Secretary's Advisory Committee for Genetics, Health & Society November 13, 2006

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Secretary's Advisory Committee for Genetics, Health & Society

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Topics for Discussion:

- Background & history of GT NPRM.
- What CLIA already does.
  - Assumes all GT are high complexity.
- Enhancing GT laboratory oversight.
- Update on GAO investigation & Congressional hearing.
- NY State genetic testing program.
- Path forward.

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Background & History:

- Final CLIA regulations—1992.
- NIH/DOE Task Force report—1997.
- CLIAC/SACGT recs to HHS—1998, 1999.
- CDC NOI—2000.
- Revised CLIAC recs to HHS--2001
- CMS CLIA Final QC regulations—2003.

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What CLIA already does:

- **Quality control** — real time evaluation of test quality.
  - External QC or PCR QC daily,
  - Test method (analytic) validation,
  - Calibration/calibration verification,
  - Instruments, reagents, supplies,
  - Functions checks,
  - Procedure manual,
  - Comparison of test results,
  - Corrective actions,
  - Test records, and
  - Specialties--# reduced when QC augmented.

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What CLIA already does:

- **Proficiency testing** – long term accuracy.
  - Analytes listed in regulations -- 83 tests.
    - Must enroll in PT program if doing test.
  - Analytes not listed -- >1000 tests.
    - Twice per year check test accuracy.
- **Recordkeeping, confidentiality, specimen integrity, labeling, complaints.**
- **Pre & Post analytic requirements**.
  - Specimen collection, processing, referral, test orders, result reporting.

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What CLIA already does:

- **Personnel**--Education, experience, training with quality responsibilities.
  - *Laboratory Director — overall responsibility*
  - *Clinical Consultant*
  - *Technical Supervisor*
  - *General Supervisor*
  - *Testing Personnel*
- **Competency** checks required annually.

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What CLIA already does:

- **Quality Assurance**
  - Ongoing mechanism—overall plan;
  - Monitor & assess quality of testing;
  - Encompasses all CLIA standards;
  - Correct problems effectively; and
  - Communicate with staff, clients.
- **Biennial surveys** look at outcomes (results).
- ***CLIA is a package deal!!***

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Why No New Reg for GT Specialty?

Three Burdens of Any Administrative Rule:

1. *Absolute Benefit*

- Is There a Problem for Which the Rule is a Remedy?
- Is It a Significant Problem
- Does the Rule Effectively Address the Problem
- How Strong is the Evidence that the Rule Addresses the Problem?

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Is There Strong Evidence of Absolute Benefit for GT Specialty?

- Lack of evidence of a problem soluble via CLIA and currently unattended by CLIA
- GT specialty will not provide clinical validity;
- GT specialty will not solve PT sample paucity;
  - Example: Pap Smear Testing
- GT specialty will not address ELSI issues;
- No widely accepted definition of a GT;
- In the very dynamic area of GT, prescriptive standards enshrined in federal rule now may run a high risk of becoming outdated and locking the field into outmoded compliance.

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Second Burden of a Proposed Rule

2. Comparative Benefit

- Do the benefits exceed the costs?
- Do the benefits outweigh alternative approaches that are:
  - Less costly, or
  - More effective, or
  - Faster to address the problem(s).

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Is There Comparative Advantage to GT Specialty?

- Labs already covered by CLIA.
- Potential for using existing regulation more effectively (e.g. with DTC surveillance)
- Disruption to existing infrastructure & specialties with a new GT Specialty (e.g. portions of existing specialties to be teased out);
- Admin Rule takes about 3 years
  - NPRM
  - Final rule

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Third Burden of Admin. Rule

3. Burden of Priority

- How does this rule compare with the urgency and importance of other rules?
- What infrastructure is needed to implement the new rule, and how does such investment compare with other needed investments?
- Scarce resources competing.

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Using Existing CLIA Rules as Effectively as Possible

What is CMS doing to strengthen GT oversight?

- Develop specific surveyor guidance;
- Conduct surveyor technical training;
- Publish educational materials for labs w/ CDC;
- Explore survey alternatives & work w/ Partners;
- Request FDA/CDC to assist w/ validation reviews;
- Design alternative PT mechanisms;

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Continued - Using Existing CLIA Rules as Effectively as Possible

What is CMS doing to strengthen GT oversight?

- Work with CLIAC, CDC, FTC, NIH & FDA;
- Collaborate with CLSI on professional standards;
- Request FDA, CDC aid in test validation reviews;
- Collect data on GT laboratory performance; and
- Enhance CLIA web site, so lab performance info is more easily accessible to the public.

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Direct to Consumer Testing

GAO Investigation & Congressional Hearing Update

- DTC is not primarily a CLIA issue. CLIA addresses (a) analytic validity, not: (b) advertising, (c) sales, (d) clinical validity, (e) interpretation of results (f) communication back to consumer.
- Oversight of laboratories performing these tests *is* a CLIA responsibility, if tests covered.
- CMS is closely monitoring labs identified by GAO & additional sites from other sources.
- Taking appropriate actions to ensure compliance.
- Facilities appear to be interrelated.
- CMS is participating on NIH DTC WG.

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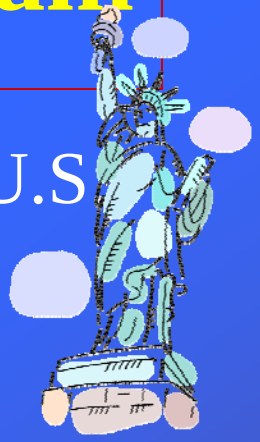
New York State Genetics Program



- Most stringent State laboratory standards in U.S
  - Higher Fees
  - Extensive infrastructure, resources & revenue.
- FDA approved/cleared tests require no prior approval.
- RUO, ASRs, in-house developed, modified, IUO must have approval prior to offering.
  - Provide guidance on materials required for review.
  - Includes analytical & clinical validity.
  - >450 reviews this year.

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Cont'd.- New York State Genetics Program

- **Cytogenetics**
  - Clinical info re test selection & interp.; patient consent, confidentiality; specimen retention.
  - TAT, # independent cultures & cells; retention (25 yrs.)
  - Repts. signed by cytogeneticist; interp. suitable for non geneticist; pre-natal & pre-implantation outcome verification.
  - PT—NY PT program.

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Cont'd.- New York State Genetics Program

- **Genetic Testing**
  - Clinical info for test selection & interp.
  - Patient consent, confidentiality, specimen retention;
  - QC each run, method doc., TAT, retention of records.
  - Repts. signed by geneticist; interp. rept for non geneticist MD, prenatal & pre-implantation outcomes.
  - PT--biannual external or internal.

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Next Steps:

- Monitor GAO & other DTC labs' compliance ongoing;
- Heighten surveyor awareness & train;
- Collect performance data;
- Collaborate ongoing with advisory groups, experts, CDC, FDA, etc.;
- Develop GT standards with CLSI; and
- Educate GT laboratories, expand web site, etc.

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THANK YOU!

QUESTIONS??

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Where to find CLIA information:

CMS/CLIA Web site:

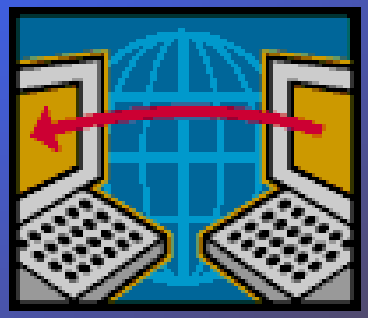
www.cms.hhs.gov/clia

CMS Central Office, Baltimore

410-786-3531

Judy Yost email:

Judith.yost@cms.hhs.gov



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