



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: Admin-Info-23-09-CLIA

DATE: July 06, 2023
TO: State Survey Agency Directors
FROM: Director, Quality, Safety & Oversight Group (QSOG)
SUBJECT: Release of Laboratory Director and Owner Names and Their Taxpayer Identification Numbers

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) is providing additional guidance related to the release of Laboratory Director and Owner Names and Their Taxpayer Identification Numbers:

- Laboratory Director and owner names on federal CLIA survey documents may be released without redaction, i.e., Form CMS-116, CLIA Application for Certification, and signature(s) on Form CMS-2567.
- Taxpayer Identification Numbers **must** be redacted.

This Admin-Info memorandum supersedes S&C-10-01-ALL (published October 2, 2009), **S&C-11-39-ALL** (published on September 6, 2011), **Admin Info: 18-19-CLIA** (published September 28, 2018), and **State Operations Manual (SOM), Chapter 6, § 6318** guidance specifically related to the release of Lab Director and owner names for CLIA-certified laboratories.

Background

CMS is providing additional guidance to State Survey Agencies (SAs) on appropriate procedures to follow if they receive certain requests for information concerning Laboratory Directors (LDs) or laboratory owners, including their Taxpayer Identification Numbers (TINs). The LD and owner name(s) on federal CLIA survey documents, including Form CMS-116, Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, may be directly disclosed when requested. This guidance aligns CLIA policy with the guidance for other CMS providers and suppliers.

If the Form CMS-2567, Statement of Deficiencies, is appropriately free of any other PII, the SAs may disclose the forms without redacting the LD and owner signatures prior to release. However, detailed information from complaint intakes related to the allegations, and information related to the complainant are not releasable.

SAs must redact TINs from federal CLIA survey documents prior to release, unless state law mandates disclosure.

Discussion

SAs may receive requests for information about the names of LDs and laboratory owners and their tax information. LDs are responsible for the overall administration and operation of a laboratory and are accountable for all activities of the laboratory related to CLIA requirements. As a result, LDs are in a position of authority and an individual's expectation of privacy is diminished with regard to matters in which he or she is acting in a business capacity.

Additionally, release of the laboratory owners names will increase transparency and is aligned with other CMS provider/supplier types. Upon request, SAs may directly release CMS-2567, CMS-116 forms, and other federal CLIA survey documents that contain LD and owner names, including a signature, without redaction. This guidance supersedes the provisions in prior guidance requiring LD and owner names to be redacted on the Form CMS-116. (See S&C-10-01-ALL (published October 2, 2009), S&C-11-39-ALL (published on September 6, 2011), Admin Info: 18-19-CLIA (published September 28, 2018), and State Operations Manual (SOM), Chapter 6, § 6318 guidance specifically related to the release of LD and owner names for CLIA-certified laboratories.)

As a reminder, CMS continues to require TIN information to be redacted prior to release of the Form CMS-116 and other federal CLIA survey documents, unless state law mandates disclosure.

Contact: For CLIA questions, please contact the LabExcellence mailbox at LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all appropriate survey and certification staff within 30 days the date of this memorandum.

/s/

David R. Wright

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the [Quality, Safety, & Education Portal Training Catalog](#), and select Quality in Focus.