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Education. Innovation & Improved Patient Care. Advocacy.
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Association for Molecular Pathology Commends Department of Health and Human Services on Decision to Lessen Regulatory Burden on Laboratory Professionals

Modernizing the CLIA Regulations is the Best Approach to Ensuring High Quality and Rapid Response Testing

ROCKVILLE, Md. – August 21, 2020 - The Association for Molecular Pathology (AMP), the premier global, molecular diagnostics professional society, commends the decision by the U.S. Department of Health and Human Services (HHS) to rescind the requirement for premarket review of laboratory developed testing procedures (LDPs) by the Food and Drug Administration (FDA). LDPs are designed and performed by molecular diagnostic professionals whose laboratories are already regulated by the Centers for Medicaid & Medicare Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA). CLIA has a longstanding and successful history of promoting patient safety. This action by HHS reduces the duplicative regulatory burden placed on molecular diagnostic professionals wishing to use their expertise to provide high-quality, innovative LDPs, including those for SARS-CoV-2 in the COVID-19 Pandemic.

"We are pleased with the decision of the U.S. Department of Health and Human Services to remove the overly burdensome requirement for molecular diagnostic professionals to submit their LDPs to FDA for pre-market review," said Karen E. Weck, MD, President of the Association for Molecular Pathology. "This regulatory hurdle delayed the U.S. response in the early days of the coronavirus pandemic. This illustrates the importance of qualified medical professionals being able to develop and quickly deploy essential new testing services, especially in response to a public health emergency."

AMP has long maintained that FDA oversight of LDPs slows innovation and compromises patient access to potentially lifesaving procedures. The regulatory process imposed by the FDA during the COVID-19 pandemic was duplicative with the CLIA regulations and impeded the ability of molecular diagnostic professionals, who practice at academic medical center, reference, and community health system laboratories across the country, to rapidly design, validate, and offer high-quality LDPs for use in patient care.

The Association believes the best option for federal regulatory authority over LDPs is the modernization of the existing CLIA regulations, which are administered by the Centers for Medicare and Medicaid Services (CMS). In March, AMP supported US Senator Rand Paul's (R-KY) introduction of new legislation that affirms molecular pathology professionals' ability to continue advancing and offering LDPs for patient care. The Verified Innovative Testing in American Laboratories (VITAL) Act of 2020 clarifies the federal regulatory authority over LDPs and encourages the modernization of CLIA and administration by CMS. The legislation was designed to enhance transparency, preserve innovation, and ensure widespread patient access to essential medical services.

"We believe this decision by HHS is a strong first step in clarifying regulatory authority and streamlining regulation of LDPs," said Dr. Weck. "Our members welcome the opportunity to share our collective expertise and engage with key stakeholders to modernize the current CLIA oversight system in order to ensure high-quality testing without impeding innovation or compromising patient access."

To view the full-text version of the VITAL Act of 2020, visit www.amp.org/VITAL. To see AMP's proposal to modernize the CLIA regulations and other resources regarding LDPs, visit here.

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that practice in a variety of settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors,

Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit
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