

Center for Medicaid and State Operations/Survey and Certification Group

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Ref: S&C-04-16

**DATE:** January 8, 2004

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Clinical Laboratory Improvement Amendments (CLIA) Policy and Data Reporting Guidance for First Survey Cycle Following the Effective Date of CMS-2226-F

**Letter Summary**

**Begin Laboratory Survey Process Effective January 12, 2004:**

The national implementation date for the State agencies to use the revised laboratory regulations, interpretive guidelines and survey protocol is January 12, 2004.

This memorandum contains information addressing:

- **ASPEN Survey Explorer** updates to include the current CLIA regulations and the associated Interpretive Guidelines
- **OSCAR System Conversion** to accommodate “new” D tags
- **Special Reporting** for tracking deficiency citations
- **Guidance** on laboratory survey protocol

In this memorandum we provide official notification to the State Survey Agencies (SAs) and Centers for Medicare & Medicaid Services (CMS) regional offices (ROs) of the date to begin using the revised regulations, interpretive guidelines and survey protocols to implement CMS-2226-F (“Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications,” 68 FR 3640). The new interpretive guidelines will be available on CLIA’s web site (<http://www.cms.hhs.gov/clia>) on that date.

The CLIA final rule reorganized portions of the prior CLIA regulations. However, the provisions outlined in Subpart K-Quality Systems for Nonwaived Testing at 42 CFR section 493.1250, Analytic systems requirements, now apply to all laboratories performing nonwaived testing.

Prior to the above rule, laboratories that performed moderate complexity tests using an instrument, kit, or test system cleared by the Food and Drug Administration through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use were not held to all of these requirements. In keeping with CMS' educational approach and the continued use of the outcome-oriented survey process, surveyors are to use the two attached letters when laboratories are not in compliance with the analytic systems provisions that are new to the laboratory. (See Attachment 1 for examples of two model letters provided in the 8/14/2003 S&C 03-33 policy letter.) In addition, refer to Attachment 2 for specific guidance on the survey protocol to follow when applying the provisions of the final rule.

The final rule also made a number of data reporting and system changes in ASPEN Survey Explorer and in the Online Survey, Certification, and Reporting (OSCAR) system, to accommodate the revised laboratory regulations. The changes include:

- **ASPEN Survey Explorer**

The ASPEN Survey Explorer has been updated to include the current CLIA regulations, published in the *Federal Register* on January 24, 2003 and their associated interpretive guidelines. Refer to Attachment 3 for specific information and guidance on the contents of the laboratory information available in ASPEN Explorer. In a separate memorandum, the QIES Technical Support Office will notify the QIES State Coordinators that the revised Laboratory Regulation Sets are available for ASPEN Survey Explorer users. The Laboratory Regulation Sets will be posted on the QTSO website to be downloaded for use during laboratory surveys.

- **OSCAR System**

The OSCAR system will be converted to accommodate the 'new D tags' associated with the revised laboratory requirements. This means that any initial or recertification surveys conducted using the 'old D tags' must be entered into the OSCAR system prior to OSCAR's software release. If the surveys using the 'old D' tags are not entered into OSCAR/ODIE until after the release, the SA data entry staff will need to convert the deficiency tags to the 'new D tags' using the 'D' tag crosswalk provided in Attachment 4. (CMS will provide additional instructions to users closer to OSCAR's software release date.)

- **Special Data Reporting**

To keep track of the citations for statistical and planning purposes and to determine subsequent eligibility for Alternative Quality Assessment Surveys (AQAS), each state will need to count the number of times each of the 30 specified 'D tags' are cited, and the number of times Letters 1 and 2 are issued. The totals will be sent to the RO on a monthly basis. The citations will be tallied on the Excel sheet provided at Attachment 5. In addition, at the time a survey record is entered into the OSCAR/ODIE system, a new field will be established to determine if the laboratory received Letter 1 or 2. This information will be used to determine eligibility for AQAS during subsequent survey cycles.

### **Timeline for Data System Changes**

**January 12:** The SAs will begin the survey process by using the revised laboratory regulations and interpretive guidelines and by following the survey policy outlined in Attachments 1 and 2.

**January 12:** The ASPEN Survey Explorer will be updated with the newest version of the 'D' tags, regulatory text and interpretive guidelines. (Refer to Attachment 3.) The QTSO will notify the QIES State Coordinators in a separate memorandum that the revised Laboratory Regulation Sets are available for ASPEN Survey Explorer users. The Laboratory Regulation Sets will be posted on the QTSO website to be downloaded.

**January 12 through the end of FY2005:** The SAs will keep track of the number of times each of the 30 specified 'D tags' are cited, and the number of times Letters 1 and 2 are issued. Send the counts to the RO on a monthly basis in the format provided in Attachment 5.

**February 26:** The SAs will complete entry of all surveys conducted using the 'old D tags' into the OSCAR/Online Data Input and Edit (ODIE) system, prior to OSCAR's system conversion.

**March 1:** The OSCAR system will be converted by changing the 'old D tags' to the comparable 'new D tags' in the OSCAR system, and the OSCAR dictionary will be revised to contain the new prefix tags and descriptions.

**March 1 and thereafter:** Surveys conducted using the 'new D tags' will be entered into ODIE by the SAs. Any surveys conducted using the 'old D tags' that are not entered by February 26 (cut-off date) will be converted to the 'new D tags' using the 'D tag' crosswalk (see Attachment 4).

If you need additional clarification on the survey policies and procedures, please contact Judy Yost at 410-786-3407 or Virginia Wanamaker at 410-786-7304. If you have questions concerning data issues, please contact Kate Kremann on 410-786-3400 or Carol Zeller on 410-786-3113.

We appreciate your ongoing dedication to the effective administration of the CLIA program and your assistance during this upcoming survey cycle.

**Effective Date:** January 12, 2004.

**Training:** This information should be shared with all appropriate survey and certification staff, their managers, QIES coordinators, and the state/RO training coordinators.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)  
RO Laboratory Consultants

Attachment 1 – Survey and Certification 03-33 policy letter, dated 08/14/2003

Attachment 2 – Survey Protocol for First Cycle Surveys

Attachment 3 – ASPEN Survey Explorer Update

Attachment 4 – CLIA Deficiency Crosswalk

Attachment 5 - Special Data Reporting (Dtag Exclusions)