

**1999 HOUSE HUMAN SERVICES**

**HB 1388**

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1388

House Human Services Committee

Conference Committee

Hearing Date January 26, 1999

Tape Number	Side A	Side B	Meter #
1	X		0.0 - End
Committee Clerk Signature <i>Susann Lindteigen</i>			

Minutes:

Rep. DARRELL NOTTESTAD, District 43, testified as sponsor of the bill it will be a way to promote preventative health care.

GALEN JORDRE, Executive Vice-president, ND Pharmaceutical Association, testified (Testimony with proposed Amendment attached).

Rep. AMY KLINISKE asked is there any specific training for individuals administering these tests? GALEN JORDRE stated with the CLIA waive instruments, anyone doing those would be considered a laboratory and you need to complete an application. This particular one does not have any specific requirements for personnel. The Medical Association voiced concerns about the open-endedness of the list of CLIA waive tests. The amendment would limit the tests that are currently being done by the College of Pharmacy. The amendment also would establish by

rule the educational requirements and quality control procedures. Rep. AMY KLINISKE asked are these finger print tests? GALEN JORDRE stated they are all finger stick tests.

Rep. WANDA ROSE asked for the criteria to have proficiency level tests. GALEN JORDRE stated when the CDC approves the test for waive status, that sets up control procedures that the pharmacist must follow. But they have no outside requirements for control. That is why they are deemed to be the waive test.

EDMUND MAGARIAN, NDSU Professor, representing self, testified (training outline attached) the National Cholesterol Education Program under the auspices of the National Institute of Health recommends that individuals age 20 and older be evaluated for cholesterol levels, including HDL. In order to identify individuals who may be at increased risk of developing coronary heart disease and stroke have tests. American Diabetes Association recommends testing of 45 years and older. Blood pressure is recommended to be tested. Dr. David Kessler, former FDA chief, said "the pharmacist can offer screening programs to the consumer.". Our students go to other states that do health screening; 60% of the states allow health screening. Our students use the CLIA waive instruments. The Center for Disease Control developed the instrument requirements and stringent guidelines regarding accuracy and precision. CLIA requires internal quality control. Student training and OSHA procedures were discussed extensively. In 1993 a study was conducted on 340 patients who were screened for cholesterol and blood pressure. About two-thirds were referred to a physician of which 45% had a health problem that they were not aware of. There is a concern of taking business away from clinics and hospitals but data shows otherwise. There is about 200 pharmacies throughout ND. The pharmacist is the closest to people who may not have readily accessible or nearby health

facilities. Dr. Tony Rahr, physician from the Lake Region Clinic wrote a letter to Bell Drug, Devils Lake, ND, which was read into testimony. If this bill passes, we will use the educational program as a model for pharmacy. This bill should be enacted because a patient sees the pharmacist 2-3 times more often than their doctor.

Rep. WANDA ROSE asked how will we insure that all pharmacists will go through this criteria?

What if they don't have a clinic or hospital to contract with to take care of all the bio-hazardous?

EDMUND MAGARIAN stated the guidelines and regulations will be developed by the Board of Pharmacy. If they do not have appropriate access to a local clinic or hospital, it won't get done.

Rep. WANDA ROSE asked where do you get your referral criteria? How do you know whether 150 or 300 cholesterol is high or low? How do you set those standards? EDMUND

MAGARIAN stated we use NS guidelines and we refer any patients with cholesterol of 200 or greater for follow-up evaluation by a physician.

DAVID DEBUHR, Community Pharmacist, Bismarck, testified on examples of a pharmacist: (1) greatest asset to the public's accessibility, (2) identified dozens of potential problems, i.e., diabetes, cholesterol, and referred to the physicians, and (3) cholesterol screening is not conducted on people 30-40 years of age.

Rep. CAROL NIEMEIER asked what is the requirement between the pharmacist and the clinic?

What test do you report? DAVID DEBUHR stated if its life threatening we call right away. If not life threatening, we refer with a letter. Rep. CAROL NIEMEIER asked is there some liability if there is a bad result. DAVID DEBUHR stated there probably would be.

Rep. WANDA ROSE asked what about those without a physician? What is the cost of the machine and how much do you charge the county? DAVID DEBUHR stated we always get



information from patient on family history, high blood pressure, family physician, etc. As a teaching site we were given the machine which is valued at about \$1800.00. We pay for all the materials. We charge the patient between \$9.00 - \$15.00 depending on the service provided.

Rep. WANDA ROSE asked if you send that LDL to the physician, do you inform the client that you're sending it even though you're not giving them the results. DAVID DEBUHR stated yes they are told up front.

Rep. TODD PORTER asked for an explanation on the reimbursement be it Medicare, Medicaid, private, or out-of-pocket? DAVID DEBUHR stated it is all out-of-pocket. The individual is responsible for it.

PATRICIA KRAMER, Director of Utilization Management, State Medicaid, Department of Human Services, testified (Testimony attached).

Rep. TODD PORTER asked is the department considering paying for these tests? PATRICIA KRAMER said yes, if this bill passes. Rep. TODD PORTER asked do they pay for other screenings now? PATRICIA KRAMER stated we do through the laboratory, yes.

Rep. WANDA ROSE asked is public health reimbursed for screening. PATRICIA KRAMER said yes they are reimbursed if they bill us.

HOWARD ANDERSON, Executive Director, Board of Pharmacy, testified (Testimony attached). Why are we doing this? Its been the opinion of the board that it is part of the pharmacy practice. After discussion with the Attorney General, the suggestion was to put something into the Pharmacy Practices Act to make it clear and that's why we propose this legislation.

NEUTRAL

JIM ANDERS, State Health Department, testified on a proposed amendment (attached). This amendment would assure training to all pharmacists who do testing. It also involves some quality control that is very specific. Each pharmacy would have to enroll in a proficiency testing. Right now, its the pharmacy school that's enrolled and not the individual pharmacist.

OPPOSITION

DAVID PESKE, Lobbyist, ND Medical Association, testified this is a very broad bill. If we just allow any CLIA waive test to be performed, there are 16 pages of CLIA waive tests. In visiting with the pharmacists, the proposed amendment alleviates some of our concerns. It would allow a determination to be made by the Board of Pharmacy and Board of Medical Examiners. It sounds like we would be in support of Mr. Anderson's amendment as well.

Rep. ROXANNE JENSEN asked for an explanation on David Peske's opposition to the bill and how the amendments affect the bill? DAVID PESKE stated we will leave it to the wisdom of the committee to decide if they are going to adopt the amendments.

LEOLA OLSON, Medical Technologist, testified and introduced a proposed amendment (attached) to protect the public safety. CLIA's original intent in allowing waive testing was referred to physicians who want to perform limited testing in a clinical setting. At first there was just a handful of waive tests, but now there are hundreds. My concern is for the pharmacist who hasn't had any formal training.

Hearing closed.

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1388

House Human Services Committee

Conference Committee

Hearing Date February 2, 1999

Tape Number	Side A	Side B	Meter #
1		X	48.8 - End
2	X		0.0 - 9.0
Committee Clerk Signature <i>Susann Lindteigen</i>			

Minutes:

GALEN JORDRE discussed the proposed amendment with the department. Rep. TODD PORTER asked what assurances are there that the pharmacist will conduct the test in a fasting manner? GALEN JORDRE stated they could not provide absolute assurance. Rep. TODD PORTER asked what controls are in place for overcharges and payment when department of human services is paying the cost? GALEN JORDRE stated he taken off-guard on testimony of reimbursement request; that screenings had been done out-of-pocket.

Rep. CLARA SUE PRICE discussed the fiscal impact. PAT KRAMER, Department of Human Services, stated if bill passes we will reimburse for screening. If they are screening for glucose level, they will have to follow clinical guidelines. A total of \$47,000-50,000 with \$13,000 state funds. Rep. CLARA SUE PRICE asked about electronic billing. PAT KRAMER stated HIT is on electronic billing list and about a dozen pharmacies that will do this service.

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House Human Services Committee

Bill/Resolution Number HB1388

Hearing Date February 2, 1999

Rep. AMY KLINISKE moved to ADOPT AMENDMENTS.

Rep. WANDA ROSE second the motion.

VOICE VOTE: 14 yeas, 0 nays, 1 absent

Rep. BLAIR THORESON moved DO PASS As AMENDED.

Rep. AMY KLINISKE second the motion

ROLL CALL VOTE #5: 13 yeas, 1 nay, 1 absent

CARRIER: Rep. BLAIR THORESON

Passed

**PROPOSED AMENDMENT TO HOUSE BILL, NO. 1388**

Page 2, after line 6, insert:

**Section 2.** A new unnumbered section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

“The board shall establish rules stipulating the educational requirements and quality control procedures for pharmacists who conduct laboratory tests provided in 43-15-01(23). These rules shall include:

*Dept of Health*

1. A requirement that pharmacists receive training for each specific test performed; and
2. A requirement that pharmacists demonstrate proficiency for each test performed following nationally recognized proficiency guidelines.”

**Section 3.** A new unnumbered section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

*Medical Assn.*

“Approved laboratory tests ~~shall include~~ <sup>are</sup> the following waived screening tests: Glucose Monitoring Devices (FDA Cleared/Home Use) 9221, Cholesterol 1020, HDL Cholesterol 2550, Triglyceride 6118, and Glycosylated Hemoglobin (Hgb A1C) 2204. Additional tests may be added to this list as jointly determined by the board and the North Dakota Board of Medical Examiners.”

Renumber accordingly

*Control of reimbursement -  
Already reimburse screenings for public health.  
follow clinical guidelines  
Total 47,000 - 50,000 +  
state funds - \$1.3,000*

*Electronic Billing HCFA - 1500 only  
Figures abt 12 pharmacies will do  
may double.*

PROPOSED AMENDMENT TO HOUSE BILL NO. 1388

On page 2, after line 6, insert:

**SECTION 2.** A new unnumbered section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

“A pharmacist may perform a laboratory test authorized under subsection 23 of section 43-15-01 only if:

1. That pharmacist has received training for each specific laboratory test performed by that pharmacist; and
2. Each pharmacy providing laboratory testing is enrolled in and has demonstrate proficiency in a nationally recognized proficiency program, covering the administration of each test conducted at that pharmacy.”

Renumber accordingly

**PROPOSED AMENDMENT TO HOUSE BILL, NO. 1388**

Page 2, after line 6, insert:

"Section 2. A new section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

The board shall establish rules stipulating the educational requirements and quality control procedures for pharmacists who conduct laboratory tests provided in 43-15-01(23). Approved laboratory tests <sup>are</sup> ~~shall include~~ the following waived screening tests: Glucose Monitoring Devices (FDA Cleared/Home Use 9221, Cholesterol 1020, HDL Cholesterol 2550, Triglyceride 6118, and Glycosylated Hemoglobin (Hgb A1C) 2204. Additional tests may be added to this list as jointly determined by the board and the North Dakota Board of Medical Examiners."

Renumber accordingly

VR  
2/3/99

**HOUSE AMENDMENTS TO HOUSE BILL NO. 1388 HUMSER 2-3-99**

Page 1, line 1, after "Act" insert "to create and enact two new sections to chapter 43-15 of the North Dakota Century Code, relating to pharmacist education requirements and approved laboratory tests; and"

**HOUSE AMENDMENTS TO HOUSE BILL NO. 1388 HUMSER 2-3-99**

Page 2, after line 6, insert:

**"SECTION 2.** A new section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

**Educational requirements - Rules.** The board shall adopt rules establishing the educational requirements and quality control procedures for pharmacists who conduct laboratory tests provided in subsection 23 of section 43-15-01. These rules must include a requirement that pharmacists receive training for each specific test performed and a requirement that pharmacists demonstrate proficiency for each test performed following nationally recognized proficiency guidelines.

**SECTION 3.** A new section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

**Approved laboratory tests.** Approved laboratory tests are the following waived screening tests: glucose monitoring devices (FDA cleared/home use) 9221, cholesterol 1020, HDL cholesterol 2550, triglyceride 6118, and glycosylated hemoglobin (Hgb A1C) 2204. Additional tests may be added to this list as jointly determined by the board and the board of medical examiners."

Renumber accordingly



Date: 2-2-99  
Roll Call Vote #: 5

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES  
BILL/RESOLUTION NO. 1388

House Human Services Committee

Subcommittee on \_\_\_\_\_  
or  
 Conference Committee

Legislative Council Amendment Number \_\_\_\_\_

Action Taken No Pass As Amended

Motion Made By Blair Thoreson Seconded By Amy Kliniske

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price - Chairwoman	X		Bruce A. Eckre		
Robin Weisz - Vice Chairman	X		Ralph Metcalf	X	
William R. Devlin	X		Carol A. Niemeier	X	
Pat Galvin	X		Wanda Rose	X	
Dale L. Henegar	X		Sally M. Sandvig	X	
Roxanne Jensen	X				
Amy N. Kliniske	X				
Chet Pollert	X				
Todd Porter		X			
Blair Thoreson	X				

Total Yes 13 No 1  
Absent 1

Floor Assignment Blair Thoreson

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1388: Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (13 YEAS, 1 NAY, 1 ABSENT AND NOT VOTING). HB 1388 was placed on the Sixth order on the calendar.

Page 1, line 1, after "Act" insert "to create and enact two new sections to chapter 43-15 of the North Dakota Century Code, relating to pharmacist education requirements and approved laboratory tests; and"

Page 2, after line 6, insert:

**"SECTION 2.** A new section to chapter 43-15 of the North Dakota Century Code is created and enacted as follows:

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Renumber accordingly

**1999 SENATE HUMAN SERVICES**

**HB 1388**

1999 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB1388

Senate Human Services Committee

Conference Committee

Hearing Date MARCH 10, 1999

Tape Number	Side A	Side B	Meter #
1	X	X	
3/10/99 1		X	4,500
Committee Clerk Signature <i>Carol Koldajchuk</i>			

Minutes:

The committee was called to order with all senators present.

The hearing was opened on HB1388.

REPRESENTATIVE DARYL NOTTESTAD, sponsor, introduced the bill.

GALEN JORDRE, ND Pharmaceutical Assoc., explained bill in written testimony.

SENATOR DEMERS asked about the rationale for Med. Assoc. approving additional tests if Board of Clinical Laboratory Practice that controls the licensing of this practice. MR. JORDRE answered that the Medical community was concerned about the breadth and numbers of CLIA Waived tests that are available. Since these are the tests that our Pharmacy students are working with in college. Board Clinical Laboratory Practice controls the licensing of individuals who practice laboratory medicine, not necessarily different types of tests. The different testing levels are controlled through Federal Clinical Laboratory Improvement.

DR. ED MAGARIAN, Instructor of Pharmacy at NDSU, supports bill. A number of medical recommendations regarding health screening; ages 20 and over be screened for cholesterol, ages 45 and over be screened for glucose level. This makes the role of the pharmacist in administering these tests feasible. NDSU implemented the Pharmaceutical Care Clerkship Rotation. During the last year the students spend 6 weeks in community pharmacies in ND and they offer and provide Pharmaceutical Care services; such as, blood pressure, glucose, cholesterol screening. They do not have the authority to administer these screening tests at this time. We offer the program because 60-70% of the states do allow pharmacists to perform these screening tests without restrictions. We teach use, care, and maintenance of instruments. There is no vein drawing; only finger prick. They are taught how to document. Our curriculum goes beyond the CLIA requirements. Pharmacists are not making diagnosis; but refer them to physicians. Students have mass screened for Diabetes Association, Dakota Medical Center, cholesterol and blood pressure. This bill is for the good of the people. SENATOR LEE: Why only cholesterol and blood glucose? DR. MAGARIAN: Because of concern by the medical association to do just CLIA test; there are about 400-500 tests. We decided to specify those tests for the time being. Future tests could be added at a later time, but that will be consultation between the Board and Medical Board. SENATOR DEMERS: Who else can do the WAIVE tests? DR. MAGARIAN: Pharmacists, health care providers. They must register with CLIA. There is a process - a form to be filled out where screening is to be held, demographics, telling who, how many are going to be doing this testing. SENATOR MUTZENBERGER: What is CLIA? DR. MAGARIAN: Clinical Laboratory Improvement Act. They set Laboratory standards for testing. SENATOR LEE: In other states are they limited to only these two tests?

DR. MAGARIAN: No, they have a broader base. SENATOR KILZER: Is this finger stick, ear stick, or what?

DR. MAGARIAN: Only finger stick. SENATOR LEE: What is the cost? DR. MAGARIAN: These are only screening tests: glucose is \$2-3; Cholesterol is \$12-14. Prices are set by each pharmacy. SENATOR THANE: Is there a possibility of being too comfortable; if your pharmacist says you are A-OK? DR. MAGARIAN stated that a physical involves more than these two tests. The gain outweighs the loss. SENATOR KILZER: What are hemoglobin cutoffs? DR. MAGARIAN: We go by the medical guidelines - 8% ADA or 7% of higher clinical guidelines.

DAVE DEBURH, Reg Pharmacist, is adjunct instructor with NDSU. We are sure they are able to perform tests. There are a number of people coming through - 20-30 a month, 18-75 years old. We are preventing them from having heart conditions/stroke/whatever. We refer them to physicians and then we follow up with patient. 75-80% have gone in to see a physician. We do send a letter to the physician for follow-up. He introduced a patient that was recently referred and whose life was probably saved because of screening.

HOWARD ANDERSON, Ex. Dir of ND State Board of Pharmacists, supports bill with written testimony. ND doesn't recognize CLIA. ND licenses the laboratory. SENATOR KILZER: What are quality controls not subject to CLIA. MR. ANDERSON: Our intention is to follow the guidelines DR. Magarian has proposed. We require each person will have proficiency with equipment; also training and be members of National Clinical Certification. The Board doesn't have the rules yet, but we are working with the college.

PAT KRAMER, Director of Utilization Management for Medical Services Division of the Dept of Human Services, supports the bill with written testimony. The Pharmacists did not come to the Dept; the Dept went to the Pharmacists with this.

Opposition.

DWIGHT HERTZ, MD and Pharmacist, opposes the bill. Excellent testimony here today. Only licensed personnel can do testing. My main concern with this bill is there can be a lack of continuum of care. Results don't get to the right places. What is the best way to spend Health Care dollars. SENATOR THANE stated that the patient is responsible. SENATOR LEE stated that there is definitely a non frightening situation in going to your drug store and being able to have one of the screenings, end up going to your physician; this is a win-win deal. SENATOR DEMERS: Do CLIA apply in this state? DR. HERTZ: Yes, CLIA was a Federal to sort of protect the public from inaccuracies of lab report tests. The state added another level to those tests and required some criteria for who could perform those tests. We looked at the qualifications and they have to be licensed by the Board of Clinical Lab Practice. SENATOR KILZER: Would you comment on the difference in these screenings if they have just wolfed down two whoppers or something like that. Do the lack of control situations have an effect on screenings? DR. HERTZ: I think not; CLIA's gotten very popular and the way its worked because the instrumentation has gotten much better. Quality control has gotten much better. The pharmacies have impressed me. SENATOR DEMERS asked why does the Medical Association feels they need jurisdiction to add tests to this list when they are outside of CLIA. DAVE PESKE: There are two reasons. The bill as first introduced it was wide open to perform CLIA WAIVE tests. It was 600-1000 tests. The pharmacists agreed to tell us which tests they wanted

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Senate Human Services Committee  
Bill/Resolution Number HB1388  
Hearing Date MARCH 10, 1999

to perform; that is why the listing is in the bill. There is a precedent for the Board of Pharmacy and the Board of Medicine to work together; they do that elsewhere in the statute prescribing and collaborating with patients. The second reason is so that they don't have to come back every two years when there happen to be more tests that pharmacists are comfortable performing.

The hearing was closed on HB1388.

Discussion resumed on 3/10/99. SENATOR FISCHER moved a DO PASS. SENATOR MUTZENBERGER seconded it. Roll call vote carried 5-1-0. SENATOR FISCHER will carry the bill.



Date: 3/10/99  
Roll Call Vote #: 1

1999 SENATE STANDING COMMITTEE ROLL CALL VOTES  
BILL/RESOLUTION NO. 1388

Senate HUMAN SERVICES COMMITTEE Committee

Subcommittee on \_\_\_\_\_  
or  
 Conference Committee

Legislative Council Amendment Number \_\_\_\_\_

Action Taken Do Pass

Motion Made By Sen Fischer Seconded By Sen Mutzenberger

Senators	Yes	No	Senators	Yes	No
Senator Thane	✓				
Senator Kilzer		✓			
Senator Fischer	✓				
Senator Lee	✓				
Senator DeMers	✓				
Senator Mutzenberger	✓				

Total 5 (yes) 1 (no)

Absent 0

Floor Assignment Sen Fischer

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)  
March 10, 1999 2:09 p.m.

Module No: SR-43-4476  
Carrier: Fischer  
Insert LC: . Title: .

**REPORT OF STANDING COMMITTEE**

**HB 1388, as engrossed: Human Services Committee (Sen. Thane, Chairman)**  
recommends **DO PASS** (5 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). Engrossed  
HB 1388 was placed on the Fourteenth order on the calendar.

1999 TESTIMONY

HB 1388

OFFICERS 1998-1999

JAMES D. CARLSON, Pharm.D., R.Ph.  
President  
KEVIN J. OBERLANDER, R.Ph.  
President-Elect  
BOB SWISHER, R.Ph.  
Vice-President  
GALEN JORDRE, R.Ph.  
Executive Vice President

# North Dakota Pharmaceutical Association

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**House Bill 1388 – Relating to the definition of practice of pharmacy.  
House Human Services Committee  
January 26, 1999 – 10:00 AM  
Testimony of Galen Jordre, R.Ph.**

Chairman Price, members of the committee – I am Galen Jordre, Executive Vice President of the North Dakota Pharmaceutical Association and a registered lobbyist for that organization.

The purpose of House Bill 1388 is to allow pharmacists to perform laboratory tests to provide pharmaceutical care services to their patients.

The concept of pharmaceutical care places pharmacists in a role of doing more than filling prescriptions. This new role asks pharmacists to work with other health care providers to meet the goal of curing or preventing a disease, eliminating or reducing symptoms, or arresting or slowing a disease. You see this role most often when pharmacists do medication counseling so patients will use them properly to achieve the outcomes expected by the prescriber. You may not notice the role when pharmacists use their resources to check for drug interactions and contraindications and consult with prescribers about doses and dosage forms. These services promote better outcomes when patients are taking prescribed medications. Pharmaceutical care also dictates that pharmacists be involved with prevention of disease and this bill presents a very simple way for pharmacists to work with other health care providers to detect conditions that can endanger their patients.

This bill allows pharmacists, as a part of pharmaceutical care, to perform waived tests used in compliance with the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988. This Act is jointly administered by the federal Centers for Disease Control and the federal Health Care Financing Administration. To obtain waived status a test must have the following characteristics:

- Use direct, unprocessed specimens, requiring no specimen manipulation before analysis or analyst intervention during analysis, and providing direct readout of results.
- Contain fail-safe mechanisms rendering no results when the results are outside the reportable range or when the test system malfunctions.
- Require no invasive test system troubleshooting, or electronic or mechanical maintenance.
- Contain instructions at a comprehension level no higher than the seventh grade.

Pharmacists, in their education, take extensive courses in chemistry, biological sciences, and physics that easily qualify them to perform these waived tests. In over thirty-five states health care providers can perform these tests without any restrictions. Dr. Ed Magarian of North Dakota State University College of Pharmacy will testify about these waived tests in more detail.

### **Why are pharmacists asking for this special allowance in pharmacy law?**

The State Board of Clinical Laboratory Practice regulates laboratory personnel and requires that laboratory personnel be licensed with the board. Physicians and nurses practicing within the scope of the nursing license are exempted by law for all types of laboratory tests. By placing performance of waived tests within the pharmacy practice act, pharmacists will be exempted only for those specific tests. There is no state regulation of laboratories, as all laboratories in the state must meet the requirements of the federal Clinical Laboratory Improvement Amendments. The lowest level of laboratories in this act are those that only perform waived testing. It is important to note that there are no personnel requirements for those particular laboratories. Pharmacists who apply to perform waived testing will be complying with the federal law and meeting all legal requirements for that classification of laboratories.

### **How will test results be used?**

The tests performed will be for screening and monitoring. The most common screening tests are those for blood glucose and cholesterol. Because the screening test results provide only a numerical value that indicates there may be a potential problem, patients will be referred to physicians for evaluation, additional testing, and diagnosis. Pharmacists have developed the trust of their patients and can be powerful tools in emphasizing the importance of getting to a physician for a complete evaluation. Published data from test programs operated by the North Dakota State University College of Pharmacy indicated that 81% of patients who were counseled to visit physicians actually did so. The tests can also be used when following patients who are taking medications. A recent national study indicated that patients taking cholesterol-lowering agents who were counseled and tested by pharmacists were twice as compliant as those who were followed in other ways.

### **Why is there a need for pharmacists to provide testing?**

The public has become more aware of the importance of knowing about their health status. Groups such as the American Diabetes Association and American Heart Association stress the importance of early screening and intervention to prevent progression of disease. Early detection of high cholesterol and diabetes through screening programs can do much to improve the health of our citizens and lower health care costs. By allowing pharmacists to perform these tests, many more patients will be screened - resulting in early interventions that improve health and save lives. It has been said that the equivalent of the population of the United States passes through the doors of America's pharmacies every month. Pharmacies are open in many areas with hours that give patients ready access to a health professional. While there are mass screening programs in malls and at other public places, they are sporadic and often associated only with special events. Screening in pharmacies will increase the number persons who are referred to physicians for early interventions. Early interventions for persons with cholesterol problems and diabetes will lower health care costs. Increased monitoring during drug therapy and reporting of results to other health care providers will improve patient adherence to drug therapy.

### **Conclusion:**

Pharmacists are not asking for a complete exemption from the state laboratory practice act. They are asking for the authority to screen and monitor their patients using tests that have been deemed to be safe and simple by the federal government.

We ask for your support of this legislation. The public will benefit by having greater access to screening and monitoring tests where early intervention results in improved health and saved lives.

# Outline

## Cholestech/AccuChek Easy Training

### Maintenance and Quality Control for Cholestech/AccuChek Easy

- Handout on "Infection Control Procedure"
- Cholestech Operation
  - ❖ Selftest
  - ❖ Printer port
  - ❖ Power socket
  - ❖ Rom pack
  - ❖ Power supplies for instrument and printer
  - ❖ Configuration Menu
  - ❖ Components of test cassettes
  - ❖ Quality Control
    - Environmental conditions for Cholestech operation
    - Cleaning of instrument
    - Optics Check Cassette
    - Quality Control Solutions - how often to test
      - ◆ Sample type in configuration menu for internal controls – whole blood
      - ◆ Sample type in configuration menu for external proficiency controls – serum
      - ◆ Storage and stability of control solutions
      - ◆ Students perform QC using level.1 & 2 controls
      - ◆ Documentation of quality control
        - "Cholestech Optics Check Log"
        - "Cholestech Quality Control Log"
        - "Cholestech Daily Maintenance Log"
- AccuChek Easy Operation
  - ❖ Code Key – Lot Specific
  - ❖ Components of Glucose Strips & Sample Application
  - ❖ Quality Control
    - Environmental Conditions for Cholestech Operation
    - Cleaning of instrument
    - Testing glucose strips for acceptability
    - Testing performance of instrument
    - Quality control glucose solutions – how often to test
      - ◆ Storage and stability of control solutions
      - ◆ Application of controls
      - ◆ Documentation of quality control
        - "AccuChek Easy Quality Control Log"
        - "AccuChek Easy Daily Maintenance Log"

### Evaluation of Student's Technique – Proficiency of Cholestech Cholesterol Testing

- Proper handling and disposal of hazardous biological materials
- Fingertick technique
- Application of capillary blood to test cassette
- Sources of error
- Perform total cholesterol assay in duplicate on volunteer
- Difference between duplicates must be  $\leq 5\%$  of their mean – if not, assay repeated until acceptable results are obtained

**TESTIMONY BEFORE THE HOUSE HUMAN SERVICES COMMITTEE**

**REGARDING HOUSE BILL 1388**

**JANUARY 26, 1999**

Chairman Price and committee members, I am Patricia Kramer, Director of Utilization Management for the Medical Services Division of the Department of Human Services. I speak in support of HB1388.

HB1388 would permit pharmacists to perform routine screening laboratory tests which are waived under the federal Clinical Laboratory Improvement Act (CLIA) of 1988. Those tests which include tests for diabetes and elevated cholesterol could be performed by pharmacists and provide greater access to needed services, particularly in those areas of the state that may be under served by health care professionals. The Department should benefit in the long-term by improved health of the Medicaid population and, therefore, lower future costs for the program. The Department should also benefit in the short-term by decreased costs to administer the tests.

With the potential benefits that would be available to recipients and the Department, I urge a do pass on HB1388.



**Board of Pharmacy**  
STATE OF NORTH DAKOTA  
EDWARD T. SCHAFFER, Governor

**OFFICE OF THE EXECUTIVE DIRECTOR**

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Turtle Lake, Executive Director

**HOUSE BILL No. 1388**  
**HUMAN SERVICES COMMITTEE**  
**TUESDAY - JANUARY 26, 1999 - 10:00 AM - FORT UNION ROOM**

Chairman Price members of the House Human Services Committee, for the record I am Howard C. Anderson, Jr., R.Ph., Executive Director of the North Dakota State Board of Pharmacy.

The Board of Pharmacy has worked with the North Dakota Pharmaceutical Association and the profession of pharmacy, as well as NDSU College of Pharmacy in suggesting these changes in the Century Code governing the practice of Pharmacy. When the program we had in place for the training of our students came under question from the Clinical Laboratory Board, through our Special Assistant Attorney General David Lindell, we consulted with the Attorney General's Office. The Attorney General's Office indicated we needed to place authorization in the Pharmacy Practice Act to make it clear that pharmacists have your authority to actually perform these simple clinical laboratory tests.

This activity on the part of pharmacists is intended to facilitate the screening of patients who have potential health problems, as well as monitor patients who are under a physician's care, or have been prescribed medications for specific illnesses. Patients who wish to take control of their own health status can go into to an easily accessible pharmacy for a blood sugar, cholesterol, or other health test and learn if their current health status suggests a visit to their physician. This will facilitate patients who have put off going to their physician because they don't feel that bad, but may have some underlying conditions that the pharmacist can help them understand needs to be taken care of.

The monitoring of therapy concerns patients such as those on cholesterol lowering medications who are placed on the medication by their physician and told to return, usually at a set appointment, but often in one year for a follow up visit. These medications work slowly and though we know they can reduce the risk of a stroke or heart attack, it is a challenge for patients to pay \$60 to \$100 a month for their medications without some regular assurance that the medication seems to be working. By coming to the pharmacy when they need to refill their medication and having their cholesterol checked, for a very



nominal fee, these patients can reassure themselves that their medication is working or at least receive the pharmacist's assurance that they are gradually improving and that they should stay on their medication. Should the pharmacist's test indicate that the patient is not doing as well as expected an immediate referral to a physician is always appropriate. In these cases, without the knowledge that the pharmacists could provide, these patients may go longer than necessary before returning to their physician.

Again, these tests are not intended to replace a visit to the physician or laboratory, but in fact, should increase the appropriate visits to either as a follow up to what the patient has learned about themselves.



**NORTH DAKOTA DEPARTMENT OF HUMAN SERVICES**

STATE CAPITOL - JUDICIAL WING  
600 E BOULEVARD AVE DEPT 325  
BISMARCK, NORTH DAKOTA 58505-0250



February 2, 1999

Carol K. Olson, Executive Director

Edward T. Schafer, Governor

Representative Clara Sue Price  
North Dakota House of Representatives  
House Chambers  
600 East Boulevard Avenue  
Bismarck, ND 58505

RE: House Bill 1388 - Definition of practice of pharmacy; allow CLIA waived screening tests in pharmacies

Dear Representative Price:

Following is the fiscal information you requested on House Bill 1388. The estimates are based on past billing experience and inquiries to PHS and pharmacy providers. Limits will be set in the payment system for each test based on clinical guidelines.

ESTIMATED COST OF PROVIDING 4 CLIA WAIVERED SCREENINGS

PUBLIC HEALTH SERVICE UNITS - based on 3 sites  
- Medicaid patients only - 10% of patient base

TEST*	COST	# TESTS PER WEEK	COST PER WEEK	COST PER YEAR	TOTAL ANNUAL SCREENINGS
CHO	\$4.00	6	\$24	\$1,248	312
HDL	\$9.66	6	\$58	\$3,016	312
HgA <sub>1c</sub>	\$13.42	3	\$40	\$2,080	156
Glucose	\$4.00	3	\$12	\$624	156
			<u>PHS TOTAL</u>	<u>\$6,968</u>	<u>936</u>

PHARMACIES - based on 18 sites  
- Medicaid patients only - 10% of patient base

TEST	COST	# TESTS PER WEEK	COST PER WEEK	COST PER YEAR	TOTAL ANNUAL SCREENINGS
CHO	\$4.00	36	\$144	\$7,488	1872
HDL	\$9.66	36	\$348	\$18,096	1872
HgA <sub>1c</sub>	\$13.42	18	\$242	\$12,584	936
Glucose	\$4.00	18	\$72	\$3,744	936
			<u>PHARMACIES TOTAL</u>	<u>\$38,168</u>	<u>5,616</u>

GRAND TOTALS                      \$45,136      6,552

70% FEDERAL FUNDS              \$31,595

30% STATE FUNDS                 \$13,541

\* CHO = total cholesterol, HDL = high density lipids, HgA<sub>1c</sub> = hemoglobin A<sub>1c</sub>, glucose = blood sugar

Sincerely,

*Patricia A. Kramer, R.Ph.*  
Patricia A. Kramer, R.Ph., Director, Utilization Management  
Medical Services, Department of Human Services

GENERAL INFORMATION	(701) 328-2310	ECONOMIC ASSISTANCE	(701) 328-2332
FAX	(701) 328-2359	EXECUTIVE OFFICE	(701) 328-2538
TDD	1-800-366-6888	FIELD SERVICES	(701) 328-2310
		PROGRAM & POLICY	(701) 328-2310

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GALEN JORDRE, R.Ph.

Executive Vice President

# North Dakota Pharmaceutical Association

1906 E Broadway Ave. ♦ Bismarck ND ♦ 58501-4700

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## **House Bill 1388 – Relating to the definition of practice of pharmacy. Senate Human Services Committee March 10, 1999 – 9:00 AM Testimony of Galen Jordre, R.Ph.**

The purpose of House Bill 1388 is to allow pharmacists to perform simple laboratory tests to provide pharmaceutical care services to their patients.

The concept of pharmaceutical care places pharmacists in a role of doing more than filling prescriptions. This new role asks pharmacists to work with other health care providers with a goal of curing or preventing a disease, eliminating or reducing symptoms, or arresting or slowing a disease. You see this role most often when pharmacists do medication counseling so patients will use them properly to achieve the outcomes expected by the prescriber. You may not notice the role when pharmacists use their resources to check for drug interactions and contraindications and consult with prescribers about doses and dosage forms. These services promote better outcomes when patients are taking prescribed medications. Pharmaceutical care also dictates that pharmacists become involved with prevention of disease and this bill presents a very simple way for pharmacists to work with other health care providers to detect conditions that can endanger their patients.

This bill allows pharmacists, as a part of pharmaceutical care, to perform waived tests used in compliance with the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988. This Act is jointly administered by the federal Centers for Disease Control and the federal Health Care Financing Administration. To obtain waived status a test must have the following characteristics:

- Use direct, unprocessed specimens, requiring no specimen manipulation before analysis or analyst intervention during analysis, and providing direct readout of results.
- Contain fail-safe mechanisms rendering no results when the results are outside the reportable range or when the test system malfunctions.
- Require no invasive test system troubleshooting, or electronic or mechanical maintenance.
- Contain instructions at a comprehension level no higher than the seventh grade.

Pharmacists, in their education, take extensive courses in chemistry, biological sciences, and physics that easily qualify them to perform these waived tests. In over thirty-five states health care providers can perform these tests without any restrictions.

The State Board of Clinical Laboratory Practice regulates laboratory personnel and requires that laboratory personnel be licensed with the board. The law exempts physicians and nurses practicing within the scope of the nursing license. By placing performance of waived tests within the pharmacy practice act, pharmacists will be authorized to conduct only those specific CLIA waived tests. There is no state regulation of laboratories, as all laboratories in the state must meet the requirements of the federal Clinical Laboratory Improvement Amendments. The lowest level of

laboratories in this act is those that only perform waived testing. It is important to note that there are no personnel requirements for those particular laboratories. Pharmacists who apply to perform waived testing will be complying with the federal law and meeting all legal requirements for that classification of laboratories. In addition, the amendments placed on the bill in the House will require the Board of Pharmacy to establish standards for quality and education for pharmacists performing these tests.

Laboratory tests performed will be for screening and monitoring. The most common screening tests are those for blood glucose and cholesterol. An amendment in the House, agreed to by the Medical Association, limits the approved CLIA waived tests to those areas. Any additional tests will require joint approval of the Board of Pharmacy and Board of Medicine. Because screening tests provide only numerical values that indicate potential problems, patients will be referred to physicians for evaluation, additional testing, and diagnosis. Pharmacists have developed the trust of their patients and can be powerful tools in emphasizing the importance of getting to a physician for a complete evaluation. The tests can also be used when following patients who are taking medications. A recent national study indicated that patients taking cholesterol-lowering agents who were counseled and tested by pharmacists were twice as compliant as those who were followed in other ways.

The public has become more aware of the importance of knowing about their health status. Groups such as the American Diabetes Association and American Heart Association stress the importance of early screening and intervention to prevent progression of disease. Early detection of high cholesterol and diabetes through screening programs can do much to improve the health of our citizens and lower health care costs. It has been said that the equivalent of the population of the United States passes through the doors of America's pharmacies every month. Pharmacies are located where the people are and offer convenient and frequent access to a health professional. While there are mass screening programs in malls and at other public places, they are sporadic and often associated only with special events. Screening in pharmacies will increase the number persons who are referred to physicians for early interventions. Early interventions for persons with cholesterol problems and diabetes will lower health care costs. Increased monitoring during drug therapy and reporting of results to other health care providers will improve patient adherence to drug therapy.

We ask for your support of this legislation. The public will benefit by having greater access to screening and monitoring tests where early intervention results in improved health and saved lives.

## Revised Position Statement on Screening for Type 2 Diabetes<sup>1</sup>

Each year the Association's Professional Practice Committee reviews and, if necessary, revises the clinical practice recommendations. A change was made to the position statement on screening for diabetes that will impact co-sponsored community screening programs. The committee determined that there is sufficient evidence to support the use of random (defined as "non-fasting") whole blood glucose tests in community screening programs. Individuals with a random whole blood glucose test  $\geq 140$  mg/dl should be referred to a physician for evaluation.

The fasting plasma glucose test remains the preferred test when screening for diabetes. Glycemic testing of individuals should be limited to those found to be at high risk for having undiagnosed diabetes through the use of the Association's diabetes risk test. Minors, individuals with diagnosed diabetes, and pregnant women should not receive glycemic testing in community screening programs.

The chart below contains the cutoff values for diabetes screening tests. For additional information, refer to the revised position statement titled "Screening for Type 2 Diabetes" in the January 1999 *Diabetes Care* supplement.

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Cutoff values for diabetes screening tests that warrant additional testing and evaluation by a physician<sup>1</sup>

<p>Fasting plasma glucose <math>\geq 126</math> mg/dl</p> <p>Fasting capillary whole blood glucose <math>\geq 110</math> mg/dl</p> <p>Random capillary whole blood glucose <math>\geq 140</math> mg/dl</p> <p>Fasting plasma glucose is the preferred test. Fasting is defined as no food or drink other than water for 8 hours.</p>
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<sup>1</sup>American Diabetes Association: Screening for type 2 diabetes (Position Statement). *Diabetes Care* 22 (Suppl. 1): S20-S23, 1999



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**HOUSE BILL No. 1388**  
**HUMAN SERVICES COMMITTEE**  
**WEDNESDAY- MARCH 10, 1999 - RED RIVER ROOM**

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Chairman Thane members of the Senate Human Services Committee, for the record I am Howard C. Anderson, Jr., R.Ph., Executive Director of the North Dakota State Board of Pharmacy.

The Board of Pharmacy has worked with the North Dakota Pharmaceutical Association and the profession of pharmacy, as well as NDSU College of Pharmacy in suggesting these changes in the Century Code governing the practice of Pharmacy. When the program we had in place for the training of our students came under question from the Clinical Laboratory Board, through our Special Assistant Attorney General David Lindell, we consulted with the Attorney General's Office. The Attorney General's Office indicated we needed to place authorization in the Pharmacy Practice Act to make it clear that pharmacists have your authority to actually perform these simple clinical laboratory tests.

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**TESTIMONY BEFORE THE SENATE HUMAN SERVICES COMMITTEE  
REGARDING HOUSE BILL 1388  
MARCH 10, 1999**

**CHAIRMAN THANE AND COMMITTEE MEMBERS, I AM PATRICIA KRAMER, DIRECTOR OF UTILIZATION MANAGEMENT FOR THE MEDICAL SERVICES DIVISION OF THE DEPARTMENT OF HUMAN SERVICES. I SPEAK IN SUPPORT OF HB1388.**

**HB1388 WOULD PERMIT PHARMACISTS TO PERFORM ROUTINE SCREENING LABORATORY TESTS WHICH ARE WAIVED UNDER THE FEDERAL CLINICAL LABORATORY IMPROVEMENT ACT (CLIA) OF 1988. THOSE TESTS WHICH INCLUDE TESTS FOR DIABETES AND ELEVATED CHOLESTEROL COULD BE PERFORMED BY PHARMACISTS AND PROVIDE GREATER ACCESS TO NEEDED SERVICES, PARTICULARLY IN THOSE AREAS OF THE STATE THAT MAY BE UNDERSERVED BY HEALTH CARE PROFESSIONALS. THE DEPARTMENT SHOULD BENEFIT IN THE LONG-TERM BY IMPROVED HEALTH OF THE MEDICAID POPULATION AND THEREFORE LOWER FUTURE COSTS FOR THE PROGRAM AND ALSO IN THE SHORT-TERM BY DECREASED COSTS TO ADMINISTER THE TESTS.**

**WITH THE POTENTIAL BENEFITS THAT WOULD BE AVAILABLE TO RECIPIENTS AND THE DEPARTMENT I URGE A DO PASS ON HB1388.**