House
Legislative
Analysis
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LICENSE MED. TECHNOLOGISTS

House Bill 4485 (Substitute H-2)
First Analysis (12-13-94)

Sponsor: Rep. Michael J. Bennane
Committee: Public Health

THE APPARENT PROBLEM:

According to a 1992 article in the Washington Post, until 1975 most medical tests were performed in hospitals or independent medical laboratories. But rapid advances in technology led to the development of products for out-of-hospital (and out-of-medical-laboratory) use, such as fingerstick glucose monitors that diabetics use to measure blood sugar and portable cholesterol-measuring devices. This, in turn, fueled the growth of labs in physicians' offices, nursing homes, shopping malls and other nontraditional settings. Although no one knows exactly how many medical laboratories exist (because there is no central national registry), estimates have ranged from 100,000 to 600,000 laboratories, many if not most of which are unregulated. According to the Washington Post article, in 1992, fewer than 20 states had laws governing labs; and until the passage of the federal Clinical Laboratory Improvement Act of 1988 (CLIA '88, to distinguish it from an earlier CLIA passed in 1967) the federal government regulated only about 12,000 labs nationally (namely, those that received reimbursement by Medicare or Medicaid, the federally subsidized programs for the elderly and the poor).

The federal reform bill was the result of a series of Wall Street Journal articles published in 1987 which disclosed that one of the most commonly performed laboratory tests -- the Pap smear, which is used to detect cervical cancer -- also was one of the most inaccurate, with an error rate of 20 to 40 percent. One of the chief reasons for the high error rate -- which killed many women who were erroneously told that they had normal test results -- was the proliferation of "Pap mills," cut-rate, high-volume labs staffed by poorly trained, underpaid workers who were pushed to read hundreds of slides daily. But then ensuing Congressional investigations revealed that the problem of bad tests was not limited to the Pap test nor confined to fly-by-night Pap mills. A 1989 investigation by the HHS Inspector General found, for example, that cholesterol testing was riddled with errors, that blood samples were drawn by untrained workers who left dirty needles lying around, failed to wash their hands between patients, performed the test incorrectly, and didn't know how to calibrate instruments. AIDS testing also was found to be error-plagued.

The result of these investigations was CLIA '88, which established minimum standards for lab quality, greatly expanding federal jurisdiction. For the first time all labs that test human specimens (with a few exceptions) were required to be licensed and inspected by the federal government every two years. That means that labs in shopping malls, home health agencies, nursing homes, prisons, student health clinics, and, most important, doctors' offices, will be regulated. Only those medical tests with an "insignificant risk of an erroneous result" will be exempt, limits are set on the number of Pap smear slides a technician can read in a 24-hour period, and lab employees are required to meet minimum educational standards and pass proficiency tests.

However, consumer groups and some professional organizations (notably the American Society for Clinical Laboratory Science, formerly the American Society of Medical Technology) have charged that the new federal regulations weakened, rather than strengthened, the oversight of medical labs and testing. At the request of the Michigan Society of Medical Technologists, legislation has been introduced that would license medical laboratory workers.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to prohibit individuals from doing most laboratory tests (defined in the bill) without a license, "grandfather" in existing lab workers, establish three licenses with three defined levels of practice, set minimum

licensing requirements, create a board of laboratory testing, and impose certain sanctions for violations.

"Laboratory test." The bill would define a "laboratory test" to mean "a microbiological, serological, chemical, hematological, radiometric, cytological, biophysical, immunological, histological, genetic, or other clinical or anatomic pathological examination or procedure" done on human specimens (whether body organs, tissues, or fluids) that provided information for the diagnosis, prevention, monitoring, or treatment of a disease or assessment of a medical condition or predisposition.

A "laboratory test" would not include the following:

* certain "waivered" tests, as defined in federal regulations (these would include such tests as home pregnancy tests and blood sugar tests done at home by people with diabetes);

* in vivo (that is, done on a living body) diagnostic imaging (such as ultrasound done during pregnancy or labor);

* noninvasive vascular diagnostic studies;

* the collection, handling, and preparation of body fluids or microbiology culture specimens for laboratory test; or

* tests whose results were used only for evidentiary purposes in court proceedings.

License levels. The bill would establish a three-tiered licensure system analogous to existing distinctions between medical technologists (called, in the bill, "laboratory scientists"), medical technicians ("laboratory technicians"), and medical assistants ("laboratory practitioners"). The lowest level of licensure, with the most restricted scope of practice, would be the laboratory practitioner, the middle level would be the laboratory technician, and the highest level would be the laboratory scientist. The two lowest levels of worker would be able to practice only under predetermined criteria established or approved by either the laboratory director or a laboratory scientist, who would prepare or approve information that provided step-by-step descriptions of how lab tests were to be performed. These "testing protocols" would then have to be followed by anyone performing tests at that laboratory. The highest level of worker, the laboratory scientist, however, could make decisions without these predetermined criteria and could independently identify causes of improperly done tests and decide either how to get correct tests results or to solve problems caused by incorrect tests.

Laboratory practitioners would be able to do laboratory tests (including automated tests) according to established protocols, compare patient data to established or approved reference ranges, and do arithmetic or algebraic calculations according to protocols. Laboratory technicians would be able to do what laboratory practitioners could do, and, in addition, could, using established or approved criteria, evaluate data, do arithmetical, mathematical, or statistical calculations according to protocol, and, using established strategies, identify and correct the causes of improper test performances. Laboratory scientists could do anything that laboratory practitioners and technicians could do, as well as establish the criteria under which a practitioner or technician would practice.

Licenses and requirements. Licenses would be effective for three years. The bill would prohibit licensees from doing anything outside of the scope of practice of the level for which they had been trained.

Applicants for licenses at each of the three levels would have to have "sufficient knowledge essential to the safe and competent practice of [their] profession." The board could accept national certification as evidence that an individual had enough knowledge to meet this requirement. However, the board could accept only certification that required successful passage of a competency-based examination validated by the certifying organization.

In addition, applicants for a laboratory practitioner's license would have to have completed high school, an accredited educational program at the laboratory practitioner level (or at a board-approved equivalent level), and a year of supervised, full-time board-approved laboratory experience in the three years immediately preceding the date of application.

Applicants for a laboratory technician's license would have to have successfully completed or attained any one of the following: (a) an accredited educational program at the medical laboratory technician, clinical laboratory technician, or

histologic technician level; (b) sixty hours of board-approved college course work and a year of supervised, full-time board-approved laboratory experience in the three years immediately preceding the license application; or (c) licensure as a laboratory practitioner and four additional years of supervised, board-approved laboratory experience.

Applicants for a laboratory scientist's license would have to have completed or attained one of the following: (a) an accredited educational program at the medical technologist, cytotechnologist, clinical laboratory scientist, or histotechnologist level; (b) ninety hours of board-approved college course work and two years of supervised, full-time board-approved laboratory experience in the four years immediately preceding the license application; or (c) sixty hours of board-approved college course work and four years of supervised, board-approved laboratory experience.

Limited licenses. The board could grant (and revoke or suspend) a limited license at any of the three levels of practice defined in the bill, in addition to existing sanctions under the health code. A limited license would be effective for four years. People with limited licenses could provide laboratory test services only under the supervision of either a licensed physician (either M.D. or D.O.) or someone licensed under the bill to do the test.

License renewals. Laboratory scientists and laboratory technicians applying for their license renewal would have to either complete 30 hours of continuing education or be recertified by a board-approved national certification agency. Laboratory practitioners who applied for their license renewals would have to have either ten hours of continuing education or be recertified by a board-approved national certifying agency.

"Grandfather" clause. The bill would allow people who had been trained in laboratory testing or who had practiced laboratory testing for at least a year to be licensed under the bill if they applied for a license within a year after the bill took effect. The board would issue a license either for the level at which the individual either was currently employed in a laboratory or was trained or nationally certified to practice. Anyone applying for a renewal of a "grandfathered" license would have to meet the bill's continuing education requirements.

Board of Laboratory Testing. The bill would create a seven-member Michigan Board of Laboratory Testing. The board would have to have at least two public members and at least one member engaged in each of the practice levels under the bill. The professional members would have to have ("among them") anatomical and clinical pathological testing experience and would have to meet the health code's general requirements for health professional board membership. Within 180 days after the bill took effect, the board would have to submit for public hearing rules to implement the bill.

The board would promulgate rules specifying the qualifications of physicians authorized to provide supervision under the bill, and would annually review the supervision of people licensed under the bill. The board could revoke or suspend a limited license if the limited licensee lacked adequate supervision.

Exemptions. The bill would exempt from its provisions the following:

* teachers or researchers, or students enrolled in courses involving laboratory testing, where the test results weren't used for "diagnosis, prevention, monitoring, or treatment of a disease or assessment of a medical condition or predisposition;"

* other statutorily recognized professionals, so long as they didn't claim to be licensed under the bill;

* certain "perfusionists" (people who operate blood circulating equipment, such as, for example, during surgical operations) under specified conditions;

* people doing "point-of-care testing" (lab tests performed in licensed hospitals or freestanding outpatient surgical facilities that met certain standards, basically that the tests were performed on or near the patient because the test results were so critical to the patient's immediate care) under specified conditions; and

* certain "respiratory care practitioners" under specified conditions (certified respiratory therapy technicians, registered respiratory therapists, and certified or registered pulmonary function technologists).

Client confidentiality. Communications between licensees and clients and their test results would be confidential and could not be disclosed to a third party without the client's consent or as otherwise required by law. "Third party" would not include licensed health professionals who requested the laboratory test(s) for the client.

Fees. The bill would establish annual fees for each level of lab worker: $10 for laboratory practitioners and $20 for laboratory technicians and scientists and for limited licenses. There also would be a $20 application processing fee, and a $10 temporary license fee.

MCL 333.16131 et al.

BACKGROUND INFORMATION:

Training and terminology. Generally speaking, there are three levels of non-physician medical laboratory workers, distinguished by their level of education or training and allowed practice. The education and training of these lab workers -- and their professional and certifying organizations -- appear to divide along the lines of whether or not their training is primarily "on the job," academic, or proprietary.

The International Society of Clinical Laboratory Technicians represents and certifies all three levels of lab worker, with its members apparently mostly trained on the job regardless of level. The American Society for Clinical Laboratory Science (formerly the American Society for Medical Technology) represents and certifies (either itself or through its affiliate, the National Certification Agency for Medical Laboratory Personnel) medical technologists (which it calls "clinical laboratory scientists") and medical technicians ("clinical laboratory technicians), whose members tend to hold bachelor's or associate's degrees, respectively, in clinical laboratory science. A third organization -- the American Medical Technologists -- represents and certifies all three levels of worker, though its members apparently tend to be educated in proprietary programs. Finally, there is an organization of physicians (the American Society of Clinical Pathologists) which represents pathologists but also offers associate membership to medical technologists and certifies not only medical technologists but also medical laboratory technicians, cytotechnologists (baccalaureate level laboratory workers who specialize in cytology, examining cells for evidence of cancer), histotechnologists and histotechnicians (lab workers at the high school or associate level and the bachelor's level, respectively, who use different levels of techniques to prepare tissue samples for microscopic examination by pathologists), phlebotomists (lab workers trained to collect blood samples, and, in some cases, to do additional tasks such as bed-side glucose testing or specimen handling and storage).

Laboratory settings. Traditionally, medical laboratories were either in hospitals or were independent, free-standing clinics; all were under the direction of a pathologist, a licensed physician who has completed a residency program in pathology, and were staffed with medical technologists or medical technicians. Non-traditional laboratory settings include physician office labs (POLs), urgent care centers, health and exercise facilities, and cholesterol screening in shopping malls. These kinds of settings typically use nurses, medical assistants, or on-the-job trained workers rather than medical technologists or technicians and are under the direction of a pathologist.

FISCAL IMPLICATIONS:

Fiscal information is not available.

ARGUMENTS:

For:

Proponents of the bill argue that current laboratory regulations -- including current regulations under the 1988 federal lab reform law -- allow untrained or formally uneducated individuals to perform tests. Given the vital importance of accurate, reliable lab test results to the diagnosis, treatment, and monitoring of disease, it is imperative that lab workers meet at least minimum standards of education and training so as to protect the safety and health of consumers and their health care providers who depend on lab tests. While studies have shown a decrease in lab errors when lab workers are required to meet minimum qualifications, economic pressures on labs -- and physicians' reluctance to have their office labs regulated and inspected -- serve as a counterforce to the drive to require adequate education and training standards for lab workers.

Medical labs are big business. According to a 1992 Washington Post article, "Americans spend $30 billion annually on the 6 billion clinical lab tests performed annually -- 4.5 percent of the total national health care spending, according to [the federal Department of Health and Human Service]." For a doctor, having a lab in the office is both convenient and lucrative: according to the Washington Post article, one study found that revenue from office labs accounts for 8 to 12 percent of a physician's income depending on the specialty. Federal regulations (under CLIA '88) allow labs performing "moderately complex tests" (about 75 percent of all procedures) to use, until 1997, employees with only a high school education and on-the-job training. Since many labs are moneymakers first and serve the public health second, there are great economic pressures to hire unqualified (and therefore cheaper) workers to perform lab tests in an effort to cut costs. Without more stringent state regulations, labs will be free to hire staff without any background related to laboratory testing. The federal rules specify a high school equivalency, but not even a high school college preparatory program or other curriculum with a background in science and mathematics.

Although the state of Michigan currently licenses laboratories serving six or more physicians, it requires only the lab director to meet certain standards and not the workers actually performing the tests. This means that most labs -- the overwhelming number of which are physician office laboratories -- are not regulated. In fact, according to one estimate, only some 425 of the estimated nearly 4,000 labs in the state fell under state regulation. But even this regulation of only some eleven percent of the state's labs was suspended, pending implementation of the federal law (which was delayed for two years, from 1990 to 1992).

As the Congressional investigations in 1987 showed, there are serious problems resulting from the poor or nonexistent regulation of medical labs and workers, including physician office labs. For example, the American College of Obstetrics and Gynecology found that 15 to 40 percent of Pap tests are inaccurate -- which means that this vital cancer screening test can be wrong two out of five times a woman goes for an annual exam. And the problem with poorly trained lab workers isn't restricted only to the so-called "Pap mills"; labs in doctors offices, long unregulated by the state or federal government, also have problems. A 1992 Food and Drug Administration study of 100 physician office labs in Michigan reported, for example, that 75 percent of the problems encountered with the use of laboratory devices stemmed from human factors. And in a December 1993 report, the American Medical Association listed "quality control (or lack of it)" -- with untrained personnel who were unfamiliar with lab terminology and testing practices performing tests -- as "the most frequently identified and most serious problem" of 13 specific problems found in physician office labs. Conversely, there is evidence that improved lab testing is associated with training and experience of the lab workers. For example, a 1991 controlled study published in the Archives of Pathology and Laboratory Medicine demonstrated that labs requiring minimum academic degrees and over 24 months of experience of people doing the studied tests showed improved performance. Similarly, a report in the Clinical Laboratory Science Journal reported that error rates on proficiency testing decreased in some cases as much as 50 percent following implementation of personnel standards in Tennessee.

By providing minimum qualification for clinical laboratory workers, state licensure would ensure that lab tests were performed with the maximum of accuracy and reliability. The bill would fill the regulatory void which currently exists at the state level and would improve on the inadequate minimum standards established by the federal government.

Against:

Opponents of the bill argue several points. In the first place, since the federal reforms set into motion by the 1988 law haven't yet taken effect, they argue that it would be premature to create yet another layer of bureaucracy at this point. What is more, much of the emotional force of some of the arguments for the bill depend on tragic anecdotes in which people died because of mistakes in lab tests or test results. But licensure won't prevent people involved in lab testing from ever making any mistakes and certainly, licensure hasn't prevented currently licensed health professionals from making -- sometimes tragic -- mistakes. What is more, the current regulation of health care professionals has inspired little public confidence in the ability of the present underfunded and understaffed process to protect the public's health. There also is the fact that with increasingly automated medical technology, highly trained lab workers aren't needed, since the machines do virtually all of the

work. Finally, it can be argued that licensure will increase health care costs and, possibly, decrease the pool of available lab workers. While it may very well be the case that there is a need to protect the quality of testing, state licensure -- particularly in the face of federal regulations -- would be a costly mistake.

Reply:

In response, proponents of the bill argue that the federal law has been so weakened by intense lobbying by special interest groups that additional protections for consumers are needed. So waiting for the full effect of the implementation of the federal law will not mean that additional state regulation still will not be needed. And although licensure certainly will not prevent all mistakes, it can work to minimize such mistakes by requiring minimum educational and training standards and would provide a mechanism for getting rid of bad lab workers by withdrawing their licenses. The regulation of health professionals, moreover, has recently been changed in Michigan to provide more effective regulation and adequate funding for the regulators, and lab workers should be added to this process. With regard to advances in lab technology, while it is true that advances have greatly simplified testing in some senses, the increased complexity of the technology also requires extensive training for the workers who use them. They must be familiar with instrument operation, maintenance, and malfunction, as well as the interpretation of patient and quality control data. Finally, a number of studies refute the notion that licensure will increase costs and reduce the number of lab workers. In fact, by providing a "career ladder," the bill could attract more people to the field, while eliminating inaccurate testing -- which results in repeat testing, wrong diagnoses, and delayed treatment -- not only reducing the risk for human tragedy but also reducing health care costs.

POSITIONS:

The Michigan Society for Medical Technology supports the bill. (12-13-94)

The Service Employees International Union, Council 35, supports the bill. (12-13-94)

The American Association of Retired Persons (AARP of Michigan) supports the bill. (12-13-94)

The Michigan Association of Laboratory Science Educators supports the bill. (12-13-94)

Representatives of the following testified (or submitted testimony) in support of the bill (12-8-94):

The Michigan Federation of Teachers and School Related Personnel

The National Organization for Women -- Michigan Conference

The American Society for Clinical Laboratory Science (formerly the American Society for Medical Technology)

The Michigan State Medical Society opposes the bill. (12-13-94)

The Economic Alliance for Michigan opposes the bill. (12-13-94)

Representatives of the following testified (or submitted testimony) in opposition to the bill (12-8-94):

The Department of Public Health

The Michigan Society of Pathologists