CLIA PERFORMANCE GOAL IN CMS' ANNUAL PERFORMANCE PLAN: IMPROVE LABORATORY TESTING ACCURACY

Description:
This goal commits CMS to continued improvement in the accuracy of diagnostic laboratory tests regulated under the Clinical Laboratory Improvement Amendments (CLIA) as demonstrated by improved PT performance. Specifically, further improvements are expected in laboratory scores on proficiency (accuracy) testing (PT) while the rate of compliance with PT enrollment requirements in CLIA also increases. It is important to measure progress on both enrollment and PT scores so that eventually all laboratories subject to PT under the CLIA rules are both participating in a PT testing program and performing well on those PT challenges.

Rationale: PT, along with the other CLIA quality requirements, offers each laboratory performing non-waived testing and CMS a means of measuring a laboratory's performance. It also increases patient and physician confidence in a particular laboratory by producing a snapshot of the laboratory's ability to perform tests accurately according to objective standards. Increased laboratory test accuracy reduces the need or inclination for repetitive laboratory testing and thereby reduces overall costs of medical care related to diagnostic testing. Typically, a laboratory that performs well on PT tends to provide more accurate testing results to clinicians, which aids in rapid and appropriate patient diagnoses and contributes to effective treatment. There is a well documented educational value for the laboratory staff from PT performance and evaluation of PT results.

PT involves sending samples with results unknown to the laboratory, three times per year to evaluate whether the laboratory's results compared to its peers. The CLIA regulation requires that the PT samples be tested in the same manner and by the same individuals as those performing patient testing. The PT samples are provided by private non-profit organizations, Federal or State agencies. The PT programs that provide the samples undergo an annual and ongoing review process coordinated by CMS and CDC.

Under CLIA all entities providing laboratory testing are certified. Laboratories performing non-waived tests are required by law to perform PT. CLIA defines laboratory testing as "the examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings." There are currently 86 tests or analytes for which laboratories must perform PT under CLIA. This list of 86 analytes is largely made up of diagnostic tests which are commonly performed and whose results are important to health care treatment decisions. Each laboratory performs PT on the regulated analytes that are a part of its specific test menu. There are other tests performed by laboratories, regulated under CLIA, for which there is no required PT under CLIA regulations. Tests for which PT is required may be added as the CLIA regulations are updated by CDC and CMS. Some laboratories voluntarily participate in any PT which is available, even if not yet required under CLIA regulations. If there is no PT available for a test, a laboratory must, at least two times each year, demonstrate the accuracy of any test performed.

Calendar years 1993 and 1994 were phase-in years for PT enrollment and performance under CLIA for previously unregulated laboratories, such as those in physicians' offices. Calendar year 1995 represents the first year for which there is complete PT data. This data indicates that 69.4% of the total scores reported from all laboratories enrolled in PT demonstrated no failures. The data also indicate that 89.6%of the laboratories that were required to be enrolled in PT were actually enrolled. This represents the baseline from which to improve. The following year, 87.4% of the scores from enrolled laboratories demonstrated no failures on any PT challenges and the percentage of regulated labs actually enrolled was 93.2%. These figures indicate increases in both performance (accuracy) rates and enrollment rates from 1995 to 1996, consistent with the start-up of PT testing. As the PT program becomes a routine part of laboratory operations, further more modest gains are expected in both measures.

Interventions in place from which the improvement has occurred and will continue to occur include:

- State surveyors and CMS-approved accrediting bodies employing an educational, outcome oriented survey approach and continual monitoring of laboratory PT performance;
- In most instances, recommending training and technical assistance for laboratories that fail to meet the standards set for PT performance in lieu of sanctions for the first occurrence;
- Not allowing laboratories refusing training and technical assistance to conduct the test(s) in question until they have met two PT challenges successfully;
- Taking enforcement actions or sanctions if a laboratory's accuracy does not improve or is so poor as to pose a threat to the public health and safety;
- State surveyors and CMS-approved accrediting bodies assisting laboratories in understanding all aspects of PT performance and ongoing monitoring of enrollment;
- Taking enforcement actions or sanctions if a laboratory continually or repeatedly fails to enroll in PT for all appropriate tests;
- Requesting PT providers to be available to assist laboratories in enrolling appropriately; and
- Laboratories reviewing their own findings of PT performance and taking appropriate actions in their laboratory to identify and correct the problem.

Ultimate Target: Having 90% of the total scores reported from all laboratories enrolled in PT to contain no failures. Also, the percentage of CLIA laboratories properly enrolled and participating in PT to increase to 95%.

Data Sources: CMS Online Survey and Certification Reporting System (OSCAR)
The PT enrollment rate is calculated using: (1) the number of laboratories in the OSCAR data base that were subject to on-site survey and PT testing for at least one analyte; and (2) the number of laboratories cited as deficient for failing to be appropriately enrolled in PT. The rate at which enrolled labs perform successfully on PT is calculated using totals from the OSCAR data base for: (1) the total number of tests performed for the year; and (2) the total number of failed scores received for the year.

Means of Verification / Validation: Surveyors verify this data by ongoing monitoring of PT information, communicating with the laboratories and conducting biennial on-site surveys.