QUESTIONS AND ANSWERS

CMS 2226-F
Medicare, Medicaid, And CLIA Programs: Laboratory Requirements Relating To Quality Systems And Certain Personnel Qualifications

1. **What is "CLIA"?**

   "CLIA" is the acronym for the Clinical Laboratory Improvement Amendments (CLIA) of 1988, Public Law 100-578. CLIA applies to all entities that perform tests for health purposes on human specimens. On February 28, 1992, the *Federal Register* published a CLIA final regulation with comment period that set forth uniform quality standards for laboratories. The CLIA requirements are based on the complexity of tests (high, moderate and waived) and not the type of entity where the testing is performed.

2. **What was the impetus for CLIA?**

   The impetus for CLIA was significant problems in cytology testing and deaths from inaccurate Pap smear testing, and the proliferation of unregulated laboratories. In an effort to establish quality standards for all laboratories and to ensure the accuracy, reliability, and timeliness of patient test results, the Congress decided that all laboratories would be under the authority of CLIA, must register with HHS to obtain a CLIA certificate, and pay a certificate fee. The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the CLIA program. Currently, there are 176,000 laboratories certified by CLIA.

3. **Why is CLIA important?**

   CMS data indicates that CLIA has helped to improve the quality of testing in the United States. The total number of quality deficiencies decreased approximately 40% from the first laboratory survey to the second under CLIA. Similar findings were demonstrated in the review of proficiency testing (PT) data. To ensure continuous quality, the CLIA outcome-oriented survey procedures principally focus on the effect of the laboratory's practices on patient test results and/or patient care. Also, CMS monitors laboratory quality through the use of PT challenges.

4. **Will the CMS-2226-F regulation include requirements for laboratories that perform only waived testing?**

   No, the CMS-2226-F regulation will not include requirements for laboratories that perform only waived testing.

5. **Why was the 1992 CLIA final rule published with a comment period?**

The May 21, 1990 CLIA proposed rule generated approximately 60,000 comments from the public. Consequently, numerous changes were incorporated into the February 28,1992 final rule with comment period based on the outpouring of public interest. Due to these changes and the fact that this rule would affect many entities that previously had never been regulated, the final rule was published as a final with comment period to allow another opportunity for public comment. We received 16,000 comments to the 1992 final rule with comment.

6. Why did the 1992 CLIA final with comment period contain "phase-in" effective dates?

Because many entities (physician office laboratories (POLs), clinics, small laboratories, etc.) were previously not subject to regulatory oversight, certain CLIA requirements were given prospective effective dates to allow time for laboratories to understand and implement the requirements and to allow certain personnel to meet the qualification requirements.

7. What were the "phase-in" requirements of the 1992 CLIA final regulations?

The "phase-in" provisions included:

- An effective date for enrollment and performance in proficiency testing (PT) for previously unregulated laboratories.
- An end to the limited quality control (QC) requirements applicable to certain moderate complexity tests and the effective date required to meet the high complexity requirements.
- The implementation date by which an FDA review of manufacturers' test system QC instructions for compliance with CLIA QC, which was intended to allow laboratories to meet certain, but not all, CLIA QC requirements by following manufacturers' FDA CLIA-cleared instructions.
- The date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing.

8. When did the "phase-in" requirements expire?

The phase-in for PT expired in 1994; now all laboratories are required to meet the PT requirements in Subpart H, i.e., be enrolled and participate successfully in a PT program. On December 31, 2002, the "phase-in" requirements for QC pertaining to certain moderate complexity tests and certain high complexity director requirements expired. The final rule removes FDA review of manufacturers' QC instructions as meeting certain CLIA QC requirements that was to be effective on January 1, 2003.

9. If CMS 2226-F were not implemented, how would the expired "phase-in" requirements be affected?

The expiration of the "phase-ins", without implementation of the new rule, would require laboratories that perform certain moderate complexity tests to meet the current more stringent high complexity requirements and certain doctoral degreed directors would no longer qualify to serve as directors of high complexity testing and would lose their jobs as directors.

The FDA review of manufacturers' QC instructions as meeting certain CLIA requirements would also become effective.

10. What will the CMS-2226-F regulation entail?

The CMS-2226-F regulation will:

- Consolidate the requirements for the existing subparts J-Patient Test Management; K-Quality Control and P-Quality Assurance into two new subparts, J-Facility Administration for Nonwaived Testing and K-Quality Systems for Nonwaived Testing;
- Eliminate redundancy, clarify requirements, and use plain language where possible;
- Complete the QC phase-in resulting in one set of QC requirements for all nonwaived testing;
- Reduce the frequency of QC in many of the specialty and subspecialty areas and incorporate the use of manufacturers' instructions;
- "Grandfather" current experienced doctoral degreed directors of high complexity testing without board certification and adopt board certification for new doctoral degreed directors of high complexity testing effective January 1, 2003;
- Eliminate FDA review of manufacturers' test system QC instructions for equivalency to certain CLIA QC requirements;
- Require adherence to Federal, State, and Local laboratory laws; and
- Incorporate recommendations of the Clinical Laboratory Improvement Advisory Committee (CLIAC) and comments from 12 previously published CLIA rules.

11. Are there any changes in the CMS-2226-F regulation that address PT?

Yes, in this final rule, there is a change in Subpart I in the percentage of required agreement among participant or referee laboratories to 80 percent in the specialties and subspecialties. Previously, 90 percent agreement was required.

12. Will the CMS-2226-F regulation address comments received from the February 28, 1992 final rule with comment period?

In the CMS-2226-F regulation, we are addressing the comments received not only in response to the February 28, 1992 final rule with comment period concerning subparts J, K, M (limited to doctoral degreed individuals without board certification that direct high complexity testing), and P, but also to comments received in response to the date-extension rules for certain provisions of subparts K and M, to the proposed rule regarding alternative requirements for doctoral degreed individuals without board certification that direct high complexity testing, and one change to subpart I.

13. Will the CMS-2226-F regulation address comments received from the December 28, 2001 proposed rule?

Yes, we are addressing the comments received in response to the December 28, 2001 proposed rule, CMS-2049 P, regarding alternative qualification requirements for directors of laboratories performing high complexity testing.

14. Did CMS consider maintaining the provisions for concluding the phase-in of quality control requirements and making all complexity test systems subject to the more stringent high complexity testing QC requirements on January 1, 2003?

We considered not publishing this rule and allowing the QC phase-in provisions, which would make all moderate complexity testing subject to the current high complexity testing requirements, to become effective. This option would ignore the technical improvements made to test systems manufactured since 1992 and impose the current stringent, prescriptive, high complexity requirements on small laboratories such as POLs. We did not adopt this option since the new rule was intended to reduce requirements and decrease costs for the laboratories. While both moderate and high complexity tests are now subject to the same QC requirements, those requirements have been adjusted to reflect advancements in laboratory technology.

15. Did CMS consider maintaining the current CLIA QC requirements for moderate complexity test systems?

Yes. We also considered maintaining the February 28, 1992 QC requirements for certain moderate complexity testing. However, since the 1992 regulations, over 944 test systems have been granted waived status, reducing the number of simple-to-perform moderate complexity tests. The remaining moderate complexity test systems are more complex and require standards more enhanced than the current moderate complexity QC standards. In an effort to ensure quality for patient testing and to eliminate the potential for medical errors, we are requiring the same QC standards for all moderate and high complexity testing.

16. Did CMS consider the option to qualify individuals with a doctoral degree and laboratory training and experience as directors of laboratories performing high complexity testing?

Yes. We considered and proposed in the December 28, 2001 rule, to qualify non-board certified individuals with a doctoral degree and 6 years of laboratory training and experience as directors of laboratories performing high complexity testing. The majority of commenters rejected this pathway for qualifying individuals, because the provision is not commensurate with the responsibilities of a high complexity laboratory director or consistent with the qualification requirements and responsibilities specified for the other CLIA high complexity personnel categories. In addition, the Clinical Laboratory Improvement Advisory Committee expressed strong support for requiring board certification for laboratory directors of high complexity testing. Therefore, we rejected this pathway to qualify individuals. In developing this final rule, we have also determined that there is a sufficient pool of qualified individuals to serve as high complexity laboratory directors, thus assuring continued access to high complexity testing.

17. Will the laboratory industry be in favor of this new regulation?

We expect a favorable response to the regulations. The laboratory community has been requesting a final CLIA rule for some time and will appreciate the conclusion of the phase-ins and clarifying the requirements. Because it was never implemented, the removal of the FDA review of test systems as meeting certain CLIA QC requirements should be a non-issue for the laboratory community. CMS utilized laboratory experts to gather information on QC frequency. Therefore, requiring less frequent QC monitoring and increased flexibility of certain test systems and reagents will be well received.

The majority of the laboratory community will appreciate our requiring board certification for individuals with a doctoral degree serving as directors of a laboratory performing high complexity testing and allowing the "grandfather" of individuals with a doctoral degree without board certification who have served or are serving as high complexity laboratory directors at the time of publication of this final rule.

Overall, the regulation will provide clearer language and a more logical format while remaining current as the dynamic laboratory and healthcare technology environment evolves.

18. Why is the future FDA review of manufacturers' test systems' QC instructions for equivalency to CLIA QC requirements being eliminated from CLIA?

CLIA is a user fee funded program, supported by the laboratories it certifies. We considered allowing the provisions for the FDA review process of manufacturers'

test system QC instructions to meet certain CLIA QC requirements to take effect at the completion of the phase-in. However, implementing these provisions would require additional FDA personnel, resulting in significant increases in program costs that would need to be recouped through higher fees imposed on laboratories. Higher laboratory fees are not feasible at this time. Since CMS certifies compliance for all QC routinely, the FDA review of manufacturers' instructions for partial CLIA QC requirements would be a duplicate and incomplete effort.

19. Will CMS-2226-F have any budget impact on the Medicare, Medicaid or SCHIP programs?

CLIA is a user fee funded program. CMS-2226-F will have no fiscal budgetary impact on the Medicare, Medicaid or SCHIP programs. The impact statement demonstrates that the changes in the regulation result in an overall decrease in CLIA costs (compared to those of the 1992 regulations) for laboratories.

20. How will the small laboratories meet the new QC requirements?

Most of the requirements are not new to the small laboratories that perform moderate complexity tests. The final rule adds a one time only requirement for moderate complexity laboratories to validate a test system to ensure it works accurately before patients are tested. Validating a test system is the standard of practice in the industry and most accrediting organizations already require validation regardless of the complexity of the test. In addition, many manufacturers assist laboratories with this validation.

We will provide "CMS Surveyor Guidelines" that will assist laboratories to comply with the CLIA requirements. (Input will be solicited to these guidelines from professional organizations, healthcare providers, and other State and Federal agencies that may be affected by the regulation.) Educational sessions at professional, medical, and State meetings will be offered upon request. Individuals may access educational information on the CLIA website at: www.cms.hhs.gov/CLIA. Further, CMS will convene educational trainings for our surveyors and accrediting organizations to aide in assisting laboratories with compliance, and we anticipate the CDC will offer educational materials and training through the National Laboratory Training Network (NLTN). To reach the NLTN office serving your region, call 1-800-536-NLTN (6586).

21. What impact will the implementation of CMS-2226-F have on physician office laboratories (POLs)?

We anticipate limited impact since many tests performed by POLs are waived. (In 1992, approximately 30% of laboratories performed only waived tests. Currently, 55% of the laboratories perform only waived tests; of these, approximately 45,000 or 46% are POLs.) POLs performing certain moderate

complexity testing, may perceive that the implementation of this rule will require additional resources in the area of personnel, materials, technical education and training. However, with implementation of this rule, we are reducing the frequency of QC in many of the specialty and subspecialty areas including eliminating concurrent controls in General Immunology and Syphilis Serology. Additionally, this rule will simplify and clarify the requirements, and use plain language when possible to make it easier for testing personnel to comprehend. We will also develop plain language interpretive guidelines and continue to offer training to assist laboratories with interpreting and implementing the CLIA requirements. Furthermore, our changes will decrease costs for the laboratories and there will be a 90-day effective date to allow all laboratories time to comply with the new requirements

22. How will manufacturers respond to the new QC requirements?

The regulatory requirements for QC are not new; however, with implementation of the final rule, we expect the corresponding interpretive guidelines to allow laboratories the flexibility to customize their QC program based on the laboratory testing personnel's expertise and the technology of the test system. This should encourage manufacturers to continue to develop new test systems. Additionally, CMS plans to solicit manufacturers' input into the surveyor guidelines. Therefore, they should respond favorably to the rule and guidelines.

23. Are Quality System Concepts included in the final rule?

Yes, the reorganization of the QC requirements to follow the path of a patient specimen thru the laboratory will facilitate the initiation of basic quality system concepts. The various components of the laboratory's quality systems are used to meet the QC and quality assessment requirements and must be appropriate for the testing the laboratory performs, services it offers, and clients it serves.

Each of the laboratory's quality systems must include an assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, resolves and prevents recurrence of problems.

24. Was any outside expertise solicited to craft the new concepts in QC?

In March of 2001, CMS held a 1-day interactive QC conference with experts in laboratory medicine. Additionally, CDC hosted 2 separate conferences on quality control before we crafted the final rule.

25. Are there a lot of changes to the requirements?

No. We clarified, simplified and, based upon a CLIAC recommendation, reorganized the existing requirements to parallel the flow of a patient specimen

through the laboratory. Studies indicate that most errors occur in the pre-analytical phase of testing. With the revised regulation, all CLIA requirements applicable to this phase of testing are in sequential order and in one place in the regulation. We anticipate a reduction in laboratory errors due to these changes.

The final rule reduces the frequency of QC testing in some specialty and subspecialty areas. Alternatively, it added a requirement for moderate complexity laboratories to validate a test once before use to ensure it works accurately before patients are tested. We have also merged moderate and high complexity QC requirements to simplify compliance. To balance these requirements and to reflect new technologies that may be more robust, we will make routine QC more flexible via surveyor guidelines. This permits laboratories to determine their quality needs based on their own unique environment and personnel.

26. Is the format for CMS-2226-F the same as the 1992 regulation?

No. There has been a restucturing and consolidation of the requirements in Subparts J-Patient Test Management, K-Quality Control and P-Quality Assurance into two new Subparts, J-Facility Administration and K-Quality Systems. The reorganization allows the regulatory requirements to follow a specimen through the preparatory, testing, and reporting processes in the laboratory. The new Subpart J Facility Administration contains requirements for facility environment, record retention (consolidation of all the retention requirements), and transfusion services.

The new Subpart K-Quality Systems consists of all testing phases, general laboratory systems, pre-analytic systems, analytic systems and post-analytic systems. The existing quality assurance requirements are reflected throughout all testing phases as applicable. Most QC requirements for the laboratory specialties and subspecialties are combined under the control procedures in the analytic systems section; however, some specialties and subspecialties, (e.g., cytology), continue to have unique requirements.

27. When will CMS-2226F become effective?

For the Ph. D. director requirements, the regulation will be effective 30 days after publication of the regulation. For all other requirements, the effective date will be 90 days after publication in the *Federal Register*.

28. When will surveyor guidelines be available?

They are currently in the process of being developed and we plan to have them available as soon as possible.

29. Where can I get information about how to meet the requirements?

The regulation will be published in the Federal Register. You may access the Government Printing Office website at http://www.access.gpo/nara/index.html to download a copy. You may purchase a copy with a credit card by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The guidelines will be available through the National Technical Information Services, 5285 Port Royal Road, Springfield, VA 22161, (703) 487 4650.

30. Can laboratories use the guidelines to facilitate compliance?

Yes, CMS surveyor guidelines can be used as guidance in meeting the requirements. Additionally, you may contact our State Agencies or Regional Office Laboratory Consultants for compliance help. A listing can be found on the CLIA website at www.cms.hhs.gov/CLIA . The National Laboratory Training Network (NTLN) operated by the Centers for Disease Control and Prevention will offer trainings for laboratory personnel. You may reach the NLTN by calling 1-800-536-NLTN (6586), and you will be automatically connected to the NLTN office serving your region. Some of the accreditation organizations will also offer trainings and help to their clientele.