DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Admin Info: 23-05-CLIA

DATE: February 3, 2023

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Procedural Guidance for Clinical Laboratory Improvement Amendments (CLIA) Form CMS-116 Changes that Require a New Form CMS-116 or Written Notification (UPDATED)

Memorandum Summary

- This memorandum summarizes what laboratory changes require a new Form CMS-116 to be completed, and when written notification of a change is sufficient.
- Form CMS-116s must be retained for at least seven years.
- We are also including some updated instructions for Certificate Type Changes. CMS has updated the guidance in Admin Info: 09-09-CLIA to include email addresses and deleted the guidance for potential fraudulent Form CMS-116 applications. The fraudulent Form CMS-116 information is outdated.

This memo supersedes Admin Info: 09-09-CLIA

Background:

Regulation requires that State Agencies must receive notification from a laboratory if certain changes are made. To administer the program more effectively, the Centers for Medicare & Medicaid Services (CMS) Central Office is providing additional guidance specific to those laboratory changes that require a new Form CMS-116 and those laboratory changes that require only written notification at a minimum.

Discussion:

Written notification 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, the change(s) being made, and the signature of the Laboratory Director or designee. In lieu of written notification, a new Form CMS-116 form is also acceptable. Please note that each section of the Form CMS-116 applicable to the certificate type must be completed in its entirety when a Form CMS-116 is submitted for changes.

Laboratory Changes that Require Submitting a New Form CMS-116

A new Form CMS-116 MUST be obtained when any of the following laboratory changes takes place:

- Initial Application
  - When applying for the temporary testing site exception, a list of the temporary testing sites must be included on or attached to the Form CMS-116. QSO-22-13-CLIA.
- Survey, Initial or Recertification
- Certificate Type Change
- Reinstatement of CLIA certificate
- Adding a multiple site exception, including temporary testing sites, to an existing CLIA certificate
  - A list of temporary testing sites must be included on or attached to the Form CMS-116.
- Director Change (Provider-Performed Microscopy (PPM) Certificate or Certificate of Compliance)
- Ownership

Laboratory Changes for which Written Notification (at minimum) is Acceptable

At a minimum, written notification must be obtained when any of the following laboratory changes take place:

- Name of the Laboratory
- Location (Physical location)
- Location (Mailing Address)
- Tax ID (EIN)
- Specialty or Subspecialty Change
- Total Test Volume Change
- Telephone and Fax Numbers
- Email Address and requests to receive future notifications via email
- Reinstatement- Activate without Gap
- Changes to Multiple Site Information
  - Laboratories must submit written notification when changes occur to the number or location of temporary testing sites. See QSO-22-13-CLIA.
- Change in Accreditation Organization
- Voluntary Closure/Termination
- Personnel-Technical Supervisor

Retention Requirements for Form CMS-116

According to CMS record retention policies, Form CMS-116 needs to be kept for at least seven years. If State law states that CMS-116 forms need to be kept for a longer period or in specific formats, then State law is controlling.

New Instructions for Certificate Type Changes When CoA Laboratories are Performing only PPM or Waived Tests

We want to clarify CLIA policy concerning laboratories that conduct 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 certificate to a Certificate for PPM procedures. It may not continue to hold a CoA. The same policy applies to laboratories that perform only waived testing that are operating under a CoA and decide to only perform waived testing. The laboratory must update their certificate to a Certificate of Waiver.

Implementation

Attachment 1 is a reference tool for your use in ensuring that laboratory changes are handled in a consistent manner.

Contact:

For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Indicators

Attachment 1

Acceptable Methods of Written Notification For Laboratory Demographic or Certificate Changes (Updated 2/3/2023) CMS has updated the guidance to include email addresses.

Over-arching Guidance: All requests must be written (SOM Section 6006)

Change Type	CMS-116*	Written	Justification
Initial Application	X		Regulation
Survey, Initial, or Recertification	X		2006 Mandatory Training, 116 Instructions, Online edits
Certificate Type Change	X		SOM 6006, SOM 6014, SOM 6137, 493.37(g) Online edits for waived and PPM test counts and director signature
Reinstatement of a CLIA Certificate (with a gap)	X		Considered an initial application
Adding a multiple site exception	X		QSO-22-13-CLIA
Personnel – Director (PPM, Certificate of Compliance)	X		493.39(b), 493.51(a), 493.53(b), 493.63(a) SOM 6006.7,
Name of Laboratory		X	493.39(b), 493.51(a), 493.53(b), 493.63(a) SOM 6006
Location – Physical		X	493.39(b), 493.51(a), 493.53(b), 493.63(a) SOM 6006
Location – Mailing/Billing and/or Corporate Address		X	SOM 6006
Ownership	X		493.39(b), 493.51(a), 493.53(b), 493.63(a)
Tax ID (EIN)		X	Refund implications
Specialty or Subspecialty Change		X	493.51(b) and (c), SOM 6006
Total Test Volume Change		X	Fee implications, Online edits
Telephone/Fax Number(s)		X	Compliance contact implications
Email Address		X	Needed for electronic communication, including issuing electronic certificates
Reinstate – Activate without gap		X	Not considered an initial application
Changes to Multiple Site Information		X	SOM 6006, Part of "lab operations," change in location
Change Accrediting Organization		X	Letter with instructions generated by system and sent to lab

Voluntary Closure/Termination		X	Compliance/fee implications
Personnel – Technical Supervisor (High Complexity)		X	493.51(a), SOM 6006

* Must be filled out in its entirety.

NOTE: As previously instructed for laboratories holding a Certificate of Accreditation (CoA), the Accrediting Organization is responsible for verifying qualifications of changes in director and a new Form CMS-116 is not required.