Implementation of Cytology PT

Cheryl Wiseman, MPH, CT(ASCP)
Health Insurance Specialist
Centers for Medicare & Medicaid Services
Presentation Topics

- Law, Regulations
- Approved PT Programs - 2005
- Cytology PT Implementation
- Diagnostic Categories
- Data Collection, Reporting
- Cytology PT After 2005
- Additional Information
“Periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions.”
• Contain specific requirements for Cytology

Proficiency testing – Subpart H and Subpart I
  o Subpart H – Laboratories
  o Subpart I – Proficiency Testing (PT) Program

Subpart H---Laboratory Requirements

The laboratory must ensure:

• Each individual performing gynecologic cytology examinations is enrolled in a program

• Each individual obtains a passing score (90%)

• Required remedial actions are taken following any failure of a testing event
The PT program must:

• Submit application by July 1 for approval to begin regulatory testing the next calendar year
• Be private, non-profit
• Provide annual testing and retesting (for failures)
• Provide announced and unannounced testing
Subpart I---PT Program Requirements (Continued)

• Compile 10 and 20 glass slide test sets
  ▶ Reference slides with consensus of a minimum of 3 pathologists
  ▶ Include one slide from each diagnostic category
• Score tests using CLIA scoring for pathologists (TS) and cytotechnologists (CT)
• Provide test reports to participants, laboratories, CMS
• Maintain documentation of testing
Reapproval of PT Programs

PT program must:

• Submit reapproval application by July 1 for next calendar year

• Provide information on testing experience for previous testing cycle
  - Number of CT and TS Enrolled and Tested
  - Pass/Fail Data
  - Retest Data
  - Changes to Program
  - Additional Information
CLI A Approved PT Programs
2005

• State of Maryland Cytology Proficiency Testing Program (1994)
• Midwest Institute for Medical Education, Inc. (2004)

*Enrollment in one of these programs is required.
## Implementation Timeline

<table>
<thead>
<tr>
<th>Ensure each person:</th>
<th>Laboratory Dates</th>
<th>CMS Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is enrolled</td>
<td>June 30, 2005</td>
<td>June 30, 2005</td>
</tr>
<tr>
<td>Has been tested</td>
<td>December 31, 2005</td>
<td>April 2, 2006</td>
</tr>
<tr>
<td>Has passed</td>
<td>December 31, 2006</td>
<td>December 31, 2006</td>
</tr>
</tbody>
</table>
What does this mean?

The laboratory must ensure each CT and TS examining gynecologic preparations:

• June 30, 2005 is enrolled in a CLIA approved PT program
• December 31, 2005 has been tested at least once
• December 31, 2006 has achieved a passing score
• December 31, 2006 has taken remedial actions, for any testing event failure
Testing Sequence

• Initial - 10 slide test
• Retest - 10 slide test
• Second retest – 20 slide test
• Third retest – 20 slide test
Testing Sequence

10 slide test

- Pass ≥ 90%
  Annual testing met

- Fail
  Retest within 45 days

20 slide test

- Pass ≥ 90%
  Annual testing met

- Fail
  Cease examining slides
  35 hours formal training

20 slide test

- Must achieve ≥ 90%
  To resume slide examination
PT Diagnostic Categories

• **A** **Unsatisfactory** for diagnosis due to:
  - Scant cellularity
  - Air drying
  - Obscuring material (blood, inflammatory cells, or lubricant)

• **B** **Normal or Benign Changes**--includes:
  - Normal, negative or within normal limits
  - Infection other than Human Papillomavirus (HPV) (e.g., Trichomonas vaginalis, changes or morphology consistent with Candida spp., Actinomyces spp. or Herpes simplex virus)
  - Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation)

• **C** **Low Grade Squamous Intraepithelial Lesion**--includes:
  - Cellular changes associated with HPV
  - Mild dysplasia/CIN-1

• **D** **High Grade Lesion and Carcinoma**-- includes:
  - High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in situ/CIN-3
  - Squamous cell carcinoma
  - Adenocarcinoma and other malignant neoplasms.
Remediation for 2005

If remedial action is required:

- Laboratories must ensure individuals receive appropriate training
- Laboratories must document training and submit information to PT provider
- PT provider will submit this information to CMS
- Individual must be retested
- CMS is giving wide discretion the first year
Reportable Information

Within 15 days, the PT Provider must report results to CMS and the following:

• To the Individual – score, pass/fail, and if appropriate, area of failure

• To the Laboratory Director – summary of results for all participants in the laboratory – score, pass/fail, and if appropriate area of failure

• In the event the individual works at multiple laboratories, results will go to the Laboratory Director at each laboratory
CYPERS

• Cytology Personnel Record System
• Monitor enrollment and participation
• Record of individual scores
• Ensure compliance with CLIA requirements
Testing in 2006 and Future

- Individuals must be enrolled and tested annually
- Laboratories must ensure enrollment, annual testing and remedial actions (if needed)
- Laboratories must stay in a program for one year before switching to another program
Approval of Other Programs

The program must:

• Submit application by July 1, 2005 for approval and testing beginning January 1, 2006
• Meet requirements in subpart I
  ❖ Be non-profit
  ❖ Provide annual testing and retesting (for failures)
  ❖ Provide announced and unannounced testing
  ❖ Compile 10 and 20 glass slide test sets
    o Reference slides with consensus of 3 pathologists
    o Include one slide from each category
  ❖ Score tests using CLIA scoring for pathologists (TS) and cytotechnologists
• Provide test reports to participants, laboratories, and CMS
• Maintain documentation of testing
The laboratory must ensure each CT and TS:

• June 30, 2005 is enrolled in a CLIA approved PT program

• December 31, 2005 has been tested at least once

• December 31, 2006 has achieved a passing score

• December 31, 2006 has taken remedial actions, for any testing event failure
Questions and Concerns

CDC CLIA hotline 770-488-8155
http://www.phppo.cdc.gov/clia/default.aspx

CMS 410-786-3531
http://www.cms.hhs.gov/clia/default.asp