

Revisions to Form CMS-116, Clinical Laboratory Improvement Amendments (CLIA) Application Form

Section # on CMS-116	Type of Change	Reason for the Change
I. GENERAL INFORMATION	Delete: word “Closure”  Switch order of fields “SEND CERTIFICATE TO THIS ADDRESS” and “SEND FEE COUPON TO THIS ADDRESS”	Redundant and confusing  Improve data entry
II. TYPE OF CERTIFICATE REQUESTED	Revise: language for Certificate for Provider Performed Microscopy Procedures (PPM)	Enhance completion of application
III. TYPE OF LABORATORY	Delete: “Is this a shared lab?” and check boxes under 21 Physician Office	Not needed for CLIA compliance
VI. WAIVED TESTING	Add: To title area “If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).  Add: “If additional space is needed, check here and attach additional information using the same format.”	Communicate more clearly  Enhance completion of application
VII. PPM TESTING	Add: To title area “If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).”  Revise: instructions for completing section to include “If also performing waived complexity tests, complete Section VI.”	Communicate more clearly  Enhance completion of application
VIII. NON-WAIVED TESTING	Add: To title area “Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.”	Enhance completion of application

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	<p>Add: “Identify the non- waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory. (e.g., Potassium, Acme Chemistry Analyzer)</p> <p>Add: "If additional space is needed, check here and attach additional information using the same format." Include text box similar to Section VII.</p>	<p>Same information as required by Part VI and VII of form and Enhance completion of application</p> <p>Enhance completion of application</p>
Bottom of Page 4 of currently approved form	<p>Add: section to capture printed name of laboratory owner/director</p> <p>Add: “Do not send any payment with your completed 116 application.”</p>	<p>Improve data entry</p> <p>Enhance completion of application</p>
Instructions for Completion	<p>Add: to introduction section “Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing.”</p> <p>Remove: Under “Type Of Laboratory”, “If selecting ‘physician office’ (code 21), also answer a related question regarding ‘shared labs’. A shared laboratory is when two or more sole practicing physicians collectively pool resources to fund one laboratory’s operations. The definition</p>	<p>Communicate more clearly and Enhance completion of application</p> <p>To coincide with changes made to section III TYPE OF LABORATORY and Enhance completion of application</p>

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	<p>of a shared laboratory may also include two or more physician group practices that share the expenses for the laboratory’s operation.”</p> <p>Add: New section for reminders on completing application  “Reminders - Before submitting the Form CMS-116:  1. Include the current or estimated annual test volume.  2. For Certificates for PPM, Certificates of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.  3. Do not send any money with your application.  4. Send the completed Form CMS-116 to the appropriate State Agency (<a href="http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf">http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf</a>).”</p>	<p>Communicate more clearly and Enhance completion of application</p>
<p>GUIDELINES FOR COUNTING TESTS FOR CLIA</p>	<p>Revise: wording “macroscopia examinations” to “macroscopic examinations”</p>	<p>Correct misspelling</p>