

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



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

Ref: S&C-10-11-CLIA EXPIRED

DATE: December 04, 2025

TO: State Survey Agency Directors

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

SUBJECT: **EXPIRED:** Cautions Regarding the Release/Use of the Name of the Laboratory Director and Employer Identification Number (EIN) listed in the Clinical Laboratory Improvement Amendments (CLIA) Data System

Memo Information:

Memo expiration date: 2025-12-04

Original release date: 2010-01-29

Memorandum Summary

- **Privacy in Correspondences:** The Centers for Medicare & Medicaid Services (CMS) currently has a broad System of Records (SOR) in place which includes privacy practices for all of its correspondence called “Correspondence Tracking Management System” (CTMS).
- **Information Covered Under SOR:** The name of the laboratory director and related Federal Tax ID contained in the CLIA data system from entry of the Form CMS-116 into ASPEN/QIES are now more easily accessible and are covered under a subset of that SOR to ensure privacy.
- **Privacy of the Lab Director Information:** Surveyors are therefore strongly cautioned NOT to release this information publicly, to use it carefully and only when necessary to assist with their routine regulatory and survey-related duties under the 1864 (Social Security Act) agreement. See body of memo for specific citations and guidance.

When the CLIA data system was initially developed, i.e., Online Survey Certification and Reporting system/On-line Data Input and Edit (OSCAR/ODIE), the name of the laboratory director was not easily obtainable, nor could it be released publicly due to privacy concerns. This information was used only by CMS and the State Agencies (SA) for enforcement and other similar internal regulatory and survey-related purposes as specified in the 1864 agreement.

With the most current release of the Automated Survey Processing Environment/Quality Information Enterprise System (ASPEN/QIES) for CLIA, there is no unique Privacy Act SOR; instead, the overall CMS SOR covers and tracks all CMS correspondence and serves as a master SOR for all correspondence databases. The notice for this SOR was published in the Federal

Register; Vol. 67, No. 173, on September 6, 2002, and established a new system of records, called the “Correspondence Tracking Management System” (CTMS).

Thus, the latest ASPEN/QIES release for CLIA, which includes the CLIA application (Form CMS-116), is covered by this CTMS and therefore, the laboratory director’s name/Federal Tax ID can be sorted and is easily available to facilitate the surveyor’s routine regulatory needs and uses. For example, it can be included in reports for State surveyors and regions.

This memo reinforces the importance of an SOR and reiterates a firm word of caution to the SA and regions not to share, release or leave this information unprotected per the above regulatory requirements. The following contracting requirements apply to this situation:

5 U.S.C. 552a, subsection (m) (1) Government Contractors reads (in part): “For purposes of this section any such contractor shall be considered an employee of an agency.”

5 U.S.C. 552a, subsection (b) Disclosures: No agency shall disclose any record which is contained in a system of records by any means of communication to any person, or to another agency,unless disclosure of the record would be—(1) to those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

Additionally, when using this information for routine business, we suggest the following.

- Place a watermark on your documents as a reminder that it is private;
- Redact the laboratory director’s name and accompanying EIN on any releasable CMS-116s.

When requests for the release of information are received, follow the policies and procedures indicated in the Admin. Info letter 07-06, released on January 12, 2007, on that topic or contact the CMS Privacy Officer. Contact information is listed below.

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

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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.

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- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

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