

**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 recently reapproved by OMB for 3 years, ending March 31, 2021.

On March 29, 2019, the notice CMS-3375-N [Announcement of the Approval of the Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (Formerly Known as the American Osteopathic Association/Healthcare Facilities Accreditation Program) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988 was published in the Federal Register. This means that any qualified laboratory seeking CLIA accreditation may elect to be accredited by Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP). Unfortunately, during the March 22, 2018 approval of the CMS-116, we were unaware of the name change for the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) to AAHHS/HFAP. AAHHS/HFAP has requested that CMS revise the CMS-116 now rather than waiting until 2021.

This minor revision 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 change to Part II on page 1 showing where AAHHS/HFAP will be added; and
2. CMS-116: clean copy with AAHHS/HFAP printed on page 1.

Point of Contact (POC):

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