STATE OF NEBRASKA

DEPARTMENT OF HEALTH

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DIRECTOR

MEMORANDUM

TO: Senator Don Wesely
Chairman, Health & Human Services Committee

FROM: Gregg F. Wright, M.D., M.Ed.
Director of Health

DATE: March 16, 1987

SUBJECT: Recommendations Regarding Credentialing of Medical Technologists

INTRODUCTION

In their proposal, the applicant group requested a multi-tier licensing system for laboratory personnel in Nebraska. The technical committee recommends against the regulation of medical technology at this time. A majority of the committee were not convinced that there is a clear harm and danger in the current situation. Only one member of the committee, the representative of the applicant group, voted that all three of the criteria required by the 407 process were met in favor of licensure.

In contrast, the Board of Health finds that there is danger to the public in the current situation, that the public could benefit from an assurance of professional ability, and that less cost-effective remedies do not exist. However, in contrast to the applicant group, the Board of Health recognized that current regulatory mechanisms provide the public protection in several types of laboratories, and recommended that credentialing be required only in laboratories which are currently unregulated (primarily in physician's offices and non-Medicare certified labs). The Board also recommended that the state establish quality control and proficiency standards for currently unregulated laboratories.

The review of this application is complicated by the great diversity of types of practitioners in the field of medical technology, by the tremendous diversity in the complexity of laboratory procedures, and by the rapid changes occurring in the instrumentation of laboratory procedures. The applicant's proposal is necessarily complex. Strongly held views and the economic impact of such a proposal on all parts of a very complex medical system have blurred the arguments presented on all sides. With these considerations in mind I have reviewed the technical committee findings, the information presented at public hearing and to the Board of Health and their deliberations, and other information available on the subject.

RECOMMENDATIONS

Based upon this review, it is my recommendation that licensure of laboratory personnel not be enacted at this time. However, the state should recognize the potential for harm that exists due to inaccurate laboratory results, and take steps toward assuring the quality of laboratory results in Nebraska. The applicants have failed to show that the benefits of licensing laboratory personnel justify the reduction in test availability that would likely result or the costs associated with such a system that would be incurred at all levels of the health care system. In addition, they have not shown that licensing alone would provide an adequate quality assurance to the public. In moving towards a system of quality control in Nebraska laboratories, all levels of laboratory should be considered but emphasis should be placed upon the laboratory settings that do not currently receive any regulatory oversight. The conclusion of a recent article reviewing the experience with state regulation in Idaho, written by a medical technologist, summarizes my views:

> Timely availability of reliable test results enhances the office practitioner's ability to provide high-quality care that is personally satisfying to patients. Modern technology allows physicians to have available such timely information through test analyses performed in an office laboratory. With increasing dispersion of this technology, it is essential that standards of practice for the office laboratory be developed that ensure, with reasonable limits, the reliability of test information used in patient care. If widespread acceptance of such standards cannot be developed with a voluntary approach, states should consider regulation of office laboratories within their jurisdiction. Inclusion of personnel standards for office laboratory personnel is probably unnecessary. The current excellent level of performance in large hospital and independent laboratories evolved over the past three decades as a result of increased awareness on the part of professional laboratorians and of industry about issues affecting laboratory quality. Regulation of office laboratories should, similarly, promote improved performance in office laboratory practice in a way that does not excessively deter, financially or administratively, the appropriate application of this technology to patient care."

I recommend that the state encourage such a voluntary system of standards and begin to define the system of regulation that would be necessary should widespread acceptance of such voluntary standards not be possible. This regulation should focus on quality control standards and proficiency testing in laboratories not specifically regulated now, and should not focus on personnel licensure.

DISCUSSION

Is there a problem in Nebraska?

Yes, the evidence presented would suggest that there is likely to be a problem with quality control of laboratory tests primarily in settings that do not have specific laboratory regulations. After review of the issue, the Board of Health recognized this harm. The strongest evidence comes from studies that have been done in other states. Most of the data from Nebraska were anecdotal and could not be generalized.

In what laboratory settings is the problem most likely?

In agreement with the Board of Health, I believe that the primary focus of this problem is in laboratories which currently have no specific regulatory oversight. Most of the examples of harmful practice given by the applicant group were drawn from such settings. Medicare regulations, state licensing regulations, and/or JCAH standards do provide a degree of regulatory oversight in hospitals and certified private labs. Little evidence was presented to indicate that the quality in hospital or independent certified labs was a problem in Nebraska. Most of the currently certified medical technologists now work in regulated laboratories, indicating that licensure is less needed in such settings and that current pressures serve to foster the hiring of trained and certified personnel.

An important argument by the applicants concerns the trends for performing laboratory tests outside of the hospital or certified laboratory because of three related forces: the pressure from DRGs to perform laboratory work outside the hospital; the Medicare regulation that prohibits a physician from charging for laboratory work sent out to another laboratory (these labs are billed directly by Medicare); and the development and marketing of office machines for laboratory procedures. There is little doubt about these trends and the potential they have for decreasing the reliability of test results, and they primarily affect the quality of tests in the currently unregulated setting.

Does the responsibility of the physician in these settings provide protection?

Yes, but not completely. The applicants argue that testing in physician's offices is unregulated. Opponents argue that it is adequately regulated because it is all done under the supervision of a licensed physician. This disagreement should be looked at with care. In contrast with their exposure to the details of taking x-rays, physicians do receive first-hand training in many of the subjective aspects of laboratory procedures. Medical students are commonly taught the subtleties of looking at blood and urine cells and bacteria through the microscope, and the technique of preparing blood, urine, and other body

fluids for examination. More importantly, they are routinely taught to put the interpretation of laboratory tests in the context of the whole patient, and to be skeptical knowing that the best of laboratories can give results that are misleading. Many of the examples given by the applicant group are examples of incompetent medical care and not evidence that the physician cannot supervise such testing. The responsibility of the physician for lab tests done under his or her supervision provides an important level of control. Opponents to the application would argue that this is sufficient. I am recommending that although it is an important level of control, it may not be enough to ensure reliable tests in such situations, hence the recommendation to begin a process that will assure quality control standards in all settings.

Will licensure of personnel increase costs?

Yes. The applicants argue that their licensure would be entirely supported by fees, and that there would be no cost to the general public. This claim must be viewed with skepticism. Although the licensure costs would be borne, in the first place, by fees from the licensee, the legislature should have every expectation that these fees would get passed on to the consumer of medical care. They would be a part of the cost of delivering medical care and would be reflected in the salaries paid to such personnel. In addition, in many settings higher-cost licensed personnel would be required to replace current unlicensed personnel, or current personnel would be required to undergo expensive training in order to keep performing some of their present functions.

The applicants also make the argument that the most-regulated labs have the lowest costs, and therefore regulation will not increase the cost of the tests. This involves a comparison of apples and oranges. The most-regulated laboratories are also the laboratories with the greatest volume of tests. The test volume is one of the most important determinants of the cost of tests. These are larger, independent laboratories that do tests for physicians over a very wide region, and they have the benefit of maximum economies of scale. It tells little to compare them with smaller labs that have the advantage of giving immediate results to the patient in the physician's office.

Dealing with the problem of quality control of laboratories will be an expensive proposition whether the approach is to regulate the personnel or to regulate the laboratories. Care should be taken not to look at licensure of personnel as a free approach.

Would licensing of personnel decrease access?

Yes, and this is an important concern. This will depend somewhat on how the limited-scope license is defined. Clearly, most physicians would not be able to hire a full-time, full-scope medical technologist. If the limited-scope license were defined to reduce the shifting of lab tests to

more remote labs, then this category of licensure would provide most of the protection inherent in the regulation.

It will be difficult to keep up with technology in drawing the line between tests requiring a full-scope medical technologist and those that can be provided by a limited-scope licensee. As mentioned, developments in the field of test automation and instrumentation are increasing the availability of tests (and the pressure to do tests) in the physician's office. With this availability, there is a real danger that "super machines" will lead to an attitude that the machines are infallible and can be operated without care. There is also the danger that the physician will get into more technology than can be managed or maintained. These tendencies should be recognized and dealt with. But it is also true that because of this technology, some tests are much simpler and can be done reliably with much less training. Modern antibody techniques have made available simple screening tests for many bacterial infections that require much less expertise than older culture methods. It will be very difficult for a two-tiered regulatory system to reliably divide tests into those that can be done by a limited practitioner and those that require a fully licensed person, and to keep up with rapid technological advances. We must be careful not to restrict the availability of rapid and reliable tests as they are developed.

Should patients have direct access to licensed laboratory personnel?

No, there should be no consideration of setting up laboratory technologists as independent practitioners. This is recognized by many medical technologists as well, and is not put forward as a major aspect of this application. However, at one point in the application process, the applicants argue for a direct access of the public to licensed medical technologists. In response to a question from the technical committee, they stated, "We feel that if the consumer were given direct access to these individuals he/she may have a better chance of controlling costs of his/her laboratory testing and he/she could also choose which laboratory performs the tests much the same way he chooses at which pharmacy to get his prescription filled." This attitude misstates the role of laboratory testing in the process of medical care in a manner that could prove dangerous. A laboratory test should only be considered in the context of the whole patient including the history and physical examination. To encourage laboratory tests outside of this context (except for a very narrow range of screening tests) would set up a chaotic situation that would likely delay appropriate medical care. Laboratory tests are very different from prescribed medications and the analogy does not hold.

How should the potential harm be addressed?

A Laboratory Proficiency Committee should be appointed to develop a statewide program of quality control for office-based laboratories; a

uniform program of proficiency testing, and a coordinated program of continuing education for laboratory professionals. This committee should attempt to evaluate and coordinate the current resources available for upgrading the skills and knowledge both of physicians who supervise laboratory procedures, and of laboratory personnel. In addition, a system of proficiency testing should be designed which would be instituted first on a voluntary basis, and later on a required basis if needed.

The costs of such a system will vary widely depending on the comprehensiveness of the program. As one example, we can look at the program currently in place in the state of Idaho.

Under this system laboratories must satisfy minimum standards pertaining to space, equipment, and supplies, and keep records on the identity of the personnel performing the tests as well as the results of these tests for at least two years. Laboratories are required to perform analyses of sample materials submitted to them by the Department consistent with rules and regulations. Laboratories consistently unable to demonstrate proficiency in the analysis of such samples would be denied certification under the voluntary system I am proposing.

SUMMARY

In summary, a system of licensing laboratory personnel is not recommended. Several non-governmental certifications are available so that those who hire laboratory personnel can judge their qualifications. Current regulations on hospital and independent laboratories serve to place well-trained and certified laboratory personnel in key positions and ensure the quality of the outcome. The physician has the responsibility for the quality of work done on his or her patients and under his or her supervision. The training and experience of physicians lends itself to such supervision, but recent trends in automation make this more difficult. A widely used, voluntary system of quality control and proficiency testing would provide an increased level of control while protecting the patient's access to timely and accessible laboratory information. Such a system should be mandatory if a voluntary system does not work, and should be developed carefully to provide the maximum assurance to the patient with the minimum of regulatory intervention.