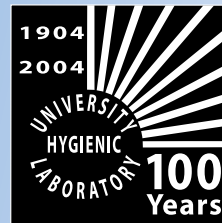


CLIA Corner

The University of Iowa Hygienic Laboratory

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Notification Requirements Update

The CLIA regulations require laboratories to notify the State Agency or its designee responsible for oversight of the CLIA program in the state in which the laboratory is located when certain changes occur. In a Memorandum dated November 26, 2008, the Centers for Medicare and Medicaid Services (CMS) provided the State Agencies with guidance that specified the appropriate method of event or change notification; i.e., those laboratory changes that require a new CMS-116 form and those laboratory changes that require only written notification at a minimum.

The chart with this issue describes the acceptable methods of notification to be used by the laboratory depending on the type of CLIA certificate held and the type of event or change. The following are additional requirements:

- ❖ The regulations require all certificate types to notify, in writing, the State Agency within 30 days of changes to the following:
 - Ownership;
 - Name of laboratory;
 - Location (physical or mailing address); and
 - Laboratory director.
- ❖ Laboratories with a Certificate of Compliance (CoC) must also notify the State Agency within six (6) months, of any additions or deletions to its tests/test methods and specialties/subspecialties.
- ❖ Laboratories with a Certificate of Accreditation (CoA) must also notify its Accrediting Organization (AO) within six (6) months, of any additions or

deletions to its tests/test methods and specialties/subspecialties.

- ❖ When the notification requires the **Form CMS-116, Application for Certification**, to be completed, the form must be filled out in its entirety and signed by the individual designated and qualified as the Laboratory Director. The form can be printed from the following website: www.cms.hhs.gov/clia. Click on the link for **How to Apply for a CLIA Certificate, Including International Laboratories**, and then go to Related Links Inside CMS and click on **CMS-116 Form and Instructions**.
- ❖ When the change or event only requires **written notification**, this includes an email, fax, or hard copy letter. The written notification must include laboratory name, CLIA number, name of the Laboratory director and/or owner or his/her designee. In lieu of written notification, a new CMS-116 form is also acceptable. The entire form must be completed and signed.
- ❖ Notifications must be submitted to the State Agency or its designee in the State in which the laboratory is located (i.e. laboratories located in Iowa submit notifications to the Iowa CLIA Laboratory Program, whereas laboratories located in Nebraska submit notifications to the Nebraska's CLIA program, and so forth.) To locate the State Agency or its representative for each State's CLIA program, go to www.cms.hhs.gov/clia, click on link for **State Agency & Regional Office CLIA Contacts**, and go to links under Downloads.

Policy Clarification for Laboratories with Certificate of Accreditation Performing Only PPM Procedures

The memorandum also clarified the CLIA policy concerning laboratories that conduct provider-performed microscopy (PPM) procedures and are operating under a CLIA Certificate of Accreditation (CoA). When a laboratory that operates under a CoA decides to conduct PPM procedures ONLY, the laboratory must downgrade its CoA to Certificate of PPM. It may **not** continue to hold a CoA.

New Email Addresses for Nancy and Kristi

Want to send a question or be added to the CLIA Corner Google Group? Email us at: Nancy-grove@uiowa.edu or Kristine-rotzoll@uiowa.edu

Acceptable Methods of Written Notification for Laboratory Demographic or Certificate Changes												
TYPE OF CLIA CERTIFICATE	Certificate of WAIVER (CoW)			Certificate of PROVIDER PERFORMED MICROSCOPY (PPM)			Certificate of COMPLIANCE (CoC)			Certificate of ACCREDITATION (CoA)		
	Event or Change	CMS-116	Written	Fee Coupon	CMS-116	Written	Fee Coupon	CMA-116	Written	Fee Coupon	CMS-116	Written
Initial Application	X			X			X			X		
Survey-Initial or Recertification							X					
Survey-Validation										X		
Status/Certificate Type Change to PPM, CoC or CoA	X			X			X			X		
Status/Certificate Type Change to CoW		X			X			X			X	
Change of Accrediting Organization (AO)											X	
Personnel-Laboratory Director		X	X	X			X				X	X
Personnel-Technical Supervisor (Labs perform high complexity only)								X				
Name of Laboratory		X	X		X	X		X	X		X	X
Location-Physical		X	X		X	X		X	X		X	X
Location-Mailing Address		X	X		X	X		X	X		X	X
Ownership		X	X		X	X		X	X		X	X
Federal Tax Identification Number (EIN)		X	X		X	X		X	X		X	X
Telephone and/or Fax Number		X	X		X	X		X	X		X	X
(Sub) Specialty Change [Addition or Deletion of Test(s)]								X			Send to AO only	
Total Volume Change								X			Send to AO only	
Multiple Sites (addition or deletion of location sites)		X			X			X			X	
Voluntary Closure/Termination		X			X			X			X	
Reinstatement (less than 6 months after certificate expiration)		X			X			X			X	
Reinstatement (more than 6 months after certification expiration)	X			X			X			X		