

# CLIA Certificate of Waiver Program Update

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# Background

- CLIA Law - *waived tests are so simple & accurate that erroneous results are negligible*
- Waived, PPMP tests *have no routine oversight under CLIA*
- 183,874 labs enrolled in CLIA
  - 77% (140,972) = Waived & PPMP
  - 56% (102,123) = Waived

# Background- Continued

## ■ 42CFR 493.35

CLIA authority to survey COW laboratories

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

## ■ 42CFR493.15-waived labs must follow manufacturer's instructions

# Background- Continued

- 1999: CO & OH visited 100 Waived & PPMP laboratories
  - 50% had quality problems
  - 10% had certificate issues
- NY independent study w/ similar findings
- OIG (Office of Inspector General) study of waived laboratories supports CMS findings
- CDC studies concur

# CMS Expanded Pilot Plan

- CMS follow-up to verify problem
- 8 additional states: (\*licensure)  
MA\*, NY, PA\*, MS, NM, IA, AZ, ID\*
- 2.5% sample - 270 Waived & 190 PPMP labs
- Surveys
  - Announced, Educational, Information Gathering
- Project survey period - Oct 2000 to Jan 2001

# CMS Pilot Statistics

- 436 Laboratories surveyed
  - 270 Performing Waived Testing
  - 190 Performing PPMP
- Facility: POL= 67%, SNF= 11%, ESRD= 3%
- Location: Urban= 69%, Rural= 31%
- States with lab licensure programs:  
ID, MA, PA--performed 10X better

# CMS Pilot Findings

- Waived Testing Personnel : RN, MD, LPN, MA
- Quality Problems in Waived labs:
  - 32% failed to have current manufacturer's instructions
  - 32% did not perform QC as required by manufacturer or CDC
  - 16% failed to follow current manufacturer's instructions
  - 7% did not perform calibration as required by manufacturer

# CMS Pilot Findings Continued

- Additional Quality Problems in Waived labs:
  - 23% certificate issues
  - 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

# CMS RECOMMENDATIONS

- Institute an educational program for COW/PPMP laboratories
- Validate the effectiveness of the educational program
- *Survey a percentage of waived laboratories annually to educate & collect information*

# Education is Primary Focus

- CMS sent a letter to organizations, partners, stakeholders
  - to solicit interest & assistance
  - to inventory existing educational programs
  - includes professional, medical, accreditation, manufacturers, CLIAC & Federal agencies
- CMS compiled responses to create an educational program Clearinghouse for waived laboratories

# Educational Materials for Labs

- To facilitate education, CMS has:
  - Updated CLIA Website
  - Developed a basic laboratory practices document for waived laboratories
  - Collaborated with private organizations to develop & promote self-assessment tools & other educational programs, workshops, etc. using various media
  - Worked with manufacturers to improve labeling & to assist with initial laboratory education with device purchases

# Status of Waived Surveys

- Three year project initiated April 2002 to survey 2% of all waived labs each year
- Includes more comprehensive information collection than pilots
- Evaluate effectiveness at conclusion of 3 years
- Determine next steps, if any for these laboratories

# 2002 Process

- All 50 states- 897 Laboratories visited
- Alerted professional groups, e.g. AMA
- Training provided to surveyors
- Focused on education, information gathering
- Expanded questionnaire
- Survey period – April to September

# 2002 Findings

	2002	Pilot 2001
Did not have manufacturer instructions	<b>13%</b>	<b>32%</b>
Did not perform QC as required by manufacturer /CDC	31%	32%
Did not follow manufacturer storage and handling	<b>3%</b>	<b>9%</b>
Personnel not trained/evaluated	21%	19%

# Additional 2002 Findings

- COW laboratories were operating safely, but there were 2 cases of IJ (revised by CMS following the meeting)
  - *Immediate Jeopardy (IJ) synonymous with imminent & serious risk to human health*
- 84% instructed to retain current manufacturer PI (product insert)
- 90% instructed to read & follow PI
- 60% instructed to document test name, lot number, expiration date  
(note: good laboratory practice)

# Additional 2002 Findings- continued

- 44% laboratories had change in testing personnel in last 12 months
- 99% of laboratories provide timely results
- 8% voluntarily enroll in PT

# Additional 2002 Findings - continued

*Tests COW laboratories would continue to perform regardless of waived status:*

**Most frequent:** Urinalysis, Glucose

**Occasional response:**

None, Occult Blood ,Rapid Strep, Pregnancy,  
Hemoglobin

# 2003 Process

- All 50 states- 1,555 laboratories visited  
(revised by CMS following the meeting)
- Slight revisions to the questionnaire
- Computer database developed – allows  
direct entry of questionnaire and real-time  
results
- Continued surveyor training
- Survey period- January to September

# 2003 Preliminary Findings

	2002	2003
Did not have manufacturer instructions	13%	12%
Did not perform QC as required by manufacturer *	24%	20%
Did not follow manufacturer storage and handling	3%	3%
Personnel not trained/evaluated	21%	16%

\*Question revised regarding performing QC as required by CDC-  
part of QC requirements in PI

# Additional 2003 Preliminary Findings

- COW laboratories were operating safely, but there were 3 cases of IJ (revised by CMS following the meeting) *IJ: Rh slide testing, Rhogam administered to men*
- 73% laboratories routinely check incoming PI to ensure there have been no changes in the product or procedure
- 50% documented test name, lot number, expiration date (note: good laboratory practice)

# Additional 2003 Preliminary Findings- continued

- 44% laboratories had change in testing personnel in last 12 months
- 97% of laboratories provide timely results
- 5% voluntarily enroll in PT

# 2004

- Maintained 2003 format
  - Questionnaire
  - SSIS database
  
- Survey Period
  - in process
  - ends September 2004

# Next Steps...

- Partner with private organizations to provide education and training, e.g. NCCLS, National Laboratory Training Network
- Possibility of future visits to COW laboratories?
- CLIAC recommendations

# Conclusions

- Measurable improvements since Pilot
- Quality issues remain
- High turnover of testing personnel
- Laboratory Needs identified:
  - Education on CLIA
  - Training in lab procedures

# Positive Feedback

- “Survey was very understandable, complete and timely.”
- “When notified that someone was coming to our office, we had no idea of what to expect, i.e., comprehensive inspection with searches, etc., or just questions asked... Much easier than expected!”
- “Very informative.”
- “Good experience; qualified and knowledgeable reviewer.”

# Where to Find Information

- CLIA Homepage:

[www.cms.hhs.gov](http://www.cms.hhs.gov) ; click on *CLIA*, *CMS CLIA waived/PPMP Laboratory Project*

- CLIA Division Central Office in Baltimore:

410-786-3531 (phone)

410-786-1224 (fax)

THE END!!!

Thank You!!

Questions????

