March 20, 2024

The Honorable Brett Guthrie
Chairman
House Committee on Energy and Commerce
Subcommittee on Health
2123 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
House Committee on Energy and Commerce
Subcommittee on Health
2123 Rayburn House Office Building
Washington, DC 20515

Re: House Committee on Energy and Commerce Subcommittee on Health hearing titled, "Evaluating Approaches to Diagnostic Test Regulation and the Impact of FDA's Proposed Rule"

Dear Chairman Guthrie and Ranking Member Eshoo:

The Medical Group Management Association (MGMA) thanks the Subcommittee for holding this important hearing examining the Food and Drug Administration's (FDA) proposed rule (88 FR 68006) to regulate laboratory developed tests (LDTs) and alternative approaches to diagnostic regulation. 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.

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 LDTs to provide essential diagnostic and testing services to patients. MGMA requested a pause in rulemaking in response to the FDA's proposed rule.

The 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*, including when the manufacturer of the IVD is a laboratory. The proposed rule phases out the FDA's general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would fall under the same enforcement approach as other IVDs. The proposed oversight framework includes premarket review requirements. FDA's stated intent in proposing this phaseout is to better protect public health by helping to ensure the safety and effectiveness of LDTs.

While MGMA supports ensuring the safety and effectiveness of LDTs, we remain concerned the proposed 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 laboratories to narrow or cease test offerings, further restricting patient access.

The rollout of the European Union's In Vitro Diagnostic Medical Device Regulation (IVDR) offers important lessons for diagnostic regulation. 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]

Given the concerns outlined above, MGMA urged the FDA to not finalize the proposed rule. Instead, we recommend Congress examines a less burdensome approach to diagnostic regulation that is tailored to meet the specific needs of clinical diagnostics, promotes innovation, and integrates existing Clinical Laboratory Improvement Amendments (CLIA) requirements. CLIA regulations currently provide quality and safety oversight for LDTs. Any update to the oversight of laboratory testing is incomplete and potentially duplicative without integrating CLIA requirements.

In 2023, the *Verifying Accurate Leading-edge IVCT Development Act* (VALID Act) was reintroduced. This legislation would create a risk-based framework for regulating LDTs that resembles the existing approach FDA takes toward other medical devices. MGMA and over 100 other organizations expressed concern in response to this legislation, highlighting that certain provisions were duplicative of existing CLIA and state requirements. The VALID Act's provisions on quality systems, adverse event reporting, and laboratory inspections are all requirements that exist within CLIA. Should Congress once again consider the VALID Act as a legislative pathway for the regulation of diagnostic tests, we urge the Subcommittee to consider these concerns.

MGMA looks forward to working with the Subcommittee in developing an alternative approach to diagnostic regulation that supports group practices as they care for patients. Should you have any questions, please contact James Haynes, Associate Director of Government Affairs, at jhaynes@mgma.org or 202.293.3450.

Sincerely,

/s/

Anders Gilberg
Senior Vice President, Government Affairs

Cc:

The Honorable Cathy McMorris Rodgers
The Honorable Frank Pallone

[1] Huanjia Zhang, *IVDR Rollout Brings New Hurdles for Clinical Labs, Smaller Diagnostic Firms in Europe*, 360Dx, Sept. 18, 2023.
[2] Susan Reilly, *EU to Delay Portions of the IVDR Rollout*, MEDIcept, Feb. 7, 2022.