December 4, 2023

The Honorable Robert M. Califf, MD
Commissioner
The U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Medical Devices; Laboratory Developed Tests (FDA– 2023–N–2177)

Dear Commissioner Califf:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the Food and Drug Administration's (FDA) Medical Devices; Laboratory Developed Tests proposed rule, published in the Federal Register on Oct. 3, 2023.

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 medical groups comprising more than 350,000 physicians. These groups range from small independent practices in remote and other underserved areas, to large regional and national health systems that cover the full spectrum of physician specialties.

For years, MGMA has advocated for a robust clinical laboratory infrastructure to support the delivery of routine patient care. Medical groups rely on Laboratory Developed Tests (LDTs) to provide essential diagnostic and testing services to patients. As such, MGMA is well-positioned to offer the following feedback.

Proposed Enforcement Policy

FDA is proposing to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the *Federal Food, Drug, and Cosmetic Act* (FD&C Act), including when the manufacturer of the IVD is a laboratory. FDA is proposing a policy to phase out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would fall under the same enforcement approach as other IVDs. FDA's stated intent in proposing this phaseout is to better protect the public health by helping to ensure the safety and effectiveness of LDTs.

MGMA recognizes the FDA's efforts to ensure the safety and effectiveness of LDTs through the proposed oversight framework. However, we have serious concerns that regulating LDTs as medical devices could inadvertently limit patient access to critical clinical testing. Specifically, the new premarket review requirements may delay or deter modifications to existing tests and the introduction of new ones, hindering laboratories' ability to keep pace with scientific advances

and clinical practice guidelines. The increased administrative and financial burdens of the proposed framework would exacerbate existing cuts in laboratory reimbursement. These compounding impacts could force many laboratories to narrow or cease offering tests, further restricting patient access.

The rollout of the European Union's In Vitro Diagnostic Medical Device Regulation (IVDR) offers important lessons for the FDA. The IVDR, enacted in 2017, aimed to bring all diagnostics under a uniform regulatory scheme by 2022. To avoid widespread shortages, regulators postponed deadlines and granted grace periods for certain tests.[1] According to the European medical device industry association (MedTech Europe) without these delays, 22% of marketed diagnostics could have been pulled from the market during the transition.[2]

CLIA Modernization

Given the concerns outlined above, MGMA urges the FDA to not finalize the proposed rule. Instead, we recommend modernizing the Clinical Laboratory Improvement Amendments (CLIA) to better regulate high-complexity clinical tests. Modernizing CLIA requirements would create a more sustainable system that encourages innovation and promotes emerging clinical guidelines. This pathway would enable healthcare professionals to deliver precise, accurate, and the most up-to-date tests to patients.

Further, many stakeholders have acknowledged the need to modernize the CLIA program implemented more than thirty years ago. CLIA modernization is the most streamlined, cost-effective, and least burdensome approach to ensure the clinical and analytical validity of LDTs. Any update to the oversight of laboratory testing is incomplete and potentially duplicative without considering updates to CLIA.

Expanding Definition of 1976-Type LDTs

The FDA proposes to exercise a general enforcement discretion approach for certain categories of tests manufactured by laboratories, including "1976-type LDTs" and tests exclusively used for public health surveillance.

Should the FDA move forward with finalizing the rule, we urge the agency to work with stakeholders to continue to identify tests that should be exempted from this regulation to avoid stifling patient access to care.

Conclusion

We appreciate the opportunity to share our comments regarding proposed changes to the regulation of LDTs, and to offer recommendations to improve and simplify these policies to support group practices as they care for patients. Should you have any questions, please contact

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[1] Huanjia Zhang, *IVDR Rollout Brings New Hurdles for Clinical Labs, Smaller Diagnostic Firms in Europe*, 360Dx, Sept. 18, 2023, https://www.360dx.com/policy-legislation/ivdr-rollout-brings-new-hurdles-clinical-labs-smaller-diagnostic-firms-europe#:~:text=With%20the%20increase%20in%20resources,tests%20for%20rare%20disease%20patients.

[2] Susan Reilly, *EU to Delay Portions of the IVDR Rollout*, MEDIcept, Feb. 7, 2022, https://www.medicept.com/2022/02/07/eu-to-delay-portions-of-the-ivdr-rollout/.

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Sincerely,

/s/

Anders Gilberg

Senior Vice President, Government Affairs