MINUTES

MONTANA SENATE
53rd LEGISLATURE - REGULAR SESSION

COMMITTEE ON PUBLIC HEALTH, WELFARE & SAFETY

Call to Order: By Senator Dorothy Eck, Chair, on March 5, 1993, at 3:00 p.m.

ROLL CALL

Members Present:
Sen. Dorothy Eck, Chair (D)
Sen. Eve Franklin, Vice Chair (D)
Sen. Chris Christiaens (D)
Sen. Tom Hager (R)
Sen. Terry Klampe (D)
Sen. Kenneth Mesaros (R)
Sen. David Rye (R)
Sen. Tom Towe (D)

Members Excused: None.

Members Absent: None.

Staff Present: Tom Gomez, Legislative Council
Laura Turman, Committee Secretary

Please Note: These are summary minutes. Testimony and discussion are paraphrased and condensed.

Committee Business Summary:
Hearing: HB 241, HB 27, HB 211
Executive Action: HB 27, HB 211

HEARING ON HB 241

Opening Statement by Sponsor:

Rep. Bill Strizich, House District 41 in Great Falls, said HB 241 will establish minimum standards for clinical laboratory practitioners, which includes medical technologists, specialists and technicians. There are approximately 900 of these practitioners currently working in Montana. Laboratory scientists perform a wide range of duties and testing, but there is no licensure requirement in Montana, although most people assume they are licensed. Their work has direct and serious effects on the consumers of these services, and this is the key issue of HB 241. Rep. Strizich said the bill endorses current practice, and requires no general fund dollars.

Proponents' Testimony:

Susan Reavis, President of the Montana Society for Medical Technology, said there are 28 states that have licensure laws, and seven more are pursuing licensure. This is the number one objective of the Society, and a licensure committee was formed and the bill was drafted. Now that physicians are relying more and more on laboratory tests for the diagnosis and treatment of patients, it is imperative that those performing these tests be qualified. Montanans should be guaranteed quality laboratory testing.

Anne Weber, President-elect of the Montana Society of Medical Technology and Chair of the Laboratory Coalition Group, said she is currently employed as a lab manager in Helena. Ms. Weber said their scope of practice was defined on Page 5 of the bill. There are three levels of practice outlined: clinical laboratory scientist, clinical laboratory specialist, and clinical laboratory technician. HB 241 would require a clinical laboratory practitioner to be licensed. There are some exemptions to the bill, including pathologists and physicians, other licensed professions, and waive tests as defined by the federal government. The Clinical Laboratory Improvement Amendments (CLIA) rules have defined simple laboratory tests, but is not a personnel regulator.

Russ Morrison, Manager of a Billings hospital laboratory and President of the Montana Chapter of the Clinical Laboratory Management Association, said Section 6 of HB 241 creates a board which will administer the bill. Clinical Laboratory Scientists will be required to have a baccalaureate degree and completion of a certifying examination. Clinical Laboratory Specialists will be required to have a baccalaureate degree and completion of a certifying examination in that individual's specialty. Clinical Laboratory Technicians will require an associate degree or six semester hours of relevant education, and completion of a certifying examination approved by the board. Mr. Morrison said HB 241 would not limit services in Montana, and that licensed personnel produce quality products for the consumer much sooner than individuals who are not specifically trained.

Kay Crull, Medical Technologist and a Laboratory Manager of the American Red Cross Blood Bank, said HB 241 provides a grandfather clause for any person currently working to continue functioning at their current level. Ms. Crull said they intend to improve the quality of health care in Montana by requiring continuing education of all licensed personnel so they can keep up to date with the dynamic field of medicine.

Dr. Sam Dax, Pathologist at Montana Deaconess Medical Center in Billings, said he is a consumer of health care as well as a physician. Dr. Dax said physicians depend upon laboratory tests, and they must be absolutely accurate. It is assumed that the individual running the laboratory tests is doing it correctly,

and life and death decisions are made based on these results. HB 241 enhances the chances that the tests will be done correctly, and the American Society of Pathologists supports the bill.

Dr. Keith Popovich, internist and Medical Director of Respiratory Therapy at a Montana hospital, said the difference is "night and day" between someone who is licensed and someone who has minimum standards of training. It is important that laboratory technicians and scientists understand when results are out of range to make judgement decisions. Dr. Popovich said this kind of insight comes from a higher level of training and certification.

Karen Searle, Laboratory Manager at Livingston Memorial Hospital, provided written testimony. (Exhibit #1)

Chuck Volf, Medical Technologist from Great Falls, told the Committee of an in-house trained individual misdiagnosing the results from a pap smear on two separate occasions for cervical cancer. Without insuring the licensure of laboratory technicians, this kind of incident will become more common.

Amy Gessaman, Medical Technologist at Montana Deaconess Medical Center, provided written testimony. (Exhibit #2)

Marsha Waterman, Medical Technologist, President-elect of the Clinical Laboratory Management Association and administrative director of a large private laboratory, said she has found the cost issues in a laboratory are very important. Ms. Waterman said there would be no negative economic impact on her facility.

Anita Osborne, consumer from Great Falls, said she has lupus, a chronic disease of the immune system. When life and death decisions are being made on the basis of a blood test, HB 241 will protect the consumers of health care services. Everyone in Montana deserves to have confidence in the health care they are receiving from providers.

Jerry Loendorf, Montana Medical Association, said the Association supports HB 241. Mr. Loendorf went over the amendment (Exhibit #3) to exempt profusionists, the individual who operates the heart/lung machine during surgery. The exemption is needed so the profusionists can continue to function as they have been.

Opponents' Testimony:

Jim Ahrens, President of the Montana Hospital Association, said that Rep. Strizich had been willing to address the concerns of the Association. They oppose HB 241 because it would be another added cost, it would dictate how hospitals would be operated, and there would be a duplication of efforts with federal standards. Mr. Ahrens said the federal standards for hospital personnel are adequate and HB 241 calls for "more government and more

regulation." This bill will contribute to hospital costs, it will hamper recruiting, and increase licensure fees.

Harry Uffolussy, profusionist from Missoula, submitted a letter to the Committee. (Exhibit #4) Mr. Uffolussy said there was a point-of-care issue that had not been addressed. If clinical profusionists are prohibited in any way from providing services in the operation room, profusion will regress by fifteen years. Many different tests can now be done in the operating room, and it is essential that certain tests be performed at the point of service in a timely fashion which will cut hospital costs. He suggested that there are maybe other areas which were overlooked in HB 241. Their primary concern is what is best for the patient, and he urged the Committee to consider the amendments and the exemption of the profusionists.

Carl Hanson, Administrator of the Ponderay Medical Center, said the Center is considered a rural facility. He asked the Committee to consider the amendments offered by Rep. Strizich. Mr. Hanson said HB 241 will create problems with bureaucracy, and there are already too many regulations.

Jerry DeVos, American Society for Extracurritorial Technology, said the licensure process is good, and SB 241 is a good bill. However, he has concerns that it could prevent on-site tests required by profusionists. Mr. DeVos said the timely results of the tests they do are imperative for the patient. The equipment and tests covered have all been designed for profusionsists and other professionals, and the point-of-care centers follow the same quality assurance guidelines as clinical laboratory test sites. The difference is that profusionists are running the tests. Any other method would result in a less timely manner of gathering test results, increasing the cost of health care to the patient, and increasing the length of the operation.

Informational Testimony:

Karen Bryys, Mallinkrodt Censor Systems, said they manufacture equipment for point-of-care testing which is used by profusionists and others who are not licensed by the state. She asked the Committee to consider the unintended consequences of HB 241. Technology has changed a lot, and it is being designed to be used by non-laboratorians. Much of the human judgement has been removed. Only less than 3% of point-of-care tests require less than a three minute turn around, and she asked the Committee to consider the amendments. As far as national trends are concerned, there is a trend towards licensure with a change for point-of-care testing. She urged the Committee not to complete work on HB 241 until the affected parties reach an agreement on the amendment language. Ms. Bryys provided information for the Committee. (Exhibit #5)

Opponents' Testimony:

Chuck Brown, Laboratory Manager at the Teton Medical Center in Choteau, said there are horror stories about individuals in any field or level of medicine. Mr. Brown said the problem with HB 241 is that it would limit the supply of applicants to jobs in Montana hospitals, and health care costs will increase as a result of this. He said that quality was not an issue because there are already proficiency standards and regulations.

Thomas Nordwick, Administrator of Sheridan Memorial Hospital and Nursing Home, provided written testimony. (Exhibit #6)

Questions From Committee Members and Responses:

Sen. Christiaens asked Dr. Dax to address the CLIA standards. Dr. Dax said the CLIA standards are institutional standards that do not provide for individual qualifications.

Sen. Christiaens asked how the CLIA standards would affect laboratories if HB 241 passed. Dr. Dax said that he thought HB 241 would "mesh" with the CLIA standards, and will enhance the CLIA standards.

Karen Bryys said CLIA standards put the responsibility on the laboratory director to choose appropriate personnel to run certain tests. It must be documented that the individual has been trained, and that they understand the test method. Individuals are retrained every six months and reevaluated for competency.

Sen. Christiaens asked Mona Jamison to respond. Mona Jamison, Laboratorians for Licensure, said that CLIA regulates facilities. HB 241 regulates personnel. Ms. Jamison said that she was not suggesting there was no overlap. Under CLIA, there must be a licensed medical technologist present in all hospitals doing any complex testing, and to that extent, HB 241 meshes with CLIA. CLIA allows for individuals with high school degrees to perform tests, but HB 241 will not allow for that. Ms. Jamison said that federal law does not license people within the state where they perform various functions because that is a legitimate power of the state.

Sen. Christiaens asked Mr. Uffolussy if he had been aware of the amendment. Mr. Uffolussy said that until yesterday, he had not even been aware of the bill. He said that he would like to have input in the amendment, so that their (profusionists) scope of practice in the operating room would not be limited. If HB 241 were passed without the amendment, they would not be allowed to do any laboratory work in the operating room.

Sen. Towe asked Mona Jamison if HB 241 had been through a Sunrise (audit). Ms. Jamison said it passed unanimously through the Sunrise (audit).

Sen. Towe asked Ms. Jamison if HB 241 would limit licensure to those individuals with a baccalaureate degree. Ms. Jamison said there were three categories of licensure, and the Laboratory Technicians would be required to have a two year associate degree.

Sen. Towe asked Ms. Jamison what HB 241 did to protect the people of Montana that the federal law does not do. Ms. Jamison said HB 241 would regulate the quality of the personnel performing the tests.

Sen. Towe asked Ms. Jamison if the federal law already did that. Ms. Jamison said that CLIA regulates the facility, and does not regulate or license the personnel. State law regulates and licenses personnel.

Sen. Towe asked Ms. Bryys to respond. Ms. Bryys said Arizona had dropped their effort to license medical technologists because CLIA was sufficient.

Sen. Eck asked if there were a Board of Health in Arizona which regulates and inspects facilities. Ms. Bryys said there was no Board of Health in Arizona.

Sen. Eck asked Ms. Bryys if it was the federal government who did the inspections in Arizona. Ms. Bryys said the state contracts those services with the federal government. CLIA fees pay for the inspections.

Sen. Klampe asked Ms. Bryys if licensed technologists were not necessary for point-of-care testing. Ms. Bryys said there are 28 allied health professions represented by CLIA, most of whom do testing and may not be licensed.

Sen. Klampe said he was talking specifically about point-of-care testing. Ms. Bryys said the allied health professionals represented by CLIA would no longer be able to do point-of-care testing if HB 241 passed.

Sen. Klampe asked Ms. Bryys if it were true that point-of-care testing does not require a licensed technologist because the machines do all the work. Ms. Bryys said "absolutely" and that there were many published studies to prove this.

Sen. Klampe asked if an amendment would suffice to take care of this. Ms. Bryys said it would.

Sen. Mesaros asked Ms. Jamison to clarify the amendment regarding the profusionists. Ms. Jamison said they were not happy with the exception of profusionists, but they support the amendment. Under HB 241, profusionists are exempt. Ms. Jamison said HB 241 does not regulate point-of-care testing. HB 241 regulates the personnel. Ms. Jamison said that the amendment is not necessary because the bill does not address point-of-care testing. CLIA

regulates point-of-care testing.

Dr. Uffolussy said when point-of-care testing is referred to, it does not just mean performing a test at the point of care. It means that the people who do the testing should be able to do the tests without requiring a medical technologist to be present. Dr. Uffolussy said point-of-care testing contains health care costs, and it meets CLIA standards.

Chairman Eck said additional work needed to be done on HB 241. She urged the parties involved to work out a compromise.

Sen. Towe said there were some serious questions that need answers.

Chairman Eck said that there would be ample time taken for executive action, and appropriate parties should be present at that time.

Closing by Sponsor:

Rep. Strizich said there does not need to be much more work on this bill because it has been worked on for over a year. He said most of the questions could be explained very well and in detail. Rep. Strizich said he was "surprised" at the people who claim to have been left out of the discussions. He said the amendment drafted is an excellent one, and it addresses the problems raised. Rep. Strizich asked that the Committee not let "eleventh hour confusion" kill HB 241. Regarding added costs and added bureaucracy, nothing more is being done with HB 241 than is currently done. Federal regulations that allow high school graduates to do complex laboratory work are "not good enough for Montana." Profusionists are a small, but greatly respected, group and the amendment clearly exempts them from HB 241. Rep. Strizich said it is the one exemption that everyone feels comfortable with. HB 241 does not address point-of-care testing, and it can continue. HB 241 addresses the accurate interpretation of the tests done so that physicians can make an informed decision. Regarding the testimony from Karen Bryys, Rep. Strizich said it was "a bale of horsefeathers from out of state" to protect their interests. By replacing humans with machines, as was suggested, judgements are made with no reference to science, and humans will never be removed from medicine. Rep. Strizich said workers are doing a "wonderful job" and the intention of HB 241 is not to produce more government regulation or higher costs. He emphasized that HB 241 had a full hearing, extensive testimony, and a long Floor debate in the House, and the bill is in "good shape". They have come a long way to try and accommodate the needs of rural hospitals, rural clinics, and the profusionists.

HEARING ON HB 27

Opening Statement by Sponsor:

Rep. Carolyn Squires, House District 58, said during the last legislative session, a bill was passed licensing respiratory care providers. HB 27 cleans up some of the mistakes in that bill. The respiratory care providers would like an annual renewal date for licenses of May 1. Also, the language would be made gender neutral. Lastly, HB 27 allows for a temporary permit.

Proponents' Testimony:

Patricia Johnson, member of the Board of Respiratory Care Practitioners, provided written testimony. (Exhibit #7)

Opponents' Testimony:

None.

Questions From Committee Members and Responses:

Sen. Christiaens asked why what HB 27 does could not have been accomplished by rule. Helena Lee, Administrative Assistant for the Board of Respiratory Care Practitioners, said that the statute stated the renewal date had to be a year after the issuance of the license. Therefore, every licensee had a different expiration date, and the law had to be changed to allow for a uniform date.

Sen. Christiaens asked Helena Lee how many respiratory therapists were licensed in the state of Montana. Ms. Lee said there were 341.

Sen. Christiaens asked Ms. Lee if all of them would renew their licenses on one day. Ms. Lee said the license would expire on May 1, but they would have 90 days to renew the license. All licensees would also have six weeks before May 1 to renew.

Sen. Christiaens asked Ms. Lee if she was familiar with other licensure requirements, and if they all worked in the same way. Ms. Lee said she worked with three other boards, and this procedure was "normal," to have one renewal date. She was not aware of any "date of issuance" expiration dates.

Sen. Towe asked Ms. Lee about the language on Page 2, "or is a student who has graduated within six months of application for a license". Sen. Towe said he assumed that if a student who had graduated and had applied for a license within six months of graduation, he was okay. Ms. Lee said that was correct.

Sen. Towe said that was not what the language says, and he would draft an amendment to take care of it.

Closing by Sponsor:

Rep. Squires said there are many nurses in Montana who renew their licenses on May 1, so this bill would not be overwhelming. She encouraged the passage of HB 27, and said she would be pleased with Sen. Towe's amendment to clarify the language. Sen. Franklin will carry the bill on the Floor of the Senate.

HEARING ON HB 211

Opening Statement by Sponsor:

Rep. Vivian Brooke, House District 56, said HB 211 provides licensure for residential in-patient hospital facilities. It is an important piece of legislation, and there is no cost for the bill. HB 27 was requested by the Hospice Association. Licensure proceedings need to begin to fill the gap for terminally ill persons who do not need the intensive care provided by hospitals or nursing homes. Rep. Brooke provided information from the Montana Hospice Organization. (Exhibit #8)

Proponents' Testimony:

Bonnie Adee, Montana Hospice Organization, said there is need for in-patient hospice facilities in Montana. There were many referrals to hospices, where the hospices were not prepared to offer care for a variety of patients. Hospice providers must look at in-patient hospice care to meet the needs of patients. The state of Montana has licensed hospice programs since 1983 so there would be minimum hospice standards. Seven of the nineteen programs that Rep. Brooke talked about are not Medicare certified, but are governed by state licensure. Licensure assures quality care the public deserves. Ms. Adee called the Committee's attention to the language on Page 7, Lines 8-11 of HB 211 regarding federal regulations. HB 211 offers options for hospices that are licensed but not Medicare certified, in Lines 12-14. These facilities could be managed by licensed hospices. There are no in-patient facilities in Montana, and they feel that as providers, they are being responsible to request licensure before it is required. Cost to Medicaid patients would not increase with licensure. Also, hospice providers are willing to pay higher fees to off set the costs of a survey. The language of HB 211 is intended to ensure quality but not exclude providers. Certificate of need does not apply to hospices. Ms. Adee urged the Committee to pass HB 211.

John Flink, Montana Hospital Association, said hospices are closely affiliated with hospitals. Hospices are seen as a very humane and cost effective way to provide treatment to individuals who need hospice care.

Mike Craig, Licensure Bureau Chief of the Department of Health

and Environmental Sciences, said the Department supports HB 211 because they believe it is model legislation. The hospice organization is doing the bulk of the work to research and develop standards in this area. HB 211 creates two types of hospices, the in-patient facility which would have to meet Medicare regulations and the residential facility that would not have to meet Medicare regulations but state-defined regulations. Hospices are needed facilities. Mr. Craig said that Sen. Towe had a bill about licensing personal care facilities, and it is important that conflicting messages are not sent to the legislature. The Department is supportive of that legislation as well. Sen. Rye is carrying a bill about out-patient facilities which is a different concern. The Licensure Bureau is in a situation where it must prioritize, and HB 211 fits in nicely. Much of the work will be done for the Department, and there is not much growth foreseen in this area.

Opponents' Testimony:

None.

Questions From Committee Members and Responses:

Sen. Christiaens asked Mike Craig about the removal of statutes requiring inspections, and yet there are three bills that require inspections. Sen. Christiaens asked how the state could afford to do these inspections. Mr. Craig said this is not as much about affordability as it is about liability. In the area of out-patient facilities, the Department's liability still exists, and they would like that type of licensure exempted. There are many types of out-patient facilities. Mr. Craig said the appearance is that the Department is sending conflicting messages, but they are trying to prioritize. In this area, it is not a question of affordability.

Sen. Christiaens asked Mr. Craig if there would be an increase in their workload, even though no additional money was appropriated to the Department. Mr. Craig said there was "no doubt about it".

Sen. Christiaens asked Bonnie Adee if the hospice programs were all receiving Medicaid reimbursement. Ms. Adee said only those programs that were Medicare certified are eligible to receive funding from Medicaid. That covers 12 hospice programs in the state.

Sen. Christiaens asked Ms. Adee if that were the reason for HB 211. Ms. Adee said it was not.

Sen. Christiaens asked Ms. Adee if HB 211 were passed, if those other facilities could receive Medicaid reimbursement. Ms. Adee said no, that is a federal certification process.

Sen. Christiaens asked Ms. Adee if all hospice programs cared for

AIDS patients. Ms. Adee said, to her understanding, no hospices in Montana would refuse care to an individual with AIDS, regardless of if the hospice is all volunteer or funded.

Sen. Towe asked Ms. Adee if there were a licensing fee provision in HB 211. Ms. Adee said a small licensing fee is paid now, and they are looking for that to increase.

Sen. Towe asked Mike Craig to respond. Mr. Craig said the Department of Health is expecting a fee increase. They expect the Legislature to tell the Department with HB 2 to have a fee-based system for all licensure. That is preferred.

Sen. Towe asked Mr. Craig if a larger fee were expected to be collected if HB 211 passed. Mr. Craig said no, it would not be directly tied to the passage of this bill.

Sen. Towe asked Ms. Adee about the two types of hospice facilities, and at what point a residential facility became an in-patient facility. Ms. Adee said it would be an in-patient facility that could care for three or more patients.

Sen. Towe asked Ms. Adee if three or more residents would be an in-patient facility. Ms. Adee said that was the definition used.

Mike Craig said the bill might be confusing. The in-patient facility will have to meet standards as defined under federal law. A residential facility would not, other than fire regulations.

Sen. Towe said the definition on Page 7, Lines 14-16 specifically states that a "residential hospice facility... houses three or more hospice patients". Sen. Towe asked Mike Craig if the facility has three or more patients, does that determine whether or not the facility is in-patient. Sen. Towe said only Medicare certification qualifies an in-patient facility. Mr. Craig said that was correct.

Sen. Towe asked Mike Craig if a residential facility was any facility with three or more patients. Mr. Craig said that was correct.

Sen. Towe asked Mr. Craig that if there were less than three patients, a license would not be necessary. Mr. Craig said he thought that was considered their home, and patients could still receive hospice services in their home.

Sen. Towe asked Ms. Adee about the last paragraph in the statement of intent where it reads "the rules shall reflect current regulations and go beyond the existing relevant regulations for in-patient hospice facilities and provide for two levels of site-based hospice services". Ms. Adee said that current federal regulation only describes one type of hospice, the in-patient hospice facility. Only Medicare certified

hospices can provide that. They would like to define a second, residential hospice.

Closing by Sponsor:

Rep. Brooke said the hospice state-wide network has done a lot of work on this. In this area, we are ahead of the curve. There is certainly a need for hospice facilities in Montana, and high standards should be set. Other types of facilities are expensive and specialized, whereas hospices provide care that alleviates pain and helps patients die. This country needs to be accepting of this kind of care. Rep. Brooke said HB 211 did pass with a substantial majority in the House, and said Sen. Klampe had agreed to carry the bill in the Senate.

EXECUTIVE ACTION ON HB 211

Motion/Vote:

Sen. Towe moved that HB 211 BE CONCURRED IN. The motion carried unanimously. Sen. Klampe will carry the bill.

Further Discussion on HB 241:

Chairman Eck asked Mr. Craig if they did inspections of laboratories. Mr. Craig said the Certification Bureau was starting the CLIA program, and they were working with the federal government to inspect and certify all laboratories in the state. There are several exceptions.

Chairman Eck asked Mr. Craig if they were paid to do the inspections. Mr. Craig said it had been explained to the Appropriations Subcommittee, and CLIA is supposed to fund the Certification Bureau.

Sen. Towe asked Mr. Craig if the inspections made included the individuals who operate the facilities. Mr. Craig said the inspection does not include the qualifications of the individuals, but it does include how the tests are performed and if they are performed correctly. Mr. Craig said that Claudia Towne could explain CLIA to the Committee.

Sen. Christiaens requested that Claudia Towne come for executive action on HB 241, and it would be helpful to see the rules of CLIA.

Mr. Craig said it is very comprehensive, but a synopsis of the regulations would be provided to the Committee.

EXECUTIVE ACTION ON HB 27

Motion:

Sen. Towe moved the amendment, which reads on Page 2, Line 17 strike "is a student" and "has graduated" and insert in lieu thereof "applies for a license." On Page 2, Line 20, strike "of application for a license" and insert "after the person has graduated." Sen. Towe read the entire amendment.

Vote:

The motion carried unanimously.

Motion/Vote:

Sen. Towe moved HB 27 BE CONCURRED IN AS AMENDED. The motion carried unanimously.

ADJOURNMENT

Adjournment: Chairman Eck adjourned the hearing.

Dorothy Eck
SENATOR DOROTHY ECK, Chair

Laura Turman
LAURA TURMAN, Secretary

DE/LT

ROLL CALL

SENATE COMMITTEE Public Health DATE 3-5-93

NAME	PRESENT	ABSENT	EXCUSED
Eck	✓		
Franklin	✓		
Klampe	✓		
Hager	✓		
Towe	✓		
Mesaros	✓		
Rye	✓		
Christiaens	✓		

FC8

Attach to each day's minutes

SENATE STANDING COMMITTEE REPORT

March 9, 1993

MR. PRESIDENT:

We, your committee on Public Health, Welfare, and Safety having had under consideration House Bill No. 211 (first reading copy -- blue), respectfully report that House Bill No. 211 be concurred in.

Signed: Dorothy Eck
Senator Dorothy Eck, Chair

M - Amd. Coord.
___ Sec. of Senate

Sen. Klampe
Senator Carrying Bill

531056SC.Sma

SENATE STANDING COMMITTEE REPORT

March 9, 1993

MR. PRESIDENT:

We, your committee on Public Health, Welfare, and Safety having had under consideration House Bill No. 27 (first reading copy -- white), respectfully report that House Bill No. 27 be amended as follows and as so amended be concurred in.

Signed: Dorothy Eck
Senator Dorothy Eck, Chair

That such amendments read:

1. Page 2, line 19.
Following: "or"
Strike: "is a student who has graduated"
Insert: "who applies for a license"

2. Page 2, line 20.
Following: "months"
Strike: "of application for a license"
Insert: "after the person has graduated"

-END-

M- Amd. Coord.
___ Sec. of Senate

Sen. Franklin
Senator Carrying Bill

531046SC.Sma

LIVINGSTON MEMORIAL HOSPITAL

SENATE HEALTH & WELFARE
EXHIBIT NO. 1
DATE 3-5-93
BILL NO. HB 241

Livingston Memorial Hospital
504 South 13th Street
Livingston, Montana 59047
December 11, 1992

Brian Sanders
Government Relations Liaison
Great Falls Clinic
1400 29th Street S
Great Falls, MT 59405

Dear Mr. Sanders,

It is my intention to testify during the January hearings for the Personnel Licensure Bill. In the event that these hearings are scheduled during the CLMA mid-year meeting in San Antonio, then I will be unavailable and I want you to present this information.

I do not believe that it should be entirely a matter of scaring ourselves into the idea of personnel licensure. Somewhere "right reason" should prevail. I've included a copy of the ASCP Clinical Laboratory Levels of Practice and the companion book developed by the Competence Assurance Council of ASMT titled Model Criteria For Peer Review. I would ask the legislators to please review this material to get a sense of the volumes of technical information that we are taking about when we refer to the work that a laboratory technician does on a day to day basis. It is lengthy and it is detailed, but by no means comprehensive. Not something that a high school graduate can readily assimilate.

* On the other hand, if it is "war stories" that you want, I can tell a few that will point to the seriousness of the matter of licensure. One situation that impacted my family very dramatically occurred a few years ago with my uncle. My uncle became anemic and required blood transfusions. He was given the wrong type of blood as a result of testing by an unqualified laboratory worker. This person typed my uncle incorrectly. Not a matter of making a clerical error as you might expect to be the cause of an ABO Incompatibility. The result was a hemolytic transfusion reaction that then was not even recognized by the laboratory worker. Now when a person is given ABO incompatible blood, a hemolytic transfusion reaction results. That means his body hemolyzed the transfused cells and they plugged his kidneys. Without functioning kidneys you die. This was but a factor in my uncle's death as there were comorbidities.

Again, this was not a case that you heard about in the papers because my aunt chose not to sue, she did not want to press action that would financially impair the hospital. Not surprisingly, that hospital recently closed its doors.

A clear case for the cost effectiveness of licensed qualified workers.

504 South Thirteenth Street, Livingston, Montana 59047 • 406/222-3541 • FAX 406/222-0540

Testing errors do not always result in fatalities. Errors or negligence may result in serious consequences for patients, disruption of hospital operations or serious financial loss. The cost of unwarranted follow up testing is a wasted resource. For example if liver enzymes are reported as abnormal, the patient may be scheduled for an unnecessary nuclear scan costing hundreds of dollars. (This has happened.) Patients being heliocoptered to regional centers for treatment of a myocardial infarction only to find that the referral diagnosis was incorrect. (This has happened.) Costly mistakes.

Ignorance of the technical issues surrounding testing can result in false negatives. I'm referring specifically to a clinic in a neighboring town who could not seem to understand the importance of CO2 enrichment for culturing of Neisseria. The patients were being charged, and they were getting results that were "Negative for GC". The only thing worse than having venereal disease is having it and being told that you are clear.

This same clinic lab (staffed with unregistered personnel) repeatedly draws the wrong vacutainer tubes for certain tests. Because they never developed an understanding of specimen requirements, they submit specimens that do not produce valid tests results for specific testing methodologies.

Take the most common blood test that a diabetic requires: glucose. Here you are striving for accuracy of testing because good control of diabetes prolongs life. Again, it may not be a matter of an individual glucose result contributing to demise, however, over time, the patient develops symptoms of poorly controlled diabetes (loss of vision, loss of circulation etc) and poor quality of life.

What about the drug store cholesterol story relayed to me by a coworker. The results were 165, 165, 165, 165, patient after patient only to find that this was an error code for the machine. Again, lack of basic understanding of the technology. Easy to learn how to push the button. Hard to learn what to do with the information that is generated. To determine the clinical relevance of test results and balance that quality control data.

In conclusion, errors or negligence by laboratory workers may result in serious consequences for patients, disruption of hospital operations or serious financial loss. Please urge the legislators to facilitate adoption of please support this licensure bill to ensure that qualified licensed workers perform laboratory testing. support

Sincerely,

Karen Searle

Karen Searle
Laboratory Manager
Livingston Memorial Hospital

SENATE HEALTH & WELFARE
EXHIBIT NO. 2
DATE 3-5-93
BILL NO. HB 241

Madam Chairman and Committee Members thank you for your time and the opportunity to speak with you.

My name is Amy Gessaman, and I am presently working as a medical technologist at the Montana Deaconess Medical Center.

During my twenty years of experience, I had the opportunity to work at a small, rural hospital where a fellow laboratorian crossmatched for transfusion the inappropriate blood type for at least two patients. He was not aware that a few second's incubation at room temperature or 37°C could make a difference in his patient's blood typing results.

His educational background was not commensurate to his level of practice.

Rural hospitals especially need well-trained, qualified laboratory scientists - often there is no other technologist or pathologist on hand with whom one may easily and rapidly consult in a difficult situation.

Clinical lab practice is a very technical and complex science. Montanan's assume that the care received at their medical institutions is the best. Most Montana residents assume that their medical facilities hire licensed laboratory scientists, However, many people do not have the education necessary to assess the quality of their lab care.

Only by licensing our lab professionals and thus developing a vehicle by which we may assess education and training can we ~~do~~ assure ~~this~~ quality care in a reliable and consistent manner.

Living in a rural state does not mean we must "settle" for less than quality care. I ask that you support H.B. 241 - Montanan's deserve it!

SENATE HEALTH & WELFARE
EXHIBIT NO. 3
DATE 3-5-93
BILL NO. SB 241

Amendments to House Bill No. 241
Third Reading Copy

Requested by Representative Bill Strizich
For the Senate Public Health, Welfare, and Safety Committee

Prepared by Tom Gomez
March 5, 1993

1. Title, line 11.
Following: "DATES"
Insert: "AND A TERMINATION DATE"

2. Page 4, line 17.
Following: "performs"
Strike: "LOW AND MEDIUM COMPLEXITY"

3. Page 7, line 5.
Strike: "or"

4. Page 7, line 8.
Following: "493"
Insert: ";
(f) a perfusionist or cardiopulmonary technician who, as part of a surgical team, performs laboratory tests in an operating room during surgery or during the perioperative period; or
(g) clinical laboratory science practitioners, employed by certified rural health clinics, who perform only those basic laboratory services required under federal regulations set forth in 42 CFR 491.9(c)(2)"

5. Page 11, lines 15 and 20.
Strike: "act"
Insert: "section"

6. Page 11, line 18.
Following: "years."
Insert: "The applicant's level of practice on [the effective date of this section] determines the type of license issued."

7. Page 16.
Following: line 9
Insert: "NEW SECTION. **Section 17. Termination.** [Section 5(2)(f) terminates July 1, 1997."

SENATE HEALTH & WELFARE
EXHIBIT NO. 4
DATE 3-5-93
BILL NO. HB241

DRS. CLEVELAND and OURY
CARDIOVASCULAR and THORACIC SURGERY
554 W. BROADWAY
MISSOULA, MONTANA 59802
406-728-4558

James H. Oury, MD, FACS

Joseph C. Cleveland, MD, FACS

March 4, 1993

THE HONORABLE WILLIAM STRIZICH
MT HOUSE OF REPRESENTATIVES
STATE CAPITOL
HELENA MT

Dear Representative Strizich:

I am writing in response to House Bill #241 regarding the licensing of clinical laboratory personnel. I want to urge you to work with the American Society of Extra-Corporeal Technology to incorporate language to protect perfusionists' ability to continue to perform laboratory tests in the operating room.

Perfusionists are an integral component of my surgical team, albeit the only member who is unlicensed. I am dependent upon them for accurate laboratory test results pertaining to the patient's blood-gas analysis, electrolytes, and activated clotting times. It has taken many years for technology to reach the point where we can perform these tests in the operating room, and I strongly believe that we must preserve the use of that technology in Montana. Test results which used to take upwards of thirty minutes can now be performed in the operating room in less than five minutes. I believe that this quality of patient care is not only in the best interest of my patients but also reduces cost by shortening their hospital stay through maximum quality care.

I urge you not to restrict the scope of practice of non-licensed allied health professionals, such as perfusionists, who utilize their skills and training by employing laboratory technology for which we have waited years and by which patients unquestionably receive better and more cost effectivecare.

Sincerely,

Joseph C. Cleveland, MD
Cardiac Surgeon

James H. Oury, MD
Cardiac Surgeon

SUMMARY - PERFUSION ISSUES WITH MONTANA HOUSE BILL 241

H.B. 241 is sponsored by Rep. William Strizich of Great Falls, Montana. The bill would restrict the performance of all laboratory testing to only those licensed as medical technologists/technicians. This would prevent perfusionists from performing tests critical to safe patient management, such as blood-gas analysis, electrolytes and activated clotting times. AmSECT is requesting that the bill be amended to protect non-licensed professionals, such as those recognized by the American Medical Association as distinct allied health professions (including but not limited to perfusionists, anesthesia assistants, cardiovascular technologists, and medical assistants), performing laboratory tests germane to their scope of practice at the point of care.

We request that H.B. 241 be amended to read (allowing for changes as required by Legislative Counsel to make the wording consistent with state laws):

Insert in Section 3. Definitions; [From the Alternate Site Testing Task Force of the College of American Pathology]

(11) Alternate site testing is any laboratory testing done under the administrative control of a hospital, but performed outside the physical or administrative confines of the central laboratory.

Insert in Section 5. Exemptions:

(f) Non-laboratory personnel functioning in an alternate test site as defined herein. Such practitioners must: 1) be in full compliance with the standards required by the federal Clinical Laboratory Improvement Amendments of 1988 for "testing personnel;" and 2) practice under the supervision of a licensed health care provider. Such personnel are restricted to: 1) performing laboratory tests exclusively for the diagnosis and treatment of their own patients; and 2) practice exclusively within an alternate test site.

KEY TALKING POINTS

1. Although the MTs have tried to pass legislation in several states in recent years, only Rhode Island adopted a MT licensure bill, in 1992. Because the state must be in compliance with the federal CLIA standards, the House Majority Whip, Rep. Vincent J. Mesolella introduced a bill in February 1993 to delay the implementation of the MT bill, citing the unnecessary and duplicitous burden of separate state and federal regulations on the same issue;

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2. The state of Florida, which is the largest consumer of health care per capita of any state in the union has this year incorporated statutory language recognizing Alternate Site Testing. This is a major philosophical shift for a state that has licensed medical technologists since 1948. Their decision was based on 1) the need to provide better patient care by incorporating laboratory testing at the point of care; 2) minimizing the inefficiency of STAT labs dedicated to the Operating Room suite by utilizing technology (such as blood gas analyzers and ACT equipment) which non-laboratorians such as perfusionists can safely operate; 3) lowering overall patient costs by reducing patient hospital stays.

3. The number of perfusionists in Montana may be only ____, but with an average case load of approximately 150 per year, per perfusionist, a total of _____ open heart surgery patients will now be subject to a lower standard of care than they currently enjoy if this bill is enacted.

4. Perfusionists along with the other AMA recognized allied health professions actually represent more non-laboratorians who perform tests at the point of care, than those who perform tests as laboratorians in central hospital and independent laboratories.

SENATE HEALTH & WELFARE
EXHIBIT NO. 5
DATE 3-5-93
BILL NO. HB 241

ALLIANCE FOR RESPONSIBLE TESTING

ART OBJECTIVES

- To collect, organize, and disseminate accurate, unbiased information about laboratory testing performed in traditional, point-of-care, and physician office laboratory sites.

- To proactively work together to:

  - Serve as a forum to share viewpoints, ask relevant questions, and constructively discuss legislative and regulatory proposals.

  - Serve an educational role in those states where legislative or regulatory changes are proposed.

- To serve as a clearinghouse to disseminate information about the status of state legislative and regulatory proposals.

ALLIANCE FOR RESPONSIBLE TESTING

Meeting Minutes

DATE: September 18, 1992
LOCATION: Mayflower Hotel, Washington D.C.
ATTENDEES:

Name		Organization Represented
Mark Adams		American Society of Echocardiography
Don Balasa	*	American Association of Medical Assistants
Sabrina Beacham	*	American Association of Electroneurodiagnostic Technologists
Karen Brzys	*	Mallinckrodt Sensor Systems
Bill Davies	*	American Association of Electroneurodiagnostic Technologists
Jill Eicher	*	American Association for Respiratory Care
Marcha Feichter	*	Clinical Laboratory Management Association
Michael Groves	*	i-STAT
Susan Hildebrandt		American Academy of Family Physicians
Linda Ivor		Hybritech
Keith Knudson	*	International Society of Clinical Laboratory Technology
George Mann		American Society of Anesthsia Technologists and Technicians
Joan Metcalf	*	bioMerieux/Vitek Systems
Pamela Pepe	*	American Society of Extra-Corporeal Technology
David Phillips	*	Ciba-Corning
Stephen Ross		Holt, Ross & Yulish (representing i-STAT)
Dr. Judith Prask		American Society of Clinical Pathologists
Frank West		Society of Vascular Technology and American Institute of Ultrasound in Medicine
Anne Wright	*	American Hospital Association

Other Organizations which have requested minutes

Eddie Allen		Health Industry Manufacturers Association
Kim Banks		Commission on Office Laboratory Accreditation
Mark Birenbaum	*	International Society for Clinical Laboratory Technology and
	*	American Association of Bioanalysts
Jerome Cordts		Association of State and Territory Public Health Lab Directors
Peggy Kalowes		American Association of Critical Care Nurses
Beth Knowles		Joint Commission on Allied Health Personnel in Ophthalmology
Paul Landaur		Abbott
Betty Logan		Laboratory Licensure and Development Section (Georgia)
Susie McBeth		Joint Commission for the Accreditation of Healthcare Organizations
Peggy McElgunn		National Society for Cardiovascular Technology
Dr. George Miller		Society of Thoracic Surgeons
Pamela Mittelstadt		American Nurses Association
Janet Pailet		American Society for Medical Technology
Lisa Parks		Society of Critical Care Medicine
Bob Rogers	*	PPG Biomedical
Rosanne Savol		Miles
Dr. Ben Thomas		Bureau of Laboratories (Washington D.C.)
Robert Waters		American Association of Bioanalysts

NOTE: This initial meeting was intended to share and discuss information only. Attendance at this meeting and/or receipt of meeting minutes does not constitute a commitment to ART.

* Have given verbal and/or written commitment to join ART as of 12/1/92.

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NOTE: This initial meeting was intended to share and discuss information only. Attendance at this meeting and/or receipt of meeting minutes does not constitute a committment to ART.

Minutes

- After the group was welcomed, meeting goals were described: (1) To share information and discuss potential impacts (both positive and negative) of laboratory personnel licensure; (2) To identify possible roles the Alliance for Responsible Testing (ART) can have in working to resolve identified issues.

- It was suggested and agreed by meeting attendees that:

  - Attendence at this initial meeting does not constitute a formal committment to ART. Individual organizations can evaluate the direction of ART and subsequently decide whether to join.
  - The ART will not support or oppose MT licensure. Instead, ART will serve an educational role in collecting/organizing/disseminating relevant information. ART members can, of course, lauch individual lobbying efforts.

- Karen Brzys described the history/status of CLIA '88. She also summarized CLIA personnel requirements and described requirements which impact/govern point-of-care testing.

- Pamela Pepe described the characteristics and status of laboratory personnel licensure bills. She reviewed a copy of a side-by-side analysis (copy enclosed) of the ASMT and ASCP model bills as well as the bills proposed in MI, RI, and LA.

- Pamela suggested that if the ART effort goes forward, any outputs from ART should take into consideration the needs of different target groups: bill sponsor, lobbyiests, legislators, committee chairs, regulators, and other special interest groups.

- It was explained that Susie McBeth from JCAHO had expressed an interest in attending the meeting, but was unable due to the unavability of travel funds. A copy of a memorandum from JCAHO regarding personnel standards is attached.

- After the initial presentations, participants were divided into three discussion groups.
  - Individuals representing traditional laboratory sites
  - Individuals representing alternate testing sites
  - Manufacturers

- Representatives from HCFA have declined to "join" ART because many of the groups interested in joining ART are regulated by HCFA requirements. They have, however, offered to speak at a future meeting to share any perspectives and relevant data.

- The discussion groups were asked to identify issues/impacts of state personnel licensure bills as well as expectations they have for the Alliance. After lunch, the groups presented the following:

Issues/Expectations identified by the working group representing traditional laboratories sites

1. What are the advantages of state personnel licensure?
   a) Relies on educational credentials and/or experience rather than on national credential examinations.
   b) CLIA '88 personnel standards may not ensure quality in testing.
   c) Standarizes hiring practices.
   d) Allows for the input of regulated professionals into the promulgation of personnel requirements (via Board).
   e) Provides for the statutory recognition of the profession.
   f) May provide for financial incentives/increases in salaries.

2. What are the disadvantages of state personnel licensure?
   a) May limit entry into the field.
   b) Licensure on the state level may result in a lack of uniformity of requirements from state to state.
   c) May prevent persons with alternative training from performing simple testing.
   d) A restrictive bill may cause the demand for qualified personnel to outstrip the current supply of MTs.
   e) A restrictive bill will limit point-of-care testing.

3. Expectations from the Alliance
   a) Serve as a conduit of educational/unbiased information.
      1. Status of state legislative proposals.
      2. Status of legislative sessions.
      3. Information about hearing dates/committee actions.
   b) Compile a base-level educational compendium with information collected about common points of agreement.
   c) Ensure that Alliance efforts/materials represent a multitude of view points.
   d) Testify at state hearings.
      1. Provide assistance/information for drafting testimony.
      2. Present only common points of interest/agreement.
      3. Individual organizations should advocate their own positions.
   e) Establish a network to alert Alliance members about issues/matters of a common cause.
   f) Pool finances to fund joint efforts.
   g) Conduct periodic meetings.

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Issues/Expectations identified by the working group representing alternate site testing

1. Issues
   a) Short term: MT licensure proposals do not accomodate the role/need of alternate site testing. Long term issue: other legislative proposals may have similar "unintended consequences."
   b) The definitions of a laboratory and a laboratory test are not clear. Consequently, the potential impact of these MT licensure proposals can vary depending upon the actual definitions as well as on the resulting interpretations/enforcement actions.
   c) The differences and consequences between the licensure of laboratory facilities and the licensure/credentialing of testing personnel is not clear.
   d) There is little or no documented information about testing personnel (especially non-MTs).
      1. credentials/education
      2. types of tests
      3. settings
      4. supervision
      5. number of practitioners performing tests
      6. consumers/patients impacted (how impacted)
   e) The possible sources of information have not been identified/contacted/collected. Some possible sources include:
      1. HCFA
      2. JCAHO
      3. Medicare reimbursement statistics
      4. States which have implemented lab requirements different from CLIA
      5. Clarify how state laws affect personnel qualifications under CLIA
      6. C.L.E.A.R.
      7. NCCLS
      8. NGA
      9. CSG
      10. Published studies (e.g., on turnaround time, clinical needs/benefits)

2. Expectations of ART
   a) Differentiate/clarify point-of-care testing from "traditional testing."
      1. invasive testing
      2. non-invasive monitoring
   b) Promote quality patient care.
   c) Maintain a balance between availability/accessibility of testing and quality of testing.
   d) Compile accurate information.

Issues/Expectations identified by the working group representing manufacturers

1. Issues
   a) The impact of alternative definitions for lab/lab test are not understood.
      1. What is a laboratory?
      2. What is a laboratory test?
      3. Where does medical practice end and laboratory practice start?
   b) The role/impact of point-of-care testing has not been clarified and has not been considered in these MT licensure bills.
   c) Although new automated test methods may be effectively operated by personnel who do not have formal training in laboratory science, no allowances have been made for the use of new technology by non-MTs in these licensure bills.
   d) Clinical needs for test results are not fully considered (timeliness, preanalytic error, etc.).
   e) Testimony (by both sides) at legislative hearings may be misrepresenting facts and/or not telling the whole story. There is a need to sort fact from fiction.
   f) Manufacturer's input is neither recognized nor consulted (despite the fact that we are technology experts).
   g) Licensure bills do not preserve "access to care" in POLs, home care, rural sites, etc.
   h) The problems these MT licensure bills are "fixing" have not been accurately documented -- nor have they been identified in some cases.
   i) CLIA '88 has not yet been given a chance -- we do not even know what "problems" CLIA will fix and what may be needed beyond CLIA.
   j) It is unclear what the cost and benefits are for states to go beyond CLIA '88.
   k) It is unclear where federal rules stop and state rules start under the state exemption process.
   l) The window of opportunity to get involved in the state legislative process is significantly narrower than it has been on the federal level.

2. Expectations of ART.
   a) Document the environments (who, where, what), clinical roles/benefits, numbers, and costs of all forms of testing (especially alternate site testing).
   b) Document the true problems that exist with different forms of testing.
   c) Implement proactive rather than reactive educational strategies (get involved before bills are introduced) as well as have a structure in place to effectively work in an educational capacity in states where legislation is introduced.
   d) To do what can be done to ensure that testimony by all parties at legislative and regulatory hearings is accurate and accountable to facts.
   e) To ensure that public policy takes into consideration patient care needs and costs.
   f) To minimize impediments to the introduction of new technology that will improve patient care.
   g) To work with HCFA to clarify needs for thoroughly evaluating state rules in making state exemption rulings.
   h) To clarify lab/lab test definitions so there are no unintended consequences that negatively impact medical practice.
   i) To have input into legislative proposals BEFORE they are introduced.
   j) To have input/influence in the regulatory promulgation process for legislation that is passed as well as in states reviewing/updating their requirements.

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Agreement of ART Direction/Objectives

At the end of the meeting, it was suggested that ART focus on the following objectives:

1. To collect, organize, and disseminate accurate, unbiased information about laboratory testing performed in traditional, point-of-care, and POL sites.

2. To serve as a clearinghouse to disseminate information about the status of state laboratory bills and regulatory updates.

3. To proactively work together to:
   - serve as a forum to share viewpoints, ask relevant questions, and constructively discuss licensure proposals.
   - share ART information with key players in all states.
   - serve an educational role in those states where laboratory bills are proposed and/or current statute chapters/regulations are being updated.

Meeting participants were asked to demonstrate their support via a show of hands for formally establishing ART and implementing the programs required to achieve the agreed upon objectives. The vote was unanimous.

Action Items

1. Karen Brzys agreed to compile and distribute meeting minutes along with a committment request letter.

2. Pamela Pepe agreed to draft and distribute a membership demographic survey to collect relevant data about ART member constituents.

3. It was suggested by Martha Feichter after the meeting that ART members should collect copies of the CLIA '88 Form 109s sent in by their constituents. These forms will provide useful information about who is performing what types and quantities of testing.

4. The decision as to when ART will meet again was postponed until after the results of the committment survey are compiled. All interested ART members will be contacted once the survey results are available.

USE OF POINT-OF-CARE TESTING EQUIPMENT IN HOSPITALS

CURRENT STATUS OF POINT-OF-CARE TESTING

The clinical laboratory industry has changed significantly over the last decade. In hospitals, laboratory testing has traditionally been performed in centralized facilities or in satellite laboratories where trained personnel are available to operate large, complex analyzers. In the last decade, equipment has become available which allows clinical tests to be performed at the patient's bedside, known as "point-of-care" testing. It has been shown that the use of this automated equipment, through quicker availability of test results, can improve patient care and reduce treatment costs.

Information about point-of-care testing is contained in this package. Included is information about clinical needs for timely laboratory test results as well as information about GEM Systems which can be used at the point of health care delivery to provide information needed by clinicians to make life-sustaining patient care decisions.

BENEFITS OF POINT-OF-CARE TESTING

WHAT IS POINT-OF-CARE TESTING?

During the last decade, there has been a proliferation of testing done outside of large laboratories to a diverse array of alternative sites. Point-of-care testing in hospitals refers to clinical tests performed directly at the patient's bedside in critical care units, emergency rooms, and other locations outside the centralized laboratory. Testing at these locations, also known as "decentralized sites," can now be done safely and accurately by means of specialized testing equipment.

IMPROVED PATIENT CARE

Point-of-care testing creates rapid availability of test results allowing physicians to make improved patient care decisions, particularly in critical care areas where immediate information is often necessary to save lives. Quicker test results can be a significant advantage to a physician in determining treatment and may reduce patient complications. (See enclosed references regarding published standards of care.)

COST SAVINGS

Point-of-care testing reduces the cost of health care both directly and indirectly. Direct costs are less because expenses for transporting specimens to a centralized laboratory are eliminated. Incremental labor costs are also eliminated because patient care professionals operate these systems in the normal course of their duties. Indirect cost savings result from the reduction of patient hospital stays when treatment modalities are determined from immediate and accurate information. A study by Gary Zaloga (enclosed) demonstrated that point of care testing performed by nurses helped to reduce average hospital stay and overall cost in the treatment of diabetic patients by $1,545 per patient.

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SPECIALIZED TESTING EQUIPMENT IS AVAILABLE TO PERFORM POINT-OF-CARE TESTING

Specialized testing equipment is now available that has been specifically designed for use by patient care professionals at point-of-care test sites. The accuracy and reliability of patient testing can be ensured by the design of point-of-care systems, such as GEM Systems, which can be operated as follows:

- This equipment is automated such that many of the tasks performed by laboratory technologists on traditional analyzers are now performed by the instrument.
- Instrument components require little or no maintenance and have few operational steps.
- Internal software automatically performs calibrations and other self-validation checks to measure and verify accurate performance. If there are problems, GEM Systems will not report test results for subsequent patient samples.
- Quality control and calibration solutions are readily available to adjust and verify proper instrument performance. If these checks are not performed or are performed unsuccessfully, GEM Systems will not report test results for subsequent patient samples.

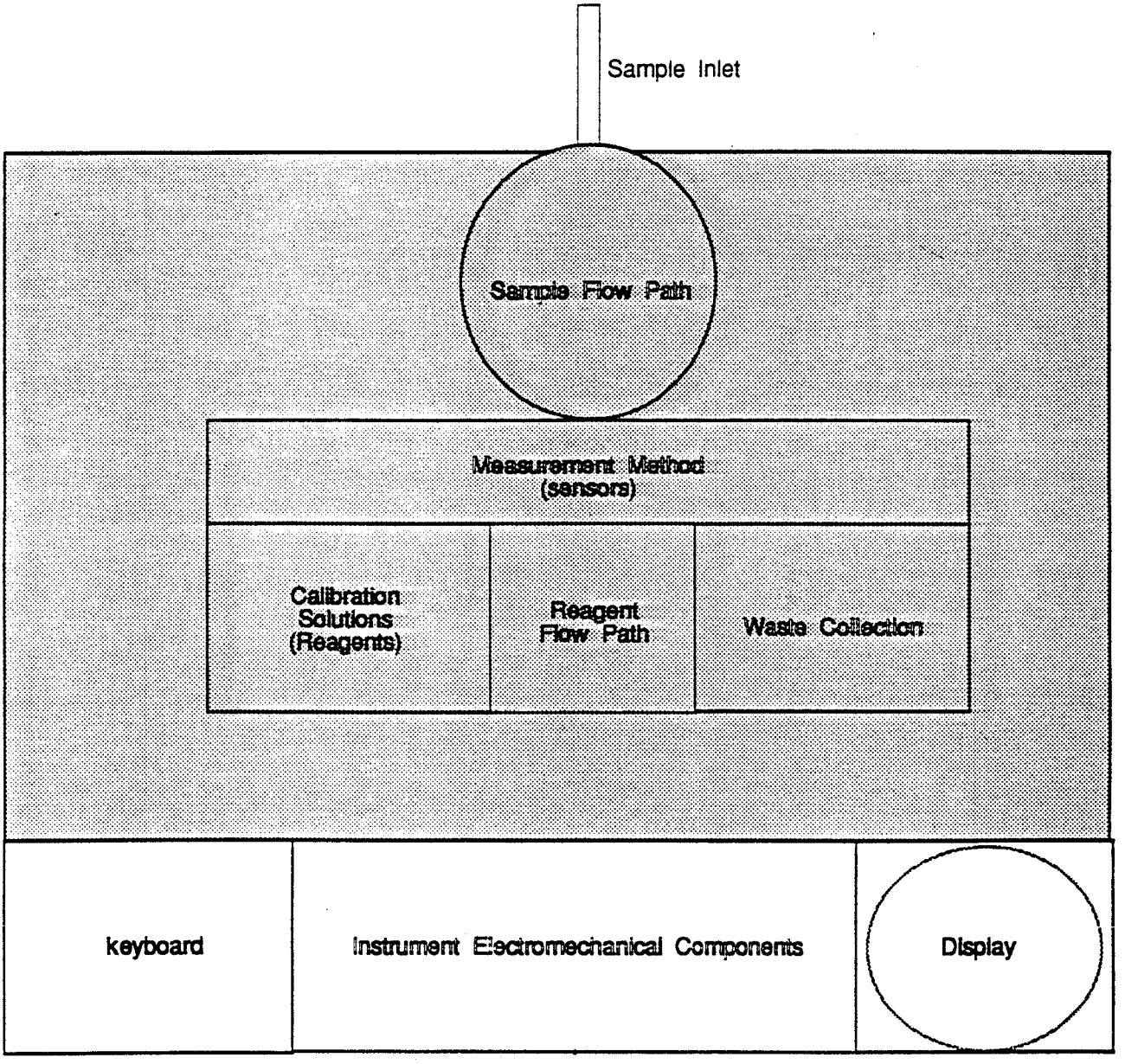
POINT-OF-CARE TESTING REPRESENTS A SMALL PERCENTAGE OF LABORATORY TESTS PERFORMED IN A HOSPITAL

Point-of-care testing systems, like GEM Systems, are only used to perform a few types of tests, primarily blood chemistry and hematology procedures (e.g., blood oxygenation levels, electrolytes). The testing that can benefit from being performed nearer to the patient constitutes only a small fraction of clinical laboratory testing, approximately two percent. In many cases, these tests are performed more accurately at the point of care because the properties of the patient specimens will not change as they can during transport to a centralized laboratory.

COMPARISON OF POINT-OF-CARE TESTING EQUIPMENT AND TRADITIONAL LABORATORY EQUIPMENT

In traditional laboratory equipment, the components in the shaded area must be installed, maintained, and operated by the user.

In specialized testing equipment, the components in the shaded area are contained in a disposable cartridge or other automated configuration that is maintained by the instrument. This easy-to-use format obviates the necessity for highly trained operators.



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COMPARISON OF POINT-OF-CARE TESTING EQUIPMENT AND TRADITIONAL LABORATORY EQUIPMENT

The following chart compares the complexity of GEM Systems with that of traditional laboratory equipment used to perform blood chemistry tests. The figures represent averages calculated from information contained in operating instructions for representative equipment in each category.

SYSTEM FEATURE	25 50 75 100 125 150 175 200 225 250 275 300 10,500
Number of components maintained by the operator.	GEM Systems: 4 Traditional analyzers: 55
Number of system setup steps performed by the operator.	GEM Systems: 8 Traditional analyzers: 77
Number of possible error messages to which the operator must respond.	GEM Systems: 7 Traditional analyzers: 146
Number of possible corrective actions which the operator can perform to remedy problems.	GEM Systems: 2 Traditional analysers: 135 + 109 functional checks
Number of maintenance steps recommended per year performed by the operator.	GEM Systems: 12 Traditional analyzers: 10,450

POINT-OF-CARE TESTING:
CONCLUSIONS FROM RELEVANT JOURNAL ARTICLES

A New Standard of Care

"Information on blood clotting time and chemistry (pH and electrolytes) and blood gases should be available on a 'stat' basis (within 5 minutes). If this cannot be achieved using the hospital lab, the hospital should consider purchasing blood gas equipment for the surgical suite."

> Emergency Care Research Institute. "Risk Analysis: Cardiopulmonary Perfusion Equipment." Journal of Extra-Corporeal Technology. 1987; 19(2): 235-240.

"A core laboratory in the surgical suite is convenient for the rapid performance of blood gases, pH, and electrolytes. . . . Blood gas results must be available within five to ten minutes during cardiopulmonary bypass."

> Inter-Society Commission for Heart Disease Resources. "Optimal Resources for Cardiac Surgery: Guidelines for Program Planning and Evaluation." Circulation. 1975; 32: A23-A41.

"The requirements for appropriate laboratory monitoring of patients undergoing cardiopulmonary bypass are unique. . . . A rule of thumb for the majority of laboratory procedures performed, including blood gases, sodium, potassium, ionized calcium, and hemoglobin/hematocrit, is that the laboratory must return results within five minutes of receipt of specimen. This is a difficult task and has led to the provision of dedicated services in most well-developed cardiac surgery programs. In those situations where the institution has not seen the way clear to provide the resources for dedicated services, the turnaround time for testing performed in a more centralized facility is inadequate and can do more harm than good. Fortunately, there is at least one new monitoring device now available that provides real-time laboratory testing in the operating room."

> Frederick Van Lente. "Question and Answer Column." Editor: Richard A. Savage. CAP Today. 1990; 4(3): 47-48.

"Rapid detection and prompt treatment of changes in oxygenation, pH, and electrolyte levels might reduce patient morbidity and mortality. However, in many hospitals, interoperative and postoperative arterial blood gases, electrolytes, and hematocrits are performed in laboratories remote from the clinical setting because of cost and staffing considerations. Remote laboratories are sometimes associated with delays in the return of vital laboratory data, which consequently may result in delays in institution of corrective therapy. Recent advances in technology have made available new portable instruments for monitoring of blood gases and electrolytes."

> Jeff Riley, et. al. "In Vitro Measurement of the Accuracy of a New Patient Side Blood Gas, pH, Hematocrit and Electrolyte Monitor." Journal of Extra-corp Technology. 1987; 13(3): 322-329.

"Significant progress has been made recently in the measurement methods and instrumental approaches applicable to bedside testing of critically ill patients. . . . It appears that the user-friendly point of care type stat analyzers that can provide accurate values for all the key analytes, used in conjunction with existing noninvasive trend monitors (eg, pulse oximetry), will offer the most attractive approach for the effective treatment of critically ill patients."

> Domenic R. Misiano, et. al. "Current and Future Directions in the Technology Relating to Bedside Testing of Critically Ill Patients." Chest. 1990; 97(5): 203S-214S.

"In recent years, laboratory testing in the critical-care setting has increased, a trend due, in part, to the evolution of electrochemical sensors. Various innovations have extended sensor lifetimes, reduced sensor maintenance, and led to the development of single-use and unit-use disposable sensors. These sensor technologies allow the accurate and precise determination, either at or near the bedside, of several analytes."

> Mary F. Burritt. "Current Analytical Approaches to Measuring Blood Analytes." Clinical Chemistry. 1990; 36(8B): 1562-1566.

"The effective management of critically ill patients often requires frequent measurement of a select group of analytes in blood. . . . Historically, such tests have been performed in centralized laboratories remote from the patient, but recent years have seen increased demands for measurement technologies that enable such tests to be carried out rapidly at or near the patient's bedside. The availability of instruments with such capabilities can provide clinicians with essentially 'real time' diagnostic information, and this can result in more timely and proper therapeutic intervention. . . . Ideally, instrumentation designed for in vitro bedside or nearby stat-lab testing should be capable

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of measuring several of these 'critical-care' analytes simultaneously in a small sample of undiluted whole blood. . . . It is also highly desirable that multi-analyte bedside and stat-lab instrumentation be 'user friendly,' such that reliable test results can be obtained even when the instruments are operated by personnel with little or no training in clinical chemistry. Such performance requires low- or zero-maintenance-type equipment that is convenient to use (el., with autocalibration, etc.) for both analyses of samples and quality-control purposes."

Mark E. Meyerhoff. "New In Vitro Analytical Approaches for Clinical Chemistry Measurements in Critical Care." Clinical Chemistry. 1990; 36(8B): 1567-1572.

"Significant progress has been made to move the measurement of critical blood parameters to the point of patient care (POC); most commonly bedside), using easy-to-use, automated instrument approaches. . . . POC testing offers the intensivist the near equivalent to "real time" treatment. On average, the clinician loses half an hour to two hours if a critically ill patient's sample is measured in the hospital's central or satellite lab. The delay in the subsequent therapeutic intervention is even greater because the physician often leaves the bedside area to attend to other duties or patients. In addition, less than optimum therapies may be administered while awaiting the central lab's data."

"Critical Care Technology -- Moving the Laboratory to Point of Patient Care." MedPRO Month. 1991; 1(1): 4-6.

"Fourth-generation instruments have been developed more recently to fill the need for bedside testing and 'office laboratory' testing. These instruments are small, portable, and can be easily used by physicians, nurses, respiratory therapists, and other health care workers. Accuracy and variability of results differ between instruments, and can be improved with user training and experience. Instruments that use whole blood and require no manipulation of specimens (ie, dilution, pipetting) are more accurate. Most instruments require little maintenance."

Gary P. Zaloga. "Evaluation of Bedside Testing Options for the Critical Care Unit." Chest. 1990; 97(5): 185S-190S.

"The standard of care is a legal concept. It is a burden for the physician, but it is also a shield. . . . However, there is one area of medical practice where juries tend to be more strict. This concerns the clinician's failure to use available technology, which can be regarded as both affordable and highly protective of the patient. . . . [Point-of-care monitoring] must be seen as essential, both from the standpoint of patient safety and the prevention of devastating malpractice suits."

David S. Rubsamen. "Continuous Blood Gas Monitoring During Cardiopulmonary Bypass -- How Soon Will it be the Standard of Care?" Journal of Cardiothracic Anesthesia. 1990; 4(1): 1-4.

"Anesthesiologist-reviewers examined 1,175 anesthetic-related closed malpractice claims from 17 professional liability insurance companies. The claims were filed between 1974 and 1988. The reviewers were asked to determine if the negative outcome was preventable by proper use of monitoring devices available at the time of the review even if not available at the time the incident occurred. . . In 1,097 cases sufficient information was available to make a judgement regarding preventability of the morbidity or mortality by application of additional monitors."

John H. Tinker, et. al. "Role of Monitoring Devices in Prevention of Anesthetic Mishaps: A closed Claims Analysis." Anesthesiology. 1989; 71: 541-546.

Cost Advantages

"Laboratory testing provides essential information that aids in both diagnosis and treatment of critically ill patients. Such testing may be performed in a 'central' clinical laboratory or near the patient [at the bedside]. . . . Bedside testing allows for 'real-time' treatment of patients because it decreases the 'turnaround time' for obtaining laboratory results. . . . Bedside monitoring decreased [ventilator] weaning time, ICU stay, total hospital stay, and total hospital costs. The major reason for the savings was the more rapid treatment received by patients in the bedside-monitored group."

Gary P. Zaloga. "Evaluation of Bedside Testing Options for the Critical Care Unit." Chest. 1990; 97(5): 185S-190S.

"In satellite buildings, in corners of the emergency room and surgical suite, at the bedside, and elsewhere, a wide variety of testing is being done that was formerly restricted to the main laboratory. Many institutions that have not yet spread their labs' wings in this way are considering doing so in the near future. . . . A recent study has shown that where bedside testing is done in the critical-care setting, such as in the recovery room, patients heal faster and leave the hospital sooner . . . Estimations of the full cost of medical care, however, must take into account the length of hospitalization and the possibility of increased morbidity as a result of delayed therapy. If you can get a patient out of the hospital faster by doing this kind of testing, . . . the cost to the patient is markedly decreased."

Marcia Ringel Barman. "Alternate-site Testing: Mixed Feelings about the inevitable." Medical Laboratory Observer. 1990; December: 22-29.

"The cost of providing testing includes a variety of different expenses that vary with each laboratory testing configuration. . . . The example in Table I estimates the cost of moving testing to a new stat lab or to a beside instrument. Using the assumptions given, servicing the testing load [50 tests per day] with the bedside testing alternative seems to be more economical [$211,385 annual cost for bedside versus $364,664 for a stat lab]."

Bernard E. Statland et al. "Evaluating STAT Testing Alternatives by Calculating Annual Laboratory Costs." Chest. 1990; 97(5): 198S-203S.

3-5-93
HB-241

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Question and Answer Column, Editor: Richard A. Savage, MD

Q. We have a new open heart program at our hospital. At issue now are turnaround times for clinical lab tests when the patient is on the heart/lung machine. What is the standard of practice for potassium, glucose, hemoglobin/hematocrit, platelets, and blood gases? Is instrumentation to monitor these parameters available?

A. The requirements for appropriate laboratory monitoring of patients undergoing cardiopulmonary bypass are unique. The perfusionist must maintain vital blood constituents within defined tolerances in order to support adequate peripheral tissue metabolism and hemostasis during the period that both the heart and lungs are inoperable. This process is essential for minimizing adverse effects secondary to tissue ischemia, electrolyte imbalance, and coagulopathy during the entire sequence of induction, bypass, and weaning. Postsurgical course is quite dependent on the efficiency of this procedure.

The period of total extracorporeal circulation may last for several hours and adjustments must be made on a regular basis during this time. Because the individuals responsible for this monitoring are required to make decisions in a short time frame, the turnaround requirements for testing are stringent. A rule of thumb for the majority of laboratory procedures performed, including blood gases, sodium, potassium, ionized calcium, and hemoglobin/hematocrit, is that the laboratory must return results within five minutes of receipt of specimen. This is a difficult task and has led to the provision of dedicated services in most well-developed cardiac surgical programs.

In those situations where the institution has not seen the way clear to provide the resources for dedicated services, the turnaround time for testing performed in a more centralized facility is inadequate and can do more harm than good. Fortunately, there is at least one new monitoring device now available that provides real-time laboratory testing in the operating room. This technology is designed specifically to be incorporated in the bypass circuit, is modular, and provides a profile of blood gases, sodium, potassium, ionized calcium, and hematocrit. It is called the GEM-6 Plus System and is distributed by Mallinckrodt. This may be a viable alternative. However, the laboratory must be involved to ensure that quality control and quality assurance measures are undertaken. The provision of coagulation testing, including platelet counts, remains more problematic.

Frederick Van Lente, PhD
Chairman,
Department of Biochemistry
The Cleveland Clinic Foundation
Cleveland, Ohio

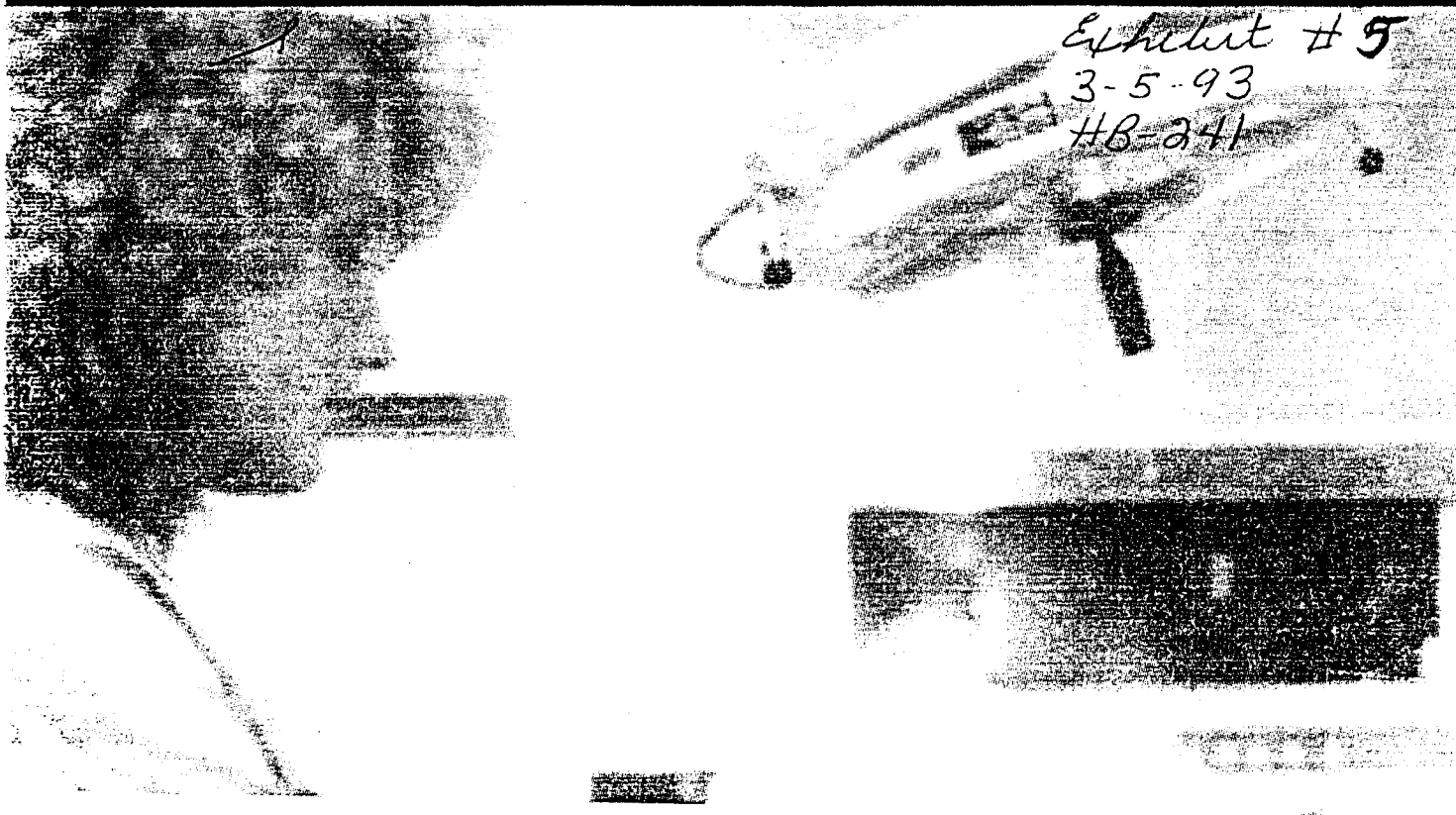
Senate Public Health, Welfare + Safety Com

November 23, 1992
Vol. 2, No. 47

MT today

The Nation's Largest Weekly Newsmagazine for Laboratory Professionals

Exhibit #5
3-5-93
HB-241



The original is stored at the Historical Society at 225 North Roberts Street, Helena, MT 59620-1201. The phone number is 444-2694.

Point-of-care testing creates a new role for laboratorians

SHERIDAN MEMORIAL HOSPITAL AND NURSING HOME
440 West Laurel Avenue
Plentywood, MT 59254-1596
Phone (406) 765-1420
Fax (406) 765-1711

SENATE HEALTH & WELFARE
EXHIBIT NO. 6
DATE 3-5-93
BILL NO. HB 241

March 5, 1993

I am asking that you vote against HB 241 which establishes a board of Clinical Laboratory Science. This bill adds additional regulation and cost at a time in which our state and the health care industry needs to be focusing on cost containment.

This bill if passed will in effect increase the cost of health care in the State of Montana. It will make it very difficult to recruit and retain technologists meeting the qualifications outlined within this bill. CLIA 88 had initially included some of the same type of educational requirements as this proposed bill, but after the comment period these cost inflating, unnecessary limitations were removed. Now this group of professionals is trying to bring these regulatory requirements in at the state level.

Hospital laboratories are essential for the provision of primary care in the rural setting. The equipment cost and sophistication is of a level which categories this department as one of the higher cost centers in our operations. While it is true that certain Laboratory Technologists have better interpretation skills than others, the sophistication of much of the equipment allows many of the complex tests to be performed automatically by the equipment and does not require the expertise of a degreed technologist. Our laboratories are subjected to continual proficiency testing which are referred to as CAP (College of American Pathologists) studies. This proficiency testing is required by law under CLIA 88 standards and compliance is enforced by the State of Montana.

This bill does not represent a quality issue, but rather an issue of protectionism within a profession and does not belong in the legislature. The passage of this bill has the potential to limit the access to diagnostic laboratory testing in rural Montana and will not benefit anyone, but the degreed Technologists.

In the spirit of cost saving reforms and equal access to quality care, this bill does not serve the best interests of all Montanans.

Respectfully,

Thomas J. Nordwick,
Administrator

SENATE HEALTH & WELFARE
EXHIBIT NO 7
DATE 3-5-93
BILL NO. HB 27

HOUSE BILL 27
TESTIMONY OF PATRICIA JOHNSON
MARCH 5, 1993

INTRODUCTION

Madam Chair, members of the committee, my name is Patricia Johnson and I am a Board Member on the Board of Respiratory Care Practitioners.

PAGE 1 LINE 16 annually on May 1

The board would like an annual renewal date for the following reasons:
1. It would be easier for medical facilities and the directors of respiratory care departments to verify that all their therapists are currently licensed.

2. This is also for administrative purposes for better tracking of all licensees at any given time.

3. Since continuing education is also required on an annual basis, this gives a common date in which the sponsors of c.e. can plan their workshops, seminars, in-service training, etc.

PAGE 2 LINES 19 and 20 for a license or is a student who has graduated within 6 months of application for a license.

Without this addition to current law, students only have a 30 day opportunity to apply for a Temporary Permit before they graduate. The Board would like to allow students of respiratory care a reasonable amount of time to apply for a Temporary Permit after graduation.

This also allows the recent graduate to work under the Temporary Permit while he is waiting for the next regularly scheduled exam administered the NBRC.

CLOSING

In closing, the Board of Respiratory Care Practitioners urges the committee members to PASS HB 27.

I am available for any questions concerning House Bill 27 and Helena Lee, Administrative Assistant for the Board is also available to answer any questions you might have.

Senate Public Health,
Welfare & Safety Committee
March 5, 1993
House Bill No. 211

Exhibit No. 8 is a packet of letters from various Montana Hospices presented by Representative Vivian Brooke on HB 211. The originals are stored at the Montana Historical Society at 225 North Roberts, Helena, MT 59620-1201. The phone number is 444-2694.

DATE 3-5-93

SENATE COMMITTEE ON Public Health

BILLS BEING HEARD TODAY: ~~HB~~ HB 241, HB 211, HB 2

Name (please print)	Representing	Bill No.	Check One: Support	Oppose
Wally Henkelman, RN	Mont. Nurses Ass'n	HB 241	✓	
JERRY M DEVOSE B.S. CLP	AMERICAN SOCIETY FOR EXTRACORPOREAL TECHNOLOGY			✓
Harry S. UFFelussy CCP	St. Patrick Hosp	HB241		✓
Kay Crull	American Red Cross	HB241	✓	
KAREN SEARLE	LIVINGSTON MEMORIAL HOSP.	HB 241	✓	
MARSHA WATERMAN	Clinical Lab. Mgmt. Assoc	HB241	✓	
SUSAN REAKIS	MONTANA SOCIETY FOR MEDICAL TECHNOLOGY	HB 241	✓	
Kirk J Rogowski PT	Self Physiotherapy	HB241	✓	
[illegible]	[illegible] Technologist	HB 241	✓	
Chuck Daly	Montana Deaconess - Med Tech	HB241	✓	
Carol Colgan	Medical Technologist	HB241	✓	
Anita Osborne	~~Med Tech~~ Consumer	HB241	✓	
DONNA GOLLEHON	Boz mt MSMT Med Tech	HB24[illegible]		
Rhonda Craven	Boz mt Med Tech	HB241		
Jeanne Strizich	Mont. Deac - Med Tech	HB241	✓	
Patti Liston	Mont Deac - Med. Tech	HB241	✓	

VISITOR REGISTER

PLEASE LEAVE PREPARED STATEMENT WITH COMMITTEE SECRETARY

F10

DATE 3-5-93

SENATE COMMITTEE ON Public Health

BILLS BEING HEARD TODAY: _____

Name (Please Print)	Representing	Bill No.	Check One Support	Oppose	Inf. Only
Helena Lee	Bd RCP Adm Assist	27	Info		
Patricia L. Johnson	Bd. RCP, MSRC	27	✓		
Karen Bryan	MALLINCKRODT	241			✓
Deborah Hanson	Am Red Cross Blood Svcs Helena & Great Falls	241	✓		
Anne Weber	MSMT	241	–		
Barb Boohen	Mt. Nurses Assoc.	241	✓		
Russell Morrison	Mt. Clinical Lab Mgmt Assn.	241	✓		
mary leanne morrison	"	241	✓		
Jan Baker		241	✓		
Greg L. Mauer	Daniels Mem Hosp	241			✓
Tom Woodcock	Sheridan Mem Hosp	241			✓
Janet Bastian	MT Health Network	241			✓
Tim Russell	Stillwater Comm Hosp.	241			✓
Jay Pettenger	Teton Medical Center	241			✓
Sam Hubbard	Deaconess Medical Center (Billings)	241			✓
Henry x. Young	Liberty County Hospital Chester MT	241			✓

VISITOR REGISTER

PLEASE LEAVE PREPARED STATEMENT WITH COMMITTEE SECRETARY

F10

DATE _____

SENATE COMMITTEE ON _____

BILLS BEING HEARD TODAY: _____

_____

Name	Representing	Bill No.	Check One Support	Oppose
Harry Reed	Org Sandy Medical Center	HB241		✓
Carl Hanson	Pondera Med CTR	HB241		✓
Bill Schultz	Self.	HB241	X	
Ron Clevenger	Self	HB241	X	
Joyce Fruichl		241	X	
Ed Adams	Self	241	X	
James Reed MD	Self	241	X	
Allyn Christiaens	Med. Technologis	241	X	
John Flink	MHA	211	X	
Bonnie Adee	MHO	241	X	
Mike Janssen	Med-Techs	241	X	

VISITOR REGISTER

PLEASE LEAVE PREPARED STATEMENT WITH COMMITTEE SECRETARY

F10