a 20-page recap of a multi-hundred-page document.”

While that conciseness may make the document useful as a quick summary of the FDA’s LDT final rule, there’s little new here for those familiar with the original, she says. (Also see "*It’s Official: FDA Drops Final Rule On LDTs*" - Medtech Insight, 29 Apr, 2024.)

Resources linked in the document have not been tailored for clinical laboratories, Javitt says. And she does not believe it will be easy for clinical labs to extrapolate the FDA’s expectations from references intended for traditional device manufacturers.

Recalls are one example, Javitt says. Federal regulations specify how device makers must respond if a problem with a product is discovered, which may involve notifying customers not to use the product or to return it to the manufacturer. But the waters are much murkier for clinical labs that develop, validate and perform their tests on-site.

“What is the analogue [to a device recall] when you are a laboratory?” she asks. “What are you recalling? When do you need to recall something?”

And because faulty clinical tests are unlikely to cause direct harm to patients, it’s similarly unclear how medical device reporting (MDR) rules would apply to labs, she says.

To Be (a device) Or Not To Be. That’s The Legal Question

By Brian Bossetta

08 May 2024

Now that the US FDA has published its final rule regulating lab developed tests, litigation challenging the rule and the FDA’s authority to enact it is sure to follow. And the central argument will likely focus on whether the tests are defined as medical devices, which the agency regulates without question.

Read the full article here

“The answers are not obvious, and I'm not sure if the FDA has figured out all those questions itself,” Javitt says. “So labs are a position of having to derive it for themselves and hoping they get it right and if they don't, they could be subject to penalties.”

One section of the compliance guide that may appear to offer some breathing room is a list of tests for which the FDA still plans to exercise at least some enforcement discretion, including:

- Simple tests similar to those on the market when the FDA began regulating IVDs in 1976;
- Certain Human Leukocyte Antigen (HLA) tests performed prior to transplant surgery;

- Forensic tests exclusively used by law enforcement;
- LDTs manufactured and performed within the Veterans Health Administration (VHA) or the Department of Defense (DoD);
- LDTs that are approved by New York State Department of Health's Clinical Laboratory Evaluation Program;
- Some modified versions of FDA-cleared LDTs developed by another manufacturer when performed in CLIA-certified labs;
- LDTs manufactured and performed by a laboratory within a health care system to meet an unmet need of patients of the health care system;
- IVDs that received FDA clearance before 4 May 2024 and are currently offered as LDTs; and
- Non-molecular antisera LDTs for rare red blood cell (RBC) antigens for transfusion compatibility.

The FDA will publish further guidance documents on the tests for which enforcement discretion will apply as needed, the compliance guide states.

However, Javitt cautions that even if the agency says it doesn't plan to enforce certain expectations for certain categories of LDTs, that might change in the future. "If they want to regulate your test, 'enforcement discretion' will not constrain them," she points out.

Clinical Lab Recounts Challenges

"The FDA has significantly underestimated the negative impact of the final rule on small clinical laboratories and small entities in general," ARUP Laboratories CMO Genzen told *Medtech Insight*.

He is particularly concerned about the burden FDA regulation will pose for new test development, as well as common modifications such as automation. Lack of resources could make it impossible to sustain "significant, clinically important testing" for many clinical labs and other small entities, he says.

The final rule provided some regulatory exemptions for tests serving unmet needs. But even that poses challenges, Genzen says. Clinical labs that are owned by a larger health care system would not qualify for small-business discounts on FDA user fees, while independent clinical labs cannot qualify for the unmet needs exemption at all. As a result, new tests for rare diseases may become much more expensive.

"In an environment where we'd ideally like to promote innovation in small business, I believe the FDA Final Rule unfortunately disincentivizes such innovation and rather promotes

consolidation of testing in far fewer locations and for fewer clinical conditions and rare diseases," Genzen concludes.