COLLEGE of AMERICAN PATHOLOGISTS

September 7, 2017

Jeffrey Botkin, MD
Committee Chair
Keck Center
500 Fifth St. NW
Washington, DC 20001

Dear Dr. Botkin:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the National Academies of Science Engineering and Medicine Committee the proposed study of the Return of Individual-Specific Research Results Generated in Research Laboratories. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists are physicians whose diagnoses drive care decisions made by patients, primary care physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value is recognized throughout the care continuum and many patient encounters.

The CAP supports empowering patients and participants to be more engaged in their healthcare decision-making; however in order for them to make informed decisions, patients and participants must receive accurate and reliable information. As an accreditation agency, the CAP has had oversight responsibilities in a variety of laboratory settings, from complex university medical centers to physician office laboratories covering a complete array of disciplines and testing procedures available in today's laboratory. Therefore, we have a keen interest in ensuring high quality diagnostic services to patients. **To that end, the CAP opposes the return of individual-specific research results to participants which are generated in research laboratories which do not have the Clinical Laboratory Improvement Amendments of 1988 (CLIA) certification.** The lack of CLIA certification raises significant concerns that these results would not have the necessary oversight to ensure their reliability and accuracy.

CLIA was established to strengthen federal oversight of clinical laboratories to ensure the accuracy and reliability of patient test results. Congress intended for CLIA to establish quality standards for personnel qualifications and responsibilities, quality control, quality assurance, record maintenance, and proficiency testing for all laboratories in order to safeguard against false test results that may cause improper treatment, unnecessary mental and physical anguish for patients, and higher health care costs. Although research laboratories comply with FDA regulations and inspection

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governing research studies, these laboratories are exempt from CLIA requirements and are not subject to laboratory-specific standards that address these quality requirements.

UNINTENDED CONSEQUENCES

Patient Safety

The CAP is gravely concerned about potential patient safety implications if the release of research results directly to participants is permitted. This proposal could create a loop-hole which allows for a large variety of research labs of unknown provenance and lacking any oversight for testing quality to generate ACTIONABLE results directly to participants without any guarantee of medical oversight or judgment. The potential for misunderstanding and misuse of test information by participants is significant. Participants with access to this information without any medical guidance may have unnecessary treatments or even avoid known beneficial health decisions (eg, smoking cessation, alcohol abstinence, weight loss).

Electronic Health Record

In addition, this information, when given to the participant, has the potential (if not the absolute likelihood) of being incorporated into the permanent medical record of that participant/patient. Because the only laboratory results which are currently legally provided to patients and providers for clinical care are from CLIA certified laboratories, there is no standard in place to clearly differentiate results generated from entities which do not follow CLIA requirements. Similarly, laboratories not certified by CLIA may not be aware of nor follow CLIA safety requirements for inclusion of specific data elements into their reports, and reports may not follow national and international standards for usability, thereby increasing the risk of misinterpretation of results regardless of their degree of accuracy. Providers, who are not aware of these risks or of the potential for false results from laboratories not certified by CLIA, may scan or import these results into their EHRs and unknowingly expose the participant, now patient, to misinterpretation and harm as others who were not aware of the study are able to view these results.

RECOMMENDATION

The CAP recommends CLIA certification for research laboratories that wish to return of individual-specific research results generated in their research laboratories directly to participants. However, if a very significant finding occurred in a research laboratory that elects not to have CLIA certification, then the result should be confirmed in a CLIA certified laboratory.

The CAP greatly appreciates the opportunity to advance medical advancements through innovative research methods; however, we support a process that protects patients from unnecessary or improper medical treatments. We welcome the opportunity to work closely with NASEM in finding a solution that balances the advancements of research

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while protecting patients with accurate and reliable test results. Please contact Helena Duncan, CAP Assistant Director, Economic and Regulatory Affairs at hduncan@cap.org if you have any questions on these comments.

Closing,

The College of American Pathologists

Sent via email

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