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The Honorable Joe Barton
House of Representatives
Washington, DC 20515

Dear Mr. Barton:

Thank you for your letter to Acting Secretary Charles E. Johnson regarding the application of the Clinical Laboratory Improvement Amendments (CLIA) to forensic testing. He has asked me to respond to you directly.

The Centers for Medicare & Medicaid Services' (CMS') memorandum, to which you refer, titled "Drug or Alcohol Screening/Testing and Clinical Laboratory Improvement Amendments (CLIA) Certification," did not communicate a change in policy; rather, it clarified that CLIA certification is required when testing is not solely utilized for forensic purposes (i.e., when it is used for forensic purposes and for another purpose, such as being a basis for concluding that the individual must be placed in a treatment program).

One of the key goals of the CLIA program, as reflected in section 353 of the Public Health Service Act (Pub. L. 100-578), is to help ensure clinical laboratory testing used for a health purpose (including the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of individuals) is performed only by facilities certified by CLIA as meeting minimum quality-based laboratory testing standards. Our policies reflect that statutory requirement.

The CLIA requirements are designed to promote accuracy of testing, and were passed by Congress after findings of widespread inaccuracies in the Nation's laboratories. Federal regulations at 42 CFR 493.3(b)(1) specify that the forensic testing exception to the generally applicable CLIA certification requirements are only applied in circumstances where a facility or component of a facility only performs testing for forensic purposes. If forensic testing results are also used to diagnose or treat a person, or if they are also used to assess the health of a human being, the testing must be done by a laboratory (as that term is defined in the CLIA regulations at 42 CFR 493.2), and the laboratory conducting the "forensic testing" must possess the appropriate CLIA certificate for conducting that test. These rules implement the statutory mandate that laboratories comply with CLIA requirements if they perform testing of human specimens for health care purposes.

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I appreciate your taking the time to alert us to your concerns and I assure you we will continue to monitor the impact of the CLIA regulations. I will also provide this response to the cosigner of your letter.

Sincerely,

A handwritten signature in black ink that reads "Charlene Frizzera". The signature is written in a cursive style with a large, prominent initial "C".

Charlene Frizzera
Acting Administrator