Opportunities for Change in CLIA Waivers

If you've ever gone to a doctor's office or an urgent care center, chances are you've had a CLIA Waived Test – these are easy to use diagnostic tests that can be performed while you wait. However, although there are CLIA Waived tests available today for such things as strep, flu, and HIV, there are many new useful tests which are being delayed or going undeveloped due to FDA regulatory policies. At the direction of Congress, by the end of 2017, FDA will be proposing revisions for policies for public comment. This is a process everyone with an interest in point of care testing should participate in because it could have a major impact on facilitating or limiting access to these important tests.

The Coalition for CLIA Waiver Reform

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The Coalition for CLIA Waiver Reform

An organization dedicated to improving access to safe and effective diagnostic testing at the point-of-care by reforming the U.S. Food and Drug Administration's CLIA Waiver Program.

What is CLIA-Waived Testing?

Point-of-care testing ("POCT") is a cornerstone of patient care, and in coming years, will play an increasingly important role in improving patient outcomes and the public health. POCT results are received in the exam room or at the patient's bedside, speeding diagnosis and treatment decisions and reducing instances in which patients get tested, but never return to receive their results.

Roughly 80% of POCT facilities are so-called "Certificate of Waiver" laboratories, which include physician offices, health clinics, urgent care centers and other points of care. By law, Certificate of Waiver laboratories may only use FDA-approved/cleared in vitro diagnostic ("IVD") tests which are designated as low ("waived") complexity by FDA.

Being waived complexity means that the test can be used safely and effectively by personnel at these points of care who are generally not trained laboratorians (e.g., physicians, nurses, and medical technicians).

CLIA Waiver Regulation

Congress revised the CLIA waiver standards in 1997 as part of the FDA Modernization Act ("FDAMA") to encourage development of new waived tests. Generally, a waived test must be "simple" so non-laboratory experts can use it, and "accurate" – which means that a test gives comparable performance in the hands of traditional "trained" laboratorians and the physicians, nurses, techs and others who use the test at the point of care.

Although FDA proposed to follow FDAMA in 2001, it published a new guidance in 2008 rejecting Congressional standards and limiting development of new CLIA-waived diagnostic tests for nearly a decade. Although there have been *some* hard-won successes, development progress is far beyond where it should be, and the cause is FDA imposing arbitrary accuracy requirements that Congress tried to eliminate through FDAMA.

For purposes of CLIA Waiver, an FDA approved test is "accurate" if it "performs the same in the hands of untrained users as it does in the hands of laboratory professionals when using the device under realistic conditions." – FDA Draft Guidance (2001)

In 2016, Congress responded by directing FDA to propose new policies in the form of updated guidance reinterpreting the meaning of "accurate" as part of the 21st Century Cures Act. The law gives FDA until December 2017 to propose draft guidance, and until December 2018 to finalize that guidance following public comment.

Correcting the flaws regarding accuracy in the 2008 Guidance is **critical** to removing unnecessary impediments that are preventing patient access to innovative CLIA-waived point-of-care tests, and preventing providers from giving their patients the best care.

Get Involved

Later this year, FDA is required to propose an update to its CLIA waiver guidance. All members of the public will have the opportunity to comment. To stay up to date on the guidance's release and how to submit comments, as well as on waiver regulation generally, we encourage you to sign up for our newsletter by contacting us.

Contact Us

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