



**Center for Clinical Standards and Quality/Survey & Certification Group**

**Ref: S&C: 17-11- CLIA**

**DATE:** December 1, 2016

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Advanced Copy –Revisions to State Operations Manual (SOM), Appendix C –  
Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory  
Services (Clinical Laboratory Improvement Amendments (CLIA))

**Memorandum Summary**

**Revisions to Appendix C of the SOM:** The entire document has been revised and updated to include comments and recommendations from:

- Regional Office (RO) and State Agency (SA) surveyors, professional and accrediting organizations (AO);
- Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC);
- CMS Office of General Counsel (OGC); and
- General Accounting Office (GAO) on reporting complaints.

**Deletion**

- D-tags (D2018, D6001, D6002 & 6077).

**It also includes:**

- New D-tags for surveyors; and
- Board certification in dermatology by American Osteopathic Board of Dermatology is equivalent to board certification in dermatology by American Board of Dermatology (ABD)

**Background**

CMS is issuing this advance copy of the revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. The revisions include edits recommended by RO and SA surveyors, professional and AO's, OGC, and other Health and Human Services (HHS) components.

**Contact:** For questions related to this memorandum, please contact Minnie Christian at 410-786-3339 ([minnie.christian@cms.hhs.gov](mailto:minnie.christian@cms.hhs.gov).) or Daniel Cajigas at 410-786-0793 ([daniel.cajigas@cms.hhs.gov](mailto:daniel.cajigas@cms.hhs.gov)).

**Effective Date:** Immediately. This information is current policy and becomes effective no later than 30 days after the release of the memorandum. The Interpretive Guidelines should be distributed to all CLIA Survey and Certification staff, their managers, SAs, and State RO training coordinators within 30 days of this memorandum. There may be minor revisions in the final document that are not included in this advance copy.

/s/  
David R. Wright

Attachment- Advanced Copy – Appendix C

cc: Survey and Certification Regional Office Management

*The contents of this letter support activities or actions to improve patient or resident safety and increase quality and reliability of care for better outcomes.*