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CENTER FOR MEDICAID AND STATE OPERATIONS
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ON
CLIA AND GENETIC TESTING
BEFORE THE
SENATE SPECIAL COMMITTEE ON AGING**

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Chairman Smith, Senator Kohl, distinguished members of the Committee; I thank you for your invitation to appear before the Committee. This morning I will address CMS' efforts to ensure quality results in our nation's labs, including those conducting genetic tests. To accomplish that task, the Centers for Medicare & Medicaid Services (CMS) works with a number of different entities, including state government agencies, professional associations and independent survey groups, to ensure that laboratories receiving Medicare payments comply with established conditions of participation for their provider type and that all laboratories in the U.S. meet standards established under the Clinical Laboratory Improvement Amendments (CLIA).

CLIA Background

In 1988, Congressional hearings concerning deaths of women from erroneously read Pap smears, and the proliferation of bench top laboratory technology into non-traditional testing sites, led to passage of CLIA. CLIA established nationally uniform quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of the setting in which the test was performed. A laboratory subject to CLIA is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of a disease or impairment, or to assess the patient's health. CLIA is user fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

Final CLIA regulations were published on February 28, 1992 and are based (as required by statute) on the complexity of the test method; thus, the more complicated the test, the more stringent the compliance and oversight requirements. Three categories of tests have been established: waived; moderate complexity, including the subcategory of provider-performed microscopy (PPM); and high complexity. Laboratories performing only waived tests must enroll in CLIA, pay the applicable fee and follow manufacturers' testing instructions. Laboratories that perform moderate and high complexity tests are assessed additional certificate and survey fees based on their testing volumes and scope of testing. It is important to note that CLIA's application is to the methods used by the laboratories to conduct the various tests and not the effectiveness of the tests themselves. That latter point is an area of FDA authority.

Most genetic tests fall into the high complexity category. High complexity tests require more training and education, are more technique-dependent, (more complicated to perform and have more steps), and require interpretation of the results. They are therefore subject to the most stringent standards and are reviewed during laboratory surveys. CLIA also specifies detailed quality standards for moderate complexity tests.

There are a number of tests that do not fall under CLIA and laboratories or entities that perform them do not have to adhere to CLIA standards insofar as they are only performing these particular tests. They include:

- parentage testing;
- breath-a-lizer tests used by law enforcement to determine intoxication, and all other breath testing;
- drugs of abuse tests performed by SAMHSA (Substance Abuse and Mental Health Services Agency) certified laboratories;
- any clinical laboratory testing used in research, the results of which are not reported to a caregiver or to the patient and are not used in any way to treat or medically evaluate a patient for treatment;
- in-vitro fertilization testing prior to implantation;
- slit lamp testing;
- genetic tests that don't provide information related to health assessment, diagnosis, monitoring or treatment;
- forensic testing;
- tests in which a specimen is not removed from the body; and
- employee drug testing for the purpose of employment.

CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, and approving entities that test laboratory proficiency, accrediting organizations, and exempt states with equivalent requirements. The Centers for Disease Control and Prevention (CDC) is responsible for CLIA research studies, convening the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC) and providing scientific and technical support/consultation to DHHS/CMS. The Food and Drug Administration (FDA) is responsible for test categorization.

Laboratory Enrollment and Performance Standards

To enroll in the CLIA program, laboratories must register by completing an application, paying fees, and undergoing an inspection survey, if applicable, prior to receiving a CLIA certificate. Currently there are 195,000 laboratories enrolled in CLIA and it is estimated that approximately 2,000-2,400 laboratories perform genetic tests. CLIA fees are based on the type of certificate requested by the laboratory (that is, waived, provider performed microscopy (PPM), accreditation, or compliance), as well as the annual volume and types of testing performed for moderate and high complexity laboratories. Waived and PPM laboratories may apply directly for a certificate and are not subject to routine inspection, unless a complaint is registered. Laboratories that must be surveyed routinely (i.e., those performing moderate and/or high complexity testing—including genetic tests) may select between CMS and a private accrediting organization to fulfill that requirement.

The biennial CMS survey process is outcome (test result) oriented and utilizes a quality assurance focus to assess compliance. An educational approach is employed in which the surveyor may provide resources and an explanation of the requirements to help the laboratory correct deficiencies and comply with applicable standards in order to avoid enforcement actions. However, if the laboratory cannot correct the problem(s) within a reasonable amount of time, sanctions are imposed that are commensurate with the history, seriousness and pervasiveness of the deficiencies.

Laboratories subject to routine biennial surveys must comply with a number of CLIA quality requirements, including:

- Personnel: CLIA sets minimum qualifications, experience and training requirements for all persons performing or supervising moderate or high complexity tests. These individuals must also meet specific responsibilities that correspond to all of the CLIA quality standards.
- Proficiency testing: Laboratories must also participate in an approved proficiency testing program that provides an external evaluation of the accuracy of the lab's test results. Under this requirement, three times per year, laboratories purchase samples from an external source (the proficiency testing provider), whose characteristics are not disclosed to the lab. The laboratory tests the samples along with their routine patient testing and the results are returned to the testing provider to be graded. If the laboratory passes, they have met the CLIA standard. The results of proficiency testing for all laboratories in CLIA are transmitted to CMS and are routinely monitored and maintained in a database. If a laboratory repeatedly fails proficiency testing during successive testing challenges, then action is taken to limit the laboratory's ability to continue performing the test(s). Proficiency testing providers are private companies, or state laboratory departments, that must meet certain CLIA requirements to provide testing samples to labs, and are approved by CMS annually. There is no proficiency testing material available for most genetic tests. Therefore, CLIA provides an alternative mechanism to ensure accuracy: twice per year, the laboratory must perform a study to verify the accuracy of their tests. Many laboratories utilize an inter-laboratory comparison of the results of the same specimen to meet this requirement.
- Quality control (QC): Laboratories must have a process for monitoring personnel, and testing equipment and the lab's environment to ensure proper operation and accurate results each day. QC also includes verifying, or in the case of most genetic tests, establishing the analytical validity of the test to ensure that the test works correctly in this laboratory.

- Quality assessment: Laboratories must have and follow a plan to monitor, on an ongoing basis, the overall operation of the laboratory, provide communications, and resolve problems that affect the quality of their testing.
- Cytology testing: CLIA sets special rules for cytology testing including workload limits, individualized proficiency testing, personnel standards, and quality control.
- The laboratory must maintain a recordkeeping system for the entire testing process.

Data show that these regulations are helping to improve testing quality. Since CLIA was implemented in 1992, quality deficiencies cited against clinical laboratories have decreased significantly. The first on-site surveys of laboratories revealed that up to 35 percent of laboratories had quality deficiencies. Currently less than 7 percent of 11,000 laboratories surveyed by CMS in a year have quality problems. We believe that our educational rather than punitive approach has facilitated improvement in laboratory quality. Data from our Survey Evaluation Form indicate that most laboratories respond very positively to the educational, information-sharing approach to oversight, and correct their problems prior to imposition of enforcement actions. The quality assurance approach encourages laboratories to develop a plan to monitor their entire operation to identify and resolve their quality-related problems on an ongoing basis. Survey data and proficiency testing data reflect improvement in laboratory performance over time, thus demonstrating labs' accountability in knowing the regulatory requirements and preventing and correcting identified issues. Over the past five years, CMS has proposed enforcement action in 5,361 cases, and carried out such action in 395 instances.

Oversight and Surveys

CMS contracts with State Departments of Health to perform laboratory surveys. CMS' objective in developing an outcome oriented survey process is primarily to determine the laboratory's regulatory compliance, but also to assist laboratories in improving patient care by emphasizing those aspects that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process. The surveyor determines, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel and review of the laboratory's relevant documented records, whether the laboratory is meeting the requirements of the CLIA regulations to produce accurate, reliable and timely

(quality) test results. The surveyor meets the objectives by employing an outcome-oriented/quality improvement type of survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory regarding the applicable standards and the way it monitors itself, rather than on a methodical evaluation of every standard level regulatory requirement.

The quality assessment (QA) requirements of the laboratory regulations (42 CFR Part 493, Subpart K) guide the surveyors in organizing their review. The surveyors select a cross-section of information, tour the facility and observe the entire testing process, interview staff and management, review quality records and all aspects of the laboratory's operation to assess its capability to produce quality results as well as its ability to identify and correct problems and communicate with its clients. Emphasis is placed on overall laboratory performance and the structures and processes contributing to the reliability of the testing. Since it would be impossible to review every test and every document in the laboratory, the surveyor reviews the selected cross-section of information to see if the laboratory has established and implemented appropriate mechanisms for monitoring and evaluating its practices and solving its problems. The surveyors investigate further any test areas identified as a problem but not addressed by the laboratory's QA program, ensure permanent resolution of previous deficiencies and review any new tests and personnel since the last visit. If the laboratory is failing to monitor (or effectively monitor) its own systems, the surveyor may direct the laboratory to the requirements and the relevant regulatory sections for its particular setting, thereby accomplishing the educational aspect of the survey process.

If, however, problems identified during the survey, or as the result of a complaint, are not remedied in a reasonable amount of time, CMS has authority to impose a variety of sanctions on the laboratory. These range from onsite monitoring, fines, or loss of Medicare reimbursement, to revocation of their CLIA certificate, depending on the seriousness and pervasiveness of the problem. Most laboratories correct their problems as a result of the education they receive during and following the survey, and no sanctions are imposed. Only about one percent of laboratories surveyed each year have had enforcement actions taken against them. The names of these laboratories and the laboratory director are compiled annually and this list is placed on the

CLIA web site at: www.cms.hhs.gov/clia. The 2005 registry lists 240 entities. The percentages of each laboratory type experiencing enforcement actions are proportional to the total number of laboratories of that type enrolled in the CLIA program. Laboratories with repeat deficiencies are treated more aggressively with progressively severe expedited enforcement actions.

As mentioned previously, laboratories that are subject to biennial surveys can choose to obtain CLIA certification by the State agency, as an agent of CMS, or by an approved private accreditation organization. Accrediting organizations with standards that are equivalent to or more stringent than CLIA, currently approved by HHS for this purpose include:

- the Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
- the College of American Pathologists (CAP),
- COLA (formerly Commission on Office Laboratory Accreditation);
- AABB (formerly the American Association of Blood Banks);
- the American Society for Histocompatibility and Immunogenetics (ASHI); and
- the American Osteopathic Association (AOA).

States that have laboratory licensure program standards equivalent to, or stricter than those of CLIA can apply for "approval" or "exemption." Then the laboratories in those states that meet state licensure requirements are deemed to be in compliance with CLIA. There are currently only two exempt states – New York and Washington. In other states that have a state laboratory licensure program, laboratories within the state must comply with both CLIA and their state requirements.

On an annual basis, CMS, through the state agencies, surveys approximately 2.5 percent of accredited and exempt laboratories using CLIA standards to validate that these laboratories are in compliance with CLIA by meeting the accrediting organization's standards and to ensure that the organization is enforcing its own equivalent standards. After surveying the accrediting organization's laboratories, CMS compares the results of the state survey to the accrediting organization's, to determine the level of disparity. The rate of disparity is the percentage of all sample validation surveys for which a State survey agency finds non-compliance with one or

more CLIA conditions when no comparable condition level deficiency was cited by the accreditation organization. As set forth in regulation at 42 CFR 493 Subpart E, an accreditation program with a disparity rate of 20 percent or more is subject to a review to determine if that organization has adopted and maintains requirements comparable to those of CMS. No accrediting organization has even approached the maximum threshold of 20 percent disparity.

Complaints alleged against accredited laboratories from any source are either addressed by the accrediting organization or by the State agency in conjunction with the CMS Regional Office. CMS has recently implemented an automated complaint tracking system to capture all complaints to ensure timely and complete follow up and investigation. Ultimately the approved accrediting organizations and exempt States will enter their complaint data into this system to provide national data for CMS to monitor for program effectiveness.

It is important to note at this point that genetic testing is already covered by existing CLIA regulations. Tests for genetic markers are dispersed throughout various laboratory specialties and the requirements for those tests are encompassed by the current quality standards. In fact, the final CLIA Quality Control regulation that was published in 2003 incorporated certain CLIAC recommendations for genetic testing, including confidentiality requirements, facility workflow requirements to minimize contamination, and quality control requirements for the genetic test method of polymerase chain reaction (PCR). When problems are discovered with any lab, including laboratories conducting genetic tests, we take action. For example, earlier this month the in its capacity as CMS' CLIA survey agent, the State Survey Agency in Connecticut sent a letter to Genaissance Pharmaceuticals informing them that the "nutrigenomic" tests they were conducting are subject to the requirements of CLIA and that they are, therefore, required to supply documentation of their test method validation studies for such tests. Subsequently, the laboratory has agreed to permit an inspection of these tests.

Conclusion

CMS takes its responsibility to ensure the quality of laboratory tests, including genetic tests, seriously and we will continue to do so. I thank the Subcommittee for its time this morning and would be pleased to answer any questions you might have.