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Advancing Health in America

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Statement

of the

American Hospital Association

for the

Committee on Energy and Commerce

Subcommittee on Health

of the

U.S. House of Representatives

"Evaluating Approaches to Diagnostic Test Regulation and the Impact of FDA's Proposed Rule."

March 21, 2024

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the impact of the Food and Drug Administration's (FDA) proposed regulation of diagnostic tests.

Many hospitals and health care systems develop and use laboratory developed tests (LDTs), particularly larger hospitals and academic medical centers. These tests are developed, validated and performed in-house by individual laboratories — they are not commercially distributed. They range from routine tests like blood counts to more complex molecular and genetic tests for cancer, heart disease, and rare and infectious diseases. LDTs provide timely patient access to accurate and high-quality testing for many conditions where a commercial test does not exist or does not meet current clinical needs. They provide physicians with important clinical information to diagnose and treat patients and are essential to the practice of medicine.

The AHA is concerned that the FDA has overreached in its proposal to regulate LDTs as medical devices. We urge Congress to exempt hospitals and health systems from being included in this FDA device framework or help ensure that regulatory oversight of LDTs is modernized in a manner that both supports medical innovation and ensures that these clinical laboratory tests remain accessible, safe and effective.

While we support the need for additional oversight of the development and use of some LDTs and in-vitro diagnostics (IVDs) offered as LDTs, the FDA's proposal to apply its device regulations to hospital and health system LDTs is misguided. These tests are not devices — they are diagnostic tools developed and used for essential patient care. Regulating LDTs under the FDA's device regulatory framework could cause patients to lose access to many critical tests and stifle innovative advances in hospital and health system laboratory medicine.

Hospital and health system LDTs benefit from the many factors that distinguish them from companies that distribute commercially marketed IVDs. These include the integration of laboratory test development and use into the continuum of patient care, the many patient safeguards that laboratories are already subject to, and the FDA's existing ability to investigate and remove any LDT or IVD from the market regardless of the entity that develops it. The AHA has urged the FDA to continue to apply its enforcement discretion to hospital and health system LDTs and defer regulation of these tests mainly to the Centers for Medicare & Medicaid Services' strict Clinical Laboratory Improvement Amendments (CLIA) oversight, the College of American Pathologists accreditation and state law.

Enforcement discretion is particularly important for low- and moderate-risk LDTs, including modifications to FDA-approved IVDs. Modifications improve the performance of approved diagnostic tests on certain patient populations, address problems or issues with FDA-approved devices, and allow the latest research and clinical knowledge to be rapidly incorporated. They are intended to improve testing accuracy and safety. If the laboratory is following the CLIA regulations and is subject to the factors described above, low- and moderate-risk tests, including modifications to commercially marketed IVDs, should be exempt from FDA regulatory oversight.

The AHA also supports continued FDA enforcement discretion for LDTs that are subject to established laboratory evaluation programs, such as that developed by New York State. Many hospital and health system laboratories participate in these evaluation programs for their rigorous validity and quality reviews and even the FDA has accredited the New York State program as a third-party reviewer on behalf of the agency for the premarket clearance process**.**

As highlighted in greater detail in our comment letter to the FDA, we are concerned that this rule — if finalized as proposed — could significantly increase hospital burden and costs and decrease the ability to provide the most effective and appropriate care to patients.

CONCLUSION

Thank you for the opportunity to provide feedback on the FDA's proposed regulation of diagnostic tests. We look forward to working with Congress on this important issue.