White Paper: Lab Developed Tests - Are You Ready?

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SITUATION

The U.S. Food and Drug Administration (FDA) recently passed a rule to increase oversight of laboratory-developed tests (LDTs). 21 CFR 809 In Vitro Diagnostic Products for Human Use was passed by Congress in 1976 to provide a means for regulating commercially developed laboratory test systems. At that time many clinical laboratories serving a limited clientele were exempted from regulation by the U.S. Food and Drug Administration (FDA) allowing them to design in house test methods that did not require formal approval. These were classified as Laboratory Developed Tests or LDTs not readily available from commercial sources to detect and measure a wide variety of biologic constituents of human blood, body fluids, and tissues.

Over the last fifty years the complexity, scope, and range of clients using LDTs has expanded, raising the safety risks of LDTs. As a result, the FDA has become concerned that LDTs represent an increased risk to patients. As a result, the FDA has developed a sweeping new rule to bring standards for LDTs in line with commercially developed IVDs.

The rule seeks to amend the FDA's regulation in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)(1)) through a phaseout of its general enforcement discretion approach to LDTs by adding a simple ten-word statement:

"…including when the manufacturer of these products is a laboratory."

IMPACT

This short statement could have wide ranging consequences for the clinical laboratory since it allows the FDA to regulate LDTs the same way it regulates IVDs developed by commercial manufacturers who have resources to meet these standards. In addition, the FDA proposes to phase in regulations over a four-year period. There is a significant groundswell within the healthcare industry to prevent this change.

Presently, the FDA's medical device regulations include numerous premarket reviews to assess the reliability of IVDs regarding their specific use. This could increase costs and the time required to develop and validate new LDTs. Since the FDA statement does not provide for

grandfathering LDTs, a scientific risk-based approach will be needed to remediate these tests. The proposed changes could also lead to increased confidence in the safety, reliability and clinical value, leading to greater adoption of these tests by healthcare organizations to benefit patients and laboratories.

ASSESSMENT

Organizations planning to implement LDTs in the future will be able to plan proactively whereas those already using LDTs will be faced with having to respond retroactively to keep them operating.

RECOMMENDATIONS

The impacted institution should start a comprehensive risk based approach and gap analysis now to determine where the current device regulations apply to develop a strategic roadmap and approach. Armed with the results, the institution can develop an efficient and cost-effective remediation plan. To support this effort while improving economics, a rational effort to streamline laboratory operations should also be considered. And, if sufficient expertise and resources do not exist in-house, bring in consultants with expertise in regulatory requirements and quality systems to efficiently meet the challenge.

NEXT STEPS

With the final rule having arrived in April 2024, the first regulatory requirements laboratories will need to meet will arrive in April of 2025! Therefore, we will review in Part II all proposed phases and discuss how laboratories should start planning for them now.