COLLEGE of AMERICAN PATHOLOGISTS

Statement to the Clinical Laboratory Improvements Advisory Committee Meeting April 10, 2024

The use of clinical standards to improve laboratory quality

The College of American Pathologists (CAP) appreciates the opportunity to provide written comments to the Clinical Laboratory Improvement Advisory Committee (CLIAC). As previously stated, the CAP is the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, whose mission is to foster and advocate excellence in the practice of pathology and laboratory medicine worldwide in service to our patients and members.

The CAP believes that clinical standards are an important tool to improve laboratory quality. Clinical standards and guidelines, such as CAP's Practice Guidelines, help define the current standard of care practice.

The ability of clinical guidelines and standards to improve quality is enhanced when used appropriately in tandem with regulations. Clinical guidelines and standards are developed in a consensus-based framework in which all relevant stakeholders are invited to participate, and they are regularly updated as technology and practices evolve and are applied to individuals. Regulations apply to entities and are meant to be comprehensive and broad to allow for flexibility in meeting their objectives of quality, safety, or other public health needs. Clinical guidelines and standards can fill in the gaps within regulations. Additionally, clinical guidelines can be revised and updated regularly and quickly to adapt to changing practices, needs, and technology. Regulations, meanwhile, take significantly longer to revise and update due to the necessary and valuable process of public comment periods, and thus relying solely on regulatory updates to account for changes and developments is not feasible.

The CAP uses clinical guidelines and standards in our accreditation and proficiency testing programs. These take the form of the CAP's Practice Guidelines, and the CAP Checklist.

The CAP's Practice Guidelines is a form of translational research that becomes increasing valuable as they facilitate the delivery of evidence-based care. Our practice guidelines provide standardized procedures, which when followed, produce more precise and useful test results. This is a win-win for both physicians and patients. This should entail a defined and transparent process for determining if a practice guideline, once complete, is appropriate for use in assessing performance or as an oversight mechanism.

The CAP's Checklists also provide current standard of care practice. CAP checklist requirements are complete and educational, with the goal of not simply identifying issues, but ensuring processes exist that prevent them from occurring in the first place. Because CAP checklists are updated annually, they reflect the latest requirements and most recent advances in best practices. The CAP also draws on the

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collective expertise of our scientific resource committees to introduce new checklists with detailed requirements to support advances in the modern laboratory.

Additionally, the CAP checklists incorporate various US regulations, such as:

- OSHA for employees' chemical and biological safety
- CDC and APHL for infection control
- Nuclear Regulatory Commission for radiation safety
- National Fire Protection Association for fire safety
- Environmental Protection Agency for hazardous chemical waste disposal
- US Department of Transportation for shipment of specimens to other laboratories AND
- FDA guidelines for blood banking and tissue practices

CAP checklists are based on guidelines and publications from nationally and internationally recognized standard setting organizations, such as:

- Clinical and Laboratory Standards Institute
- International Standards Organization – ISO
- World Health Organization
- Cystic Fibrosis Foundation
- American College of Medical Genetics and Genomics
- American College of Surgeons Commission on Cancer
- American Society of Clinical Oncology

CAP checklists also draw from CAP Q-Probes, Q-Tracks, and evidence-based guidelines developed by the CAP's Pathology and Laboratory Quality Center.

The result of this iterative and comprehensive effort are the CAP's 21 discipline-specific checklists which define the accreditation program requirements and reflect the most recent advances in best practices. For example, the CAP added next-generation sequencing requirements to the molecular pathology checklist in 2012 and continues to update them annually as advancements in the technology occur and as its use has expanded into different applications, such as inherited genetics, oncology, histocompatibility testing, pharmacogenetics and infectious disease testing.

The CAP welcomes the opportunity to discuss our concerns and recommendations for implementation at your earliest. Please contact Andrew Northup at anorthu@cap.org or 202.297.3726.

Closing,

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Appendix

The CAP has developed and contributed to work on checklists and clinical standards covering a wide variety of activity:

- The ASCO/CAP HER2 guideline is a good example for how we have incorporated these practices in the checklist to ensure the quality of breast cancer biomarkers used to determine patient treatment with companion diagnostics. As updated guidelines are released, we evaluate them and update the checklist requirements where needed to stay current with evidence-based practices.
- A CAP Center guideline update was recently released, Principles of Analytic Validation of Immunohistochemistry Assays. We incorporated key concepts when this was first published in 2014 and will be including newer updates for our 2024 checklist edition to ensure that IHC assays used for patient testing ensure accuracy and reduce variation in IHC laboratory practices. This includes content on recommendations for the numbers and type of samples to be used for validation or predictive and nonpredictive assays, criteria for validating laboratory-developed assays, concordance rates between the new assay and comparator assay, and processes to evaluate changes to the assay.
- CAP Cancer protocols provide guidelines for collecting essential data elements for complete reporting of malignant tumors and optimal patient care. The CAP checklist require laboratories to use these protocols for synoptic reporting and have processes to implement changes to their reporting templates in response to required data element changes in updated protocols.
- The American Cancer Society recently changed its guidelines for HPV screening for cervical cancer to promote the use of the primary HPV screening test, over co-testing involving an HPV test with a PAP test, to promote availability of testing to all patients and early detection abnormal cervical cell changes (pre-cancers) to treat patients earlier of cervical cancer. This is a newer type of testing that is not widely used in laboratories, as only one instrument has received FDA-approval. The CAP will be modifying its checklist requirements for the 2024 checklist edition to ensure that the appropriate quality measures are in place for laboratories that begin performing this testing and to educate physicians on the limitations of these tests.
- The ISO 15189 Standard is an international standard for quality and competence in medical laboratories. The CAP has incorporated concepts from the standard in the CAP checklists for addressing risks and opportunities for improvement, with the goal of increasing the effectiveness of quality management systems, decreasing the probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public, and the environment. For example, the CAP has requirements for root cause analysis for certain types of non-conformances that serve to identify the source of the problem and prevent recurrence. Another example would be requirements that require a risk assessment process for laboratories to proactively identify problem areas and develop mitigation strategies to reduce risk, such as with

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pretransfusion sample misidentification and other causes of mistransfusion or evaluation of safe work practices to identify hazards and implement mitigation strategies to prevent laboratory incidents and accidents.

- The Cystic Fibrosis Foundation has published guidelines on sweat testing that are periodically updated for the screening and diagnosis of Cystic Fibrosis for newborns and adults. The CAP has incorporated concepts from these guidelines into the checklist requirements on sweat testing to ensure that the results provided by the laboratory produce accurate, reliable results using methods, collection techniques, and reference ranges appropriate for the testing.