



ASSOCIATION FOR MOLECULAR PATHOLOGY

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April 2, 2024

The Honorable Bill Cassidy
Ranking Member, Senate Committee on
Health, Education, Labor, and Pensions
455 Dirksen Senate Office Building
Washington, DC 20510

Re: Request for information from Stakeholders on Regulation of Clinical Tests

Submitted electronically at diagnostics@help.senate.gov

Dear Senator Cassidy,

On behalf of the Association for Molecular Pathology (AMP), we thank you for the opportunity to provide input to you and your colleagues on the Health, Education, Labor, and Pensions (HELP) Committee as you explore ways of ensuring patient access to timely and advanced diagnostics and improve the regulation of clinical tests in the United States. AMP is an international medical and professional association representing approximately 2,900 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with clinical laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in-vitro diagnostics industry.

Though often referred to as laboratory developed tests, or LDTs, AMP uses the phrase “Laboratory developed testing Procedures” (LDPs) to better reflect that they are a medical service—a validated testing protocol that is used in conjunction with expertise provided by laboratory medical professionals in regulated clinical laboratories that results in medical interpretation. LDPs are developed and used for a range of purposes including oncology, rare disease diagnosis, newborn screening, infectious disease testing, and more. They are designed, developed, validated, performed, and interpreted by board-certified professionals. LDPs are often created in response to unmet clinical needs, including patient access to critical testing services they may not otherwise receive, and are instrumental for early and precise diagnosis or monitoring and guidance of patient treatment. LDPs are not commercially manufactured and marketed, nor boxed and shipped, as medical devices and should not be regulated that way.

The FDA’s proposed rule threatens the ability of professionals in clinical laboratories to create, adapt, and modify LDPs to meet patients’ needs, account for supply chain issues, reflect advances in scientific understanding and practice standards, and improve performance characteristics. We encourage you to review AMP’s [comments](#) submitted to the rulemaking docket for additional information and we would welcome the opportunity to discuss further. AMP is grateful that you published this Request for

Information and hopes that this is a strong indication that Congress intends to direct the agency to halt rulemaking and instead, advance legislation to address any gaps in oversight.

AMP believes that LDPs should continue to be regulated under the framework set forth by the Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendments of 1988. AMP acknowledges that CLIA is in need of modernization, and has released a [CLIA Modernization Legislative Proposal](#) that updates statutory requirements to expand and enhance CLIA regulations to reflect the current, modern laboratory landscape. CLIA modernization could achieve a sustainable system that fosters innovation and promotes emerging medical knowledge to enable healthcare professionals the ability to offer precise, accurate, and the most up-to-date tests to patients. It is also the most streamlined and cost-effective approach, for both the government and laboratories, and the least disruptive and burdensome approach to ensuring clinical and analytical validity, transparency, and addressing other concerns expressed by interested stakeholders.

We appreciate the opportunity to comment on the following questions.

FDA Regulatory Framework for Diagnostics

As stated earlier, AMP believes that LDPs are a professional medical service distinct from manufactured, mass produced and shipped IVD test kits. AMP believes that the FDA lacks statutory authority over LDPs and, as such, AMP's responses to the questions within this section refer to the FDA regulations as they pertain to IVD test kits and that references to diagnostics and diagnostic products refer to IVD test kits and their regulated components, not LDPs.

How well is FDA's medical device framework working for the regulation of diagnostic products? Are there improvements that should be made?

AMP believes that the FDA has an important role in regulating in-vitro diagnostics (IVDs) as medical devices because IVD test kits are manufactured, boxed, and shipped to laboratories and AMP supports reform of the regulation of manufactured and distributed IVDs. Current FDA regulations prevent manufacturers from readily modifying, enhancing, or otherwise improving upon commercial kits. This flawed regulatory paradigm limits the kit choices and options molecular pathologists and other laboratory professionals have as they strive to optimally care for their patients. Still, the provision of LDP services and the design, development, manufacture, packaging, and distribution of IVD kits remain separate and distinct activities with very different underlying medical and economic models and must continue to be independently regulated. There is a need for a clear, more predictable regulatory pathway for in vitro diagnostic manufacturers.

Of these specific changes, which would require Congressional action, and which can be effectuated by FDA alone?

Legislative reform should maintain that FDA continue its role ensuring that the performance characteristics of vendor supplied instruments, test kits, software, and reagents and verifying manufacturers' claims in their labeling, promotional materials, and other activities. However, the Agency should do so using an approach that is sufficiently flexible to accommodate continual technological developments and exponentially increasing medical and scientific knowledge in a timely manner. In this

way, FDA can best contribute to patient welfare and public health, by helping molecular pathologists and other laboratory professionals have tools to provide the best care possible to our patients.

Are the regulatory pathways intended to evaluate diagnostics for special populations (i.e. rare diseases or genetic disorders) working?

No, the regulatory pathways provided through the FDA are not optimized to evaluate diagnostics for rare diseases. While FDA does have a humanitarian device exemption, it is not broad enough to be impactful. It's important to note that patients from the rare disease or genetic disorder community highly depend on LDPs, not IVDs, as most manufacturers do not design or market test kits for their specific conditions. Policies, such as the FDA proposed rule, further threaten the ability of professionals in clinical laboratories to create, adapt, and modify IVDs (thereby making them LDPs) to meet the needs of the rare disease community. As stated in its comments to the docket, AMP is very concerned the proposed rule would likely lead to a consolidation within the laboratory ecosystem in the United States. By the FDA's own estimates within its economic analysis, 90% of the affected laboratories won't be able to afford the minimum estimated cost of \$29.6 million per laboratory to comply with the rule, potentially forcing many of these labs to close, significantly impacting patient access to testing especially in the rare disease space. The impact of imposing FDA review on all diagnostics for rare diseases would be devastating on patient access.

One prime example that highlights the importance of clinical genetic testing in the context of rare disorders is Canavan disease. This is a rare "gene-linked neurological disorder in which the brain degenerates into spongy tissue riddled with microscopic fluid-filled spaces" according to the National Institutes of Health (NIH).¹ The disease develops when a child inherits two genetically altered copies of the ASPA gene,² leading to a deficiency of an essential enzyme and resulting in the progressive deterioration of white matter in the brain (demyelination). Children with Canavan disease present in early childhood with neurodevelopmental impairments, lack head control, reduced visual responsiveness and abnormal muscle tone such as stiffness or floppiness.³ Over time, children can also experience seizures, become paralyzed, blind, and deaf. Genetic testing is not only performed for diagnostic purposes, but the American College of Genetics and Genomics (ACMG) also recommends broad screening such that all pregnant patients, and those planning pregnancy, should be offered carrier testing for Canavan disease along with 100 other inheritable autosomal recessive and X-linked conditions.⁴ The prognosis for Canavan disease is poor, with a life expectancy around 10 years of age. While, at present, there is no cure, technological advances in genetic and clinical screening are allowing accurate and more prompt diagnoses and thus access to treatments to help alleviate symptoms and improve their quality of life.⁵ Testing for Canavan disease and many other genetic diseases is being performed in many CLIA-certified laboratories in the United States, giving patients widespread access to genetic testing from many different providers. If these test providers were required to seek premarket review from the FDA, AMP would be greatly concerned that the availability of this test would decrease sharply.

¹ <https://www.ninds.nih.gov/Disorders/All-Disorders/Canavan-Disease-Information-Page>

² <https://rarediseases.info.nih.gov/diseases/5984/canavan-disease>

³ https://www.canavanfoundation.org/about_canavan_disease

⁴ Gregg AR, Aarabi M, Klugman S, et al. Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics (ACMG). *Genet Med* 2021.2021;10:1- 14. doi:10.1038/s41436-021-01203-z

⁵ <https://www.huntershope.org/family-care/leukodystrophies/canavan-disease/>

What are your views on FDA's implementation of predetermined change control plans; is FDA's approach in its recent guidance readily applicable to IVDs and other diagnostic products?

Attempts to reduce the burden on the agency by allowing use of change protocols is limited as most manufacturers of IVDs do not know at the time of submission if and how they will need to modify a test. For instance, a manufacturer may discontinue a line of genomic sequencing machines or reagents, prompting the need to update the FDA authorization. Another example is when new scientific information is learned, a panel for hereditary cancer may need to be expanded to include additional genes or variants, which would also require a new submission to the FDA. It's impossible to anticipate the way an IVD will need to be modified and thus, the utility of a predetermined change control plan is greatly limited and does not provide meaningful solutions to this barrier.

Does FDA's current risk classification framework properly measure risk versus regulatory controls for diagnostics products?

No, AMP has long felt that the Agency's classification of risk to be ambiguous and inconsistent and that the FDA needlessly places burdens on IVD manufacturers that do not accurately reflect the actual risk of the product.

In considering reforms to FDA's risk classification framework for diagnostics, what types of IVDs should be exempt from premarket review?

AMP appreciates that FDA is thinking about how to reduce the burden of premarket review for IVDs and is generally supportive of reform to improve the regulatory pathway for IVD test kits, platforms, etc.

AMP has also maintained the position that data typically collected in premarket trials could be shifted to the postmarket setting and also, if some class III devices can be down classified as new information becomes available making it sufficient to use special controls. We are hopeful that the FDA will continue to streamline the regulatory pathway for IVD test kit manufacturers and improve patient access to these important tests.

Do the proposed reforms to FDA's device framework warrant the establishment of a new regulatory pathway specific to diagnostics? If yes, what are the principles that should guide such a new framework, as it would be applied to diagnostics currently subject to FDA premarket review?

We recognize that you are referring to reforms to the regulation of IVD test kits in this question. However, AMP believes it is critical to restate its concerns about the FDA proposed rule as it threatens the ability of professionals in clinical laboratories to create, adapt, and modify LDPs to meet patients' needs, account for supply chain issues, reflect advances in scientific understanding and practice standards, and improve performance characteristics. AMP maintains that FDA does not have the authority to regulate LDPs. As such, AMP believes that Congress should enact legislation that clarifies that LDPs are not medical devices and also modernize CLIA. We encourage you to review our [proposed legislative language](#) as we believe this is the best way to ensure that oversight reflects today's advances without restricting patient access and delaying innovation.

Given the important role LDPs play in patient care, it is critical that they are accurate and precise. To ensure this, clinical laboratories, laboratory personnel, and the LDPs they develop and perform are holistically regulated by the CMS under the CLIA, in addition to state-level requirements and professional accreditation bodies. This successful program ensures the quality of tests used in patient care. Importantly, CLIA establishes baseline requirements and allows third-party accreditation bodies, used in the CLIA program, to set additional and/or more rigorous requirements. Modernizing CLIA is the most streamlined, flexible, cost-effective approach and ensures high-quality patient care while continuing to foster rapid innovation and promise of new diagnostic technologies. An FDA-centric approach would lead to laboratory consolidation, testing monopolies, reduced patient access, and greatly hamper innovation. Instead, Congress should pass legislation to modernize CLIA.

AMP also urges Congress to direct FDA to halt its implementation of the LDP rule to allow Congress time to advance legislation on the regulation of laboratory testing to prevent FDA's proposed actions from harming patients, the work of laboratory professionals, and our health care system as whole. If the proposed rule is finalized, the hundreds of thousands of laboratory tests that are currently used in clinical care will be subject to FDA premarket review. The cost of review will disincentivize the development of tests. Using the numbers from the FDA's economic analysis, the one-time cost to each entity as a result of the phaseout policy is \$29.6 million. As the FDA points out, 90% of the assumed 1200 laboratories impacted by the proposed rule are small businesses. Over 4 years, those entities' revenue is only \$19.5 million each on average (calculated from the data on page 114 of the economic analysis). This would cause most of those labs to close or reduce the number of tests they provide. Further, devoting almost two-thirds of their annual revenue to FDA compliance is not practical, and would greatly limit their ability to innovate and bring the latest advances in laboratory medicine to the patients they serve.

It is also important to point out that all of the tests used for newborn screening developed and performed by states' public health laboratories would not be exempt from premarket review under the proposed rule. These already cash-strapped public health programs lack the resources to comply with FDA's medical device regulations. Additionally, each time these tests are updated to incorporate another condition, subsequent FDA review would be required. The proposed rule threatens the viability of one of the most successful public health programs in the US.

The recent FDA press release on re-classification fails to adequately reduce the harmful effects of the proposed rule. Reclassification will be a long process, and thus, the immediate impacts of the proposed rule will not be mitigated for laboratories using LDPs. We are concerned that FDA is already walking back their original statements in the press release by clarifying at a public meeting that they expect around 50% of high-risk tests to be reclassified. Even if tests are classified as moderate risk, we expect that many laboratories will need to use the 510(k) *de novo* pathway given the lack of a predicate device, which is not that dissimilar from the PMA requirements.

In the proposed rule, the agency anticipates it will receive, in a single year:

- 32,160 510(k) premarket notifications;
- 4,210 PMAs, PDPs, Panel-Track PMA Supplements; and
- 4,020 *de novo* submissions

This is 10 times the number of submissions the agency currently receives in a year ***across all device types***. These numbers look even worse when you consider that most of these LDPs would be high risk or

novel and, therefore, result in 57 times more PMAs and 61 times more *de novo* submissions than the FDA normally receives in one year.⁶ This is to say nothing of the expected doubling of annual device submissions FDA expects it will then receive on an ongoing basis. There is good reason to believe all of the above numbers are gross underestimates.⁷ The FDA has grossly underestimated the amount of LDPs used in clinical care. To date, the agency has only approved a total of 140 genetic tests; however, a study conducted by [Concert Genetics](#) released in November 2023, cites approximately 175,000 distinct genetic tests in use for clinical care today in the areas of hereditary disease and oncology.⁸

AMP is extremely concerned by the pace the FDA is moving through the rulemaking process, given the potential harm to industry, clinical laboratories, and patient access. It's unclear how they were able to consider nearly 7,000 comments in such a short time period and, given this momentum, we anticipate the final rule to be just as concerning as the proposed rule. As such, we encourage Congress to take action on this very important policy issue and protect this critical sector of our healthcare system from unnecessary, overly burdensome regulation.

CLIA Regulatory Framework for LDPs

What updates to the clinical laboratory regulatory structure under CLIA should Congress consider to reflect the latest scientific practices and safety standards?

First, Congress should clarify in statute that LDPs are laboratory procedures and are regulated under Section 353 of the PHSA and not as a medical product under the FDA.

Further, laboratory medicine has grown and evolved significantly since CLIA was enacted nearly 40 years ago and as such, the CLIA regulations need to be updated to reflect current practices. Modernizing CLIA is the most streamlined, flexible, and cost-effective pathway forward for updating laboratory testing requirements in a way that protects patients and supports innovation. Working with other stakeholders, the Association for Molecular Pathology developed a legislative [proposal](#) that modernizes the CLIA program by updating the current statute to reflect modern laboratory medicine.^{9,10}

The proposal requires new federal standards for molecular and genomic testing and expands CLIA to apply to genomic and molecular testing facilities, “dry bench” activities such as laboratory analytics, and bioinformatics-focused laboratory procedures/examinations that are used routinely to determine treatments for patients. Additionally, it clarifies that CLIA should develop minimum levels of standards

⁶ Hyman, Phelps, McNamara, The FDA Law Blog Feb 2 2024: https://www.thefdalawblog.com/2024/02/fda-cant-reclassify-its-way-out-of-reviewing-100000-ldt-submissions/?utm_source=rss&utm_medium=rss&utm_campaign=fda-cant-reclassify-its-way-out-of-reviewing-100000-ldt-submissions

⁷ Hyman, Phelps, McNamara, The FDA Law Blog Dec 21 2023: <https://www.thefdalawblog.com/2023/12/a-final-LDP-rule-in-april-will-fda-be-prepared/>

⁸ Concert Genetics, “Genetic Test Price Transparency Report.” 2023. <https://www.concertgenetics.com/wp-content/uploads/2023/11/Concert-Genetics-2023-Genetic-Test-Price-Transparency-Report-07Nov2023.pdf>

⁹https://www.amp.org/AMP/assets/File/advocacy/Amendments%20to%20CLIA%20modernization%20legislative%20text%2011_7_23%20FINAL.pdf

¹⁰ <https://www.amp.org/AMP/assets/File/advocacy/CLIA%20modernization%20SxS.pdf?pass=78>

for analytical and clinical validity, strengthening the current requirements under the regulation. Furthermore, it requires laboratories to share summary information on validation data with inspectors as well as the public. Our proposed provisions expand proficiency testing requirements so there are more robust continual assurances that laboratories are providing high-quality care. When a proficiency testing program is not available, it requires laboratories to perform certain alternative assessments deemed acceptable by the CMS. It also continues the successful role of third-party accreditation organizations and requires CMS to update regulations, including as it relates to "black box" regulations tests and laboratory errors. A section by section summary of the proposal can be found [here](#).

Summary of AMP’s CLIA modernization proposal:

Modern Field of Laboratory Medicine	<ul style="list-style-type: none"> • Expands CLIA to reflect the modern field of laboratory medicine requiring new federal standards for molecular and genomic testing, laboratory analytics, and bioinformatics-focused laboratory procedures/examinations.
Test Quality & Transparency	<ul style="list-style-type: none"> • Clarifies that CLIA should develop minimum levels of standards for analytical and clinical validity. <ul style="list-style-type: none"> ○ Laboratories are required to share summary information on validation data with inspectors. ○ Laboratories are also required to share summary validation information with the public.
Proficiency Testing	<ul style="list-style-type: none"> • Expands proficiency testing requirements so there are continual assurances that laboratories are providing high-quality care. When a proficiency testing program is not available, it requires laboratories to perform certain alternative assessments deemed acceptable by the CMS.
Third Parties	<ul style="list-style-type: none"> • Continues the successful role of third-party accreditation organizations.
Updated regulations	<ul style="list-style-type: none"> • Requires CMS to update regulations, including as it relates to “black box” tests and laboratory errors.

What are your views on the effectiveness and use of the Clinical Laboratory Improvement Advisory Committee (CLIAC) in providing scientific and technical guidance to inform potential updates to CLIA standards?

Since the CLIA standards were first promulgated in 1992, there have only been modest changes to the regulations. CLIAC identified several areas in need of modernization in 2018, including personnel standards, the use of laboratory data in medical decision-making, and the regulation of new technologies, such as next generation sequencing. We applaud these efforts. AMP believes that CLIAC should have more authority than they currently do, as most of their recommendations are ignored.

In AMP's CLIA modernization proposal, it is required that CLIAC fully represents the diversity of the laboratory community and clarifies its role in providing input on how to modernize CLIA regulations, standards for all laboratory examinations and procedures, and updating the list of analytes and methods for which proficiency testing is required.

Do the proficiency testing programs currently approved by the Department of Health and Human Services (HHS) reflect the latest clinical standards of laboratory medicine? Are there specialties, subspecialties, or analytes that should receive greater consideration for HHS approval?

AMP believes the existing CLIA regulations should be updated to better reflect the current standards of laboratory medicine. Importantly, AMP proposes to expand the definition of laboratory to ensure that CLIA can set standards for molecular pathology, an area of laboratory medicine that is not currently covered specifically in CLIA statute or regulations. Further, within our proposal, Section 3 focuses on modernizing requirements to ensure test quality and specifically requires the Secretary to regularly review and update the list of analytes and methods for which proficiency testing is required using input from CLIAC. Third party accreditation organizations set proficiency testing requirements beyond what is required under CLIA, but AMP believes that it is important for CLIA to be modernized to ensure federal standards are also set. AMP's proposed changes to the statute would lead to the expansion of the list and result in many more analytes and methods being subject to the most rigorous proficiency testing. As you understand, as part of proficiency testing, laboratories must test the samples in the same manner as patient specimens are tested and report the results of the unknown samples back to the proficiency testing program for grading. This ensures the quality of the testing but also allows for interlaboratory comparisons to be performed. When proficiency testing is not possible, AMP also strongly recommends that Congress require that each laboratory conduct an alternative assessment for each examination or procedure using methods deemed appropriate by CMS.

Importantly, AMP's proposal also works to ensure the quality of testing in other ways as well. Specifically, AMP's proposal would allow inspectors to be granted access to information about an LDP's analytical and clinical validation and to ensure that these inspectors are appropriately qualified to verify such, AMP's proposal would require that CMS set training requirements.

How well does the existing enforcement structure under CLIA work in ensuring compliance with regulatory requirements and taking action against noncompliance? What should be improved, if anything at all?

AMP believes that the existing enforcement structure ensures compliance with regulatory standards. Currently, CLIA requires clinical laboratories to report any erroneous patient test result to authorized personnel ordering the test. The laboratory must maintain a record of those errors and ensure all complaints and problems reported from the laboratory are documented. The laboratory must issue corrected reports and, when necessary, CMS investigates complaints. (42 CFR § 493.1291) Additionally, CMS-approved accrediting organizations and state licensure programs must notify CMS within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the patient or a hazard to the general public. (42 CFR § 493.555) AMP's proposal builds from these existing requirements by codifying the requirement to report laboratory errors to the Centers for Medicare and Medicaid Services and further requires the Secretary to enhance reporting requirements associated with laboratory errors.

CLIA has existing authority to issue immediate sanctions which include directed plans of correction and civil money penalties of up to \$10,000 for each violation for each day of substantial noncompliance with the requirements. Laboratories certifications may be suspended, revoked, or limited if the Secretary finds that the laboratory is not in compliance. Further, whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health, the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity.

Should legislative reforms address CLIA's quality system requirements? If yes, which of those changes would require Congressional action, and which could be effectuated by CMS alone?

Legislative reform should address CLIA's quality system requirements that can be effectuated by CMS through the Secretary's discretion. Specifically, AMP's proposal clarifies existing CLIA requirements by specifying that Secretary should set standards requiring laboratories to "maintain a quality assurance and quality control program adequate and appropriate for validating all examinations and procedures developed, performed, or interpreted by the laboratory and ensuring the reliability of reported results." AMP's proposal also requires that the Secretary modernize its regulations and as a result, 42 CFR 493 Subpart K would be amended to reflect the expanded purview of CLIA.

Where does redundancy exist, if at all, within the current CLIA regulatory structure with respect accreditation standards under federal and state licensure programs, as well as through CMS-approved accreditation organizations?

Section 7 of our CLIA Modernization proposal removes duplication by preventing any Federal, State, tribal, local government (or political subdivision thereof), or government contractor from requiring that the analytical and clinical validity of a test be assessed for the purpose of determining coverage and payment.

Section 7. Preemption

(a) After the newly designated Section 353(s), inserting the following –

“(t) Preemption Except as described under subsection (p), no Federal, State, tribal, local government (or political subdivision thereof), or government contractor may establish or continue in effect any requirement related to assessing the analytical and/or clinical validation of a laboratory-developed testing procedure for the purposes of assessing whether the procedure is reasonable and necessary for coverage and payment purposes.”

In considering legislative reforms to CLIA, should LDPs be defined in statute? What aspects of test development would characterize such a definition?

Yes, LDPs should be defined in statute. As per our proposal, the term “laboratory-developed testing procedure” should be defined in statute as:

(A) means a type of procedure that —

(i) is not approved, cleared, or authorized as an in vitro diagnostic product by the Food and Drug Administration under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3),

(ii) is performed by a laboratory that is certified or accredited as required under this section,

(iii) is utilized in the context of clinical care or public health services, and

(iv) meets the standards established by regulation under section 353(f) of the Public Health Service Act (42 U.S.C. 263a(f)).

(B) is applicable to procedures that involve the use of —

(i) test systems approved, cleared, or authorized by the Food and Drug Administration under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3) that have been modified by a laboratory and where the modified procedures are validated and performed, and results produced and interpreted, within same laboratory;

(ii) methods developed, validated, and performed, and results produced and interpreted, within a laboratory;

(iii) methods developed by the Centers for Disease Control and Prevention or another laboratory in a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention and performed and resulted by a clinical laboratory for which a certificate is in effect under this section and that is within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention,

(iv) standardized methods, as determined by the Secretary, such as those that are available in textbooks and peer-reviewed publications;

(v) methods in which performance characteristics and specifications are not provided by the manufacturer of test systems or components but are established by the laboratory;

(vi) additional methods established by the Secretary.

How should Congress consider issues relating to the practice of medicine and its relationship with labeling for LDPs? Should there be additional oversight of the information conveyed to patients serviced by LDPs?

AMP believes laboratory developed testing procedures are a part of the practice of medicine. LDPs are medical services as they are a validated testing protocol that is used in conjunction with the

the expertise of licensed and regulated laboratory medical professionals that results in medical interpretation. These services are not commercially manufactured and marketed nor boxed and shipped. Rather, they are designed, developed, validated, performed, and interpreted by board-certified professionals in a single laboratory. LDPs are often created in response to unmet clinical needs and are instrumental for early and precise diagnosis or monitoring and guidance of patient treatment. The role of the professional in every aspect of the design and use of the LDP greatly mitigates any risk to a patient or the public.

AMP's proposal specifically requires that laboratories provide information to the public about their tests, including information on analytical and clinical validity, to promote transparency about LDPs. The information would be displayed via a standardized format to be established by the Secretary to ensure that patients and their providers have access to information important for making a determination about which test is most appropriate for their care.

Should certain CLIA regulations be updated, would it necessitate a reevaluation of the CLIA fee schedule?

Separate from the Clinical Laboratory Fee Schedule (CLFS), the Secretary has existing authority to collect fees as it relates to administering Section 353 of the Public Health Service Act, and we anticipate the CMS would need to reevaluate the fees it collects to carry out the requirements in AMP's proposal. AMP supports the passage of the Saving Access to Laboratory Services Act (SALSA) to address various issues within the CLFS. Additionally, AMP has long been an advocate for qualified doctoral clinical laboratory professionals to be recognized as Qualified Healthcare Professionals (QHPs) for the purpose of Medicare billing for certain services under the physician fee schedule.

What compliance challenges would legislative reforms to CLIA create? How should new regulatory requirements apply to tests currently available to patients?

We believe that modernizing CLIA requirements could better achieve a sustainable system that fosters innovation and promotes emerging medical knowledge to enable healthcare professionals the ability to offer precise, accurate, and the most up-to-date tests to patients. It is also the most streamlined and cost-effective approach, for both the government and laboratories, and the least disruptive and burdensome approach to ensuring clinical and analytical validity, transparency, and addressing other concerns expressed by interested stakeholders. Modernizing CLIA oversight will support laboratory advances in clinical care as validated discovery and innovation continue to develop rapidly. We anticipate there may be certain categories of tests that should be exempt or grandfathered into new requirements established by CMS. As such, AMP's proposal gives the Secretary the authority to exempt certain existing examinations or procedures from having to comply with any requirements as deemed appropriate by the Secretary. The process for exempting tests should be accomplished via rulemaking and thus would allow the public to weigh in on these important decisions.

Thank you for the opportunity to provide information regarding laboratory developed tests, FDA regulation, and CLIA modernization. If AMP may be of further assistance, please do not hesitate to contact Annie Scrimenti, Associate Director of Public Policy and Advocacy at ascrimenti@amp.org.

Sincerely,
Maria E. Arcila, M.D.
President, Association for Molecular Pathology