

**Justification for Non-substantive 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). A new accreditation organization called the American Association for Laboratory Accreditation and known as **A2LA**, has been approved by CMS for deeming authority under the CLIA program. This means that any qualified laboratory seeking CLIA accreditation may elect to be accredited by **A2LA**; unfortunately, because of these timing issues, **A2LA** was not included on the form for laboratories to select. Therefore, the new accreditation organization has formally requested that CMS revise the form . This minor revision will not change the burden hours.

Attachments

1. CMS-116: form with highlighted change to Part II on page 1 showing where **A2LA** will be added; and
2. CMS-116: clean copy with **A2LA** printed on page 1.