The Coalition for CLIA Waiver Reform

Advocates for regulatory reforms that will improve access to innovative, safe, and effective Point-of-Care Testing with CLIA-waived tests

What is Point-of-Care Testing?

- Point-of-care testing ("POCT") is testing that occurs at or near the location of the patient and healthcare provider, giving fast access to results.
- POCT can improve patient management & outcomes and reduce costs.
- The closer to the point of care, the better, and the best way to improve access to new and better point-of-care tests is to expand the suite of CLIA-waived tests.

What is a CLIA-Waived Test?

- When FDA approves a laboratory test, it assigns it a CLIA "complexity" rating – "high," "moderate," or "waived" (low) complexity – which should reflect how difficult it is to use.
- The rating determines which kinds of CLIA-certified clinical labs in the U.S. can use the test.
- CLIA "Certificate of Waiver" labs – which by law only run CLIA-waived tests – include nearly 70% of laboratories in the U.S., including physician office labs, health clinics, urgent care centers and nursing facilities. These locations provide opportunities for POCT.
- Because these facilities only use low complexity tests, they are not subject to user expertise requirements that apply to labs using moderate/high complexity tests.

There are 4 Routes to a CLIA Waiver

1. **OUR FOCUS:** *Tests that are "simple and accurate . . . in the hands of the user. . . "* – This is the route the most novel tests for serious diseases and conditions would need to take
    - Often a manufacturer will first get an approval with a moderate complexity rating and will then apply for a CLIA waiver
2. *Tests waived by regulation* – old regulations waived some standard tests, like cholesterol tests. These tests constitute most CLIA-waived tests
3. *Home Use Tests* – These tests get an automatic CLIA waiver
4. *Tests which pose an insignificant risk if results are wrong* – a very small number of tests for health conditions that pose low risk with misdiagnosis (like minor irritation)

If you hear statements like "FDA waives 200 tests a year," 195 of the 200 are probably waived through routes 2 – 4 above.

FDA is misinterpreting what it means to be an "accurate" test, which is limiting access to POCT

- Congress in 1997, and FDA in 2001, said that accurate means the test performs the same in the hands of untrained users [as] it does in the hands of laboratory professionals under realistic conditions.
- In 2008 guidance, FDA changed its mind, and now takes the position that "accurate" means a test must be shown to be comparable to a gold standard procedure, i.e., the most inherently accurate test, which is most often a different test.
    - This can result in some odd conclusions. For example, FDA may approve a test that is 85% accurate for use in moderate & high complexity testing labs, but would require 90-95% accuracy in a Certificate of Waiver lab – i.e., the Certificate of Waiver lab would need to do *better* than labs with much more expertise in testing.
- To accommodate this interpretation of accuracy, FDA often requires complex clinical trials that amount to a repeat of the clinical studies that were performed to get FDA approval in the first place. This is inconsistent with the law and FDA's mission to promote innovation.

This is Not a New Problem… Congress tackled it before in 1997

- **1993**: CDC running CLIA waiver program, and denies waivers to FDA-approved tests even if studies can show that a test can be run just as well in Certificate of Waiver labs as more regulated labs
- **1997**: Congress steps in and clarifies law to explain that the only question for a CLIA waiver is whether a waived lab can run a test as well as a non-waived lab
- **2001**: FDA takes over the program and issues a guidance exactly in line with Congress' 1997 clarification of the law. Tests are waived efficiently and quickly, and at reasonable costs
- **2005**: CDC releases results of a 2003-2004 survey that concludes most Certificate of Waiver labs are doing OK, but there are concerns that labs are not regulated enough
- **2005**: FDA goes back to something closer to the old CDC standard in a draft guidance, and over objections by AdvaMed and others stakeholders, makes the guidance final in 2008
    - **This was likely FDA's way of addressing concerns raised by CDC**
- **2008**: FDA starts rejecting many tests that would likely qualify under the 2001 standard, costs of testing skyrocket, and patient access to novel POCT is being hindered.
- **May 2014**: Coalition for CLIA Waiver Reform is formed

Concerns about Certificate of Waiver labs that drove changes missed the point and are questionable

- It is important to recognize the lab issue is something *entirely separate* from the standard for a waiver. FDA's current standards for accuracy don't protect against the kinds of issues raised in 2005, and only serve to limit access to important point-of-care testing
- If there are real lab problems, they should be addressed the right way – through evaluating the regulation of the labs and how they perform tests. However, we're not sure that there really are significant problems today. The 2003-04 surveys showed most Certificate of Waiver labs were doing things the right way, and since then there have been changes that should have improved lab performance even more –
    - New technologies, and new thinking by industry as well as FDA recommendations about ease of use testing (as opposed to accuracy requirements) have promoted the development of tests that are even easier to use, and designed to prevent user errors
    - CDC and manufacturers do a lot of outreach to Certificate of Waiver labs to help them run tests in a safe and effective way and follow good lab practices. That is something we strongly support.
    - Many labs are now voluntarily participating in private lab accreditation programs.
- Any regulatory structure needs to give the necessary due to patient and physician access to testing. In many cases, FDA is not giving the value of improved access enough consideration.

To Fix the Problem with CLIA Waivers We Need Your Support

To bring about change that helps patients, we need to stand together to explain the potential benefits of expanded CLIA-waived testing, and the importance (and validity) of going back to the original head-to-head comparative studies previously recommended by FDA to assess test accuracy in the hands of a non-expert user. We would like to invite you to join the Coalition's Scientist, Physician and Healthcare Provider Division. As a member of the Division you would be able to –

- Coordinate with the broader Coalition on educational and outreach initiatives
- Help craft policy pieces (e.g., a sign-on letter) in support of needed regulatory reforms
- Play a key role in helping patients get better access to safe, effective, and innovative POCT