Key Principles for Diagnostic Reform

American Clinical Laboratory Association

1. LDTs are not Devices: LDTs are not medical devices and cannot be regulated, listed, or designated as such. Accordingly, any new framework to regulate LDTs or laboratories shall be implemented by a diagnostic-specific authority (such as a diagnostic-specific center within the Food & Drug Administration) and not an authority otherwise charged with medical device regulation or other medical product regulation;
2. Grandfathering and Transition: LDTs introduced prior to enactment must be grandfathered from any premarket review or design control requirements, and laboratories must be granted a reasonable transition period after enactment to come into compliance with any new applicable requirements;
3. Preemption: Any new federal framework for LDT and laboratory oversight shall preempt state requirements addressing the same subject matter;
4. Evidence Standards: The standard for approval, clearance, or marketing of a test must be based on a rational assessment of the test's analytical validity and clinical validity and not be based on the medical device standard of "safe and effective". Also, clinical trials are presumed not to be required;
5. Modifications: Agency review of modifications to an already marketed test (including grandfathered tests) should be limited to only those modifications which have a meaningful clinical impact or significantly modify the test's intended use after validation and verification;
6. Labeling: Labeling requirements applicable to laboratories will be limited to reasonable requirements appropriate for laboratory protocols, for instance not requiring a label to be affixed to the physical elements of a test where those elements are not distributed to another facility or third party. Legitimate scientific or medical exchanges or discussions will not constitute labeling or constitute a change in intended use;
7. Rulemaking: Implementation of any new framework must be carried out in a transparent process that includes formal notice and public comment;
8. Fees: Any fees associated with the new framework must reasonably take into account the resources necessary to implement the framework in addition to the impact on the entities from which the fees will be assessed. Fees paid for oversight of laboratory operations shall be credited towards any additional fees assessed for oversight of test development;
9. Duplication: Statutory and regulatory provisions developed under the new framework shall be designed to avoid duplication of oversight of test development and laboratory operations so as to ensure continued robust patient access to high quality clinical laboratory services;
10. Laboratory Operations: Should be governed by existing CLIA quality systems and not FDA quality system regulations;
11. Innovation: Any new federal framework should drive patient access to cutting-edge, high quality, and accurate diagnostics through incentivizing the development of novel tests, taking into account the time and resources required for the research, development, and commercialization of diagnostics.

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