FDA’s Proposed Rule for Oversight of Laboratory Developed Tests: Part II: FDA’s Proposed Phaseout Policy – Key Considerations & Open Questions

 After an over decade-long discourse amongst interested stakeholders, on October 3, 2023, FDA unveiled its **proposed rule and policy** to increase oversight over LDTs.

If finalized as proposed, FDA would implement a new “phaseout policy” that would, across five stages and within four years, apply the same regulatory requirements applicable to in vitro diagnostics (IVDs) on the majority of clinical laboratories offering tests as LDTs. Once implemented, tests offered as LDTs that do not meet the applicable regulatory requirements, including premarket review and the quality system regulation, may be expected to come off the market.

In our **first post** in this Insight series, we recapped the underpinnings of the proposed rule and policy, including the significant discussions contained in the proposed rule on (1) the rationale for the agency’s proposed phaseout policy and (2) FDA’s legal authority for issuing the rule.

In this Insight, we provide our full analysis of FDA’s proposed five-stage phaseout policy and the open questions that remain. Read the full Insight **here**.