DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

**Ref: S&C- 07-31**

**DATE:** **August 24, 2007**

**TO**: State Survey Agency Directors

**FROM:** Director
Survey and Certification Group

**SUBJECT:** New Clinical Laboratory Improvement Amendments of 1988 (CLIA) Loss of Accreditation (LoA) Procedures -- **ACTION**

**Memorandum Summary**

- Loss of Accreditation (LoA) occurs when an accreditation organization (AO) has ended the accredited status of a CLIA-certified laboratory.
- There are two classes of LoAs – 1) Voluntary, meaning the accredited laboratory has itself initiated a termination/withdrawal of its accreditation status with an AO; and 2) Involuntary, meaning the accredited laboratory has lost its accreditation status with an AO due to actions initiated by the AO.
- This memorandum establishes new LoA procedures when CLIA certified laboratories lose or change CLIA accreditation status.
- These policies and procedures will be formalized in the appropriate sections of the State Operations Manual (SOM).

Because accredited laboratories retain their accreditation certification status for not longer than 45 days after LoA, close coordination and prompt action among AOs, regional offices (ROs), and State agencies (SAs) is essential.

The attached guidance provides specific procedures for ROs, SAs and AOs to use when accredited laboratories lose accreditation.

The policies and procedures will be formalized in the appropriate sections of the SOM.

**Effective Date:** Immediately. Please ensure that all CLIA staff are fully apprised of this information within 30 days.

**Training:** The information contained in this announcement should be shared with all survey and certification staff, including managers, supervisors and surveyors.

For questions concerning this memorandum, please contact Judy Yost at 410-786-3407 or via email at Judith.Yost@cms.hhs.gov.

/s/
Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management
RO CLIA Consultants

# CLIA Loss of Accreditation Procedures

The following provides specific procedures for regional offices (ROs), State agencies (SAs) and accreditation organizations (AOs) to use when accredited laboratories lose accreditation.

## ***Definition of Loss of Accreditation and Regulatory Reference***

Loss of accreditation (LoA) occurs when an accreditation organization (AO) has for any reason ended the accredited status of a CLIA-certified laboratory, including when an accredited lab transfers to another AO or elects a Certificate of Compliance. LoAs are final determinations by an AO signifying termination of accredited status.

The regulation at 42 CFR 493.551(c) states:

> *"Withdrawal of laboratory accreditation -*
>
> *After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by CMS, whichever is earlier."*

## ***Classification of LoAs***

There are 2 classes of LoAs:

***Voluntary (VLoA),*** meaning the accredited laboratory has itself initiated a termination/withdrawal of its accreditation status with an AO; and

***Involuntary (ILoA),*** meaning the accredited laboratory has lost its accreditation status with an AO due to actions initiated by the AO.

Within each class of LoA are two general types.

VLoAs may involve:

(1) situations where there are no adverse action issues outstanding, as when a laboratory chooses to transfer to another AO, or elects CLIA certification for compliance; or

(2) situations where an accredited laboratory seeks a change of accreditation status in the face of a pending AO adverse action(s).

ILoAs may involve:

(1) quality-related denials or withdrawals by the AO when an accredited laboratory no longer meets the AO's accreditation deemed status CLIA requirements; or

(2) non quality-related denials or withdrawals by the AO when an accredited laboratory loses accreditation status due to failure to meet AO-specific (i.e., non-CLIA) requirements, failure to pay AO fees, or other non-CLIA reasons.

[See attached chart.]

***Coordination and Documentation***

All involved components share responsibility in safeguarding the public against laboratories no longer meeting CLIA requirements. Because accredited laboratories retain their accreditation certification status for not longer than 45 days after LoA, close coordination and prompt action among AOs, ROs and SAs is essential.

*AOs*

AOs have primary responsibility for ensuring that CMS Central Office (CO) and the appropriate RO are promptly notified following all ***final*** LoAs. (Final LOA notice is the point at which AO action is not subject to further actions or appeals by the laboratory within the AOs oversight and enforcement protocols.) Notification to CO/RO can be through any means, including email, fax or telephone contact, but must include the specific type of LoA the AO has taken on an accredited laboratory. LoA actions generally would be one of the following:

- Voluntary Loss of Accreditation (VLoA) with Adverse Actions Issues
- Voluntary Loss of Accreditation (VLoA) with no Adverse Action Issues
- Involuntary Loss of Accreditation (ILoA) with Quality-Related Issues
- Involuntary Loss of Accreditation (ILoA) with no Quality-Related Issues

The AO will maintain a detailed record regarding RO and CMS CO notification and may need to communicate further information about the laboratory to the receiving AO and/or RO.

*SAs*

SAs must not take any CLIA-related actions regarding LoAs unless directed to do so by the RO. If the SA receives direct information regarding an LoA, it will promptly (no later than 2 days) notify the appropriate RO. When the SA is requested by an RO to conduct a survey of a LoA laboratory, the SA should follow standard operating procedures as delineated in the SOM and/or Surveyor Interpretive Guidelines (Appendix C).

*ROs*

Upon receipt of the LoA notice from the AO, the RO has lead responsibility in determining further actions leading to a final determination on the certification status of the laboratory. The RO will document the basis for all actions. ROs should consider the following regarding each type of LoA:

*VLoA with adverse action issues* --

Review all issues relating to the AO's adverse action, particularly those impacting on CLIA requirements. (Follow-up with the AO is advisable if the reasons for the VLoA are unclear.) Consider an on-site investigation by the SA, if circumstances warrant. Maintain detailed records concerning actions taken. If the adverse action taken by the AO does not impact on CLIA requirements, process a change of certification to the appropriate requested CLIA certification.

*VLoA with no adverse action issues* --

Verify that the reasons for the VLoA do not call into question compliance with CLIA requirements. Upon verification, process the change of certification to the appropriate CLIA certification per standard data system and SOM procedures.

*ILoA with quality-related issues* --

Follow SOM 6282 ff. when the laboratory's deficiencies may pose immediate jeopardy and 6284 ff. for non immediate jeopardy non-compliance.

*ILoA with no quality-related issues* --

Review issues relating to the ILoA with the AO, if necessary, and verify that no quality-related issues are present. Upon verification, process change of certification to the appropriate CLIA certification.

[A model letter for RO use is attached.]

***ACTS Implications***

Because ILoAs are not complaints but rather AO-initiated actions, ILoAs are not entered into ACTS, unless accompanied by a complaint from an external source (e.g., generally a party external to CMS, the AO or SA).

**Attachment**

**AO Denies, Revokes or Withdraws Accreditation – RO notifies lab of CLIA certificate status**

IMPORTANT NOTICE – PLEASE READ CAREFULLY

Via facsimile to [xxx xxx-xxxx].
(Confirmation of successful transmission of facsimile constitutes proof of receipt.)

**[DATE]**

[**Name/Title**]
[**Name of Laboratory**]
[**Address**]

CLIA number: [**CLIA Number**]

RE: [**Name of Accreditation Organization (AO)**] Denial [or Revocation] of Accreditation

Dear [**Name**]:

The [**Name of AO**] has advised us by letter dated [**AO notice date**] that it has made the determination to **[choose one: deny, revoke, or withdraw]** accreditation for **[Name of Laboratory]** effective **[AO denial/revocation/withdrawal date**]. [**Name of AO**]'s decision to [**choose on**e: deny, revoke, or withdraw] the laboratory's accreditation was based on [**give reasons**].

Laboratories with a CLIA certificate of accreditation, such as [**Name of Laboratory**], must be accredited by a CMS-approved accrediting organization for all laboratory services provided. As a result of the **[choose one: denial, revocation or withdrawal]** of accreditation by [**Name of AO**], [**Name of Laboratory**] is no longer deemed to meet the CLIA requirements. In addition, the CLIA certificate of accreditation issued to the laboratory for the period [**begin and end date of certificate**] is no longer applicable.

CLIA regulations at 42 C.F.R. § 493.551(c) permit the laboratory to retain its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by CMS, whichever is earlier. Accordingly, your laboratory may retain its certificate of accreditation until no later than 45 days after **[AO denial/revocation/withdrawal date]**, or until **[AO denial/revocation/ withdrawal date + 45 days]**.

Your laboratory is reminded that no person may perform laboratory examinations or other procedures on materials derived from the human body unless there is in effect a certificate issued by the Secretary of the Health and Human Services applicable to the category of examinations or procedures which includes such examination or procedure. (See 42 U.S.C. § 263a (b)). Any person who intentionally violates CLIA requirements is subject to sanctions, including imprisonment, fines, or both. (42 U.S.C. § 263(a)(l)).

*[USE FOLLOWING ONLY IF APPLICABLE]*

We have determined that it is necessary for our agents at the **[Name of State Agency]** to conduct a survey of **[Name of Laboratory]** to determine whether your laboratory is in compliance with all CLIA requirements. To facilitate the process and avoid any gap in certification, we recommend your laboratory apply for a certificate of compliance and remit the applicable CLIA fees as soon as possible. To apply for a CLIA certificate of compliance, please contact the State agency at:

**[State Agency Name**
**Address**
**Phone number]**

If compliance cannot be determined or an application for a CLIA certificate of compliance is not received by **[AO denial/revocation/withdrawal date + 45 days]**, we may take action to suspend and/or revoke your laboratory's CLIA certificate of accreditation and, if applicable, cancel Medicare payment for tests performed. (42 C.F.R. § 493.61(c)). **[Add this sentence if a hospital laboratory: If the laboratory's CLIA certificate is revoked, [Name of hospital]'s eligibility to participate in the Medicare program as a provider of hospital services may also be affected since the Condition of Participation related to Laboratory Services at 42 C.F.R. § 482.27 will no longer be met.]** Should this action be necessary, we will notify you at the time of action and provide your laboratory with an explanation of your appeal rights.

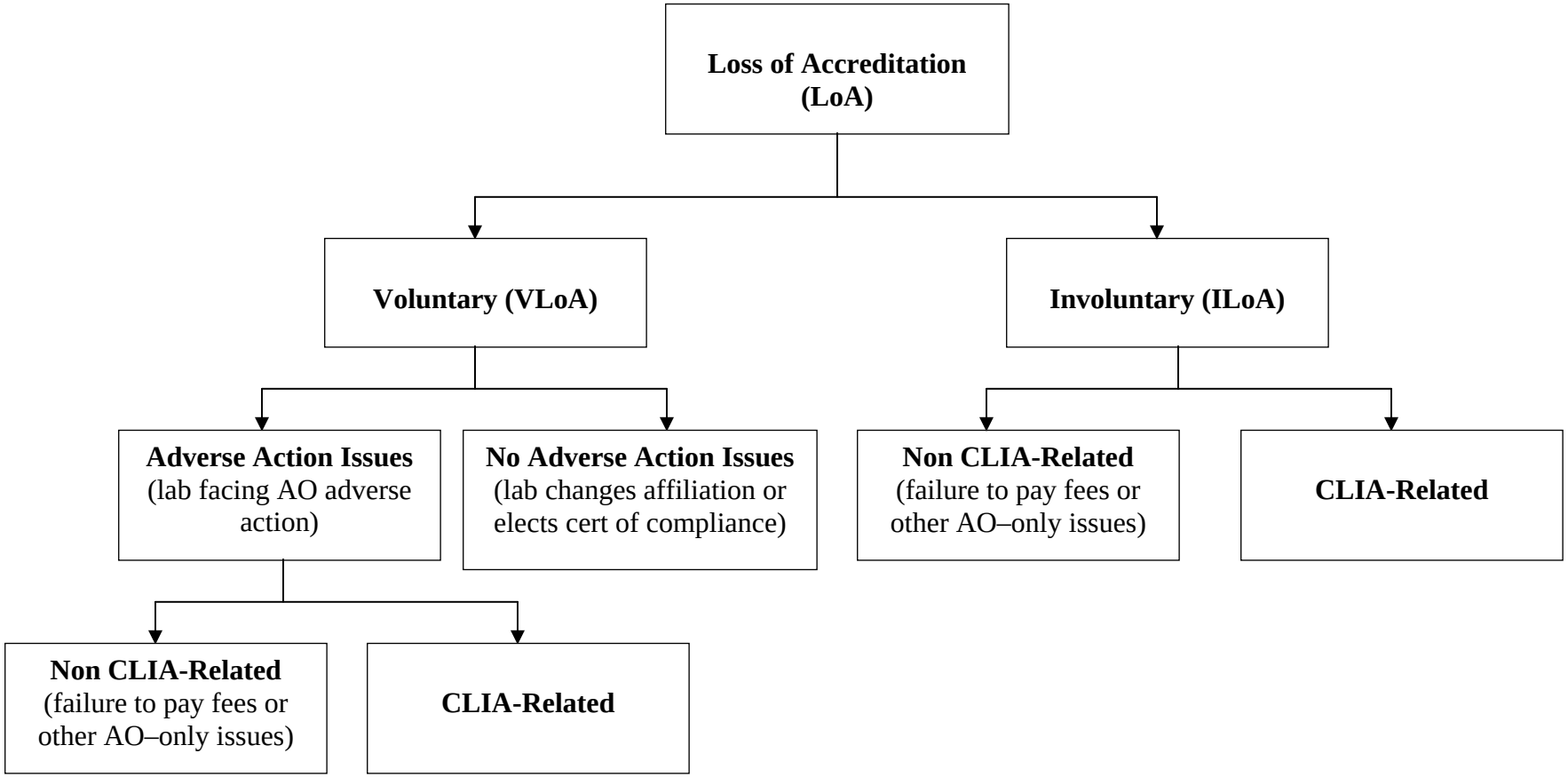
If you have any questions regarding this notice, please contact **[Staff name]** at **[Phone number].**

Sincerely,

**[Name/Title]**
**[Branch Name]**
**[Division Name]**

cc: **[Hospital Administrator, if applicable]**
**[Name of AO]**
**[State agency name]**
**[CMS CO]**

**LOSS of ACCREDITATION CLASSIFICATION**



**LOSS OF ACCREDITATION DECISION CHART**

| Action/LOA | VLoA with Adverse Actions - CLIA Issues | VLoA with No Adverse or CLIA Actions | ILoA with CLIA-Related Issues | ILoA with No CLIA-Related Issues |
|---|---|---|---|---|
| 1. AO notifies CMS CO & RO | X | X | X | X |
| 2. ROs determine if LoA is CLIA-related w/AO | X | | X | |
| 3. If CLIA, evaluate & may have SA conduct on-site survey using SOPs | X Within 45 days | | X Within 45 days | |
| 4. AO may need to notify or confer with another AO | X | X | X | X |
| 5. For deficiencies that may pose immediate jeopardy | Follow SOM §6282 | | Follow SOM §6282 | |
| 6. For non immediate jeopardy non-compliance | Follow SOM §6284 | | Follow SOM §6284 | |
| 7. Process change to appropriate CLIA certification if no outstanding CLIA issues | X | X | X | X |
| 8. Maintain detailed records | X | X | X | X |
| 9. Monitor progress of labs w/ CLIA issues ongoing | X | | X | |