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Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 17-16-CLIA

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Policy for the Data Entry of Changes in Laboratory Director for Certificate of Accreditation (CoA) Laboratories

Memorandum Summary

- **Software Release:** The Automated Survey Processing Environment (ASPEN) Data System issued software release 10.6 on February 6, 2017.
- This release included a change in Accreditation Organization (AO) user function regarding entry of laboratory director names and titles for confirmed CoA laboratories.
- The State Agencies (SA) will no longer be responsible for entering laboratory director changes for Certificates of Accreditation (CoA) after those laboratories have been confirmed in the ASPEN system by the AO.

Background

Historically laboratory directors of CoA laboratories have been qualified by their AO, as per the CLIA regulations. While the AO has qualified the laboratory director, the entry of the laboratory director's name and title into the CLIA data system was performed by the SA.

Policy Change in Entry of CoA Laboratory Directors

The AO will continue to qualify laboratory directors as before, however a change is being made to the role of the SA. The SA personnel will qualify the laboratory director and enter the laboratory director's name and title for Certificates of Registration.

Once a laboratory becomes accredited by an AO (as indicated by the confirmation checkmark in the ASPEN Web CMS 116 on the AO Info tab), and the laboratory pays all CLIA fees, the certificate type will change from a Certificate of Registration to a CoA. From this point on, the AO will be responsible for the qualification and entry of laboratory director changes. The system has been programmed to automatically generate a replacement certificate showing the new laboratory director name to the CoA laboratory.

Contact: Any questions about this policy should be directed to LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This information should be communicated to all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/
David R. Wright

Attachment: Practical Application of the Policy Change in Entry of CoA Laboratory Director

cc: Survey and Certification Regional Office Management

Attachment 1

Practical Application of the Policy Change in Entry of CoA Laboratory Director

- Laboratories applying for a Certificate of Accreditation are first issued a Certificate of Registration. This allows time for the Accreditation Organization (AO) to inspect the laboratory for compliance with its standards.
- State Agency (SA) personnel are responsible for qualification of laboratory directors listed on initial CLIA applications for Certificates of Accreditation and for entry of the laboratory director's name and title, once it is determined that they are qualified, into the ASPEN Web CLIA 116. The SA is further responsible for the qualification and entry of a change in laboratory director while the laboratory is seeking accreditation and is operating under a Certificate of Registration.
- When the laboratory attains accreditation and all CLIA fees have been paid in full, the laboratory certificate is automatically changed to a Certificate of Accreditation. From this point, the Accreditation Organization (AO) becomes responsible for qualifying the laboratory director and entering the name and title into the ASPEN Web CLIA 116.

Example 1: A State Agency receives an initial application for a Certificate of Accreditation and the laboratory has marked one of the seven approved accrediting organizations as the AO they have applied to for accreditation for CLIA purposes. Does the indicated AO qualify the laboratory director and enter the name and title into the ASPEN Web CLIA 116?

Response: No. Initial applications are entered by State Agency (SA) personnel. This includes performing the qualification of the laboratory director and entry of the name and title.

Example 2: The laboratory has been entered into the ASPEN Web CLIA 116, has paid its registration fee and received its Certificate of Registration. The laboratory has now requested to change the director. Does the AO indicated on the initial application qualify and enter the new laboratory director?

Response: No. The SA remains responsible for qualifying any laboratory director and entering the name and title changes while the laboratory holds a Certificate of Registration. The SA should send a replacement certificate after making the changes.

Example 3: The laboratory holds Certificate of Compliance and has for a long time. The laboratory has asked for a change in certificate type to a Certificate of Accreditation. Does the AO indicated on the request for the certificate type change (also known as a status change) qualify and enter the laboratory director?

Response: No. The status change is treated the same way as an initial application.

Example 4: My state also has laboratory licensing laws and I will need to know when the laboratory director is changed by an AO so that I can qualify the new laboratory director per my state regulations. Is there a report I can pull to monitor such changes?

Response: Yes. There is a nationwide report in ASPEN Web CLIA 116 that can be pulled by date range. CASPER report 104 can also be used. Remember due to the overnight upload of data from ASPEN to CASPER the information in CASPER will be a day behind the report in ASPEN which shows real time data. The advantage to CASPER report 104 is that it can be pulled for an individual state or region.

Example 5: When a CoA laboratory (not on its registration certificate) sends in a CMS form 116 with requested changes including a laboratory director change to the State Agency, is the form CMS-116 forwarded to the AO or the Regional Office (RO)?

Response: Neither. The State Agency keeps the CMS form 116 as documentation of the requested changes and notifies the laboratory that changes other than specialties and laboratory directors will be performed by the SA personnel, but that any changes to specialties and laboratory director must be handled by the laboratory's AO and the laboratory must use whatever form of documentation the AO requires to submit those changes. The AO's do not use government forms.

Example 6: Can the AO's change the demographic information associated with the laboratory?

Response: No. While the demographic information is visible to the laboratory's confirmed AO, the AO user is restricted from entering changes to those fields.

Example 7: Will a replacement certificate be automatically generated if my SA personnel make a change to the laboratory director on a Certificate of Accreditation while it is still under its registration certificate?

Response: No. The system is programmed to do that only for AO users because they do not have access to that field in ASPEN Web CLIA 116. Remember AO users can't make laboratory director changes while the laboratory is still under a Certificate of Registration. The SA should send a replacement certificate after making the changes.

Example 8: If a laboratory fails to notify an SA with state licensure requirements of a laboratory director change, will there be an alert sent to the SA?

Response: No. Alerts have not been programmed, however the new Director Change search on the ASPEN Web CLIA 116 search page or CASPER report 104 will allow the SA to find accredited labs that have had laboratory director changes. (Also see Example 4)

Example 9: Will the Accreditation Organization (AO) attach the Lab Director qualifications in the ASPEN Web CLIA 116?

Response: No. The AO does not have the security rights to save attachments to the ASPEN Web CLIA 116 record. The documentation used by the AO for the laboratory director qualification will be kept in accordance with the AO standards within their own systems.