National Rural Health Association

December 4, 2023

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD

RE: FDA-2023-N-2177: Medical Devices; Laboratory Developed Tests.

Submitted electronically via regulations.gov.

Dear Dr. Califf,

The National Rural Health Association (NRHA) is pleased to offer comments on the Food and Drug Administration (FDA) proposed rule on Medical Devices/Laboratory Developed Tests.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

V. Description of the Proposed Amendment to the Definition of In Vitro Diagnostic Products

A. Proposed Amendment

FDA is proposing to update the definition of "in vitro diagnostic products" (IVDs) to make explicit that IVDs are considered devices, including when the IVD manufacturer is a laboratory. In practice, this means that lab-developed tests (LDTs) would be regulated as devices, which puts more burden on hospitals and health systems that administer LDTs. **This is particularly problematic for rural hospitals that do not have the administrative or financial resources to comply with heightened regulations, including registration, listing, and reporting requirements.**

B. Legal Basis for the Proposed Amendment

2. Test Systems Manufactured by Laboratories Are Devices

NRHA disagrees that LDTs are devices. LDTs are a part of the clinical diagnoses process and should not be subject to the same regulations as IVDs. LDTs do not require additional regulations as they are laboratory procedures that are part of the practice of medicine and fall under trained medical expertise to administer. **NRHA is concerned that if LDTs are defined as devices, it will put a further burden on small, rural hospitals that utilize LDTs, and these hospitals will no longer offer lifesaving tests.** With the workforce

shortage that is already apparent in rural hospitals, extra regulations for administering LDTs may be costly and therefore prevent utilization of LDTs that are key to preventative measures of detecting diseases and administering treatment, particularly for tests that have few or no adequate commercially available alternatives. Loss of testing will lead to missed or delayed diagnoses, inadequate treatments, and worse outcomes for patients of rural hospitals. **NRHA would like to emphasize that this may cause a health equity issue and affect rural communities at a disproportionate rate[1,5].**

VI. Description of the Proposed Enforcement Policy

FDA is proposing to phase out its enforcement discretion with respect to LDTs. Historically, FDA has not enforced the applicable requirements for LDTs, but now believes that greater oversight is necessary due to the modern risks associated with LDTs. Specifically, FDA proposes to phase out its current enforcement discretion approach in stages and would require that LDTs meet applicable requirements following the four-year phaseout.

As such, laboratories developing and administering LDTs would be required to meet certain quality systems regulations at 21 C.F.R. § 820 within three years of the final rule, which includes regulations around design controls, purchasing controls, corrective and preventive actions, and records requirements. In addition, laboratories would have to comply with premarket review regulations, including receiving premarket approval, three and a half years following FDA's final rule.

NRHA urges FDA to delay the LDT requirements associated with premarket notification and premarket approval, quality system regulation, and labeling until more complete data on LDTs are compiled and made publicly available. We support FDA's proposal to phase out its enforcement discretion for registration and listing requirements and medical device reporting so long as FDA ensures that such requirements are streamlined and do not pose undue burden on laboratories in rural hospitals.

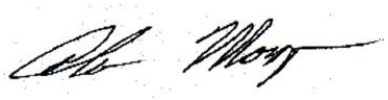
NRHA emphasizes the unintended consequences this phaseout policy would have on rural populations. Complying with new regulations will be costly and burdensome for small, rural hospitals that administer LDTs to diagnose and help treat infectious diseases[2]. Consequently, rural areas do not have the resources to adhere to these regulations, especially related to premarket notification, since it is known to be costly and time consuming[2]. As a result, rural hospitals may decline to offer LDTs which would lead to missed or delayed diagnoses and worsened patient outcomes.

The FDA also previously attempted to pass a similar policy in October 2014, where they published guidance documents suggesting that labs performing LDTs should comply with the same FDA process as manufacturers seeking IVD approval. This involved submitting validation data for a stringent "pre-market review" and continuous safety monitoring during "post-market surveillance", while also abiding to high complexity standards met under Clinical Laboratory Improvement Amendments (CLIA), to address perceived regulatory gaps in LDT oversight[5]. This proposal was met with strong opposition from stakeholders, that still hold to the current proposed rule. **NRHA voices the same concerns, along with many of these stakeholders, on the complexity of standards that would come from a phase out**

and would lead to exacerbating inequities by limiting tests for a population that succumbs to higher infection rates of infectious diseases and chronic illnesses detected by these tests, such as tick-borne diseases, tuberculosis and other respiratory diseases, HIV and STIs[6,7,8].

NRHA thanks FDA for the opportunity to submit comments on this important proposed rule. We look forward to working with the agency moving forward to protect and improve the health of rural populations across America. If you have any questions, please contact NRHA's Regulatory Affairs Manager, Alexa McKinley at amckinley@ruralhealth.us.

Sincerely,



Alan Morgan
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National Rural Health Association

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