COLLEGE of AMERICAN PATHOLOGISTS

Comments to the
Centers for Medicare and Medicaid Services (CMS)
(Docket No.CMS-3271-P)

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The College of American Pathologists (CAP), the nation's largest association of Board certified pathologists, appreciates this opportunity to provide comments to the Centers for Medicare and Medicaid Serves (CMS) on the Clinical Laboratory Improvement Amendments (CLIA); Fecal Occult Blood (FOB) Testing proposed rule to clarify that the waived test categorization applies only to non-automated fecal occult blood and remove the hemoglobin by copper sulfate method from the list of waived tests. The CAP, *celebrating 50 years as the gold standard in laboratory accreditation,* is a medical society serving more than 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. We believe your efforts to ensure that any new technology undergoes adequate review before receiving CLIA waiver status; but also have the belief that waived testing poses risk to patients in certain settings.

Under CLIA, regulatory oversight is waived for tests that are cleared by the FDA for home use; employ methodologies that are as simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly (42 CFR part 493). Advances in medical technology and instrumentation have enabled physicians to do more and more sophisticated testing which is leading to more rapid and appropriate diagnosis and therapy. Therefore, the CAP believes it is appropriate to require “automated FOB tests” to be evaluated through the FDA CLIA waiver process instead of automatically waiving these devices as the original CLIA regulations necessitate.

The CAP believes no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect result is “risk free” or inconsequential with regard to potential harm; however, it is recognized that the clinical setting, physician judgment, repeat testing, and other secondary checks may minimize risk of harm to patients in certain settings (e.g. physician office laboratories [POLs], home use). Any test that may lead to immediate and/or irreversible actions that may result in harm should not be waived from requirements for proficiency testing and quality control requirements.

The hemoglobin by copper sulfate method is not widely use but is currently performed by the Department of Defense (DoD).

Thank you for your serious consideration of these comments as we all strive to provide the best care for our patients. Please feel free to contact Helena Duncan, CAP Assistant Director, Economic and Regulatory Affairs at hduncan@cap.org if you have any questions on these comments.