Regulation of Proficiency Testing under the March 14 Rule

Cecelia Hinkel

Federal authority over clinical laboratories began in 1966 when Medicare independent-laboratory regulations established personnel standards for laboratories that participated in the Medicare and Medicaid programs. The following year, Congress enacted the Clinical Laboratory Improvement Act of 1967, known as "CLIA '67," which required licensure for laboratories testing patients' specimens in interstate commerce. CLIA '67 adopted the Medicare personnel standards and added quality-control and proficiency-testing standards. In 1974, the Medicare program also adopted CLIA's quality-control and proficiency-testing standards. Before the establishment of the Health Care Financing Administration (HCFA) in 1977, the Public Health Service, acting through the Centers for Disease Control (CDC), was responsible for the regulation of laboratories performing interstate testing. In 1979, through an interagency agreement, HCFA became responsible for the licensing and inspection of the ~1700 laboratories licensed under CLIA '67. A Memorandum of Understanding between HCFA and CDC further delineated their responsibilities, specifying that HCFA was responsible for developing the regulations relating to Medicare and CLIA '67 laboratories and that CDC was responsible for providing the scientific and technical expertise on questions related to advances in instrumentation, new technology, and proficiency testing.

CDC was responsible for providing an approved proficiency-testing program and for determining successful participation for those laboratories participating in the CLIA '67 program.

The proficiency testing managed by CDC was very prescriptive in terms of program content, frequency of shipments or testing events, grading criteria for individual analytes, and the number of challenges; the CDC determined that unsuccessful participation was defined as three consecutive unsatisfactory results or three unsatisfactory results out of four consecutive shipments for specialty, subspecialty, or analyte. Unsuccessful participation in the proficiency-testing program resulted in an action to revoke or limit the CLIA '67 license. For laboratories participating in both CLIA '67 and the Medicare programs, the results of the CDC proficiency testing and any action to revoke or limit the CLIA '67 license based on unsuccessful proficiency-testing performance resulted in the initiation of a termination action under Medicare. In the mid-1980s, CDC discontinued providing proficiency-testing services.

Meanwhile, Medicare-only laboratories were not subject to the same national proficiency-testing program but were required only to successfully participate in a state- or Secretary-approved proficiency-testing program, when available, for each of the specialties or subspecialties of service offered.

For Medicare-approved laboratories, HCFA had not yet established minimally acceptable requirements in terms of program content, challenges, frequency of testing events and grading criteria for analytes, specialties, and subspecialties of service. Instead, each state was required to develop criteria for an acceptable proficiency-testing program for the federally regulated laboratories within their own state. The federally issued State Operations Manual provided a list of Secretary-approved programs, but only minimal guidance to the state agencies for implementing proficiency testing in these laboratories. A myriad of problems stemmed from this situation.

1. There were no consistent criteria among the states for approving proficiency-testing programs. Each state approved its own state proficiency-testing program, recognized the use of the Secretary-approved program listed in the State Operations Manual, or recognized other state or private-sector programs. Therefore, technically, a proficiency-testing program had to be approved as an acceptable program on a state-by-state basis, because each state approved the programs acceptable within that state.

2. Many states merely required enrollment in a proficiency-testing program but did not monitor results.

3. Grading criteria were inconsistent from state to state. Most states accepted the grading criteria submitted by the proficiency-testing program; however, some states would regrade the results. Pass/fail standards varied from state to state.

4. Not only did satisfactory performance criteria range from 70% to 100% from subspecialty to subspecialty, but also they varied from one state to another. As a result of these inconsistencies in monitoring proficiency testing, pass/fail standards, and grading criteria, certain affiliated laboratories operating in different states would sometimes find themselves involved in an adverse action in one state as a result of proficiency-testing results but would have no adverse action in another state for the same testing scores. Depending on the analyte, some states gave notice to a laboratory after a single failure in one testing event.

5. Also, because Medicare approval was based on specialties and subspecialties of service, failure of an analyte jeopardized the entire specialty and subspecialty under Medicare.

In response to these numerous problems, CDC established a task force that developed a model proficiency-
testing regulatory scheme, which was later incorporated into the March 14, 1990, final rule.

After numerous meetings between HCFA, CDC, the Food and Drug Administration, other federal agencies, state health officials, various private-sector organizations, concerned members of the laboratory industry, and the public, it was decided to consolidate all of the CLIA '87 and Medicare/Medicaid laboratory requirements. In August of 1988, HCFA published a proposed rule to revise the federal regulations. A major goal of this proposed regulation was to have, to the extent possible, the same requirements for laboratories participating in either CLIA '87, the Medicare/Medicaid programs, or both.

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88). With the enactment of CLIA '88, it was necessary to evaluate the proposed revisions to the federal requirements for laboratories to ensure that the requirements would be appropriate under CLIA '88. We determined that our proposed requirements were consistent with the standards to be established under CLIA '88. Therefore, on March 14, 1990, the proposal was published as a final rule and the current regulations for laboratories performing interstate testing and (or) participating in the Medicare/Medicaid programs.

The final rule contains the self-implementing provisions of CLIA '88, specifically the cytology standards and some of the proficiency-testing requirements. Most importantly, it forms the framework for establishing the CLIA '88 standards for quality control, quality assurance, record keeping, and proficiency testing.

The proficiency-testing requirements in the current regulations incorporated the changes in Section 353 of the Public Health Service Act and the recommendations and major changes suggested by CDC. This resulted in specific language defining enrollment in a program, testing of samples, successful participation, reinstatement after proficiency-testing failure, and approval and disapproval procedures for proficiency-testing programs. Enrollment and successful participation have been made conditions in this rule. The current requirements emphasize the increased importance of evaluating and achieving a passing score on samples of known content, which are tested as if they were patients' samples and serve as a measure of laboratory quality.

The regulations now contain the criteria necessary to become an approved proficiency-testing program, which include for each specialty and subspecialty: program content, frequency of challenge, number of challenges per quarter (the total number of samples for each analyte per testing event is now five), format for reporting results, reporting time frames, and criteria for acceptable performance. The criteria for grading were developed through an evaluation of the current criteria in use by state and private-sector programs and an evaluation of the data CDC had for laboratory performance in their proficiency-testing program.

In addition, each specialty and subspecialty has requirements unique to that area. As of November 1991, 14 programs had been approved: for calendar year 1991 they were Acutest, Inc., American Proficiency Institute, American Thoracic Society, California Thoracic Society, the Illinois State Program, the Oklahoma State Program, the American Association of Bioanalysts, the Puerto Rico Program, the New Jersey State Program, the College of American Pathologists, the Wisconsin State Program, and the New York State Program; for calendar year 1992 they were the American Association for Clinical Chemistry and the Idaho State Program. All programs approved for 1991 have applied for reapproval for 1992, and we anticipate that most will be approved.

Today, under current regulations, CLIA-certified and Medicare-approved laboratories are required to enroll in an approved proficiency-testing program for each specialty and subspecialty of service for which they seek Medicare approval or CLIA certification: they must notify HCFA of the proficiency-testing program chosen; remain within the program for at least 1 year; notify HCFA before changing proficiency-testing programs; allow the proficiency-testing program to release to HCFA or its agents all data needed to evaluate laboratory performance; test the proficiency-testing samples in the laboratory's routine manner — i.e., test proficiency-testing samples within patient-specimen runs (by the personnel who usually perform the laboratory testing); attest on the proficiency-testing result form that proficiency-testing samples were tested according to the laboratory's routine procedures for handling and testing patients' specimens; and refrain from discussing proficiency-testing results with other testing facilities until after the reporting date to the proficiency-testing program.

Satisfactory participation is defined as obtaining a grade of 80% for each analyte, specialty, and subspecialty, with the exception of 100% accuracy required for ABO and Rh grouping and compatibility testing in immunohematology. For any unsatisfactory testing event, the laboratory is required to seek appropriate training and to use the necessary technical assistance to correct the problems associated with the unsatisfactory result. "Unsuccessful participation" is defined as two consecutive or two-out-of-three unsatisfactory testing events for the specialty or subspecialty, or two-out-of-three unsatisfactory scores for the same analyte.

If a laboratory fails to perform successfully for a given subspecialty, CLIA certification will be terminated and Medicare disapproved only for that subspecialty. If a laboratory fails to perform successfully for a given analyte, CLIA certification or Medicare/Medicaid approval will be terminated in the subspecialty that includes that failed analyte. However, to prevent termination in the subspecialty, a laboratory may elect to voluntarily withdraw from performing tests on patients' specimens and reporting results for the unsuccessful analyte, while continuing to perform and report results for the other analytes in that subspecialty.

If a laboratory fails to participate in a proficiency-testing event, consideration may be given before an automatic failure if the laboratory participated in the
last two proficiency-testing events and notifies the proficiency-testing program and the inspecting agency about cessation of patient-specimen testing and the circumstances causing the nonparticipation. Intentionally referring proficiency-testing specimens to another laboratory will result in loss of Medicare approval and revocation of a laboratory certificate as required by Section 353(i) (4) of the Public Health Service Act.

For the subspecialty of cytology, the proficiency-testing regulations require each individual who examines gynecological cytology slides to participate in two proficiency-testing events per year. Once a year, one unannounced proficiency-testing event will be conducted on site in each laboratory. In addition, at least four proficiency-testing events will be conducted off site at designated testing sites. An individual must score $\geq 80\%$ on the cytology proficiency-testing event to achieve a satisfactory score. If an individual fails a cytology proficiency-testing event, immediate remedial training and education in the area of failure must be provided, and all subsequent gynecological slides must be re-examined by another individual who has demonstrated successful cytology proficiency-testing participation, until that individual achieves a score of $\geq 80\%$ on the next testing event. In addition, at least the last 500 slides examined by an individual qualified as a technical supervisor who failed a proficiency-testing event must be re-examined by another individual qualified as a technical supervisor who achieved a satisfactory score in the most recent cytology proficiency-testing event, and the last 500 negative slides examined by an individual not qualified as a technical supervisor who failed a proficiency-testing event must be re-examined by another individual who achieved a satisfactory score in the most recent cytology proficiency-testing event. However, at present there are no approved cytology proficiency-testing programs.

On May 21, 1990, HCFA published the proposed rule to implement CLIA '88, which contained the current proficiency-testing requirements as a proposal and allowed the regulated industry and all sectors of the public to comment on them. Changes in the final rule will be made in response to the concerns raised by the commentators.

Many people perceive proficiency testing as an external tool for laboratory education. Others argue that it is not an effective measure of a laboratory’s day-to-day performance. Congress thinks of it as the “most important measure of a laboratory’s performance.” HCFA recognizes that proficiency testing is neither administratively nor scientifically without flaws or complicating factors. However, proficiency-testing results are one of the standard outcome measures used to assess laboratory performance. The CLIA statute places significant emphasis on proficiency testing as an outcome measure to gauge the performance capabilities of laboratories. HCFA is committed to implementing Congress’s intent that proficiency testing be a central part of each regulated laboratory’s quality assessment.