



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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AMP Statement on Proposed Rulemaking on Laboratory Developed Tests

Expert members from the Association for Molecular Pathology (AMP) are reviewing the Food and Drug Administration's (FDA) recently released proposed rule and assessing its implications for our members and patient care. We continue to be concerned that the FDA is again trying to overstep its authority and bypass the legislative process. If finalized, the proposed rule will impede the ability of clinical laboratories, including many academic medical centers, reference laboratories, and community health systems across the country, to rapidly develop, validate, and offer high-quality, innovative laboratory developed testing procedures (LDPs) for patient care. AMP refers to these services as LDPs instead of LDTs given they are procedures performed by medical professionals.

The proposed rule threatens the ability of professionals in clinical laboratories to create, adapt, and modify LDPs to meet patients' needs, account for supply chain issues, reflect advances in scientific understanding and practice standards, and improve performance characteristics. When we met with the White House in August, we asked for the agency to issue a request for information prior to publishing a proposed rule to better understand the potential disruption to patient care it would have on community-based clinical and academic medical center laboratories. AMP is very disappointed that the FDA is moving forward with publishing a proposed rule at this time without first fully understanding the implications this drastic policy change will have on the practice of medicine and on patients' access to needed clinical tests.

LDPs are essential testing services that professionals in regulated clinical laboratories develop and use for a range of purposes including oncology, rare disease diagnosis, newborn screening, infectious disease testing, and more. LDPs are designed, developed, validated, performed, and interpreted by board-certified professionals. They are often created in response to unmet clinical needs, including patient access to critical testing services they may not otherwise receive, and are instrumental for early and precise diagnosis or monitoring and guidance of patient treatment. LDPs are not commercially manufactured and marketed nor boxed and shipped as medical devices and should not be regulated that way.

AMP members have spent the past 10 years collaborating with many professional societies, patient advocates, diagnostic companies, hospitals, academic centers, independent laboratories, and other stakeholders from across the country to help educate lawmakers and we remain committed to working with Congress and other stakeholders to establish a more effective and efficient regulatory framework within CLIA that ensures high-quality patient care while continuing to foster the rapid innovation and promise of new diagnostic technologies.

Sincerely,

Mary Williams
Executive Director
Association for Molecular Pathology