CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Virtual Competency Assessments

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Virtual Competency Assessments in Clinical Laboratories

Historical view of virtual competency assessments:

- 71% of state agencies polled were not in favor of virtual competency assessments (2022)
- 75% of CMS CLIA locations were not if favor of virtual competency assessments (2022)
- 50% of Accrediting Organizations were opposed/not opposed
- Support for opposition to the technology cites competency assessments as the single most frequently cited deficiency in CLIA surveys.

We are clearly a pretty change adverse group.

Competency Assessment Requirements in Clinical Laboratories

Current CLIA competency assessment regulatory requirements: 42 CFR 493.1413(b)(8) and 42 CFR 493.1451(b)(8)

The regulations require “Direct Observations” of routine patient test performance including patient preparation, if applicable, specimen handling, processing and testing and performance of instrument maintenance and function tests.

CMS has defined direct observation as meaning in-person observation.

Virtual Competency Assessments in Clinical Laboratories Questions for Discussion

Would CLIAC recommend greater flexibility in regulatory interpretation to allow for virtual competency assessments in the laboratory setting?

- What is the risk of losing direct in-person observation?
  - How important are the background noise, odors or other activities to a competency assessment?
- What are the recommended limits of virtual competency?
  - Specific instrumentation and capabilities like the product demonstrated?
  - Workload limits on the number of people who can be assessed in a given day?
  - Should we create on-site regulatory requirements for Technical Supervisors and Technical Consultants?
  - Should this be a test-specific flexibility?
- What are the benefits of such a flexibility?