CLIA Update 2013

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CLIA Update 2013

I have no conflicts of interest.

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Topics For Discussion

- CMS/CLIA Laboratory Enrollment Data
- Enforcement Actions Summary Data
- Regulations Update
  - PT Revisions
  - Patient Access
  - Burden PT Referral
- Test Act Next Steps
- IQCP Implementation Plan & Status
- GPRA Goal—Waived Labs
- Competency Brochure Published
- Resources

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Current Statistics--Enrollment

Total Number of Laboratories	**235,828**
Total Non-Exempt	**228,535**
Compliance	19,235
Accredited	15,760
Waived	156,653
Provider Performed Microscopy	36,887
Exempt	**7,293**
NY	3.583
WA	3,710

CMS data base 1/2013

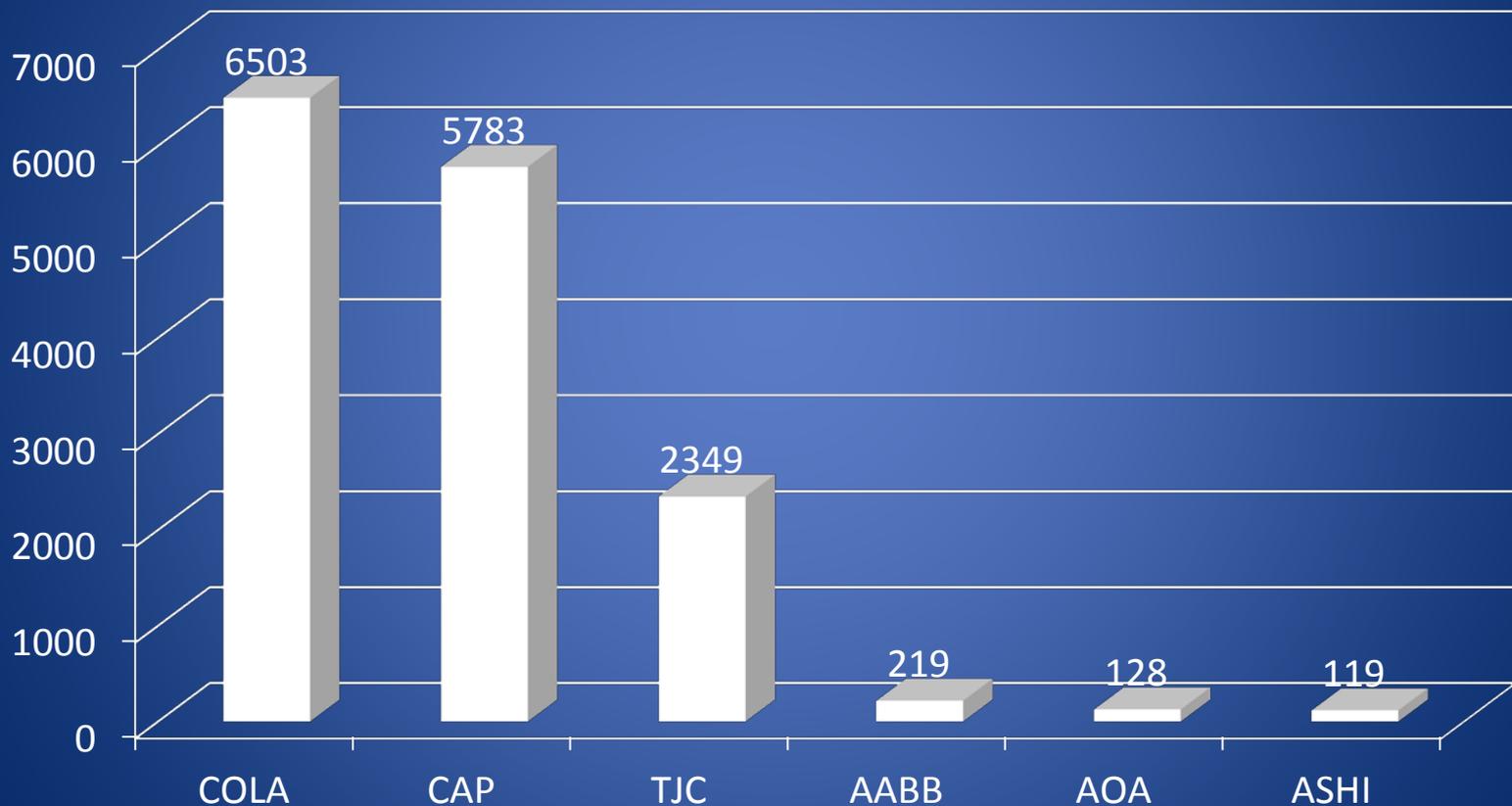# Current Statistics

Physician Office Laboratories by CLIA Certificate Type
(Non-Exempt Only)

- Waiver: 58.8%
- Provider Performed Microscopy: 25.4%
- Compliance: 10.8%
- Accreditation: 4.9%

Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization

Organization	Number
COLA	6503
CAP	5783
TJC	2349
AABB	219
AOA	128
ASHI	119

2012 Enforcement Rates for CMS Regional Offices (Proposed v. Imposed)

CMS 2319-P: Patient Access Rule

- Final rule currently undergoing HHS clearance w/ <u>tentative</u> publication date of late summer 2013.

- CDC, Office of Civil Rights (OCR) & CMS collaborative effort.

- CLIA Interpretive Guidelines will be revisited to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.

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Updating PT Regulations

- CMS collaborating w/ CDC
- Received CLIAC recommendations, based on expert input
- Requires significant levels of data compilation & analysis
- Reviewing list of analytes, grading criteria & target values, etc.
- Proposed rule will solicit comments on changes
- Final standards will be phased in to allow time for implementation

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PT Burden Rule

- Proposed regulations carves out one-time exception for confirmatory & reflex testing, if PT sample goes to another lab for testing

- Comments received generally in support

- Final under development

- Guidance will be provided to surveyors & labs

Taking Essential Steps for Testing Act of 2012
(TEST Act – HR 6118)

- Amendment to the CLIA statute signed by the President on 12/4/12.

- Clarifies that PT samples are to be tested in the same manner as patient specimens, EXCEPT that no PT samples shall be sent to another laboratory for analysis.

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Taking Essential Steps for Testing Act of 2012
(TEST Act – HR 6118)

- Allows the Secretary discretion for:
  - Revocation of the CLIA certificate for PT referral; and

  - Imposition of the 2 year owner/operator ban when sanctioned for PT referral

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Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Next steps:

    - Rulemaking to detail adverse actions for PT referrals (define when the discretion will be applied & when revocation will be imposed).

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Individualized Quality Control Plan (IQCP) Topics

- Background & History of CLIA QC
  - In the beginning…
  - 2003 Quality System Regulations
  - Inception of EQC--2004
- 2005 'QC for the Future' Meeting
  - Partnership w/ CLSI & development of EP-23
  - Publication of EP-23 in 2011
- CMS' High Level Implementation Plan for Individualized Quality Control Plan(IQCP)
  - Education & Transition Period
  - Implementation Status

IQCP Background & History

- CLIA Law passed—1988
- Final CLIA Regulations published—1992
  - 5 basic QC requirements—mod. complexity phase-in
    - Follow manufacturer's instructions
    - All QC actions acceptable during phase- in
  - All QC requirements apply to high complexity
- Many expert meetings convened by CDC/CMS to find better QC, but to no avail
- Quality System (QS) Regulations pub.—2003
  - Updated <u>all</u> QC requirements

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IQCP Background & History

- 2003 QS regulation--new provision for alternative QC in CMS' Interpretive Guidelines (IG) in lieu of changing regulations w/ new technology, as long as "equivalent quality testing" is provided--*42 CFR 493.1250 & 1256(d).*

- Default: 2 levels external QC/day of testing

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Inception of EQC

- Equivalent QC or 'EQC' developed in IG as a voluntary alternative QC--2004
    - Option employed depends on the extent internal QC monitors total testing process
    - Minimizes frequency of external QC required
    - Helps save costs/resources for labs
    - Acknowledges technological advances
    - Director responsible for choice of QC plan
    - Remaining quality systems must be acceptable

Inception of EQC

- Concerns expressed by industry, laboratories, experts, etc.
- Many laboratories adopted EQC successfully & have no quality issues; but no flexibility
  - EQC limited in scope
- CMS reached out to CLSI to facilitate development of an scientific, objective consensus QC guideline

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CMS-CLSI Partnership

- CLSI convened the well-attended 'QC for the Future' meeting in 2005
- Sponsored by accrediting orgs., industry, professional orgs. & gov't. agencies
- Outcome:
  - Stakeholder concern that manufacturers don't provide labs sufficient information
  - 'One-size-fits-all' QC doesn't work w/ new technology

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EP-23 Becomes IQCP

- CLSI meeting directed the development of Evaluation Protocol (EP)-*23—Laboratory Quality Control Based on Risk Management*
  - Chaired by James Nichols, PhD
  - Assembled expert group
  - Published October, 2011
- CMS incorporated key EP-23 concepts into CLIA IG as QC policy, called **IQCP**

IQCP Policies

- Applies to <u>CMS-certified</u> <u>non-waived</u> labs
- Covers all phases of the testing process
- May or may not reduce QC amt. or frequency
- IQCP is optional
- Default is regulation
- Includes existing & new analytes/test systems & specialties, except cytology/histopathology

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IQCP Pro's

- Can be customized based on patient pop., environment, test system, personnel, test uses
- Offers flexibility to achieve QC compliance for each test; broad in scope
- Adaptable to future technology advancements
- Permits labs to develop a QCP using their <u>existing</u> quality practices/information
  - E.g., test verification data is a start
- Considers known risks mitigated by mfr &
- Formalizes laboratories' risk mgt. decisions

IQCP Facts

- Once effective, IQCP will supersede the current EQC policy
- Existing CLIA QC & QS concepts won't change
- <u>No regulations will change!</u>
- CMS' outcome oriented survey won't change
- Minimally, labs must follow mfr's. instructions
- Lab director has overall responsibility for QCP

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IQCP Facts

- There'll be an education & transition period for labs before IQCP is fully effective

- National Surveyor Training on IQCP will be conducted

- Info & Guidance will be provided to labs

www.cms.hhs.gov/clia/

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IQCP

In the interim, <u>CMS certified labs</u> should:

- Continue to follow existing QC protocols
- Learn about EP-23 concepts & IQCP
- Plan & complete their transition accordingly
  - Phase out EQC (if using it)
  - Decide to implement default QC or IQCP

IQCP Dates

- CMS will notify labs of important dates:
  - Beginning of transition & education period
  - End of education & transition period
- At the end, labs must be in compliance w/ their QC choice
- Or deficiencies will be cited

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IQCP & Accredited Labs

- CMS will solicit accrediting orgs (AO) to determine their interest in IQCP

- Accredited labs should <u>continue to meet their accrediting org.'s QC standards</u> until they receive notice from their AO

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IQCP Educational Period

- No control procedure regulatory citations will be issued during the education & transition (E/T) period, unless serious test quality problems are found

- All questions regarding IQCP may be directed to the CMS electronic mailbox

IQCP@cms.hhs.gov

  - Please stay tuned for more information…..

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IQCP Planning Team

- CMS convened a planning team in 2011 to oversee the implementation of IQCP

- Volunteer members from Central Office w/ expertise in CLIA & lab medicine
  – includes Regional reps & former div. mgr.
  - Planning team instituted WG's to work simultaneously to accomplish multiple tasks
    – Training planning
    – Interpretive Guidelines
    – Communications
    – AO/ES re-approvals
    – Brochures

IQCP Interpretive Guidelines (IG)

- CMS Central/Regional Office (CO/RO) Meeting
  - learned & discussed EP23
  - described potential content of a new CLIA alternative QC option, IQCP
- Convened IQCP Interpretive Guidelines WG
  - co-leads from CO & RO
  - CO & RO staff volunteers collaborated to write draft IG w/ subgroups to draft each section

IQCP Interpretive Guidelines (IG)

- Worked via webinars to complete draft IGs
- Final draft approved by IQCP Planning Team for review by selected stakeholders
- Late Sept. 2012 – Solicited comments from internal & external affected parties
- Winter 2012 - Reconciled comments & revisions made to draft IGs
- Final draft approved by IQCP Planning Team
- Third S&C Letter to transmit the IG's is going through CMS clearance process

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IQCP Surveyor Training

- IQCP Training Team: CO/RO formed late 2011
- Training approach & modules planned via conference calls & face- to-face meetings
- RO/SA training will occur prior to E/T period start
- Training Team will continue to support RO/SAs post training
  - presenting at upcoming consortia meetings
  - webinars for possible "advanced" IQCP training
  - other venues as requested

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IQCP Training Modules

- History & Rationale for IQCP
- CLIA IQCP Policies
- Overview of Risk Assessment
- Scope of IQCP
- Citations (D-tags) for IQCP
- Surveying for Compliance
- Sample Quality Control Plan (QCP) Evaluations
- Education & Transition Period

IQCP Surveyor Training

- The IQCP SA Training will be conducted in Baltimore from November 18-22, 2013

- AOs, Exempt States, & our other Partners are welcome to attend

- We can accommodate up to 2 individuals per AO/ES/Agency

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IQCP Educational Outreach

- **CLIA BROCHURES**
  - <u>First</u> in a series of IQCP brochures to debut soon
  - Focus is introductory level Q&A addressing:
    - What is IQCP
    - Application
    - Participation
    - Manufacturer Instructions
    - Director Responsibility
  - Distribution
    - CLIA website
    - On-site survey of Certificate of Compliance (COC) labs
    - Booths, public venues, Partners
  - Anticipate the 2nd brochure release by end of 2013

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IQCP Educational Outreach

- **COLLABORATION with CDC**
  - CMS is collaborating w/ CDC on further educational material
  - Focus geared towards Physician Office Laboratories (POLs) & other smaller labs

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IQCP Communications

- CLIA website: two S&C letters w/ FAQs
- Mailbox for inquiries: IQCP@cms.hhs.gov
- Educational Brochures: series to be posted on CLIA website: www.cms.hhs.gov/clia/
- Working on possible CMS media venues for IQCP press release
- IQCP information/materials will be shared w/ Partners & stakeholders

IQCP Planning

- IQCP Education & Transition (E/T) Period
  - Two years long
  - Learn about IQCP & ask questions
  - Determine QC option
  - Make transition plans
  - Begin to implement choice
- IQCP is optional for AO/ES Standards

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IQCP AO/ES Planning

- During Education & Transition (E/T) Period
  - AO/ESs evaluate their standards
  - Ensure AO/ES standards contain acceptable QC options
    1. CLIA QC regulations as written or
    2. IQCP
- End of E/T Period
  - EQC no longer acceptable
- Changes in AO/ES standards
  - Submit to CMS prior to implementation
  - CMS evaluation: must be equal to or more stringent than the CMS IQCP procedure

IQCP AO/ES Planning--Validation

- Validation Surveys for IQCP
  - Surveyors to be trained to follow the standard process of surveying w/ the CLIA requirements
- Validation Surveys: Education & Transition Period
  - Labs will be cited for not following CLIA QC requirements, only if a surveyor identifies **quality testing problems**
    - doing no QC at all
    - serious test quality concerns
    - immediate jeopardy (real or potential harm to patients)

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Current Certificate of Waiver (CW) Project Data

- CW labs not subject to CLIA or routine surveys; must follow manufacturer's instructions
- Pilot studies due to complaints, concerns, growth in CW tests & labs
- 50% noncompliance in pilot visits
- Educational visits to 2% CW labs/year

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Current Certificate of Waiver (CW) Project Data 2010-12

- CW labs doing non-waived tests---avg. **3.4%**
- CW labs not doing required QC---avg. **21.3%**
- CW labs not doing QC post visit---avg. **2.6% YAY!!**
- CW labs voluntarily doing PT---avg. **7.9%**

Data Source: CDC SSIS

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Good Laboratory Practices for Waived Testing Sites

- Educational booklet with job aids

Posters and postcards

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GPRA Waived Project

Government Performance Review Act

- Goal – Increased compliance with CLIA standards as measured by increased percentage of Letters of Congratulations (no problems found).

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GPRA Waived Project

- Pilot Study – 2 states in each Region
  - Selected Waived labs received copy of 'Ready, Set, Test' prior to their CoW survey
  - Post survey information collected regarding lab use of booklet to improve lab practices

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GPRA Waived Project

- 2010 Baseline – 18% received Letters of Congratulations

  - Results from 2011 – 32%
  - Results from 2012 – 44%

  Conclusion – Educational materials like 'Ready, Set, Test' serve as excellent means of improving quality of laboratory testing

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CLIA Competency Assessment Introduction

- <u>Competency assessment (CA)</u> is used to ensure that laboratory personnel are fulfilling their duties, as required by Federal regulations; i.e., are capable of providing accurate & reliable test results.

- See CMS Brochure: *"What Do I Need to Do to Assess Personnel Competency?"*

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CLIA Competency Assessment Definition

- <u>Competency</u> is the ability of laboratory personnel to apply their skill, knowledge, & experience to perform their duties correctly.

CLIA Competency Assessment Policy

- Annual CA is required for all technical, supervisory & testing personnel.

- Various related requirements are interspersed throughout regulations.

- Six elements are necessary for all who perform non-waived testing, for <u>all</u> tests performed.

- Operator training prior to testing is critical & required.

- Competency assessments must be documented.

CLIA Competency Assessment Rationale

- Studies indicate that more education & training produce higher quality results.

- The means to confirm training effectiveness is CA.

- In CLIA, laboratory director's qualifications are stringent due to overall quality responsibility.

- But qualifications for testing personnel are minimal, based on test complexity.

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CLIA Competency Assessment Rationale

- CLIA survey experience indicates problems caused by human errors & may have a patient impact.

- Routine CA helps to prevent errors.

- This highlights the significance of competency, regardless of education.

- Quality management includes personnel, processes & procedures, as does competency.

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CLIA Competency Assessment-Key Regulation

493.1413(b)(8)(9) & 1451(b)(8)(9)—

Tech. Consultant/Supervisor *Responsibilities:*

- *Evaluating the competency of all testing personnel & assuring that the staff maintain their competency to perform test procedures & report test results promptly, accurately, & proficiently.*

- Laboratory Director has overall responsibility*.*

CLIA Competency Assessment Required Elements

Competency for all tests performed must include:

- *1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing & testing.*

- *2. Monitoring the recording & reporting of test results*

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CLIA Competency Assessment Required Elements

Competency for all tests performed must include:

- *3. **Review of intermediate test results or worksheets, QC records, PT results, & preventive maintenance records***

- *4. **Direct observation of performance of instrument maintenance & function checks***

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CLIA Competency Assessment Required Elements

Competency for all tests performed must include:

- *5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external PT samples; and*

- *6. Assessment of problem solving skills.*

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CLIA Competency Assessment Tips

- Individual conducting CA must be <u>qualified as</u> TS/GS or TC, based on test complexity.
- *Competency is not PT!* PT can be used to meet some elements of competency, but not all!
- Pathologists who read slides should be evaluated by the laboratory director as TS.
- Competency is NOT the same as performance evaluation or training.

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CLIA Competency Assessment Tips

- Competency records should match the laboratory's actual procedures as performed by its personnel.

- When observing test performance, use the procedure manual (PM)/package insert (PI) to ensure PM is current & it's being followed.

- Competency for clinical & technical consultants/supervisors is based on their regulatory responsibilities.

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CLIA Competency Assessment Tips

- Can use competency assessment for QA when confirming tests ordered match reported results.

- Checklists are only minimally ok.

- Competency evaluations must be done for Provider Performed Microscopy (PPM) individuals =moderate complexity.

- Waived testing personnel, non-testing pre/post analytic personnel & those not in regulatory positions aren't subject to CA, but it's good QA.

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CLIA Competency Assessment Tips

- Follow up on QC corrective actions or PT failures will demonstrate problem-solving ability.

- Don't have to do CA all at one time; can spread over the year's time.

- Can combine elements; e.g., pre, analytic & post observation, if it works for you.

- Can combine analytes tested on the same platform, but not test systems w/ different platforms/methods/manufacturers.

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CLIA Competency Assessment Tips

- If a service contract is used for PM, it's ok to review maintenance records.

- Lab director is accountable; must also demonstrate proficiency. Responsibilities are checked on surveys.

- If test methods are added or changed, competency must be re-evaluated prior to reporting test results.

- Build CA into existing quality practices, procedures. (Quality System)

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Where to Obtain Information

CMS/CLIA Web site:

www.cms.hhs.gov/clia/

CMS CLIA Central Office:

410-786-3531

Judy Yost's Email:
Judith.yost@cms.hhs.gov

IQCP Link: IQCP@cms.hhs.gov

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THE END!

THANK YOU!!
QUESTIONS??

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