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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-12-20-CLIA

DATE: **March 9, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Implementing the Individualized Quality Control Plan (IQCP) for Clinical Laboratory Improvement Amendments (CLIA)

Memorandum Summary

- **Formal announcement clarification:** The Centers for Medicare & Medicaid Services (CMS) is incorporating into the Interpretive Guidelines (IG), based on 42 CFR 493.1250, key concepts and graphics from Clinical and Laboratory Standards Institute (CLSI) Evaluation Protocol-23 (EP-23), 'Laboratory Quality Control Based on Risk Management', as alternative Clinical Laboratory Improvement Amendment (CLIA) Quality Control (QC) policy.
- **The New CLIA QC policy will be entitled:** Individualized Quality Control Plan (IQCP)
- **The guidance and concepts in IQCP are a formal representation and compilation of many things laboratories currently do for quality which are already included in CLIA. It is the "Right QC!"** IQCP permits the laboratory to customize its QC plan (QCP) according to environment, reagents, testing personnel, specimens, and test system, as long as the QCP provides equivalent quality testing.
- **IQCP will be voluntary:** Laboratories will have two choices for QC compliance: 1) Default QC requirement, which will continue to be two levels of QC per day [42 CFR § 493.1256(d)(3)]; or, 2) IQCP. Regardless of the option chosen, the instructions and recommendations in the package insert must continue to be met.
- **Equivalent Quality Control (EQC) will be phased out:** At the end of the education and transition period, EQC will no longer be an acceptable QC option. After the end date, laboratories found not to be in compliance will be cited accordingly. There will be no grandfathering of existing test systems using EQC.
- **State Agency (SA) training will be provided:** Principles of Risk Management will be presented at the four Consortia meetings, and national surveyor training will be conducted in late 2012. Workgroups of Regional Office (RO) and Central Office (CO) participants are being convened for IG development, and planning for training development and delivery.

A. Background

The first of a series of Survey and Certification letters, S & C 12-03, was issued on November 4, 2011, to announce that CMS was planning to adopt EP-23 for CLIA QC as a QC option. Certain plans and policy issues were communicated in this letter, for example, a policy stating that EP-23 will be voluntary. Since that time, CMS has decided to name its QC program IQCP, and to incorporate elements of EP-23 into IQCP. The purpose of this letter is to communicate updated plans and policies related to IQCP. A series of updates is planned.

B. Discussion

1. **Inclusion of EP-23 key concepts in the IG:** In collaboration with the CLIA RO and SA representatives, the 2004 IG will be updated, via an S & C letter, to incorporate those key elements of EP-23 determined by all parties to be necessary to develop a new CLIA-based protocol for alternative QC - IQCP. This change is allowed per 42 CFR 493.1250.
   It was confirmed that much of the existing IG language for EQC can be transferred, in some fashion, into the new IQCP policy. Additionally, many existing common laboratory QC practices will contribute to the laboratory's ability to design their new QCP and the surveyors to assess compliance. The QCP plan will not only include the number and frequency of traditional QC samples required, but also other quality procedures and data, such as competency, laboratory director's responsibilities, temperatures, training, proficiency testing, etc. The new QC policy will be voluntary and the default will be 42 CFR 493.1256(d)(3)—two levels of external quality control per day of patient testing. All manufacturers' instructions must be followed, per 42 CFR 493.1256(d)(2).

2. **Education and transition period:** At a future date to be announced by CMS, the education and transition period will begin and laboratories may begin to implement the IQCP policy to meet CLIA QC requirements. During this time**,** laboratories may continue to follow any existing suitable QC policies. They will have sufficient time during which they can acquire knowledge about IQCP and the concepts in EP-23, plan and adopt their laboratory's new policies. Once the education and transition period concludes, on a date to be announced by CMS, laboratories must have and meet an acceptable QC policy or they will be cited accordingly. Both existing and new test systems will be required to meet IQCP or 42 CFR § 1256(d)(3). There will be no grandfathering of existing test systems currently using EQC; however, accumulated EQC data may be used by laboratories in formulating their QCPs. The new QC policy will apply to both existing and new tests.

3. **Outcome Oriented Survey Process is not changing:** The quality focus of the current CLIA survey process will work well in conjunction with the IQCP policy, but some slight adjustments may be necessary. During the education and transition period, no QC deficiencies will be cited except in instances of immediate jeopardy or serious quality problems in the laboratory. In those cases, the surveyor should cite the specific problem on the CMS-2567, per existing CLIA policy and procedures. Otherwise, laboratories will be made aware of any problems found. The decision grid from the EQC S & C letter (S & C 07-33--see attached) will assist with that process. Following the conclusion of the education and transition period, all deficiencies identified will be cited.

4. **Ongoing training, information and education for the RO/SA's:**
    - Division of Laboratory Services (DLS) individuals and possibly outside experts will provide the attendees at each Consortium meeting an 'Introduction to Risk Management Principles' concepts.
    - Further practical Risk Management training is being planned for the ROs.
    - The ROs who volunteer for the IG, training and communications work groups will be invited to join CO again for those processes. Dates are to be determined.
    - These S & C letters and their accompanying "Frequently Asked Questions" (FAQs) will continually be updated as new information, timelines and policy decisions are determined.
    - Once the IG have been revised, a "Brochure" with similar information in plain English will be developed. Other tools will be designed as the need arises.
    - Formal SA training on IQCP, using a 'scenario' –based approach and discussion groups, will be conducted in the Fall of 2012.
    - Information regarding IQCP will be presented in various venues and professional meetings in the upcoming months.

5. **EP-23 Document:** SA surveyors will be provided with a copy of CLSI's document, "EP-23—Laboratory Quality Control Based on Risk Management". It is copyrighted and is being used for educational purposes, but cannot be shared elsewhere. Principles from the document will be used to develop the IQCP option in CLIA, but the EP-23 document itself will not be fully incorporated as written.

More information and memos will be forthcoming as they become available. If you have any questions, please contact Penny Meyers at: penelope.meyers@cms.hhs.gov for project management; Ann Snyder at: ann.snyder@cms.hhs.gov for document content and CLSI educational work group; Sarah Bennett and Cindy Flacks at: sarah.bennett1@cms.hhs.gov and cindy.flacks@cms.hhs.gov for training; or Melissa Singer at: melissa.singer@cms.hhs.gov for communication.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachment: FAQs for EP-23

cc: Survey and Certification Regional Office Management
CLIA RO Consultants

FAQs for IQCP

1. **What is IQCP?**
   IQCP stands for Individualized Quality Control Plan and is the formal policy name for the alternative CLIA QC option that provides for equivalent quality testing to meet the regulations at 42CFR493.1250. This policy will incorporate key concepts and graphics from the CLSI EP-23 document.

2. **What is EP-23?**
   Evaluation Protocol - 23 is a CLSI consensus guidance document that contains innovative QC concepts, developed around many current lab quality practices. Key concepts and graphics from EP-23 will be used to develop a new alternative QC approach for laboratories and in the development of the updated IG, but the document will not be fully incorporated as written.

3. **What is the main concept included in EP-23?**
   EP-23 describes good laboratory practice for developing and maintaining a quality control plan (QCP) for medical laboratory testing using internationally recognized risk management principles. A QCP should be established, maintained, and modified as needed for each test. The QCP is based on the performance required for the intended medical application of the test results. Risk mitigation information obtained from the manufacturer and identified by the laboratory, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting are considered in development of the QCP. This document is intended to guide laboratories in determining quality control (QC) procedures that are both appropriate and effective for the test being performed and the laboratory's patient population.

4. **Is IQCP intended to reduce the amount of quality control in laboratories?**
   This new QC protocol will not necessarily reduce QC requirements, but instead, will be the "right" QC for this lab, its environment, patients, personnel, test systems, etc.

5. **Are all specialties and subspecialties eligible for IQCP?**
   It is currently envisioned that all CLIA specialties, with the exception of pathology, will be eligible for IQCP.

6. **What happens to EQC?**
   EQC will be gradually phased out IQCP will be phased in following CO, RO and SA training and the development of the updated Interpretive Guidelines. There will be an education and transition period to allow laboratories and surveyors time to learn about and implement IQCP. Until they are notified, laboratories must continue to do what they are presently doing for QC.

7. **Will there be an education and transition period?**
   Until an implementation date is announced for IQCP, laboratories should continue to follow any existing suitable QC policies. After announcement of the implementation date, there will be a defined education and transition period where no QC deficiencies should be cited, except in cases of immediate jeopardy or serious quality problems. Existing QC policies and

procedures that are currently allowed may continue to be used until the education and transition period expires.

8. **How will the IQCP policy affect the current survey process?**
   The Outcome Oriented Survey Process is not changing but some of the information reviewed may be different. The quality focus of the current CLIA survey process will work well in conjunction with the IQCP policy, but some slight adjustments may be necessary. Any necessary adjustments will be thoroughly communicated with the RO and SA prior to the implementation of the revised IG.

9. **Will laboratories be required to use the IQCP option?**
   IQCP will be optional with 493.1256 being the default requirement for CLIA QC. IQCP will be also optional for accrediting organizations (AOs) and exempt States (ESs).

10. **Will any test systems currently eligible for EQC be "grandfathered?"**
    There will be no grandfathering of systems where EQC has been evaluated and implemented. However, data accumulated during the EQC evaluation protocol may be used in the development of the laboratory's IQCP. The new QC policy (IQCP) will apply to all existing tests and new tests

11. **The SAs are not familiar with the concepts in EP-23. Will there be training for the SAs?**
    CO individuals and possibly outside experts will provide the attendees at each 2012 Consortium meeting an 'Introduction to Risk Management Principles' concepts. SA training on the new policy and IG will be conducted in the Fall 2012. More details will follow as the training is developed.

12. **What training will be provided to the surveyors and State agencies? What type of information will be made available for laboratories?**
    Additional tools, workshops, educational materials, brochures, etc. will be developed for surveyors and laboratories. ROs will be heavily involved in the design and development of revised Interpretive Guidelines, SA training, and on-going IQCP implementation. RO input and participation are critical to the success of the realization of IQCP.

13. **How do we train the surveyors effectively to ensure consistent application of this new QC policy?**
    Training for surveyors will be developed jointly, with CO and RO participation. RO input and expertise is essential to ensure adequate and effective training. It is anticipated that follow-up training sessions will be necessary after the initial training.

14. **What do we tell laboratories and surveyors now if they make an inquiry?**
    Laboratories and surveyors can be directed to the S&C letter on the CLIA website. For the immediate future, laboratories may begin to consider the concepts in EP-23, but should continue to do what they have been doing for CLIA QC until further notice. Accredited laboratories should contact their AOs for guidance and laboratories in exempt States should contact their States directly. ROs and SAs should keep CO informed of inquiries about IQCP received from external sources.

15. **Where can I direct any questions about IQCP?**
    Please forward all inquiries to IQCP@cms.hhs.gov.

16. **What is the timeline for Implementing IQCP?**
    A timeline for SA training and implementation is under development. Surveyors and laboratories will be given an ample education and transition period.

17. **When can we expect more information?**
    Communication about IQCP implementation will be ongoing. IQCP updates will be provided on each RO call, in the CNN, and new FAQs will be distributed as needed throughout the implementation process. Always check the CMS CLIA website at : www.cms.hhs.gov/clia for the most current information.

18. **SAs have received a copy of the CLSI EP-23 document. Can we provide a copy to laboratories if requested?**
    No. The EP-23 document is copyrighted material and cannot be shared with anyone outside of the RO, SA or CO.