1999 SENATE INDUSTRY, BUSINESS AND LABOR

SB 2364

1999 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2364

Senate Industry, Business and Labor Committee

❑ Conference Committee

Hearing Date 1/25/99

Tape Number	Side A	Side B	Meter #
1	X		0-END
		X	0-340
Committee Clerk Signature			

Minutes:

Senator Mutch called the meeting to order. Roll call was taken, all were present.

Senator Mutch opened the hearing on SB 2364.

Senator Tom Fischer introduced the bill. Testimony enclosed.

Galen Jordre, Executive Vice President of the ND Pharmaceutical Association and a registered lobbyist for that organization spoke in support of SB 2364. Testimony enclosed.

Senator Heitkamp: The board that's going to allow the pharmacists to do this is the board made up from the pharmacy association?

Galen Jordre: The board of pharmacy appointed by the company.

Senator Heitkamp: Pharmacists insurance company O.K. with this?

Galen Jordre: It has not made one difference in their insurance rate.

Senator Klein: How many states are involved with this procedure?

Galen Jordre: At least 25 states are practicing theses techniques.

Senator Sand: What are the qualifications today to be a pharmacist, and on line 4 what do you mean by authorization?

Galen Jordre: The college of pharmacy in ND has gone from a 5 year program to a 6 year program. If I am authorized to administer a certain medication I will have an order from a pre scriber to administer the medication to a specific patient in a specific way.

Senator Sand: Then everything you do as a pharmacist is under a higher order?

Galen Jordre: Not everything, but when based upon a prescription order, yes.

Senator Krebsbach: Do we include administration of drugs in the pharmacy curriculum in ND?

Galen Jordre: Yes.

Senator Thompson: How would this work with county home health care providers?

Galen Jordre: My personal take on that is that our pharmacists are two things, they are health care providers, second they are entrepreneurs.

Senator Tim Flakoll testified in support of SB 2364. Concerned about certain areas where the hospital or doctor may be 3 hours away and the pharmacist is only 40 minutes away. Obligation to customer, in this case citizens of ND. Increase immunization.

Chip Storandt spoke in favor of SB 2364. Testimony enclosed.

Senator Krebsbach: Do you think there will be additional cost to Medicare and what not?

Chip Storandt: No, Medicare will not cover that to start with.

Patricia Kramer, Director of Utilization Management for the Medical Services Division of the Department of Human Services. Testimony enclosed.

Keith Johnson spoke neutrally on SB 2364. He said the only real concern they had was with child immunizations. Submitted an amendment which is enclosed.

Senator Klein: The doctor telling the pharmacist to give these isn't really going to be qualified, going to have to have somebody involved saying yes it's O.K. Mr. Pharmacist to do this.

Keith Johnson: You're correct.

Senator Sand: You use the age 21, when is the last time you immunize?

Keith Johnson: Hepatitis B and MMR upon entrance to college.

Liz Oberly testified in opposition of SB 2364. Testimony enclosed.

Senator Klein: Isn't this a way for people to sustain to home living?

Liz Oberly: They would still have to check in with a doctor or physician.

Joan Jerek, a home health care nurse from Bismarck, spoke in opposition of SB 2364. She feels that she needs the pharmacist and they need people like her. Asked who the question, "who has the ability to provide proper health care?"

David Pesky spoke in opposition of SB 2364. Testimony enclosed.

Senator Mutch: Would you have a problem working with the proponents of this bill during the session for an amendment?

David Pesky: No.

Senator Klein: You didn't have any interaction with any medical groups.

David Pesky: Yes, we visited with pharmacists.

Sharon Moos, Executive Administrator, ND Nurses Association, stood neutral on SB 2364. Because of the time she simply handed out the testimony which is enclosed.

Howard Anderson, Executive Director of the ND State Board of Pharmacy, spoke in support of the bill. Testimony enclosed.

Discussion was held.

Senator Heitkamp motioned for a do pass recommendation on SB 2364. Senator Sand seconded his motion. The motion carried with a 7-0-0 vote.

Senator Heitkamp will carry the bill.

FISCAL NOTE

(Return original and 10 copies)

Bill/Resolution No.: SB 2364 Amendment to: _____

Requested by Legislative Council Date of Request: 1-22-99

1. Please estimate the fiscal impact (in dollar amounts) of the above measure for state general or special funds, counties, cities, and school districts.

Narrative: The fiscal impact of Senate Bill 2364 will be limited to special funds collected through license fees by the State Board of Pharmacy. The primary impact will be in rule making to implement the proposed statute. The main items are publication costs of approximately $250.00 and the cost of review as to legality by the Attorney General's Office of approximately another $250.00. Inspections are done during routine annual compliance visitations by the Board of Pharmacy and should not cost additional dollars.

2. **State** fiscal effect in dollar amounts:

	1997-99 Biennium		1999-2001 Biennium		2001-03 Biennium	
	General Fund	Special Funds	General Fund	Special Funds	General Fund	Special Funds
Revenues:	0	0	0	0	0	0
Expenditures:	0	250.00	0	250.00	0	0

3. What, if any, is the effect of this measure on the appropriation for your agency or department:
   a. For rest of 1997-99 biennium: NONE
   b. For the 1999-2001 biennium: NONE
   c. For the 2001-03 biennium: NONE

4. **County, City, and School District** fiscal effect in dollar amounts:

1997-99 Biennium			1999-2001 Biennium			2001-03 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
0	0	0	0	0	0	0	0	0

If additional space is needed, attach a supplemental sheet.

Signed Howard C. Anderson Jr RPh

Typed Name Howard C Anderson, Jr., R.Ph.

Department Executive Director ND State Board of Pharmacy

Phone Number (701) 328 - 9535

Date Prepared: 1/22/99

SB1150

Date: 1/25/99
Roll Call Vote #: 3364

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

Senate INDUSTRY, BUSINESS AND LABOR COMMITTEE Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken DO PASS

Motion Made By HEITKAMP Seconded By SAND

Senators	Yes	No	Senators	Yes	No
Senator Mutch	X				
Senator Sand	X				
Senator Klein	X				
Senator Krebsbach	X				
Senator Heitkamp	X				
Senator Mathern	X				
Senator Thompson	X				

Total (Yes) 7 No 0

Absent 0

Floor Assignment HEITKAMP

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

REPORT OF STANDING COMMITTEE

SB 2364: Industry, Business and Labor Committee (Sen. Mutch, Chairman) recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2364 was placed on the Eleventh order on the calendar.

1999 HOUSE HUMAN SERVICES

SB 2364

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2364

House Human Services Committee

❑ Conference Committee

Hearing Date February 10, 1999

Tape Number	Side A	Side B	Meter #
1	X		11.7 - End
1		X	0.0 - 38.3
Committee Clerk Signature	Susanne Lindteigen		

Minutes:

SENATOR TOM FISCHER, District 46, testified (Testimony attached).

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

Rep. TODD PORTER asked currently when a community immunization center is set up, do they need a prescription for every vaccination. GALEN JORDRE said no, it can be done by roster. Rep. TODD PORTER asked does the pharmacist need a prescription for every flu vaccination? GALEN JORDRE stated we would be held to a higher standards. Rep. TODD PORTER discussed an emergency situation because of an allergic reaction, can the pharmacist deliver medication? GALEN JORDRE stated the pharmacies would have a protocol situation in place. Rep. TODD PORTER asked where does the physicians and the practitioner fit into that protocol? GALEN JORDRE stated the physician would have knowledge and approval of the protocol.

Rep. TODD PORTER asked does the physician have to write a second prescription in case of an adverse reaction emergency? GALEN JORDRE explained this is how I would work: patient in home health setting, the physician will write orders that authorizes the prescription and even for nurses will include different types of protocol and procedures to follow. If I was participating in a home health agency, I would have worked with nurses and doctors to have the orders written. It would be for all the specific elements that we are talking about. Rep. TODD PORTER asked is there any reason why the board of pharmacy doesn't feel that the pharmacist should be certified in advance for cardiac life support? GALEN JORDRE stated advance cardiac life saving is generally required for those nurses who are in emergency room situations, intensive care, operating room situations.

Rep. WANDA ROSE stated you speak only to home care situations. But, apparently, the bill is much broader to allow you to do parental IV therapy anyplace. Is that correct? GALEN JORDRE said yes, if we follow the same patterns that would happen where a nurse is authorized to administer drugs. Rep. WANDA ROSE asked can someone go into pharmacy for IV therapy? GALEN JORDRE stated this gets down to that element of trust. You have to have a physician who writes the order authorizing that activity.

Rep. CAROL NIEMEIER asked does the physician choose the method of delivery if they do the prescription of medication and treatment plan? Or is it an option of the patient? GALEN JORDRE stated the physician is going to indicate the route and method of administration. Those decisions would not be made by the patient. Rep. CAROL NIEMEIER stated I'm referring to the option of the patient. GALEN JORDRE stated its a relationship between physician,

pharmacist, and patient. The patient has the option to go where they want to go, the same as for prescriptions.

Rep. CLARA SUE PRICE asked if there is health administration in the home, isn't there other duties that the home health care nurse is responsible for, i.e., checking nutrition, hydration, bed sores, etc.? What will be the responsibilities of the pharmacist, then? GALEN JORDRE stated that the essence of home health care is providing those services, therapeutic, supportive. We would not anticipate that because the pharmacist can administer medication that they would be doing these other things. Rep. CLARA SUE PRICE stated that raises a concern when we see problems of reduction and reimbursement and talk of home health agencies having financial difficulties, and asked is there going to be enough funds to go around to have two providers? GALEN JORDRE said no, but if an emergency arises and no nursing service is available, a qualified pharmacist can take care of that.

Rep. BRUCE ECKRE asked will some pharmacists participate and some won't? Is that correct? GALEN JORDRE said we anticipate there will be more who do not rather than do.

Rep. WANDA ROSE expanded on the reimbursement component. If you are involved with a home health agency that you have contracted and its a blanket charge to the home health agency, what if the home health agency is not a part of that, how are you going to be reimbursed? GALEN JORDRE stated if a patient takes home medication from the pharmacy and is hooked up to a portable pump, there are set fees and charges that the pharmacy receives from the insurance company or Medicare.

Rep. CLARA SUE PRICE stated I received an e-mail from a public health administrator who had concerns about the bill from an immunization standpoint, i.e., well baby check,

immunization is the only time the physician or public health nurse sees the child. They're concerned about all of the other things that go with the well-baby care. How will the pharmacy be prepared to deal with that? GALEN JORDRE stated the person who is going to generate that prescription is probably the one who is going to be doing those checks. In the realm of reality, I would see very few physicians or practitioners who would write prescription to send that type of patient outside of their office when they already have schedules of care.

HARRISON "CHIP" STORANDT, Pharmacist, Fargo, testified (Testimony attached). Read letters from PAUL CARSON, Merit Care and NATHAN KOBRINSKY, Merit Care (attached).

Rep. SALLY SANDVIG asked how do prices compare to those charged by nurses for doing this? HARRISON STORANDT stated right now we don't charge anything in addition for this service. Many of our insurance contracts are per diem or blanket coverage where we receive so many dollars a day for a certain type of therapy.

Rep. ROBIN WEISZ asked could there be a problem in situations in home health care provided by a nursing service, if you come in and take care of some medication? Could you lose the nursing service because its no longer cost effective for them to come in to do the other functions? HARRISON STORANDT stated the physician is the final person that decides that. In our case, if we have a conflict and there are things that need to be done by nursing, nursing will do it.

Rep. CAROL NIEMEIER asked how many licensed pharmacists are currently practicing at Merit Care Broadway? HARRISON STORANDT stated don't know, maybe 20 to 30. Rep. CAROL NIEMEIER asked do you anticipate problems in having people out doing home visits and still have enough people in the facility for other things? HARRISON STORANDT stated

there are two of us who do home infusion therapy on the clinic side. We don't make it a point to make home visits.

Rep. TODD PORTER asked for an explanation of how Minnesota handles this problem. HARRISON STORANDT stated they aren't really handling the problem, they're creating it. In Minnesota for TPN patient, they have one flat rate that they give to pharmacy, nursing, etc. Not a lot of home health agencies even have a contract to provide the service. Rep. TODD PORTER asked do they have a definition of parental pharmacist in their state pharmacy act? HARRISON STORANDT stated I don't know. Rep. TODD PORTER asked are you outside of your scope of practice currently, when you talk about some of things that you're doing? HARRISON STORANDT said no, I don't infuse medications unless its an emergency situation and there is no one else there to respond.

Rep. CLARA SUE PRICE asked for comments on a the last sentence of one of the letters. It reads *"appropriate physician direction...and filling the occasional needs where appropriate nursing care is not available."* Is this physician feeling that nursing care or home health is a preferable option and pharmacists should fill in? What in the bill specifies that? HARRISON STORANDT stated in certain instances people don't have nursing care. It is part of the health system. Its kind of managed care. After they're done with that, they are out there on their own. That's the patients we can help. I'm not the first line out there. I'm the person when there is no one else to be there. Rep. CLARA SUE PRICE asked of the 25 states that have passed this, does this then become the first line because its cheaper? HARRISON STORANDT stated I would hope not. I don't know what insurance is going to do. I've done this for eleven

years. It isn't us who is dictating that. Its the insurance companies and whoever is cutting back to make things profitable.

Rep. SALLY SANDVIG asked will Medicare cover this? HARRISON STORANDT stated Medicare will cover home health nursing visits. Medicare covers very few pharmacy related things done in the home. Rep. SALLY SANDVIG commented about concern when an elderly person feels they must continue having the services once they start? Will they have a choice to go somewhere else to get this care? HARRISON STORANDT stated most Medicare patients won't have a problem because they have nursing coverage. Nursing makes the visits.

Rep. CHET POLLERT asked if there are circumstances in dealing with welfare cases or young children, are those covered by Medicaid? HARRISON STORANDT stated Medicaid is one of the better coverage's for patients. They can get the nursing coverage for them.

CLINT DWORSHAK, Student, College of Pharmacy, NDSU, testified (Testimony attached).

Rep. WANDA ROSE asked as a student in pharmacy, what kind of developmental knowledge do you have of a child that's 15 months old and how would you go about giving or administering medication or immunization? CLINT DWORSHAK stated one of the classes we take is pediatrics and we are trained extensively. We study diseases that they are susceptible to. We learn about their physiology. Part of the class or training we receive is triune administration, orient injections for vaccinations. We learn proper procedures of administering to pediatric patients, geriatric patients. Rep. WANDA ROSE stated I'm glad you've learned the physiology but I want to know how you would manage a 15 month old. Do you know the developmental stage, what's the milestones; and what kind of activity a 15 month old does? CLINT DWORSHAK stated you're putting me on the spot. We have studied, yes. But, right off the top

of my head, I can't pull that out for you. Those that do practice in such a setting are to go through more training in pediatrics. As has been said, its going to be qualified people who are administering. These are going to be pharmacists who have studied beyond the rotation progress. During our fifth or sixth year of the program, we do rotations in pharmacy settings and hospitals which we'll get more training in actual care of patients, i.e., adult internal medicine. There are rotations available in pediatrics where you are actually working with pediatric patients.

PATRICIA KRAMER, Director, Utilization Management for the Medical Services Division, Department of Human Services, testified (Testimony attached). As a side note per our Medicaid statistics immunization rates for kids up of two years of age is 64%, well child checks are 78%. In working with the Health Department and other providers to try to determine the 15% discrepancy, why we're not giving immunization at the same time we're giving glaucoma tests, we think it may be a billing problem.

Rep. TODD PORTER asked if a nurse goes out for home health care and gives an injection, can they bill for services twice on that day? PATRICIA KRAMER said no, just once. Rep. TODD PORTER asked aren't you creating another level of service that's already within the home health care and branching it out into a two-tier system? PATRICIA KRAMER said there would not be an extra payment from Medicaid for service because the pharmacist gets paid for drug preparation and administration. The nurse gets paid for the nursing work. There are two separate services and two separate payments, no matter what is delivered.

Rep. CLARA SUE PRICE explained if the home health nurse brings the drug or the injection with and administers it during her visit. PATRICIA KRAMER said there is one payment for that regardless of what else the nurse does.

Rep. SALLY SANDVIG asked is there any concern that the pharmacist might increase the cost of their drugs to cover their services? PATRICIA KRAMER stated they could increase their prices but our payments are fairly well established at the lower fee.

Rep. CLARA SUE PRICE asked do you have figures of how many Medicaid recipients receive immunizations in the doctors office versus public health? PATRICIA KRAMER stated for the last quarter of 1998, there were 3300 Medicaid recipients receiving up to 2 years immunization and of those 861 received those through public health. The rest, 2,439 were from general family practice, pediatrics, etc.

HOWARD ANDERSON, JR. Executive Director, ND State Board of Pharmacy, testified (Testimony attached). One of the difficulties that I have had in training our pharmacists at NDSU College of Pharmacy is that since pharmacists are not authorized to do this in North Dakota, we have difficulty getting the nurse trainers who are part of our college of nursing to do this because they don't like to train pharmacists for something that's not legal in North Dakota.

Rep. WANDA ROSE stated its nice that you say you're going to involve all these people but that is not clear in the bill. HOWARD ANDERSON stated Galen Jordre in his testimony included guidelines and rules that we talked about and which form the basis for the implementation of these rules once you pass the bill, we would start the formal rulemaking process. I don't have any problems if you want to connect it and put something specific in legislation.

OPPOSITION

DAVID PESKE, Director, Governmental Relations, ND Medical Association, testified (Testimony attached). Introduced physicians, Matt Layman and Steve Mattson.

MATT LAYMAN, MD, Anesthesiologist, Mid Dakota Clinic, Bismarck, testified (Testimony attached)

STEVE MATTSON, MD, Pediatrician, Minot, testified I have two concerns about this bill: (1) immunization practices. And I'm aware of development of a 15-month old. Those squirmy little kids aren't easy to catch. Even in our residency, we have two nurses come in to deal with older kids. Its a difficult thing. The other issue is (2) quality of care - nurses spend a great deal of time improving their skills, continuing with learning on how to put in IV's and other aspects and devices. You need a lot of experience and a lot of practice. I don't think that could happen for pharmacists who would do this occasionally.

LIZ OVERLIE, President, ND Association for Health Care, Minot, testified (Testimony attached). Stated that the definition of practitioner in SB 2176, page 1, does not match the definition of a practitioner in SB 2364, page 6.

SUSAN ARNESON, President-elect, ND Association for Health Care, Langdon, testified (Testimony attached).

JODE KOCH, R.N., ND Public Health Association, Mandan, testified (Testimony with an Amendment attached).

JOANN FERRIE, ND Association for Home Care, Bismarck, testified (Testimony attached).

PENNI WESTON, ND Nurses Association testified (Testimony attached).

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2364

House Human Services Committee

❑ Conference Committee

Hearing Date February 16, 1999

Tape Number	Side A	Side B	Meter #
1	X		0.0 - End
Committee Clerk Signature	Susanne Lindteigen		

Minutes:

Committee Discussion.

Rep. CAROL NIEMEIER expressed a problem with the pharmacy technician area of the bill.

Rep. TODD PORTER stated there may be a problem with a new layer of health care and reimbursement being invented. The other side of that is the good job Home Health Care is doing and the benefit they bring to the patient. The pharmacist can perform the work when there is an emergency.

Rep. AMY KLINISKE moved DO NOT PASS.

Rep. ROXANNE JENSEN second the motion.

Rep. BLAIR THORESON expressed understanding for the concerns but felt this was good legislation. He stated the pharmacist still has to be able to perform to get referrals from the physicians.

Rep. BRUCE ECKRE stated this is common practice and we need total assessment.

ROLL CALL VOTE #1: 13 yeas, 2 nays, 0 absent

CARRIER: Rep. TODD PORTER

Date:
Roll Call Vote #:

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2364

House Human Services Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Not Pass

Motion Made By Amy Kliniske Seconded By Roxanne Jensen

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price - Chairwoman	X		Bruce A. Eckre	X	
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 2
Absent 0

Floor Assignment Todd Porter

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

REPORT OF STANDING COMMITTEE

SB 2364: Human Services Committee (Rep. Price, Chairman) recommends **DO NOT PASS** (13 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). SB 2364 was placed on the Fourteenth order on the calendar.

1999 TESTIMONY

SB 2364

SB2364
Senator Tom Fischer

Chairman Mutch, members of the Senate Industry, Business and Labor Committee. For therecord, my name is Tom Fischer, state senator from district 46, south Fargo.

I come before your committee to introduce and support Senate Bill 2364 which allows certified pharmacists to administer parenteral drugs under certain circumstances.

Mr. Chairman, There are people here who are far more qualified than myself to explain this bill in detail and to answer your questions, so with you permission, I will have them continue.

Thank you.

North Dakota Pharmaceutical Association
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Senate Bill 2364 – Relating to Parenteral Pharmacists
Senate Industry, Business and Labor Committee
January 25, 1999 – 8:00 AM
Testimony of Galen Jordre, R.Ph.

Chairman Mutch, 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 Senate Bill 2364 is to allow qualified pharmacists to administer parenteral drugs when authorized and following rules established by the Board of Pharmacy. For sake of clarification, parenteral means a sterile product that is prepared for injection through one or more layers of skin.

At the present time, this authority is allowed to pharmacists only when there are emergency situations involving home infusion drugs and there is no nursing service available. The language of this legislation sets out a method to expand this authority while protecting the public.

The legislation proposes these specific changes and additions:
(Printed Bill)
Page 1, Line 9 – This change in definition of administration removes the current restrictive language related to home health care and the specific prohibition against administering parenteral drugs.

Page 1, Line 14 – This new definition outlines how a pharmacist obtains authority to administer parenteral drugs by stipulating that there are five elements to an authorization: an order, a practitioner, a qualified pharmacist, a specific drug, and specific patients. With any one of these five elements missing, a pharmacist would not be able to administer.

Page 5, Line 1 – Sets forth the definition of "parenteral" as was discussed earlier.

Page 7, Line 1 – Defines a "qualified parenteral pharmacist" as a pharmacist who successfully completes an education course and meets continuing education requirements established by the Board of Pharmacy.

Page 7, Line 18 – This section ties everything together by saying that qualified pharmacists may administer parenteral drugs when they receive an authorization to administer from a prescriber and when they meet rules adopted by the Board of Pharmacy.

The pharmacists of North Dakota are proposing this legislation because they feel that by using this authority they will improve the health of the citizens of the state. The ability of pharmacists to provide immunizations and administer parenteral drugs in emergencies, in teaching situations, and in other settings is beneficial as more drug therapy is instituted and administered outside institutional settings. Pharmacists trained in all types of administration will enhance the efforts of the health care team to provide drugs to patients in the most effective manner. Pharmacists now have authority to administer immunizations in over 25 states with ability to administer additional injectable drugs in many of the states. It is not the intent of pharmacists to replace - but to supplement and enhance the efforts of others in the delivery of drug products to patients.

What types of administration are envisioned?

- **Immunizations** – The 1997 North Dakota flu immunization billed rate for Medicare Beneficiaries Age 65 or older was 54.8%. Less than 30% of this group has received pneumococcal vaccine once in their lifetime. These two diseases needlessly kill thousands of people across our country every year and pose a deadly threat to the elderly of our state. Good public policy would indicate that if you have a group of highly educated health care providers who want to join the fight against these diseases by educating their patients and providing vaccinations – they should be authorized and encouraged. In other states where pharmacists have been able to immunize, immunization rates have risen. Pharmacists do not wish to replace any other providers that administer immunizations, but feel that there are many opportunities to increase our immunization rates. Pharmacists offer educational opportunities to patients and ready access to a provider. Pharmacies are taking a role in educating their patients. This last fall our Association sent out to 180 pharmacies, at the request of the State Diabetes Control Unit, a packet of materials and a poster about immunizations and diabetic patients. A number of pharmacies have hosted immunization clinics and have been pleased by the response from the public. These pharmacies want to continue this type of service and by being able to perform immunizations themselves, pharmacists can expand the opportunities to their patients. By authorizing trained pharmacists to administer, the public will have another resource, raising the opportunity for immunization and improving the public health. Passage of this legislation will give pharmacists a chance to help save lives.
- **Home Care Situations** – Pharmacists currently have limited authority in home care to administer medications in emergency situations. The changes in healthcare emphasize the team approach to caring for patients. Pharmacists prepare the home care medications, check for medication incompatibilities and interactions, are responsible for delivery of medications and supplies, and are responsible for operation of IV pumps and other equipment. It is only a natural extension that trained pharmacists who work extensively with these products be authorized to administer these medications as a part of the home care team.
- **Changes in the way drugs are dispensed to patients.** – New products are emerging on the market where the drug should be administered close to the time it is dispensed. Situations where drugs are dispensed and administered into implanted devices are starting to emerge. Pharmacists want to be prepared for future situations where they can serve their patients and the system by administering the medication by all routes, including injection.

- **Teaching situations in pharmacies** – In the future, more patients will be expected to self-administer medications in their homes. At the time the medication is dispensed in the pharmacy, it may be necessary for the pharmacist to augment other training efforts and assist the patient in learning self-administration.

What safeguards will be in place to assure safety?

- The ability of pharmacists to administer parenteral medications will be dependent upon a physician order just like all other health care providers.
- Because many College of Pharmacy graduates go to states where administration of medications by injection is currently authorized, the college teaches all new graduates injection techniques, documentation methods, procedures to follow in assessing patient reaction to injections, and emergency procedures. The College of Pharmacy is developing a program of continuing education for other pharmacists who wish to participate in this area of practice.
- The proposed change in the law provides that the Board of Pharmacy will establish rules to set educational requirements for qualified pharmacists and standards pharmacists must meet to administer injectable drugs. These rules will assure that the safety needs of patients are met and will establish procedures that pharmacists must follow.

We do not expect that all pharmacists will participate in administration of medications by injection. However we do want the opportunity open to those who are currently practicing where administration will enhance delivery of care to their patients and the patients of their organizations. The legislative language is very clear, if pharmacists do not complete the training and create a trust with the prescribers that write the orders, they will not be administering parenteral drugs. We would not want to participate in any other way. By amending the current law, trained pharmacists in those situations will be able to provide efficient and safe medication administration along with other members of the health team.

I have included with my testimony a letter from Rod Shafer, R.Ph., the Executive Director of the Washington State Pharmacists Association that outlines the experience of pharmacists and the public in his state after pharmacists were allowed to immunize. Rod was in Bismarck this weekend providing a continuing education seminar to our pharmacists. He would have liked to have stayed for the hearing this morning but they are in legislative session in Washington as well.

Two other pieces of information included along with my testimony. The first is a proposal to the Board of Pharmacy for those elements that should be included in Board of Pharmacy rules regarding administration of parenteral drugs. The second is a copy of the Guidelines adopted by the American Pharmaceutical Association for pharmacy-based immunization activities. We are proposing that these guidelines be incorporated into the Board of Pharmacy rules.

We ask for your support of this legislation. It will have a positive impact on the citizens of our state. Thank you.

Washington State Pharmacists Association
1501 Taylor Ave. SW
Renton, WA 98055-3139
(425) 228-7171 fax (425) 277-3897 wspa@pharmcare.org

January 25, 1999

The Honorable Senator Duane Mutch, Chair
Senate Industry, Business and Labor Committee
600 East Boulevard
Bismarck ND 58505-03600

Re: Senate Bill No. 2364

Senator Mutch, members of the committee, I offer this written testimony in support of Senate Bill 2364 that would allow the pharmacists of North Dakota, in collaboration with other medical providers, to provide immunization in a timely and appropriate manner to the citizens of this state. The provision of these vaccines, by pharmacists, will provide your constituents the means to reduce their risk of poor health outcomes associated with vaccine preventable diseases.

Problem:
Each year 70,000 to 80,000 Americans die needlessly from the complications of influenza and pneumonia because they did not receive the appropriate vaccinations. It is the fifth leading cause of death in the elderly and results in greater than 400,000 hospitalizations yearly. In North Dakota, the rate of influenza vaccination for those Medicare eligible citizens (age 65 and over) is only 54.8% and less than 26% for pneumococcal vaccination. The majority of these people are not immunized for three reasons; 1) of lack of understanding and motivation, 2) lack of access, and 3) missed opportunities. This is a very costly public health care issue in terms of loss of human life and suffering, not to mention, a needless financial drain on our health care system.

Solution:
Pharmacists represent a highly educated, accessible and under utilized health care provider who can address two of the major issues confronting us in the adult immunization arena, i.e. education and access. There is not another health care provider more trusted or evenly distributed demographically than the pharmacist. As a result of this high public trust and access, pharmacists can provide three very important services to help resolve this public health dilemma. One, provide education about the importance of adult immunizations and encourage their patients to get vaccinated. Two, host immunization clinics in their pharmacies provided by public health clinics, visiting nurse service, physicians or other qualified health care organizations, and three, the administration of these important vaccines by pharmacists, themselves, on a regular and ongoing basis. The elimination of the access barrier happens when health care is delivered at a site that is convenient to the patient, and when the patient wants and needs

that care. The equivalent of the U.S. population passes though the nations pharmacies every month. If they are already in the pharmacy for other care issues wouldn't it be convenient to also provide them with this important service. Health care awareness, prevention and wellness education will save us more dollars and provide better patient outcomes than any new technology that we can envision and pharmacists, in collaboration with other health care providers, are well trained and positioned to provide these services.

Result:
By implementing this legislation you immediately address the issue of increasing access to vaccination services, and the provision of that service by a trusted and competent health care provider. A health care provider who has been voted the most trusted and ethical professional, by the public, in the Gallup Polls for the last 9 years. Passage of this bill will improve the health and welfare of your constituents and reduce total health care costs. For every dollar spent on immunizations you will save $10.00 in down stream health care cost.

The Washington Experience:
In 1979 the Washington State Pharmacy Act was amended to include the "administration of medications by injection" to be within the scope of practice of Washington pharmacists and to allow pharmacists to "..modify and initiate drug therapy under a written protocol by a health care provider licensed to prescribe". The combination of these two things has provided the environment for pharmacists and physicians to enter into collaborative protocols that allow pharmacist to provide immunizations to patients in their pharmacies. Pharmacists have been providing immunization services in their pharmacies for the last four years and each year the program grows in acceptance and patient satisfaction. We currently have approximately 300 immunization protocols in place and a recent Board of Pharmacy survey, of both pharmacists and physicians, regarding satisfaction with the protocols showed a 98% approval rating. Patient acceptance has been overwhelming and pharmacists provided over 75,000 flu shots this year alone. In addition, pharmacists are providing pneumonia vaccine, Hepatitis B, tetanus and other adult vaccinations. Childhood vaccinations are also provided, but usually only in rural or isolated situations where a pediatrician is unavailable.

The Washington experience has been an unqualified success by any standard and has been duplicated in 23 other states across the nation. I hope that you will see the wisdom of this policy and move to approve this legislation. If I can be of any further assistance in you deliberations please do not hesitate to call.

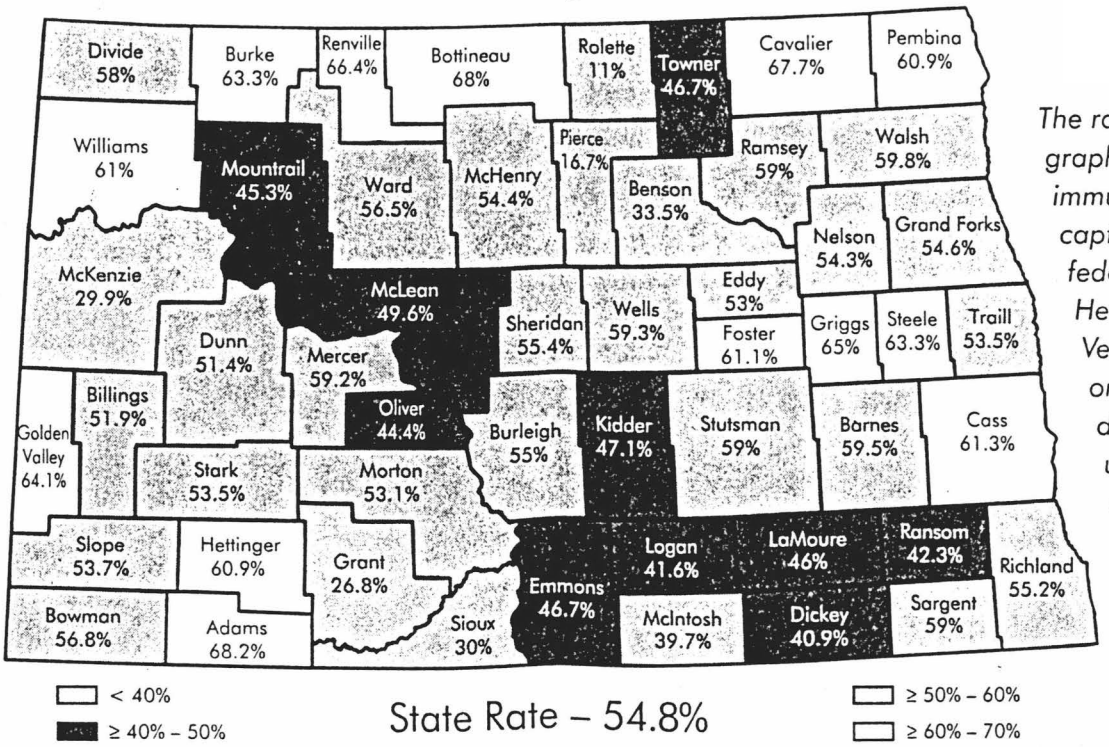
Thank you for your time and consideration of this information.

Sincerely,

Rod Shafer, R.Ph.
Executive Director

1997 North Dakota Flu Immunization Rates

Medicare Beneficiaries Age 65 or Older

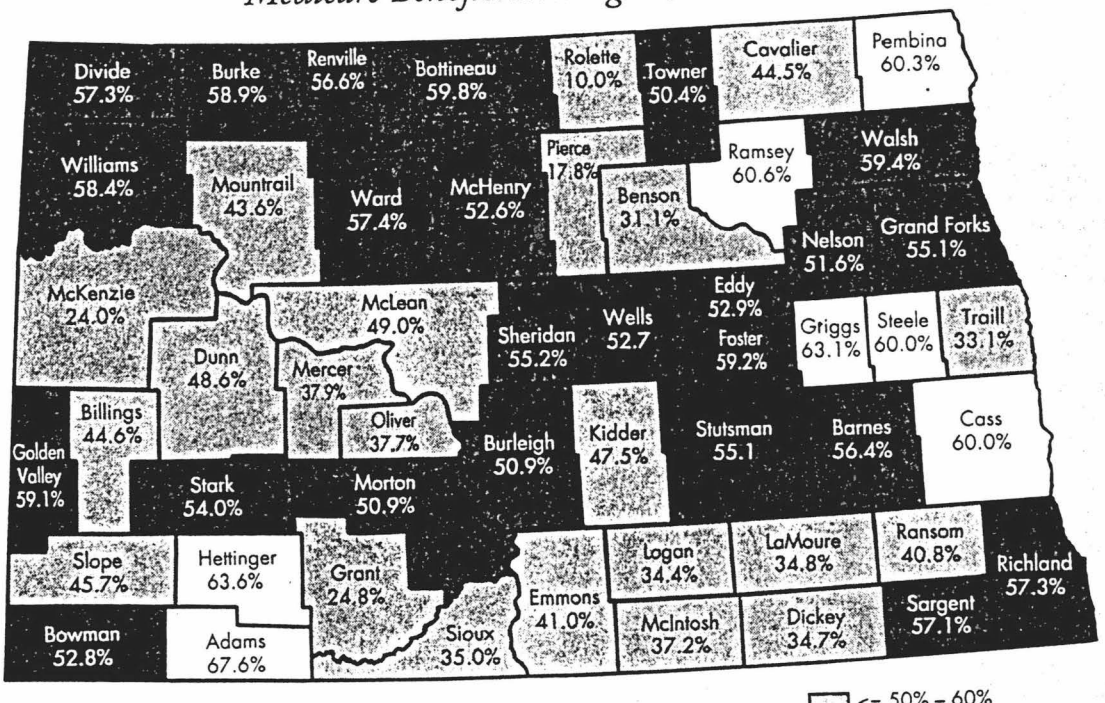


State Rate – 54.8%

The rates reflected in this graph include only billed immunizations, and do not capture flu shots given at federally designated Rural Health Centers, The Veteran's Administration, or any other entity that does not bill Medicare using roster, electronic, or standard Medicare claim forms.

1996 North Dakota Flu Immunization Rates

Medicare Beneficiaries Age 65 or Older



State Rate – 52.1%

Taken from information developed by North Dakota Health Care Review Inc.

American Pharmaceutical Association
2215 Constitution Avenue, NW
Washington, DC 20037-2985
(202) 628-4410 Fax (202) 783-2351

SEP 2 2 1997

The National Professional Society of Pharmacists–Since 1852

NEWS RELEASE

TO: Media Representatives

FROM: Tina L. Pugliese, APR
Public Relations Director

DATE: September 18, 1997

RE: Guidelines for Pharmacy-Based Immunization Advocacy and Administration

The American Pharmaceutical Association (APhA) Guidelines for Pharmacy-based Immunization Advocacy define what people should expect of pharmacists who wish to serve their communities by improving immunization rates among vulnerable populations, such as the elderly.

By establishing performance benchmarks for pharmacists, APhA hopes to instill in consumers and payors the confidence to take advantage of the ready accessibility of pharmacists to reduce preventable death and disability diseases. APhA's Guidelines for Pharmacy-based Immunizations Advocacy explicitly stress the pharmacist's role as a preventive health care services provider.

"One important message that comes through loud and clear in the new APhA Guidelines is our call for pharmacists to work in partnership with physicians and other prescribers, as well as State public health officers, to reduce vaccine-preventable morbidity and mortality, especially among the elderly," said John A. Gans, PharmD, APhA Executive Vice President.

BACKGROUND

Over the past year, APhA has invested many resources in the development of education, advocacy, and scientific programs related to the role of pharmacists in immunizations. These activities have assisted the profession to develop collaborative relationships with other health care professionals and to highlight the pharmacist's position within the health care system.

At the 1996 APhA Annual Meeting in Nashville, Tennessee, the APhA House of Delegates adopted policy encouraging pharmacists to take an active role to increase the rate of immunizations among vulnerable patient populations. This role could be fulfilled by pharmacists' becoming educators, facilitators, or immunizers of the public.

In response to a call by pharmacists and other entities for assistance in developing these expanded roles, a set of draft guidelines were developed. These proposed guidelines were presented to the 1997 APhA House of Delegates, in Los Angeles, California, as a New Business Item. The House referred the guidelines to the Board for the solicitation of further input and the adoption of a set of guidelines that would assist pharmacists in incorporating immunization activities into their practice. After receiving input from pharmacists, and other health care providers and organizations, the APhA Board of Trustees approved the attached document in August 1997. The guidelines are a dynamic document and will be periodically reviewed as the health care arena changes.

For additional information, contact:
Mitch Rothholz, RPh, (202) 429-7549; e-mail: mcr@mail.aphanet.org, or
David Schulke, (202) 429-7538; e-mail: dgs@mail.aphanet.org

Feature

by Jay Gold, MD

Accessibility is Key

Wisconsin needs pharmacists to take active role in immunizations

I am a physician and serve as Senior Vice President and principal Clinical Coordinator of MetaStar (formerly WIPRO), an organization that works to improve quality of care for Wisconsin Medicare beneficiaries and others. The Health Care Financing Administration (with whom we contract), in conjunction with the Centers for Disease Control and Prevention, has launched a major nationwide initiative designed to produce substantial increases in the rates of influenza and pneomococcal immunizations among adults. As part of this initiative, MetaStar has convened and coordinates the Wisconsin Adult Immunization Coalition (WAIC), which consists of professional and provider organizations (such as PSW), public health officials, and others committed to increasing immunization rates.

As a physician I personally endorsed Senate Bill 361 and the notion of trained pharmacists providing immunizations. I believe that it may be a viable way to help alleviate a true problem in Wisconsin: mainly, lack of greater access to immunization services.

At WIPRO our main focus is now on increasing the influenza and pneumococcal pneumonia vaccination rates among Wisconsin's elderly citizens. The pneomococcal vaccination is a one-time shot, while the flu shot should be given yearly. However, only slightly more than half of Medicare beneficiaries in Wisconsin received flu shots in 1996 and only about a third have received pneumococcal vaccinations. This is true despite the fact that both of these vaccinations are free to Medicare beneficiaries without a co-pay. As a result, influenza and pneumococcal pneumonia remain the fifth leading cause of death among elderly Wisconsin residents, and the tenth leading cause of death in Wisconsin overall. This also results in millions of health care dollars spent to treat diseases which can be effectively controlled and prevented with an $8 shot. I believe there is no more cost-effective intervention in all of medicine.

As a physician I personally endorsed Senate Bill 361 and the notion of trained pharmacists providing immunizations. I believe that it may be a viable way to help alleviate a true problem in Wisconsin: mainly, lack of greater access to immunization services.

Why, one may ask, aren't people getting immunized? It has been estimated by Dr. Gregory Poland of the Mayo Clinic, chair of the National Coalition on Adult Immunization, that perhaps 15% of the public will not consent to getting immunized under any circumstances. Either they don't like shots, don't believe in immunizations, etc. However, the remaining 85% may not get immunized for several reasons, one of which is lack of access to or knowledge of immunization services. For example, many people do not go to where shots are being given at times when they can receive them. This is where you, the pharmacist, may be able to help. Pharmacies are located in most communities, are present in many supermarkets and retail settings, and they have long hours of operation. Plus, it is estimated that the equivalent of the U.S. population goes through the doors of a pharmacy each week.

As a medical professional, I believe that the training required under Senate Bill 361, coupled with your knowledge of medications, places you, the pharmacist, in an ideal position to help increase Wisconsin's elderly immunization rates. More than half of the states in the country are utilizing pharmacists to perform this service, for it can lessen the burden of disease and death, as well as decrease health care costs and lost.

For the above-mentioned reasons I strongly encourage you to make a commitment to helping increase the elderly immunization rates in our state. If your practice is not conducive to administering the services themselves, consider hosting an immunization clinic with your local visiting nurses association, or simply serve as an advocate by asking your elderly patients whether or not they have received their vaccinations. In any event, the citizens of Wisconsin only stand to benefit from your accessibility, commitment, and services. ■

Dr. Jay Gold is the Senior Vice President and Clinical Coordinator for Metastar

PROPOSAL PRESENTED TO BOARD OF PHARMACY FOR RULES ADMINISTRATION OF MEDICATIONS/IMMUNIZATIONS

"Qualified parenteral pharmacist" means a pharmacist who has successfully completed a Board approved course of study pertaining to the parenteral administration of drugs and maintains continuing competency according to rules adopted by the Board.

Qualifications established for parenteral pharmacists. A pharmacist must meet the following criteria in order to qualify as a parenteral pharmacist:

- Obtain and maintain a license to practice pharmacy issued by the North Dakota State Board of Pharmacy;
- Successfully complete a Board approved course of study, examination, and certification consisting of a training program that is a minimum of 20 hours and shall qualify for continuing education credits. The Course of Study should include, at a minimum:
  a. basic immunology, including the human immune response;
  b. the mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines and approved medication/immunization;
  c. current immunization guidelines and recommendations of the Centers for Disease Control and Prevention;
  d. how to handle an emergency situation in the event one should arise as a result of the administration of the medication/immunization;
  e. how to educate patients on the need for immunizations;
  f. how to administer subcutaneous, intradermal, and intramuscular injection; and
  g. record-keeping requirements established by law and regulation or standards of care.
- Obtain supervised instruction on the physical administration of vaccines and medications from a qualified health professional permitted to administer such medications;
- Obtain and maintain current certification in Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS); and
- Provide the Board of Pharmacy copies of certificates of completion of all required education for placement in the pharmacist's permanent file. One copy of all certificates shall be displayed in the pharmacy at which the pharmacist is working.
- Maintain continuing competency for qualification as a parenteral pharmacist. A minimum of six (6) hours of the thirty (30) hour requirement for continuing education, every two years, must be dedicated to this area of practice.
- Any qualified pharmacist that performs venipuncture to administer parenteral medications must complete an additional board approved course that is equivalent to courses required by the North Dakota Board of Nursing for licensed practical nurses performing the same functions.

Procedures to Administer Parenteral Drugs.

- Qualified parenteral pharmacists may provide pharmaceutical care to patients by administering medications or immunizations upon receiving an authorization to administer by a practitioner so authorized to prescribe the medications or immunizations.
- Prescriptions and procedures shall meet the following requirements:
  a. prescriptions must identify the authorized routes and sites of administration allowed;
  b. procedures must include record keeping requirements and methods of notifying prescribers of administration, and
  c. procedures shall follow Guidelines for Pharmacy-based Immunization Advocacy as adopted by the American Pharmaceutical Association.

AMERICAN PHARMACEUTICAL ASSOCIATION
GUIDELINES FOR PHARMACY-BASED IMMUNIZATION ADVOCACY
Approved by the APhA Board of Trustees, August 1997

Guideline 1 – Prevention.

Pharmacists should protect their patients' health by being vaccine advocates.

(a) Pharmacists should adopt one of three levels of involvement in vaccine advocacy:
  (1) Pharmacist as educator (motivating people to be immunized);
  (2) Pharmacist as facilitator (hosting others who immunize);
  (3) Pharmacist as immunizer (protecting vulnerable people, consistent with state law).
(b) Pharmacists should focus their immunization efforts on diseases that are the most significant sources of preventable mortality among the American people, such as influenza, pneumococcal, and hepatitis B infections.
(c) Pharmacists should routinely determine the immunization status of patients, then refer patients to another appropriate provider for immunization.
(d) Pharmacists should identify high-risk patients in need of targeted vaccines and develop an appropriate immunization schedule.
(e) Pharmacists should protect themselves and prevent infection of their patients by being appropriately immunized themselves.

Guideline 2 – Partnership.

Pharmacists who administer immunizations do so in partnership with their community.

(a) Pharmacists should support the immunization advocacy goals and other educational programs of health departments in their city, county, and state.
(b) Pharmacists should collaborate with community prescribers and health departments.
(c) Pharmacists should assist their patients in maintaining a medical home, including care such as immunization delivery.
(d) Pharmacists should consult with and report immunization delivery, as appropriate, to primary-care providers, state immunization registries, and other relevant parties.
(e) Pharmacists should identify high-risk patients in hospitals and other institutions and assure that appropriate vaccination is considered either before discharge or in discharge planning.
(f) Pharmacists should identify high-risk patients in nursing homes and other facilities and assure that needed vaccinations are considered either upon admission or in drug regimen reviews.

Guideline 3 – Quality.

Pharmacists must achieve and maintain competence to administer immunizations.

(a) Pharmacists should administer vaccines only after being properly trained and evaluated in disease epidemiology, vaccine characteristics, injection technique, and related topics.

(b) Pharmacists should administer vaccines only after being properly trained in emergency responses to adverse events and should provide this service only in settings equipped with epinephrine and related supplies.
(c) Before immunization, pharmacists should question patients and/or their families about contraindications and inform them in specific terms about the risks and benefits of immunization.
(d) Pharmacists should receive additional education and training on current immunization recommendations, schedules, and techniques at least annually.

Guideline 4 – Documentation.

Pharmacists should document immunizations fully and report clinically significant events appropriately.

(a) Pharmacists should maintain perpetual immunization records and offer a personal immunization record to each patient and his or her primary care provider whenever possible.
(b) Pharmacists should report adverse events following immunization to any appropriate primary-care providers and to the Vaccine Adverse Event Reporting System (VAERS).

Guideline 5 – Empowerment.

Pharmacists should educate patients about immunizations and respect patients' rights.

(a) Pharmacists should encourage appropriate vaccine use through information campaigns for health care practitioners, employers, and the public about the benefits of immunizations.
(b) Pharmacists should educate patients and their families about immunization in readily understood terms.
(c) Before immunizing, pharmacists should document any patient education provided and informed consent obtained, consistent with state law.

References:

Center for Disease Control and Prevention Standards for Pediatric Immunization Practices, MMWR 1993; 42 (RR-5): 1-13
National Coalition for Adult Immunization. Bethesda, Maryland: NCAI 1995.

COMMENTS ON SENATE BILL NO. 2364 SCHEDULED FOR HEARING MONDAY JANUARY 25, 1999 -8:00AM BEFORE THE SENATE INDUSTRY BUSINESS AND LABOR COMMITTEE.

Chairman Duane Mutch, members of the Senate Industry Business and Labor Committee, my name is Harrison "Chip" Storandt R.Ph. I am speaking for myself as a pharmacist. I practice at MeritCare Broadway Pharmacy Fargo, North Dakota.

I am speaking in favor of Senate Bill No. 2364, which would authorize qualified pharmacists to administer parenteral drugs.

I have been a pharmacist at MeritCare for approximately 11 years, the last 9 being involved with the home infusion program. During this time I have worked as a team member in conjunction with nurses and physicians caring for home infusion patients. Our practice has seen dramatic increases in the number of patients we help to manage in the home environment.

I currently have several patients that receive various parenteral therapies at home that have limited or no nursing coverage. This is due mainly to insurance constraints. We have one patient that has been on Total Parenteral Nutrition therapy without home health nursing for over 5 years. Whenever problems arise I am her contact person and am responsible to see that these problems are resolved by consultation with her physician. These problems are not always drug related but at times will involve the central venous catheter and problems infusing her solution.

Many patients that receive home IV's who have nursing coverage may also have some gaps in nursing care for their therapies. For example when they come in for a physician visit the insurance does not always cover an additional home-nursing visit to start a new I.V. or to do catheter flushes. There are many excellent nurses in our facility. Only a few may be familiar with the types of special pumps, tubing or catheter flush procedures which are used in the home care setting. Many times these patients are referred to me for help by nurses or physicians.

There are also many new drugs that are now being developed and are being used in the home instead of more complex therapies that must be done in the hospital. Some specific examples of these are the colony stimulating factors. These medications stimulate the immune system to produce extra white blood cells which are valuable in treating cancer patients whose chemotherapy has dropped their counts to the point where infection is a real concern. These patients are able in most cases to administer a sub-cutaneous shot to remain at home and out of the hospital. Another drug that is being used is enoxaparin (Lovenox) which has reduced hospitalizations for patients with Deep Venous Thrombosis (blood clots usually in the leg). Until just recently this medical problem would need to be treated in the hospital for a minimum of 5 days with many expensive labs ordered to monitor the patient. Currently these patients are able to come in for diagnosis and return

home within 24 hours. I follow many patient's therapies such as this example. Most do not have home nursing care following them. As their pharmacist, I may be the one they call on for help with problems regarding their therapy if no one else available. These problems can range from drug side effects to the proper administration of the drug. If a patient does need help injecting these medications we attempt to arrange for home health nursing prior to discharge from the institution.

Another infusion therapy that we are involved with is the delivery of medications for pain control. These patients utilize a special pump implanted in the abdomen by a surgeon. The surgeon implants a catheter into either intrathecal or epidural space. The numbers of these patients are growing every year. Most of these patients need refills of their pumps. Many require refilling as often as once weekly or up to every 3 months. To complete this therapy a special computer is required to check the pump or reprogram the rate of infusion, if necessary. Because of the growing numbers of patients in our pain clinic, the nurses have asked me to help fill these pumps. This requires inserting a needle through a layer of skin to access the pump. I have received special training to complete this procedure from Medtronic, which is the maker of this pump.

Thank you for your time and consideration of this information. I believe that passage of Senate Bill 2364 will improve the health care for these patients and allow for an optimal outcome of their therapy.

PROPOSED AMENDMENTS TO SENATE BILL NO. 2364

On page 7, line 20, after "board" insert:

"but this authority is not applicable to the administration of any vaccine required under section 23-07-17.1 to an individual who is less than twenty-one years of age"

Renumber according

TESTIMONY IN SUPPORT OF SB2364 BEFORE
THE SENATE INDUSTRY, BUSINESS AND LABOR COMMITTEE
January 25, 1999

Chairman Mutch and members of the committee, I am Patricia Kramer, Director of Utilization Management for the Medical Services Division of the Department of Human Services. I speak in support of SB2364 today.

SB2364 would permit a qualified pharmacist, and only a qualified pharmacist, to administer specific parenteral drugs (injections) to specific individuals and only if ordered with a valid prescription. This bill would not only require successful completion of a Board of Pharmacy approved instructional course but would also require those pharmacists initially qualified to maintain continued education in parenteral therapy.

The recipients of state Medicaid would benefit from this bill by having 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 injections.

With the requirements that would be in place for qualifying pharmacists and the potential benefits that would be available to recipients and the department, I urge a do pass on SB2364.

TESTIMONY ON SENATE BILL NO. 2364 ND Pharmacy Practice Act Revisions

Senate Industry, Business and Labor Committee

Position of the North Dakota Medical Association
January 25, 1999

The ND Medical Association and its physician members enjoy an open and cooperative relationship with the ND Pharmaceutical Association and its members across the state. We have successfully worked together on joint concerns regarding patient safety and collaborative prescribing in the past. However, NDMA, in fulfillment of our mission statement to "promote the health and well-being of the citizens of North Dakota", and in acting as an advocate for our patients, wishes to indicate our **opposition to SB 2364**. Our physician's concerns include the following:

Have patients, or even pharmacists, identified a problem in this area?

There are inconsistencies in this bill and in SB 2176: definition of "Practitioner";

The scope of changes being proposed is too broad: other states regulate much more concisely, with patient safety concerns in mind; and

The proposed expansion of pharmacy practice, for the third consecutive legislative session, again crosses into other professions, and further input and study would be beneficial to reach consensus on this issue.

The North Dakota Medical Association would support a Committee recommendation of **Do Not Pass on SB 2364**, and would suggest that the interested professionals and appropriate licensing boards meet in 1999 to determine the need for the type of practice expansion proposed in this bill, before further introduction of legislative proposals.

NDNA
NORTH DAKOTA NURSES ASSOCIATION

549 Airport Rd. • Bismarck, ND 58504 • Phone: (701) 223-1385 • Fax: (701) 223-0575

January 25, 1999

TO: Members of the Senate Industry, Business and Labor Committee

FROM: Sharon Moos, Executive Administrator
North Dakota Nurses Association

RE: SB 2364 (relating to parenteral pharmacists and pharmacy definitions)

The North Dakota Nurses Association maintains a neutral position on SB 2364 relating to creating and enacting a new chapter of 43-15 relating to parenteral pharmacists and amending and reenacting section 45-15-01 relating to pharmacy definitions.
While remaining neutral, the North Dakota Nurses Association wishes to offer the following comments on SB 2364.

Physicians, nurses and pharmacists represent the three health care professions with the longest history of licensure in the state of North Dakota.

Licensure of a health care profession exists to allow professions to self govern in society's best interest.

Expansion of the scope of practice for a licensed professional in health care may mean some overlapping with another health care professional(s) scope of practice. This overlapping is appropriate if the specific professional has increased knowledge, skill and technology to safely perform the overlapping tasks. Tasks are not the essence of a

professional in health care, rather decision making and evaluation of patient outcomes are. If an established licensed health care professional incorporates specific tasks or skills in his/her scope of practice (though increased knowledge, skills and technology) this does not negate those same task or skills being performed by other licensed professionals.

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

OFFICE OF THE EXECUTIVE DIRECTOR
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SENATE BILL No. 2364
INDUSTRY, BUSINESS AND LABOR COMMITTEE
MONDAY – JANUARY 25, 1999 – 8:00 AM – ROOSEVELT PARK ROOM

Senator Mutch, members of the Industry, Business and Labor 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 been working closely with the North Dakota Pharmaceutical Association and our interested pharmacists in developing proper training and expanding their ability to care for patients through the addition of parenteral administration. We have been training our pharmacy students in the theory of parenteral administration of drugs and recent classes have some limited practical experience in this area. Several of our pharmacists have already attended national seminars on immunization administration and of course, many of our home health care pharmacists are intimately familiar with the use of intravenous and other injectable drugs. The Board of Pharmacy reviewed this legislation during our January 7th, 1999 Board Meeting. A motion was passed at that time to support the Association's efforts in this area and the Board committed to pass rules to implement such a statute as soon as the legislature has taken action. We anticipate the rules would be in place by the end of June 1999.

We look forward to your authorization for pharmacists to do this and the subsequent participation of the College of Nursing associated with NDSU College of Pharmacy, upon receiving clearance from the Board of Nursing, to train our pharmacists before they graduate from NDSU.

The Board of Pharmacy would approve training programs in consultation with the Board of Nursing to certify pharmacists in practice who wish to develop this patient service in their practice. The Board will maintain, along with the pharmacist's license, a record of their certification. We will require policy and procedures be in place in each pharmacy where these activities are preformed and our Inspectors will receive training to allow them the expertise to review the policy and procedures for completeness during the annual compliance visitations.

Senate Bill 2364
Senator Tom Fischer

Madam Chair and members of the House human services committee.

For the record my name is Tom Fischer, state senator from district 46, south Fargo.

I come before you today to introduce and support Senate Bill 2364 which allows certified pharmacists to administer parenteral drugs under certain circumstances.

Madam Chair, there are people here today who are far more qualified than I to explain this bill and answer your questions, so with your permission, I will have them continue.

Thank you.

North Dakota Pharmaceutical Association
1906 E Broadway Ave. ♦ Bismarck ND ♦ 58501-4700
Telephone 701-258-4968
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Senate Bill 2364 – Relating to Parenteral Pharmacists
House Human Services Committee
February 9, 1999 – 1:15 PM
Testimony of Galen Jordre, R.Ph.

Chairperson 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 Senate Bill 2364 is to allow qualified pharmacists to administer parenteral drugs when authorized and following rules established by the Board of Pharmacy. For sake of clarification, parenteral means a sterile product that is prepared for injection through one or more layers of skin. This definition addresses the product, not the procedure to administer. While much attention surrounding this bill focuses on the actual puncturing of the skin, it is important to note that much parenteral administration would be less invasive – such as adding a medication where a catheter or IV line is already in place.

At the present time, this authority is allowed to pharmacists only when there are emergency situations involving home infusion drugs and there is no nursing service available. The language of this legislation sets out a method to expand this authority while protecting the public.

The legislation proposes these specific changes and additions:
(Printed Bill)
Page 1, Line 9 – This change in definition of administration removes the current restrictive language related to home health care and the specific prohibition against administering parenteral drugs.
Page 1, Line 14 – This new definition outlines how a pharmacist obtains authority to administer parenteral drugs by stipulating that there are five elements to an authorization: an order, a practitioner, a qualified pharmacist, a specific drug, and specific patients. With any one of these five elements missing, a pharmacist would not be able to administer.
Page 5, Line 1 – Sets forth the definition of "parenteral" as was discussed earlier.
Page 7, Line 1 – Defines a "qualified parenteral pharmacist" as a pharmacist who successfully completes an education course and meets continuing education requirements established by the Board of Pharmacy.

Page 7, Line 18 – This section puts everything together by saying that qualified pharmacists may administer parenteral drugs when they receive an authorization to administer from a prescriber and when they meet rules adopted by the Board of Pharmacy.

The pharmacists of North Dakota are proposing this legislation because they feel that by using this authority they will improve the health of the citizens of the state. We have approximately 625 actively practicing pharmacists in the state. About 55 % of these pharmacists are in retail pharmacies, 30 % are in hospitals, and the remaining 15% are in clinic pharmacies or other specialized locations. There are 232 licensed pharmacies with 150 retail pharmacies, 35 full time hospital pharmacies, 25 clinic pharmacies, and the rest as specialized or limited practices. As you can see, we have pharmacists in a wide variety of settings. Depending upon the location, type of practice setting, and relationship to other health care institutions, many offer appropriate locations where pharmacists could administer parenteral medications.

The ability of pharmacists to provide immunizations and administer parenteral drugs in emergencies, in teaching situations, and in other settings is beneficial as more drug therapy is instituted and administered outside institutional settings. Pharmacists trained in all types of administration will enhance the efforts of the health care team to provide drugs to patients in the most effective manner. Pharmacists now have authority to administer immunizations in over 25 states with ability to administer additional injectable drugs in many of those. It is not the intent of pharmacists to replace - but to supplement and enhance the efforts of others in the delivery of drug products to patients.

What types of administration are envisioned?

- **Immunizations** – The 1997 North Dakota flu immunization billed rate for Medicare Beneficiaries Age 65 or older was 54.8%. Approximately 40% of this group has received pneumococcal vaccine once in their lifetime. These two diseases needlessly kill thousands of people across our country every year and pose a deadly threat to the elderly of our state. Good public policy would indicate that if you have a group of highly educated health care providers who want to join the fight against these diseases by educating their patients and providing immunizations – they should be authorized and encouraged. In other states where pharmacists have been able to immunize, immunization rates have risen. Pharmacists do not wish to replace any other providers that administer immunizations, but feel that there are many opportunities to increase our immunization rates. Pharmacists offer educational opportunities to patients and ready access to a provider. Pharmacies are taking a role in educating their patients. This last fall our Association sent out to 180 pharmacies, at the request of the State Diabetes Control Unit, a packet of materials and a poster about immunizations and diabetic patients. A number of pharmacies have hosted immunization clinics and have been

pleased by the response from the public. These pharmacies want to continue this type of service and by being able to perform immunizations themselves, pharmacists can expand the opportunities to their patients. We currently see immunizations administered in community halls, workplace settings, and other locations. Pharmacies – many with private consultation rooms – offer professional locations for administration. By authorizing trained pharmacists to administer, the public will have another resource, raising the opportunity for immunization and improving the public health. Passage of this legislation will give pharmacists a chance to help save lives.

- **Home Care Situations** – Pharmacists currently have limited authority in home care to administer medications in emergency situations. The changes in healthcare emphasize the team approach to caring for patients. Pharmacists prepare the home care medications, check for medication incompatibilities and interactions, are responsible for delivery of medications and supplies, and are responsible for operation of IV pumps and other equipment. It is appropriate that trained pharmacists who work extensively with these products be authorized to administer these medications as a part of the home care team. We appreciate the lead role that nursing plays in home health care and the opportunity for administration by pharmacists will not replace those aspects of care. We have a very limited number of pharmacies that participate in infusion therapy and all do so under a contractual basis with the home health agency that is directed by either a physician or registered nurse. If a pharmacist is to administer in a home health care situation, it will be with the full consent of the other partners in that arrangement.

  Pharmacists take this partnership seriously. In September the Board of Pharmacy enacted rules that allowed home health nurses to carry emergency supplies of prescription drugs. Previously prescription drugs had to be prepared specifically for the patient. This new system allows greater convenience for the nurses, is cost effective for the patient, and improves efficiency for the home health care agency. These new rules were largely implemented through the input of pharmacists and were supported and promoted by the pharmacy profession.

- **Changes in the way drugs are dispensed to patients.** – New products are emerging on the market where the drug should be administered close to the time it is dispensed. Situations where drugs are dispensed and administered into implanted devices are starting to emerge. Pharmacists want to be prepared for future situations where they can serve their patients and the system by administering the medication by all routes, including injection.

- **Teaching situations in pharmacies** – In the future, more patients will be expected to self-administer medications in their homes. At the time the medication is dispensed in the

pharmacy, it may be necessary for the pharmacist to augment other training efforts and assist the patient in learning self-administration.

What safeguards will be in place to assure safety?

- The ability of pharmacists to administer parenteral medications will be dependent upon a physician order just like all other health care providers. The bill specifically authorizes only qualified pharmacists to administer. Nothing in the bill says pharmacists can delegate administration to technicians or other persons.
- Because many College of Pharmacy graduates go to states where administration of medications by injection is currently authorized, the college teaches all new graduates injection techniques, documentation methods, procedures to follow in assessing patient reaction to injections, and emergency procedures. The College of Pharmacy is developing a program of continuing education for other pharmacists who wish to participate in this area of practice.
- The proposed change in the law provides that the Board of Pharmacy will establish rules to set educational requirements for qualified pharmacists. The requirement would be for a minimum of 20 hours and follow a course prepared by the Centers for Disease Control. Pharmacists would also be required to be certified in CPR or BCLS. If a pharmacist were to perform venipuncture to administer, we are proposing that they complete an additional course that is equivalent to courses required by the North Dakota Board of Nursing for licensed practical nurses performing the same functions.
- The board rules would also establish standards pharmacists must meet to administer injectable drugs. These rules will assure that the safety needs of patients are met and will establish procedures that pharmacists must follow. One of the main components would be the Guidelines for Pharmacy-based Immunization Advocacy as adopted by the American Pharmaceutical Association. These guidelines emphasize the need for pharmacists to partner with prescribers and community health programs and to participate in reporting programs as appropriate.
- Reporting and documentation is important and pharmacists are involved with documentation all the time. In this state almost all childhood immunizations are provided through the Department of Health Prevention Partnership Program where vaccines are distributed free to clinics and other facilities that agree to report immunizations to a state information system. Any pharmacist allowed to participate in this program will be required to meet the electronic reporting requirements and standards for this program.

We are proposing this legislation for those pharmacists who are in practices where it is appropriate for them to administer medications. Rather than place specific limitations or outline certain situations where these activities can take place, we are proposing enabling legislation. The professional marketplace will dictate who participates. We anticipate that a small portion of our pharmacists will participate in administration of medications by injection. Many pharmacies will be limited by cost of establishing this practice and

workloads that demand full-time attention to prescription dispensing. However we do want the opportunity open to those who are currently practicing where administration of parenteral medications will enhance delivery of care to their patients and the patients of their communities or organizations.

The legislative language is very clear, if pharmacists do not complete the training and create a trust with the prescribers that write the orders, they will not be administering parenteral drugs. We would not want to participate in any other way. By amending the current law, trained pharmacists in those situations will be able to provide efficient and safe medication administration along with other members of the health team.

I have included with my testimony a number of documents outlining experiences in other states, proposed elements of Board of Pharmacy rules regarding administration of parenteral drugs, and guidelines adopted by the American Pharmaceutical Association for pharmacy-based immunization activities that will incorporated into the Board of Pharmacy rules.

We ask for your support of this legislation. It will have a positive impact on the citizens of our state. Thank you.

MeritCare

MeritCare Health System
720 4th St. N.
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Roger L. Gilbertson, M.D., President

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February 4, 1999

North Dakota State Capitol
House and Human Services Committee
Clara Sue Price, Chair
600 E. Boulevard Ave.
Bismarck, ND 58505

Dear Sir or Madam:

I am writing in support of Senate Bill No. 2364, which would authorize qualified pharmacists to administer parenteral drugs. Although this has traditionally been a role filled primarily by nurses, pharmacists are increasingly becoming involved with this as more and more complex care is shifted from the inpatient to the home setting. It is the pharmacist who mixes the drugs and very often teaches the patient about the drugs and how they will be administered when they go home. Our pharmacist at Meritcare Health System is the one who nearly always teaches the patient these important steps, and also trouble-shoots for these patients when they are home and having difficulty with their infusion equipment or delivering their drugs. It would be extremely helpful if such pharmacists, certified by an appropriate accrediting board, and under direct order from an attending physician, could have the freedom to administer those drugs to better serve and teach those patients needing these therapies. I believe that under appropriate physician direction, and with assurance of proper education in the necessary techniques, that qualified pharmacists should be quite capable of performing these duties and filling the occasional need where appropriate nursing care is not available. I do not think this would replace appropriate nursing care, but supplement it in certain select circumstances.

I hope you will give due consideration to the passage of this bill.

Sincerely,

Paul J. Carson, MD
Infectious Disease Consultant, Meritcare Health System
Associate Professor of Medicine, UND School of Medicine

MeritCare
Roger Maris Cancer Center

820 4th Street North
Fargo, North Dakota 58122
(701) 234-6161

North Dakota State Capitol
House Human Services Committee
Clara Sue Price Chair
600 E. Boulevard Ave.
Bismarck, ND 58505

February 8, 1999

Dear Sir or Madame,

RE: Senate Bill #2364

I would like to lend my support to the above proposed Bill. As financial constraints on the health care system increase, the need for safe, available and cost-effective home health care services is a priority. Clearly, to optimally provide these services, the pharmacists involved in these programs must be allowed to provide various services in the home which traditionally have been provided only by nursing staff, the patient him/herself and/or other family members.

Specifically, I support the proposal that pharmacists involved in providing home health services be permitted to administer intravenous medications under defined circumstances e.g. when teaching patients to use home infusion pumps and when infusion problems arise and nursing services are not available.

Sincerely,

Nathan L. Kobrinsky, M.D.

COMMENTS ON SENATE BILL NO. 2364 SCHEDULED FOR HEARING
WEDNESDAY, FEBRUARY 10, 1999, 1:15PM
BEFORE THE HOUSE HUMAN SERVICES COMMITTEE

Chairperson Clara Sue Price, members of the House Human Services Committee, my name is Clint Dworshak. I am rising in support of Senate Bill 2364. I am speaking to you as a fifth year student in the College of Pharmacy at NDSU.

The College of Pharmacy recognizes the necessity to train the students in a wide range of skill that will make them competitive in the job market, as many students do leave the state to practice. One of the skills that we are taught is the parental administration of medication. It is important to allow pharmacists in North Dakota to be able to administer parenteral medications.

The Academy of Students of Pharmacy, the student chapter of the American Pharmaceutical Association, has a program of immunization advocacy on the national level that our chapter has participated. Operation Immunization has exposed pharmacy students to the need for immunizations and has increased our knowledge about the process.

Last year, I had the opportunity to travel to the American Pharmaceutical Association's annual meeting in Miami. During that trip, we had the opportunity to meet pharmacists and students from across the nation. It was great the see their excitement when they found out that we were from North Dakota. So many states envy our Pharmacy Practice Act, and it is up to us to make sure that we continue to improve our progressive Pharmacy Practice Act.

As a student that will be graduating May of 2000, it is my sincere hope to be able to practice here in the state of North Dakota. In doing so, I want to be able to practice those skills that I am currently learning in Pharmacy School. I know students that are opting for jobs in other states because they are unable to utilize their skills. This is unfortunate for North Dakota. I hope that you will vote in favor of this bill and continue advancing the practice of pharmacy here in North Dakota.

TESTIMONY BEFORE THE HOUSE HUMAN SERVICES COMMITTEE
REGARDING SENATE BILL 2364
FEBRUARY 10, 1999

Chairman Price and members of the committee, I am Patricia Kramer, Director of Utilization Management for the Medical Services Division of the Department of Human Services. I speak in support of SB2364 today.

Sb2364 would permit qualified pharmacists, and only qualified pharmacists, to administer specific parenteral drugs (injections) to specific individuals and only if ordered with a valid prescription. This bill would not only require successful completion of a board of pharmacy approved instructional course but would also require those pharmacists initially qualified to maintain continued education in parenteral therapy.

The recipients of state Medicaid would benefit from this service by having greater access to needed services, particularly in those areas of the state that may be underserved by health care professionals. Given the fact that caretakers and their families are in pharmacies much more often than any other health care source, the access to these services would be invaluable. 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 injections.

With the requirements that would be in place for pharmacists to qualify to provide such injections and the potential benefits that would be available to recipients and the department, I urge a do pass on SB2364.

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TESTIMONY ON SENATE BILL NO. 2364 ND Pharmacy Practice Act

House Committee on Human Services

Position of the North Dakota Medical Association
February 10, 1999

The North Dakota Medical Association Commission on Legislation first reviewed the general concept of this bill last fall, when the Pharmacy Association bill draft removed the language prohibiting a pharmacist from administering a drug parenterally, and gave broad authority to qualified pharmacists to do just that. Our members indicated unanimous and strong opposition to the concept. Physicians, as well as their patients, had seen no indication that there was a problem in gaining timely access to immunizations or other services the pharmacists were seeking. Physicians were satisfied that children and adults alike were receiving safe and appropriate services at urban and rural clinics and public health units from experienced nursing personnel. Our Commission instructed me to confer with the ND Nurses Association, and we found that staff had also been reviewing the bill draft. Nursing agreed that the proposal created many patient care concerns, and they sought a change, now incorporated in the bill on lines 15-16 of page one: "...administration of specific parenteral drugs to specific individuals".

However, SB 2364, in its present form, was again reviewed by our members in January, but the one revision did not change any minds. The position taken by the NDMA is to oppose the enactment of SB 2364. In support of this stance, we look to our Mission Statement: "To promote the health and well-being of the citizens of North Dakota". As a healing profession, we concern ourselves with preserving the safety of our patients and acting as their advocates whenever possible.

The practice of pharmacy continues to evolve in today's healthcare environment, and pharmacists remain as valuable members of the modern healthcare community. However, we feel that the focus of pharmacy training does not prepare them, as the training and education of physicians and nurses does, to function as "allopathic" (hands-on, whole-body) providers of patient care. The ability to inject drugs into a patient is not as simple a procedure as one might imagine, and it can and does carry a risk to certain patients no matter their age or apparent health status. We feel that it should not be granted as a matter of "customer convenience" in a retail setting.

A review of pharmacy laws from other states allowing the administration of drugs also indicates the additional imposition of a wide range of safeguards and limitations. Minnesota and Montana are two of the states which do not allow this type of practice under any circumstance. Some of the restrictions imposed in other states include:

May administer only if another licensed provider is not reasonably available;
May administer only in a hospice, home health, or facility setting;
May administer only if extensive training has been documented;
May only administer pursuant to a prescriber's order;
Must notify the provider responsible for the patient's care;
May NOT administer to anyone under the age of 18
May NOT delegate authority to administer to technicians;
May NOT administer drugs to patients where they reside;
The authorizing order to administer must be established by the medical licensing board; and
Administration guidelines must be jointly developed by the physician, nursing, and pharmacy licensing boards or other joint professional committees.

It would appear that many other jurisdictions have considerable patient safety concerns, and have proceeded cautiously in granting this privilege. In 1995, the North Dakota Legislature broadened the scope of pharmacy practice, allowing some pharmacists to prescribe drugs in certain controlled circumstances. Again in 1997 you increased the pharmacist's role by allowing their involvement in home infusion therapy when nursing service is not available, authority now being deleted on page one of the bill. You wisely retained the prohibition on parenteral administration at that time. Earlier this Session, the House again granted a significant expansion by passing HB 1388, allowing pharmacists to offer yet another patient-care service, the performance of laboratory testing on their "customers".

We would encourage this Committee to put the breaks on the multiple expansions being sought by the pharmacists at this time, and allow some of the earlier changes granted to settle in. There does not appear to be any sort of demonstrable need for the changes in the practice act requested in this bill, and we respectfully request that the Committee approve a Do Not Pass recommendation on SB 2364.

GREAT PLAINS CLINIC
Leading with Care

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Dennis Wolf, M.D.
Family Practice with Obstetrics
Dennis Wolf, M.D.
Stephen Winegardner, M.D.
Family Practice
Thomas Templeton, M.D.
Danuta Komorowska, M.D.
Internal Medicine
James Baumgartner, M.D.
Mark Hinrichs, M.D.
Brian O'Hara, M.D.
Bruce Olin, M.D.
Mahesh Mulumudi, M.D.
Srilatha Shoroff, M.D.
Geriatrics
Dennis Wolf, M.D.
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James Brooks, M.D.
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Pediatrics
Brian O'Hara, M.D.
Obstetrics/Gynecology
Kristi Boldt, M.D.

Great Plains Clinic, PC • 33 9th St. West • Dickinson, ND 58601 • 701-225-6017

MEMO TO: MATT LAYMAN, MD
MID DAKOTA CLINIC
BISMARCK ND 58502
FAX: 701-224-7560
FROM: DENNIS E WOLF, MD
GREAT PLAINS CLINIC
DICKINSON ND 58601
DATE: FEBRUARY 9, 1999
SUBJECT: ADMINISTRATION OF IMMUNIZATIONS AND OTHER INJECTABLES BY PHARMACIST.

DEW

1. The issue of requirements for administration space and sterile precautions is not addressed in the bill. I doubt that any pharmacy is set up to have a separate room with which to administer the vaccine. I am sure that the health department would find most pharmacies ill- equipped to administer medications. I raised this question with the pharmacists and the Pharmaceutical Association and they say that most pharmacies have a consultation room where the shot could be given. These are small sit-down rooms. It would be necessary for the pharmacy to have an area in which the patient could lie down in the event that there was a reaction or a syncopal episode. For instance, are they just going to lay them on the desk or the table to administer the injection, especially infants.

2. How are they going to handle reactions? Will they have equipment available in the event that the patient has a syncopal episode or anaphylactic reaction? Will the personnel be trained well enough to know how to handle this kind of problem?

3. The Public Health Association had put up an amendment limiting injections to over age 21. This may be too restrictive and probably should say not under 18 or under 15. I have great concern about pharmacists administering immunizations to infants.

4. Nurses do most of the injections even in clinics. Very few physicians administer injections anymore unless it is an emergency. Nurses are well trained, proficient and should be allowed to continue to do the job that they are good at. My concern is the increased risk again of complications by allowing another tier to administer medications when they won't be doing enough of them to stay proficient. This is particularly true of infants.

5. The present bill reads that they cannot administer without the approval of a physician. I can't believe that there are too many physicians who would want to take a phone call from a pharmacist, grant permission and have to record it in the patient's chart. This constitutes yet another hassle factor that is time consuming. The other factor includes the liability to the physician. Since he is giving permission, it indicates that he is assuming the liability. I question whether most of the mal-practice insurance companies would even want to cover this type of practice.

6. The Senators talked about this being a turf issue. At least, that is what one senate committee member brought up that the nursing and medical professions are concerned about turfing. Nothing was mentioned about the quality. When you have yet another tier of care, there is going to be a higher incidence of complications.

7. Then there is a cost factor. Most clinics now refer infants to the district health departments for infant immunizations because of the cost factor. Currently it costs us roughly $35.00 per injection of DPT; which, after you add the cost of administration, costs upward to $40.00. At the health clinics the State is furnishing the vaccine and that can result in a cost savings of upward to $700.00 to $800.00 for the series in infancy. I doubt that any pharmacist is going to administer these vaccines without the money up front and I question what parents would be willing to pay that kind of money. Therefore, there is a cost factor in addition to quality care issues.

8. Also, will the pharmacist be trained well enough to recognize complications and how to manage them. Will the physician be called to manage the occasional episode of anaphylactic reaction, syncope or other complication such as hitting a nerve or inadvertently administering intravascularly.

The bottom line is:

1. Cost factors.
2. Risk of complications.
3. Quality care issues.

I think that if the pharmacists want to be of service to the people in North Dakota, they certainly should be asking patient's if their immunizations are up to date and then encouraging them to go to the health district or their doctor or clinic to receive the vaccines. I fear that there may be some duplication of injections. When I ask patients if they have had their pneumovax, ~~doctor~~ they frequently don't remember if they had one and if they did, when they had it. So, if the pharmacist asks a patient if he had one and they said yes but I don't remember when, the pharmacist would have to call the clinic, the clinic would have to pull the chart and then give them the date of the last injection. Again, the hassle factor comes in. If the bill were to be amended so that the permission of the physician would not be necessary, then this would require a change in the Nursing and the Medical Practices Act. Certainly, administration of injectables by pharmacists constitutes practice of medicine and practice of nursing.

NDAHC **North Dakota** Association for **Home Care**

TESTIMONY
ON SENATE BILL 2364
February 10, 1999

Good afternoon Madam Chairman and members of the committee. My name is Liz Overlie and am the President of the NDAHC. I am also a RN from Minot and a director of a home health and hospice program. The NDAHC has some concerns about SB 2364.

We recognize that health care professionals sometimes overlap in scopes of practice. We are also aware that pharmacists have a great deal of knowledge of medications, pharmacological dynamics and physiological effects, and a strong research base.

Our concerns are not with what the pharmacists are trained to do.

On page 1, Section 1 of the bill, we believe the overstruck language should be kept in the law. The term "administration" should "include the emergency maintenance of a drug delivery device used in home infusion therapy by a qualified home pharmacist when nursing service is not available." And we believe the term "administration" should "exclude the regular ongoing delivery of a drug to the patient in a health care setting and other parenteral administration of a drug."

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We also have concerns about line 15, page 5. That is the "Pharmacy technician" definition. It is not the definition that concerns us. It is what the "technician" would be allowed to do, that causes us concern. Does this mean the pharmacy technician would be infusing the IV drugs in the home? What training and level of education would the pharm tech have? And would there be any direct supervision and by whom?

Another part of the bill of concern is on page 7, line 1. This sets out a new definition for "Qualified parenteral pharmacist." In that definition, what constitutes a board approved course of study and what makes up the continuing education requirements? With this education component, who is going to monitor the CE requirements? The bill does not address these issues.

Nurses are currently educated to take a holistic approach to the care of the patient. SB 2364 inadequately addresses the safety of the homebound patient. This bill eliminates the need for a multidisciplinary approach to home IV and would fragment the total management of the IV home patients. This legislation does not address a method to evaluate the care given to patients and a way to correct deficient practices.

Thank you for the opportunity to testify and I will try to answer any questions you may have.

NDAHC **North Dakota** Association for **Home Care**

TESTIMONY
ON SENATE BILL 2364
February 10, 1999

Good afternoon Madam Chairman and members of the committee. My name is Sue Arneson and I am the President-Elect of the NDAHC. I feel I must represent my association in asking this committee for a Do Not Pass recommendation for SB 2364.

For the past 14 years I have been clinical director for Altru Home Services branch in Langdon at Cavalier County Memorial Hospital. Altru Home Services provides home care services in 10 counties in the NE section of the state. My concern about SB 2364 is the safety and quality of care provided to the home care patient.

Administration of a parenteral medication could certainly be seen as a technical procedure, but as home care providers, we see it as much more involved. Prior to the administration of any parenteral medication, a comprehensive assessment is always done by a registered nurse. An assessment is also done during and after the medication administration to evaluate the patient's response to the medication. This assessment is essential for the safe administration of any parenteral medication. Most home care patients have serious multiple chronic illnesses; their functional status is usually severely compromised. Functional deficits and social supports are important aspects of the comprehensive assessment as they have a strong impact on the patient response.

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For example, if Lasix, a diuretic, is ordered intravenously by a physician, it is in response to assessment by the nurse noting increased shortness of breath, auscultating crackles in the lungs, edema in the lower extremities, increased pulse and blood pressure. When Lasix is given, the patient is instructed in measuring urine output, weight, and how to check for edema. It is important to note if a patient can ambulate to a bathroom, that they have help from family for fluids and nutritional needs, that there is support from home.

The nurse post-assessment includes further monitoring of the weight increase or decrease, blood pressure and pulse changes, lung sounds, signs/symptoms of electrolyte imbalances to evaluate if the patient is responding adequately to the treatment. As a general rule, home care agencies have a 24 hour call system to cover problems or concerns of the patient.

As you can see, administration of a parenteral medication such as Lasix is not just a technical skill, and safe administration is not just being knowledgeable in the medication. It requires a total comprehensive assessment of the patient for the medication to be given safely and effectively. That is what the scope of nursing involves.

Again, I ask you for a Do Not Pass recommendation on SB 2364.

Thank you for the opportunity to testify and I will try to answer any questions you may have.

Testimony in opposition to SB2364
For the North Dakota Public Health Association

Joce Koch, R.N.

I am the Nursing Supervisor for Custer District Health Unit in Mandan. I also represent the North Dakota Public Health Association, a statewide group of public health departments. One of our tasks is immunization of both children and adults against communicable diseases. We are opposed to the immunization of children in pharmacies. The CDC immunization schedule is complex, often requiring multiple injections for one child per visit. This is difficult in a clinic setting, where separate exam rooms and adequate medical help are available. It would be doubly difficult in the back of a drug store. We question the pharmacists' ability to meet the extensive recordkeeping requirements and maintenance of immunization records for years following the visit. If the committee desires, I have an amendment to submit to exempt childhood immunizations from the list of parenteral administrations allowed.

We have other concerns about this bill, including adequate staffing to handle emergency allergic reactions to injections, and proper education and assessment before and after the injection. We know that these things can be addressed in the rules promulgated by the Pharmacy Board. Right now, all we have is this very broad bill, which allows injections of virtually every kind. This bill is not in the best interest of the patient in its current form.

We urge its defeat, if it retains this very broad scope. We would gladly serve on a committee to narrow the target population to those the pharmacists actually want to serve.

PROPOSED AMENDMENT TO SB2364

On page 7, line 20, after "board", insert:

"But this authority is not extended to the administration of any vaccine required under Section 23-07-17.1 to an individual who is less than eighteen years of age."

Renumber accordingly.

NDAHC **North Dakota**
Association for
Home Care

TESTIMONY
ON SENATE BILL 2364
February 10, 1999

Good afternoon Madam Chairman and members of the committee, my name is JoAnn Ferrie. I am a registered nurse and owner and director of Professional Home Care, Inc., a private proprietary Home Health Agency in Bismarck. I am representing the NDAHC and oppose SB 2364.

I started Professional Home Care in 1987 and it is the only freestanding, licensed, and certified Home Health Care Agency in the state. My business receives no grants, mill levies, or subsidies. In order to start my business, I made a personal financial investment. I went to the bank and received a business loan.

Professional Home Care is licensed to serve 17 counties in western North Dakota and offers services in five counties. The other 12 counties are adequately served by existing Home Health Care Agencies.

Every county in North Dakota has a Home Care Agency providing services. There are 11,430 LPN's, RN's, and APRN's in North Dakota. Also, every county has at least one RN. SB 2364 is duplicative and unnecessary. I ask you to vote do not pass on SB 2364.

Thank you for the opportunity to testify and I will try to answer any questions you may have.

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NDNA
NORTH DAKOTA NURSES ASSOCIATION
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February 10, 1999

TO: MEMBERS OF HOUSE HUMAN SERVICES COMMITTEE

FROM: NORTH DAKOTA NURSES ASSOCIATION

RE: SB 2364 (relating to parenteral pharmacists and pharmacy definitions)

The North Dakota Nurses Association maintains a neutral position on SB 2364 relating to creating and enacting a new chapter of 43-15 relating to parenteral pharmacists and amending and reenacting section 45-15-01 relating to pharmacy definitions.
While remaining neutral, the North Dakota Nurses Association wishes to offer the following comments on SB 2364.

The North Dakota Nurses Association has worked with the North Dakota Pharmacists Association on the definitions and language contained in SB 2364. While differences of opinion certainly exist among nurses in different practice settings regarding the role of pharmacists in medication administration, it is the opinion of the North Dakota Nurses Association that no one provider "owns" the patient and that as long as the public is assured that licensed providers have the knowledge and skill to safely perform their tasks the public is assured of greater access and choice of providers based on their personal needs and situation.

Expansion of the scope of practice for a licensed professional in health care may mean

some overlapping with another health care professional(s) scope of practice. This overlapping is appropriate if the specific professional has increased knowledge, skill and technology to safely perform the overlapping tasks. Tasks are not the essence of a professional in health care, rather decision making and evaluation of patient outcomes are. If an established licensed health care professional incorporates specific tasks or skills in his/her scope of practice (though increased knowledge, skills and technology) this does not negate those same task or skills being performed by other licensed professionals.

Physicians, nurses and pharmacists represent the three health care professions with the longest history of licensure in the state of North Dakota. Licensure of a health care profession exists to allow professions to self govern in society's best interest.

Thank you for your consideration of the above information as it relates to SB 2364.

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

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Horace, President
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SENATE BILL No. 2364
HOUSE HUMAN SERVICES COMMITTEE
WEDNESDAY – FEBRUARY 10, 1999 – 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 been working closely with the North Dakota Pharmaceutical Association and our interested pharmacists in developing proper training and expanding their ability to care for patients through the addition of parenteral administration. We have been training our pharmacy students in the theory of parenteral administration of drugs and recent classes have some limited practical experience in this area. Several of our pharmacists have already attended national seminars on immunization administration and of course, many of our home health care pharmacists are intimately familiar with the use of intravenous and other injectable drugs. The Board of Pharmacy reviewed this legislation during our January 7th, 1999 Board Meeting. A motion was passed at that time to support the Association's efforts in this area and the Board committed to pass rules to implement such a statute as soon as the legislature has taken action. We anticipate the rules would be in place by the end of June 1999.

We look forward to your authorization for pharmacists to do this and the subsequent participation of the College of Nursing associated with NDSU College of Pharmacy, upon receiving clearance from the Board of Nursing, to train our pharmacists before they graduate from NDSU.

The Board of Pharmacy would approve training programs in consultation with the Board of Nursing to certify pharmacists in practice who wish to develop this patient service. The Board will maintain, along with the pharmacist's license, a record of their certification. We will require policy and procedures be in place in each pharmacy where these activities are preformed and our Inspectors will receive training to allow them the expertise to review the policy and procedures for completeness during the annual compliance visitations.

COMMENTS ON SENATE BILL NO. 2364 SCHEDULED FOR HEARING WEDNESDAY, FEBRUARY 10, 1999,1:15pm BEFORE THE HOUSE HUMAN SERVICES COMMITTEE

Chairperson Clara Sue Price, members of the House Human Services Committee, my name is Harrison "Chip" Storandt R.Ph. I am speaking for myself as a pharmacist. I practice at MeritCare Broadway Pharmacy Fargo, North Dakota.

I am speaking in favor of Senate Bill No. 2364, which would authorize qualified pharmacists to administer parenteral drugs.

I have been a pharmacist at MeritCare for approximately 11 years, the last 9 being involved with the home infusion program. During this time I have worked as a team member in conjunction with nurses and physicians caring for home infusion patients. Our practice has seen dramatic increases in the number of patients we help to manage in the home environment.

I currently have several patients that receive various parenteral therapies at home that have limited or no nursing coverage. This is due mainly to insurance constraints. We have one patient that has been on Total Parenteral Nutrition therapy without home health nursing for over 5 years. Whenever problems arise I am her contact person and am responsible to see that these problems are resolved by consultation with her physician. These problems are not always drug related but at times will involve the central venous catheter and problems infusing her solution.

Many patients that receive home IV's who have nursing coverage may also have some gaps in nursing care for their therapies. For example when they come in for a physician visit the insurance does not always cover an additional home-nursing visit to start a new I.V. or to do catheter flushes. There are many excellent nurses in our facility. Only a few may be familiar with the types of special pumps, tubing or catheter flush procedures which are used in the home care setting. Many times these patients are referred to me for help by nurses or physicians.

There are also many new drugs that are now being developed and are being used in the home instead of more complex therapies that must be done in the hospital. Some specific examples of these are the colony stimulating factors. These medications stimulate the immune system to produce extra white blood cells which are valuable in treating cancer patients whose chemotherapy has dropped their counts to the point where infection is a real concern. These patients are able in most cases to administer a sub-cutaneous shot to remain at home and out of the hospital. Another drug that is being used is enoxaparin (Lovenox) which has reduced hospitalizations for patients with Deep Venous Thrombosis (blood clots usually in the leg). Until just recently this medical problem would need to be treated in the hospital for a minimum of 5 days with many expensive labs ordered to monitor the patient. Currently these patients are able to come in for diagnosis and return

home within 24 hours. I follow many patients' therapies such as this example. Most do not have home nursing care following them. As their pharmacist, I may be the one they call on for help with problems regarding their therapy if no one else available. These problems can range from drug side effects to the proper administration of the drug. If a patient does need help injecting these medications we attempt to arrange for home health nursing prior to discharge from the institution.

Another infusion therapy that we are involved with is the delivery of medications for pain control. These patients utilize a special pump implanted in the abdomen by a surgeon. The surgeon implants a catheter into either intrathecal or epidural space. The numbers of these patients are growing every year. Most of these patients need refills of their pumps. Many require refilling as often as once weekly or up to every 3 months. To complete this therapy a special computer is required to check the pump or reprogram the rate of infusion, if necessary. Because of the growing numbers of patients in our pain clinic, the nurses have asked me to help fill these pumps. This requires inserting a needle through a layer of skin to access the pump. I have received special training to complete this procedure from Medtronic, which is the maker of this pump.

Thank you for your time and consideration of this information. I believe that passage of Senate Bill 2364 will improve the health care for these patients and allow for an optimal outcome of their therapy.