June 24, 2024

Chair Bernie Sanders
Senate Committee on Health,
Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member Bill Cassidy, MD
Senate Committee on Health,
Education, Labor, and Pensions
828 Hart Senate Office Building
Washington, DC 20510

Chair Cathy McMorris Rodgers
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chair Sanders, Ranking Member Cassidy, Chair McMorris Rodgers, and Ranking Member Pallone:

The Association for Diagnostics and Laboratory Medicine (ADLM) is concerned about the impact of the Food and Drug Administration's (FDA's) May 6, 2024 final rule regulating laboratory developed tests (LDTs) on the ability of clinical laboratories to provide timely, quality patient care. In the final rule, the FDA identifies several exceptions that the agency claims will reduce the regulatory burden on laboratories, particularly hospitals. ADLM recently conducted a survey of laboratories to garner feedback on how the rule and these exceptions will affect their ability to provide physicians with the information they need to diagnose and treat their patients.

Our results indicate there remains much confusion among laboratories about the final rule and how it will be implemented. Part of this uncertainty is because clinical laboratories are not medical device manufacturers and therefore have a different regulatory structure and terminology. Also, the regulation of LDTs, which is a professional service offered by laboratories to caregivers, does not align well with the FDA model, which regulates products sold to any healthcare provider.

We received 128 responses to our survey, which focused on the impact of the previously marketed or grandfathering provisions and the unmet need exceptions for laboratories within a single healthcare system. Despite mitigating exceptions for previously marketed tests and continued, limited enforcement discretion for tests meeting unmet needs, the new requirements are unfamiliar to most clinical laboratories and represent a substantial bureaucratic and financial burden that will lead to discontinuation of large numbers of critical tests. The results and our interpretation are below.

Key Findings:

Previously Marketed or grandfathered tests

- More than 70% of laboratories responding stated they do not have the staff or resources to meet the requirements set forth for previously marketed (i.e., grandfathered) LDTs under the final rule.
    - More than one-half of these labs anticipate discontinuing some LDTs.

Unmet Need Exceptions

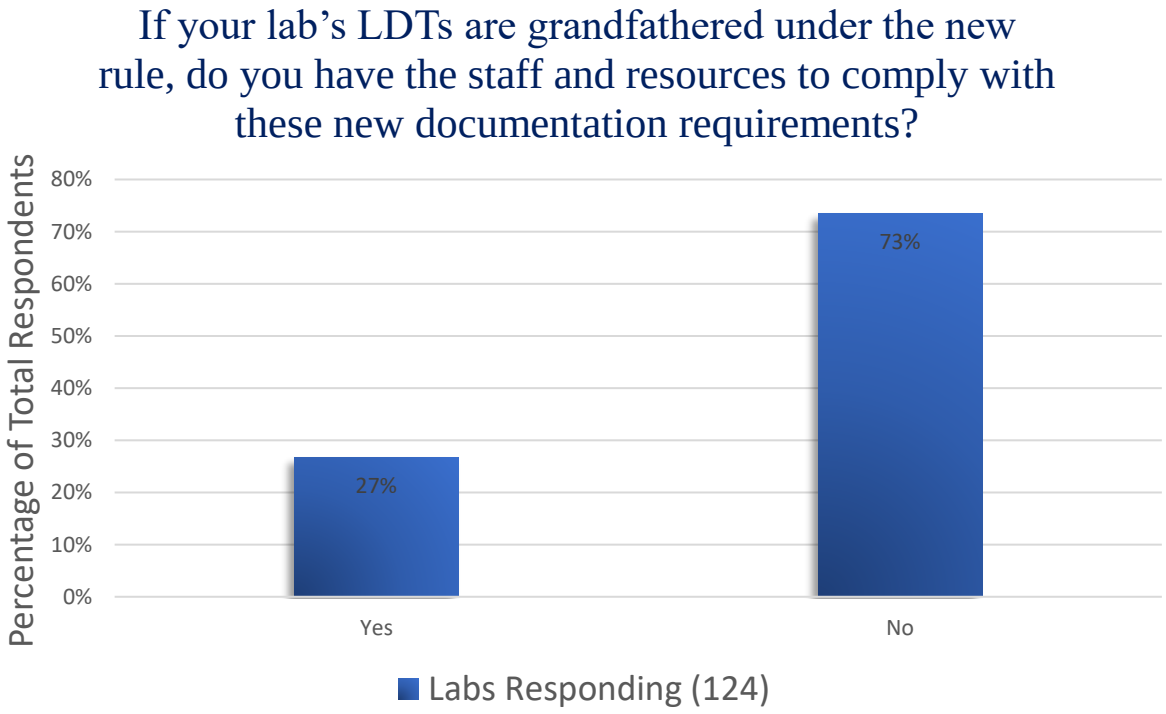
- A majority of laboratories responded they would be unable to comply with the FDA's requirements associated with the unmet exceptions in the final rule.
    - 60% of the hospitals stated they would be unable to comply with the requirements associated with the exception.
    - Nearly 70% of those labs who stated they would be unable to comply with the requirements responded they would discontinue LDTs.

Previously Marketed or grandfathered tests

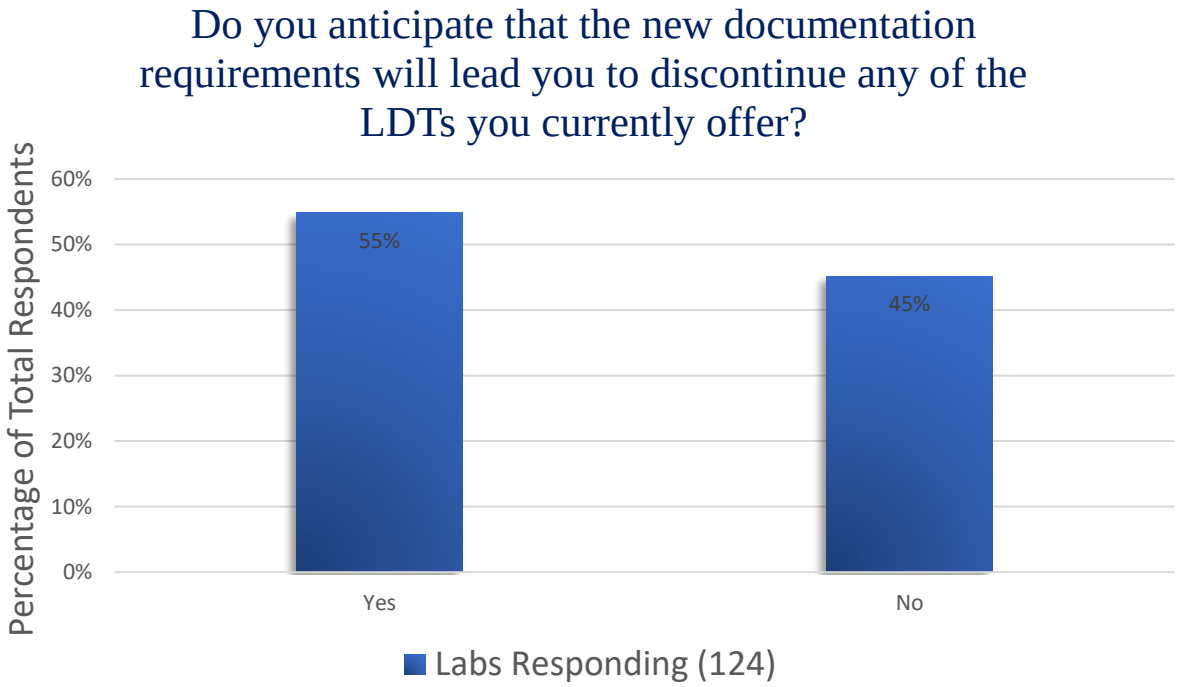
The FDA stated that laboratories could continue to perform LDTs that were marketed prior to the publication of the final rule if the tests were unmodified or remained largely the same moving forward. While laboratories would be exempt from FDA premarket review of the test and the agency's quality system regulation requirements, laboratories would remain subject to a variety of other standards, including:

- registration;
- listing;
- labeling;
- investigational device requirements;
- medical device reporting; and
- complaint tracking.

These requirements are covered in hundreds of pages of federal regulatory documents. These requirements are new for laboratories that develop LDTs. 73% of responding laboratories stated that they did not have the staff or resources to comply with the requirements listed above.



More than one-half (55%) stated they were likely to discontinue some of their previously marketed tests. We are concerned the number of laboratories who may discontinue testing will increase if these facilities are unable to obtain the resources needed to comply with the new standards.



The most common types of tests laboratories mentioned that may be discontinued were body fluid tests (Body fluid tests are performed on fluid that is collected around body organs, such as the heart, or located within joints) and toxicology testing.

Common body fluid tests include: amylase; total albumin; creatinine; and glucose. These tests inform diagnoses and procedures in a variety of rare but serious clinical situations.

Common toxicology tests include: methamphetamine; fentanyl; opioids (e.g., oxycodone); barbiturates; and cocaine.

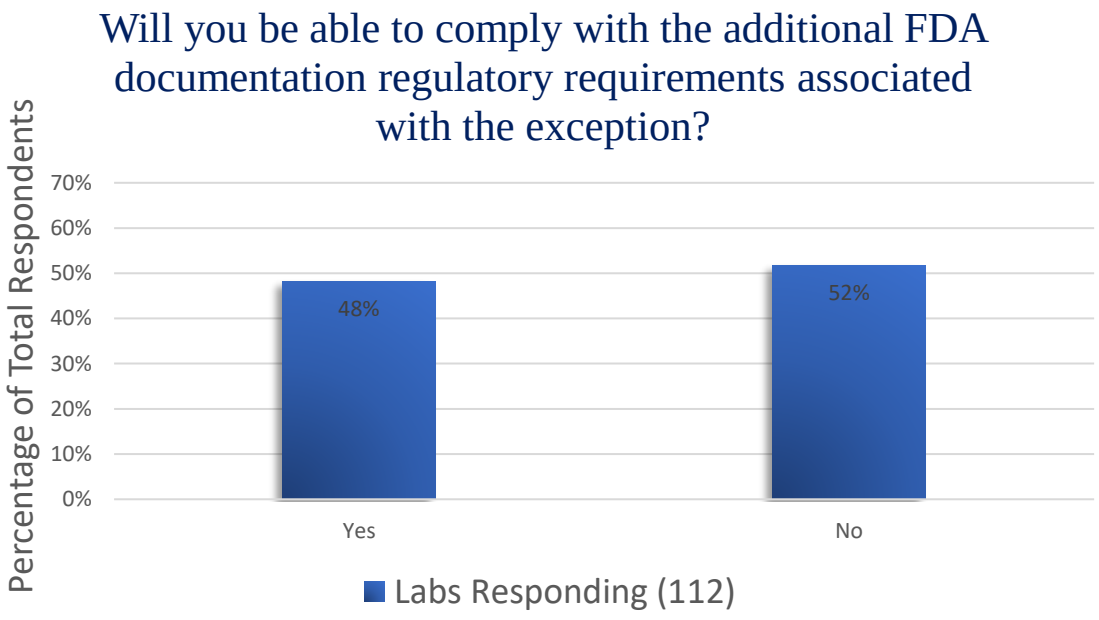
Many FDA cleared test kits are only approved for use with serum or urine. Laboratories may modify the test to use it in body fluids to obtain specific information needed by the physician. Laboratories must validate the accuracy of the test before using it and comply with the rigorous CLIA standards overseen by the Centers for Medicare and Medicaid Services. Laboratories are concerned that the additional LDT requirements set forth by the FDA will force them to discontinue performing these tests, adversely affecting patient care.

Previously marketed body fluid test - Amylase - A laboratory can measure amylase in a peritoneal fluid and learn whether the patient has ruptured their pancreas, without having to do exploratory surgery to determine it. A high peritoneal fluid amylase suggests ruptured pancreas. While there is an FDA-approved test, it is only approved to use with serum. Performing the test using peritoneal fluid makes it an LDT – an LDT that improves the quality of patient care, while also potentially reducing overall healthcare costs.

Previously marketed toxicology test – Methamphetamine - Another common class of tests that participants mentioned they may stop performing are toxicology tests. Many FDA approved assays for drug testing are not sensitive or specific enough to detect drugs at their lowest concentrations. Laboratories modify these assays to obtain the information the physician needs to care for their patient. There are FDA-approved immunoassay drug screens for methamphetamines, but these screening tests were designed decades ago to detect concentrations found in workplace drug testing. These assays are unable to detect drugs at low concentrations found, for example, in urine from neonates. LDTs are crucial to diagnosing and treating a person using methamphetamine and its designer derivative like MDMA (ecstasy). If these LDTs are delayed by new regulatory pathways, by the time the test is approved or cleared it will already be obsolete because the relevant substances will have changed.

Unmet Need Exceptions

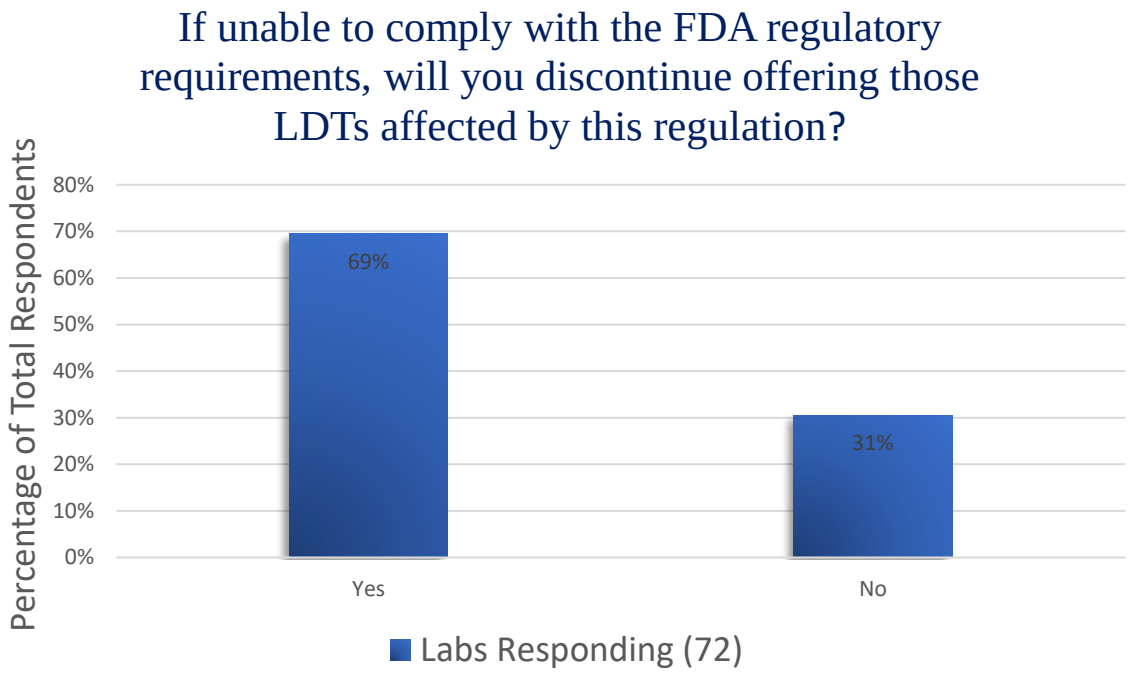
In the final rule, the FDA identifies several situations where once more it will remove some of the requirements for a laboratory performing an LDT, such as when there is an unmet need situation. This means there is not an FDA approved or cleared test on that market for that condition. This exception only applies to a laboratory within a single healthcare system. The laboratory cannot perform the test on a specimen from outside of the network. Also, once an FDA approved or cleared test is on the market, the unmet need exception for that condition no longer exists and the lab must obtain FDA clearance for that LDT if it wants to continue performing it.



Two-thirds of the 128 laboratories that responded to the survey said they were familiar with the unmet need exceptions. The vast majority – 60% -- did not know if they qualified for one of the exceptions. More than 50% of the respondents stated that they would be unable to comply with the requirements even if they met one of the exceptions.

The requirements for laboratories meeting the unmet need provision are the same as those for using previously marketed tests, such as registration, listing, labeling, investigational device, medical device reporting, and complaint files. For those laboratories answering No, that they could not meet the FDA requirements, 69% of those respondents stated they would be forced to discontinue some LDTs.

While the intent of this exception is noted, laboratories throughout the country already collaborate to fill unmet needs but do not typically consider specific health systems when doing so. Many tests for rare diseases in children are distributed across the country to academic pediatric laboratories so each individual laboratory does not need to develop and maintain a test. By restricting LDTs to a single health system, the already efficient system in place will be irrevocably broken. The FDAs intent to regulate will lead to worse care for children.



ADLM looks forward to working with you on this issue as Congress continues to discuss federal oversight of LDTs. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org.

Sincerely,

Octavia M. Peck Palmer, PhD, FADLM
President, ADLM