

**Justification for Nonsubstantive Change Clinical Laboratory Improvement
Amendments (CLIA) Application for Certification
(CMS-116) OCN# 0938-0581**

We are requesting that a non-substantive change be made to the CLIA Application for Certification form (CMS-116), which was reapproved on March 22, 2021 by OMB for 3 years, ending March 31, 2024.

These are the changes made to the CMS-116 that was reapproved on March 22, 2021:

- Page one, Section II (TYPE OF CERTIFICATE REQUESTED) and page 4, VIII (NON-WAIVED TESTING)
The merger of the Accreditation Association of Hospitals and Health Systems, Inc. (AAHHS/HFAP) into Accreditation Commission for Health Care, Inc. (ACHC) occurred on October 19, 2020. Unfortunately, during the March 22, 2021 approval of the CMS-116, we were unaware of the name change for the AAHHS/HFAP to ACHC until after this form entered the clearance process. ACHC has requested that CMS revise the CMS-116 now rather than waiting until 2024.
- Page 6, INSTRUCTIONS FOR COMPLETION, under E-mail address
The words “is optional and” were removed. This is a typo that should have been removed before the CMS-116 was submitted for the last reapproval.
- Page 7, INSTRUCTIONS FOR COMPLETION, under VI. WAIVED TESTING and VIII. NON-WAIVED TESTING
The language referencing a CMS website and the associated URLs were removed. These websites no longer exist and have been removed from the CMS.gov pages. The removal of this information occurred late in 2020 after the CMS-116 started the clearance process.
- Page 8, section prior to TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALITIES
The first line on page 8 says “VI. WAIVED TESTING”. This is a typo and should not be on this page.

These revisions will not change the existing burden hours and responses that were already approved with the 0936-0581 clearance package.

Attachments

1. CMS-116: form with highlighted changes; and
2. CMS-116: clean copy with all revisions.

Point of Contact (POC):

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