Does CLIA '88 Mandate Regulation of Physician Utilization of Laboratory Testing?

Readers of this issue will find a provocative position put forward by Pedencord and Hammond (Clin Chem 1990;36:2027-35). In their article reviewing the Clinical Laboratory Improvements Act (CLIA) of 1988, they present, within the historical context for laboratory regulation, a comprehensive view of the proposed regulations implementing this law and provide insight into the complex process of making law and implementing law through regulations. Moreover, their article is unique in asserting the concept that the intent, implied or otherwise, of Congress is to regulate the practice of medicine. This extraordinary assertion has implications of immense proportions for the future role of the government in healthcare. If they are correct, the potential for CLIA '88 to affect the clinical chemistry and laboratory community at large would be equalled by its impact on clinical medicine.

The conventional approach to assessing CLIA '88 involves dissection of the numerous specifics that detail the various issues relating to the provision of testing results, the maintenance of appropriate analytical conditions, and the assessment of the product in a conventional focus on the analytical result. Indeed, this occupies the bulk of the presentation in the current paper. However, Pedencord and Hammond go much farther. They state:

We believe that the dominant objective of this law—the objective that reflects the public's expectations—is the abstract goal of improving the contribution of the diagnostic testing process to the delivery of health services and to the maintenance of health itself. Furthermore, the patient should be protected from errors in the testing process, regardless of where these errors occur and regardless of who makes the error—the laboratory or the physician who orders and uses the test. If and when this objective dominates laboratory standards policy, it will be as important that these standards (both professional and governmental) improve the physician's selection and use of tests as it will be to assure the accuracy and precision of the laboratory test itself.

With these words, the authors introduce a new reading into the law. The requirement to carry out this objective would entail the monitoring, not only of the laboratory analytical process, but also of the practice of medicine. The authors proceed to cite evidence from the literature that the goal of patient protection cannot be realized by merely promoting accuracy in the analytical phase of the testing process. How tests are ordered and interpreted and how they impact the patient are, they assert, the real issues to be dealt with. This is unequivocally true. Any student of medicine is acutely aware that the laboratory information, if taken outside of the context of the clinical setting, is grossly limited and that the selection of tests by clinicians could be significantly improved. The reader should consider whether Pedencord and Hammond are persuasive in interpreting CLIA '88 as representing a regulatory mandate to extend to the practice of medicine. I think they are well-intentioned but in error. They do not persuade that this is the congressional intent at this time.

Pedencord and Hammond go on to suggest that the implementation of CLIA '88 already restricts the physician in terms of the regulation of physician's decisions regarding who can be hired to run tests in the office and what level of training is required. They suggest that this serves as evidence that the regulation of laboratory testing on the basis of its impact on medical care "is a difference of degree, not one of philosophy." I disagree. In CLIA '88, physician's office activities are regulated in the form of the business of office management. They are not directed toward and do not have the authority to regulate the practice of medicine, which is a totally different philosophy and would impact the application of medical judgment involving individual patients.

Although I strongly concur with the estimate of Pedencord and Hammond that, to optimally impact laboratory testing, one must influence the selection of testing and the use of the testing results in the clinical context, I do not believe that governmental regulation could possibly succeed. These processes relate to the entire medical education process, they are founded on the basic science education provided to the individual physician, and they are developed under a process of tutelage extending through the third and fourth or clinical years and on into residency. They cannot easily be regulated by a governmental decree. If these processes are found wanting, and I find them wanting, then we are challenged to modify the entire educational process.

We have a mandate to modify the utilization of laboratory testing, which is put before us by the issue of an ethical requirement to distribute limited resources in a just way. The random use of testing is wasteful and contributes to the overall inequitable distribution of healthcare, resulting in the embarrassment of the reality of having 30 million uninsured Americans. We must do better. The appropriate utilization of laboratory testing is an important part of it. However, CLIA '88 will not do this and does not state that it should.

I suggest that the progress the authors seek will not be made in the regulatory arena, but can be made within the next several years by aggressively implementing the effective fulfillment of the promise of the computer age. It is at hand and doable. We may expect the routine incorporation of "knowledge-based systems"—also known as "expert systems" (2, 3) or "medical informatics"—to present effective physician enhancement in the appropriate selection and utilization of laboratory testing (4). We may expect the physician to receive prompts from the laboratory that result in more timely selection of testing in response to initial screening, e.g., appropriate and complex reflex testing algorithms ("If, if . . . Then, then") that will be transparent to the clinician. In turn, critical laboratory information will be evaluated in terms of the electronic medical record in relation to multiple databases. For example, the reporting of a positive blood culture will be related to the database in the pharmacy with regard to existing antibiotic orders, and guidelines for appropriate antibiotic selection;
such a system will call to the attention of the physician when there is the need for revision of an existing order. Similarly, therapeutic drug monitoring will result in closer integration with pharmacokinetic principles and continuing monitoring with feedback. Transfusion medical practices and component therapy will be guided.

I suggest that we must go to meaningful patient-oriented quality assurance. Concerning this, I concur with Peddecord and Hammond. On the other hand, I do not believe that the Congress intended for CLIA '88 to break this new ground. We must do that collectively ourselves. However, make no mistake: we must make this progress without the hindrance of well-intentioned regulation. Let us find the better way to do it.

In conclusion, I encourage readers to make their own assessment by thoughtfully reviewing this article. Peddecord and Hammond provide excellent insight into the overall issues. The anticipated correspondence in the journal provoked by this discussion should be productive and of continuing interest.

References

Joseph H. Keffer
Univ. of Texas
Southwestern Medical Ctr.
Dept. of Pathol.
5323 Harry Hines Blvd.
Dallas, TX 75235-9072