Urgent Care® Association of America

Leslie Kux, J.D.
Associate Commissioner for Policy
Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Associate Commissioner Kux:

We are writing on behalf of the Urgent Care Association of America to comment on the FDA's draft "Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of *In Vitro* Diagnostic Devices." We have reviewed the draft guidance carefully over the past several months and, as written, it appears to make no fundamental change to the current 2008 FDA guidance, which we believe will continue to deny Americans from accessing new and better point-of-care diagnostic tests.

In brief, the FDA needs to remove its proposed discussion of accuracy and focus on the relevant question for the guidance – whether trained and untrained users will get comparable results when using the *same* to-be-waived test.[1] Congress has said that if a diagnostic test allows trained and untrained users to get comparable results, and the test is simple, it is entitled to a waiver. FDA's guidance needs to reflect Congress's intent, and recognize – as Congress has – the value of expanded access to new and innovative CLIA-waived tests.

The Urgent Care Association was established in 2004 and based in Warrenville, IL. It is a member association dedicated to advancing and distinguishing the role of urgent care medicine as a healthcare destination and support the ongoing success of its membership through education, advocacy, community awareness, benchmarking and promoting standards of excellence. We define urgent care as follows:

An urgent care center is a medical clinic with expanded hours that is specially equipped to diagnose and treat a broad spectrum of non-life and limb threatening illnesses and injuries. **Urgent care centers are enhanced by onsite radiology and laboratory services** and operate in a location distinct from a freestanding or hospital-based emergency department. Care is rendered under the medical direction of an allopathic or osteopathic physician. Urgent care centers accept unscheduled, walk-in patients seeking medical attention during all posted hours of operation.

Urgent care centers successfully include CLIA-waived laboratory tests as a key component of their diagnostics.

[1] In the current (2008) guidance, FDA states that its uses "the term "accurate" to refer to those tests that are comparable to tests whose results of measurements are traceable to designated references of higher order, usually national or international standards." *See* page 12 of the 2008 Guidance. The proposed draft FDA guidance states a test is "accurate… if the measurement results obtained by untrained operators in CLIA-waived testing settings are comparable to the results of an established quantitative test (i.e., for which results have been traced to references of higher order, usually national or international standards) performed by laboratory professionals" or comparable to "gold standard" test results obtained by trained users. *See* pp. 9, 12-13 of the draft FDA guidance. So, untrained users employing the to-be-waived test are being compared to trained users employing a gold standard test. The focus is clearly not on the way users affect results.

CLIA-waived tests improve the lives of patients every day. While our member organizations are typically CLIA-waived or CLIA Moderate laboratories, nearly all depend on access to point-of-care tests. . If urgent care providers cannot get test results to patients at the point-of-care it can lead to delays in diagnosis and treatment, and significant loss to follow-up, all of which hurts individual patients and the public health.

As other public interest groups have explained, the current FDA guidance for waivers delayed access to tests with significant public health implications, such as tests that can detect HIV during patients' most infectious phase,[2] and tests for syphilis (which reemerged as a significant problem during the years that a CLIA-waived point-of-care test option was unavailable).[3] Tests were eventually waived, but only after years of delay, and independent patient advocacy and public interest groups implored FDA to waive tests that were held up in review due to the current guidance. The delays and harm that were caused could have been avoided by adopting the right standards for waivers.

Congress was clear when it said the 21st Century Cures Act – which mandated this guidance development process – "require[s] FDA to update guidance on certain tests performed in doctors' offices to ensure that the guidance on this matter aligns with the FDA Modernization Act's intent that, if the results by trained and untrained users are comparable, a test is considered to be accurate for CLIA waiver purposes."[4] In other words, a test meets the standard for a CLIA waiver if it (1) is simple (per another requirement in the statute), and (2) results obtained by "trained" and "untrained" will generally agree.[5] This can be easily evaluated after a test is cleared or approved for professional laboratory use (as a moderate or high complexity test) by conducting a study to show how often "trained" and "untrained" users get the same results or perform the test the same way (e.g., through a human factors study).

We support the above "user agreement" approach because it makes sense and addresses the right question for deciding whether to grant a CLIA waiver. In the interest of patients and public health, we ask that the FDA revise the draft guidance to remove its discussion of accuracy, and to focus on assessing whether there will be a reasonable level of agreement between trained and untrained users using the same test.

Sincerely,

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CEO
Urgent Care Association of America

Pamela Sullivan, MD, MBA, FACEP, PT
Chair, UCAOA Board of Directors

[2] AIDS Advocacy groups previously spoke to this issue as FDA held up waivers for 4th Generation HIV Tests. *See* "The CLIA Waiver Process and HIV Testing – More Cost than Benefit?" *available at*, ftp://ftp.cdc.gov/pub/cliac_meeting_presentations/pdf/addenda/cliac1114/19_PublicComment_Krellenstein_HIVTesting.pdf.
[3] *See* "Desperately Awaiting Approval: When is a Rapid Syphilis Test Coming to Market?" *available at*, https://groups.google.com/forum/#!topic/hiv-pja-strategy/HrRosBvDrK0.
[4] See 162 Cong. Rec. S6791 (daily ed. Dec. 7, 2016) (emphasis added).
[5] We are using the terms "trained" and "untrained" because these are the terms FDA uses in its guidance. Of course, untrained users are often medical professionals with years of training and experience in the practice of medicine, just not specific to laboratory testing.