programs, and a rational approach to oxygen therapy may play a large part in helping patients to benefit the most from this increased life expectancy. These areas all need more study to give the clinician the proper therapeutic guidelines and risk-benefit relationships.

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The Impact of New Federal Regulations on the Blood Gas Laboratory

The federal government has been very active in the past few years, issuing rules that profoundly affect the ability of blood gas laboratories in the United States to operate. These rules are intended to apply to all clinical laboratories performing blood gas analysis. Coping with these changes is going to be a challenge!

A major problem is sorting through the mountain of documents that have been issued lately. Most of this has been published in the Federal Register—a total of 227 pages (with very small type). There are two recurring acronyms in these documents: CLIA and HCFA. The first refers to the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88); these are acts of Congress which attempt to ensure quality in laboratory analysis. The Health Care Financing Administration (HCFA) is in the executive branch and is part of the Department of Health and Human Services. The HCFA has been given the responsibility to transform the intentions of Congress into specific regulations.

The intention behind CLIA '67 was to give the federal government oversight of clinical laboratories. However, not all laboratories were covered, and there was no direct federal licensing of laboratories. Nevertheless, these regulations served as standards that inspecting agencies and state surveyors used to rate laboratories.

In 1987 a stir was created in Congress, mostly because of widely publicized reports that PAP smear readings were often unreliable and that shopping mall cholesterol testing was completely unregulated. From these isolated problems, a consensus seemed to develop that all clinical laboratory testing needed to be federally regulated. Both HCFA and Congress acted. The HCFA decided to add more detail (and more teeth) to existing rules based on CLIA '67. A set of proposed rules was published in August 1988, and comments were solicited. A cornerstone of this document was a detailed set of rules regarding proficiency testing. Very specific methods were proposed for providing unknowns to laboratories and for calculating acceptable limits of performance. Proficiency testing programs would have to be federally approved, and only nonprofit organizations would be eligible. Another interesting feature of these proposed rules was that personnel requirements were rather lax; the stated philosophy was that outcome measures, rather than credentials, were to be stressed.

Just a few months later, Congress passed CLIA '88. It was short on specifics (this was left to HCFA), but there were key features that set the stage for what has followed:
1. All laboratories that examine human specimens must obtain a certificate (and renew it every two years) to perform a specified set of tests.
2. Proficiency testing programs are mandatory.
3. Laboratories can be sanctioned with license revocation or by means of lesser measures.
4. Certificate fees shall be sufficient to cover operation of the certifying program.

The HCFA decided to finalize its update on the CLIA '67 rules before working on rules pursuant to CLIA '88. In March 1990, the final rule relating to CLIA '67 was published. Proficiency testing was required to be in place by January 1991. For blood gas analysis, five vials of proficiency testing materials constitute the quarterly challenge. Eighty percent of the responses for a given analyte (Po2, PCO2, and pH) have to be within "acceptable" limits to be considered "satisfactory" performance. "Unsatisfactory" performance in two of three consecutive quarters is considered "unsatisfactory" and subjects a laboratory...
to sanctions. Besides proficiency testing, there are instructions on test ordering, specimen labeling, report issuance, and quality control procedures.

The next publication proved to be extremely controversial. On May 21, 1990, the proposed rules to implement CLIA '88 were published. Instead of the roughly 12,000 laboratories regulated under CLIA '67, from 300,000 to 600,000 would need to be certified under CLIA '88. This includes physicians' office laboratories, health fairs, and laboratories in operating rooms, which had previously been largely untouched. There was a categorization of tests by complexity, but the vast majority (including blood gas analysis) were considered high complexity.

The personnel standards were the bombshell of these rules. Although it is impossible to do full justice to these complex standards in a brief summary, the following is the net effect for blood gas laboratory staffing. In most cases, the laboratory director would need to be a physician certified in clinical pathology by the American Board of Pathology. The technical supervisor would need at least a master's degree in chemistry plus four years of clinical chemistry experience. The general supervisor would need a master's degree in one of the sciences plus experience or formal training as a medical technologist plus experience. An important point is that a general supervisor would be required to be on site throughout the hours of operation of the laboratory. Technicians would need to have completed a structured college-level curriculum in medical laboratory techniques or to have a high school diploma plus one year of formal training or to have completed a two-year technician traineeship. It is crystal clear that these standards would not be achievable by pulmonary-based blood gas laboratories.

A 12-week period was allowed for comments on these proposed rules. There was a major scramble to coordinate a response. By the time the comment period had expired, roughly 60,000 comments had been received. At the time of this writing, HCFA (with the help of the Centers for Disease Control) is still sifting through these comments.

The HCFA has issued three additional proposed rules. The first deals with fees for issuing certificates to laboratories. These fees would cover the expenses of administering the program, including an on-site inspection every two years. Preliminary estimates call for biennial fees ranging from $840 to $2,870, based on the analytes and the sample volume of the laboratory. Another set of proposed rules specifies how organizations could qualify to accredit laboratories. Apparently HCFA does not want to monitor and inspect laboratories itself, but wants nonprofit organizations and state agencies to step forward to do the job. With the projected tremendous increase in regulated laboratories, there should be a lot of work for accreditng organizations to do! The last publication to date was issued in April 1991. It deals with enforcement procedures for laboratories failing to meet standards of performance. Sanctions short of revocation of license are specified. Among these sanctions are fines ranging from $50 to $10,000 per day or per violation.

At the time of this writing, HCFA and the Centers for Disease Control are working hard to compose a final rule implementing CLIA '88 and to publish it by the end of 1991. Will the blood gas laboratory directed by a pulmonary physician and staffed by respiratory care practitioners be put out of business? This would seem distinctly inappropriate, since pulmonologists have historically played a pivotal role in the development of clinical blood gas analysis. I can report that substantial alterations in the proposed rules are being considered, including modification of some of the personnel standards. A change of focus away from overly rigid personnel requirements and toward outcome criteria would certainly be helpful. We seem to be in for an interesting time!

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Tetracycline Pleurodesis
Adios, Farewell, Adieu

Intrathorale instillation of tetracycline combined with thoracostomy tube drainage has gained accep-