HCFA Studies-Waived Laboratories & Moderate Complexity Standards-Myths & Facts

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Background

- CLIA Law - waived tests are simple and have an insignificant risk of an erroneous result
- Waived tests have no standards or routine oversight under CLIA regulations
- 54% (92,000/170,000) of the laboratories in CLIA have a Certificate of Waiver (COW)
42CFR 493.35-CLIA authority to survey COW laboratories

- If laboratory tests beyond the scope of its certificate
- If a complaint is alleged
- If there is serious risk of harm to patients
- To collect information on waived tests

42CFR493.15-waived labs must follow manufacturer’s instructions
Background Continued

- CO, OH, NY conducted studies of COW laboratories
- 50% had quality problems
- Office of Inspector General (OIG) study of waived laboratories supports HCFA findings
- CDC studies concur
HCFA Expanded Studies

- 8 additional states - MA, NY, PA, MS, NM, IA, AZ, ID
- 2.5% sample - 270 COW laboratories surveyed
- Announced, educational and information gathering surveys
- Project survey period - Oct 2000 to Jan 2001
HCFA Study Findings

- Waived Testing Personnel - RN, M.D./D.O., LPN
- Quality Problems in COW labs:
  - 32% - failed to have current manufacturer’s instructions
  - 32% - didn’t perform QC as required by manufacturer or per CDC’s contingency
  - 16% - failed to follow current manufacturer’s instructions
  - 7% - didn’t perform calibration as required by manufacturer
HCFA Study Findings Continued

- Additional Quality Problems in waived laboratories
  - 20% - cut occult blood cards and urine dipsticks
  - 19% - personnel neither trained nor evaluated
  - 9% - didn’t follow manufacturer’s storage and handling instructions
  - 6% - using expired reagents/kits
Laboratories not following manufacturers instructions,
Failure to identify incorrect results,
Testing beyond laboratory’s CLIA certificate,
Untrained staff,
Lack of quality controls,
Poor equipment,
Poor storage of reagents,
Poor record keeping, and
Misunderstanding of CLIA requirements.
STATISTICS

- Waived laboratories surveyed - 270 (2.5%)
- Facility Types: POL--67%, SNF--11%, ESRD--3%
- Location: Urban--69%, Rural--31%
- States in HCFA study with laboratory licensure programs: ID, MA, PA
HCFA RECOMMENDATIONS

- Institute an educational program for COW laboratories
- Validate the effectiveness of the educational program
- Survey a percentage of COW laboratories annually
HCFA RECOMMENDATIONS

- Develop a self-assessment tool for COW labs
- Provide information on CLIA requirements to new COW laboratories
- Have State Agencies randomly telephone a sample of COW laboratories to determine if problems or questions exist
ADDITIONAL RECOMMENDATIONS BY OIG

» Require labs applying for COW certificates to identify which test systems they will use (checklist on application)

» Establish a mechanism whereby Medicare claim denials can be used to inform State Agencies about labs billing Medicare outside their certificate

» Review waived testing at moderate/high complexity labs during routine surveys
HCFA Study Summary

- Corroborates findings of the Colorado/Ohio pilots, OIG, CDC & New York studies
- 48% of waived laboratories have quality testing problems
- M.D.’s & R.N.’s not following manufacturer’s instructions/CDC QC requirements
- Laboratories located in states with regulations have fewer problems
- All labs visited want to produce quality results
HCFA Study Summary
Continued

- Appreciated by labs; considered educational
- The number of waived laboratories continues to increase due to increase in waived tests
- CLIA-regulated laboratories demonstrate improved performance over time
- Significant findings have serious implications for patients:
  - Not following manufacturer’s instructions AND
  - Lack of testing personnel training
Moderate Complexity vs Waived Myths & Facts

- Application process identical for Moderate & Waived Certificates
  - Application on HCFA web site or state agency
- Waived laboratories
  - Enroll in program
  - Pay certificate fee
  - Follow manufacturer’s instructions
Moderate Complexity vs Waived
Myths & Facts

Moderate Complexity

- One certificate per site or:
- Limited public health option for multiple sites
  - Federal, state or local public health or not-for-profit
  - Combination of 15 waived and moderate tests
  - One certificate saves survey and certificate costs
- Biennial onsite survey via accred. org. or HCFA
  - Certificate & survey fees based on annual test volume; low volume bargains available
  - Educational approach with QA focus
  - Good performers rewarded with self-assessment
Moderate Complexity vs Waived Myths & Facts

Moderate Complexity Quality Standards include:

- **Personnel**
  - Director qualifications = B.S. degree in science
  - Testing personnel = H.S. with training

- **Quality Control**
  - Built- in controls acceptable (2 levels/day of testing)
  - Manufacturers require QC for **BOTH** waived & moderate tests
  - Use package insert for SOP manual
Moderate Complexity vs Waived Myths & Facts

Moderate Complexity Quality Standards

Proficiency testing (P.T.)
- Enroll with vendor of choice
  - 16 providers; modules corresponding to test menu
- Accuracy twice per year if no P.T.
  - Example: Split specimens
- Educational value to laboratory
- One enrollment per certificate (limited public health)

Patient Test Management
- Record keeping system/audit trail
- Use patient chart or unique system
- No required forms
Moderate Complexity vs Waived Myths & Facts

Moderate Complexity Quality Standards

Quality Assurance
- Encompasses quality standards
- Effective communication
- Problem resolution
- Compare lab data to patient information
- Includes things you already do

Enforcement
- Educational approach successful in resolving problem findings
- Sanctions imposed only on labs with serious problems
Summary Moderate vs. Waived

- Minimal basic standards to safeguard quality
- Low cost & burden to labs
- Use existing mechanisms, if applicable
- Technical assistance available from states
- Accredited labs doing waived tests easily meet mod./high standards e.g., ancillary sites
- 9 years of CLIA demonstrate no loss of access
  - Number of POL’s enrolled in CLIA increased
  - Lab performance improved