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Comments of the Association for Molecular Pathology

For the New York State Department of Health Proposed Policy for Risk-based Evaluation of Laboratory Developed Tests

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Comments submitted electronically to clep@health.ny.gov

The Association for Molecular Pathology (AMP) appreciates the opportunity to submit these comments on the proposed policy titled, “NYSDOH Proposed Policy for Risk-based Evaluation of Laboratory Developed Tests (LDTs).” AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics (IVD) industry.

Risk Classification

It is our understanding that the New York State Department of Health (NYSDOH) has put forth this risk-based model for the purposes of prioritizing tests that are submitted to the Department, and that the proposal is not intended to change the level of evidence required to obtain approval for a test that falls within a particular risk category. The proposal outlines how risk classification will be determined in order to evaluate whether 1) review will be required, and 2) whether a lab can receive conditional approval for a moderate risk test if a laboratory holds the appropriate permit category. AMP is generally supportive of a risk-based approach to the regulation of laboratory developed testing services and agrees that a classification system of this sort can be a useful tool for setting review requirements. Our initial assessment using the information provided in the proposal suggests that most, if not all, molecular testing services will be considered either moderate or high risk. We ask that NYSDOH provide examples of tests that they would consider as low, moderate, and high risk.

Criteria for Risk Classification Determinations

Well-Established

In the proposal, risk classification is based on the three determinations, the first being whether the methodology and indications for use are well established. The definition of “well-established” indicates that NYSDOH will use external indicators for whether a methodology or indication for use meets this criteria. These external indicators include whether there is a similar FDA approved test or whether the tests has been described in multiple peer-reviewed publications. However, it is our experience with the NYSDOH review process that a laboratory’s

experience is also a very important factor. For instance, laboratories with a high level of experience under a specific permit category with next generation sequencing (NGS) may be given conditional approval by NYSDOH for other NGS based tests under the same category. Please provide additional clarity on how the Department plans to factor in a laboratory's individual experience, and other possible *internal* indicators, into decisions about risk classification and/or conditional approval. Additionally, AMP is interested in learning if it is possible for a test's risk classification to be downgraded as the result of a laboratory's experience with a particular methodology. Additionally, if internal indicators will be considered as a part of decision-making process regarding risk classification and/or conditional approval, what criteria will be used to evaluate a laboratory's level of experience and expertise? AMP believes that is reasonable to include evidence generated from a laboratory's previous submissions to the Department in the assessment for whether a methodology is well-established or not. We ask that NYSDOH use a transparent process for these determinations.

Similarly, AMP seeks clarification for how NYSDOH would define "multiple laboratories" as well.

AMP believes that it would be overly restrictive to not allow any modifications for the purposes determining that a test is well established. We urge NYSDOH to allow for minor modifications such as those that do not compromise the performance characteristics of an assay. For example, some modifications are necessary to achieve optimal performance. This would include temperature adjustments to account for differences in laboratory location and altitude. AMP believes that a minor modification should also include any change to the laboratory's work flow to make a component automated or manual to account for laboratory-specific needs.

Key Determinant and Impact

Whether a test is a key determinant and whether it has a high impact cannot be completely distinct determinations. Therefore, we hope that NYSDOH will take steps to ensure that tests are not inappropriately put into a higher risk class due to these concepts' inter-relatedness. Examples of tests that illustrate how these terms will be used to determine risk classification would be helpful in clarifying the Department's intent.

Laboratory Practice

Unlike conventional, manufactured, and distributed medical devices, laboratory developed testing procedures are a medical service throughout the design, performance, and interpretation of the results. Therefore, AMP believes it is inappropriate to apply concepts related to the regulation of medical devices to laboratory professional practices. AMP appreciates that the Department has historically treated laboratory developed testing procedures as a professional activity and that NYSDOH has approached the regulation of testing services by taking into consideration a laboratory's entire process and expertise. It is important that regulatory activities associated with laboratory permitting, laboratory activities, and test procedures are conducted within the same overarching entity. AMP believes that laboratory practices, the "tests", and the professional expertise within each laboratory are all inextricably linked. We implore the Department to continue using a holistic approach as you work to clarify and implement these updates to your review process.

We are hopeful that this proposed policy, in conjunction with the successful regulatory practices that are already in place in New York State for laboratories, can serve as model for regulatory strategies and standards that are applied on the federal level. Indeed, AMP has incorporated a great deal of NYSDOH's practices into our [proposal](#) to modernize the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare & Medicaid Services (CMS) so that they can be applied as a national standard.

Thank you again for the opportunity to submit these comments. We look forward to reviewing any changes or clarifications made to NYSDOH's proposal policy. AMP hopes that any updates to the Department's regulatory policies will preserve the nimbleness necessary to foster innovation and enable patient access to appropriate testing. If you have any questions or if AMP can be of further assistance, please contact Tara Burke at tburke@amp.org or 301-634-7962.

Sincerely,

Charles E. Hill, MD, PhD
AMP President