

MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION

SFN 2053 (2/85) 5M



ROLL NUMBER

DESCRIPTION

2350

2001 SENATE HUMAN SERVICES

SB 2350

2001 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2350

Senate Human Services Committee

Conference Committee

Hearing Date January 30, 2001

Tape Number	Side A	Side B	Meter #
2	X		0.1
3	X		23
Committee Clerk Signature <i>Paul Kolodziejchuk</i>			

Minutes:

The hearing was opened on SB 2350.

SENATOR FISCHER, sponsor of the bill, introduced the bill. This bill makes it more convenient for people to receive injections.

GALEN JORDRE, R.Ph. Executive Vice President, NDPHA, supports bill. (Written testimony)

HOWARD ANDERSON, JR., R.Ph., Executive Director of the ND State Board of Pharmacy,

supports bill. (Written testimony) SENATOR KILZER: What size needle would you like to

use? MR. ANDERSON: It varies with the kind of injection, but we like to use the smallest that we can.

DAVE PESKE, ND Medical Assoc., supports bill. (Written testimony)

Opposition:

JOAN JIRAK, RN, opposes bill. Concern is for patient safety. Will this bill allow pharmacists to order and give patient's medication without physician.

Page 2

Senate Human Services Committee

Bill/Resolution Number SB 2350

Hearing Date January 30, 2001

The hearing on SB 2350 was closed.

Discussion was held. SENATOR MATHERN moved a DO PASS. SENATOR FISCHER

seconded the motion. No discussion. Roll call vote carried 6-0. SENATOR ERBELE will carry

the bill.

REPORT OF STANDING COMMITTEE (410)
February 5, 2001 1:32 p.m.

Module No: SR-20-2369
Carrier: Erbele
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2350: Human Services Committee (Sen. Lee, Chairman) recommends DO PASS
(6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2350 was placed on the
Eleventh order on the calendar.

2001 HOUSE HUMAN SERVICES

SB 2350

2001 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2350

House Human Services Committee

Conference Committee

Hearing Date February 20, 2001

Tape Number	Side A	Side B	Meter #
Tape 1	X		Tape didn't work
Committee Clerk Signature <i>Corinne Pastor</i>			

Minutes:

Chairman Price, Vice Chairman Devlin, Rep. Dosch, Rep. Galvin, Rep. Klein, Rep. Pollert, Rep. Porter, Rep. Tieman, Rep. Weiler, Rep. Weisz, Rep. Cleary, Rep. Metcalf, Rep. Niemeier, Rep. Sandvig

Chairman Price: Open hearing on SB 2350.

Senator Tom Fischer: Presented Bill. I am hear today to support SB 2350.

Galen Jordre: Executive Vice President of the N.D. Pharmaceutical Association. (See written testimony.) The purpose of SB 2350 is to allow qualified pharmacists to administer immunizations and other medications by injection when authorized and following rules established by the Board of Pharmacy. The pharmacists of North Dakota support this legislation because they feel that by using this authority they will improve the health of the citizens of the state. At the present time, pharmacists have authority to administer oral drugs, topical drugs and home infusion drugs in emergency situations when there is no nursing service available. The

language of this legislation sets out a method to expand this authority while protecting the public. Presently pharmacists are authorized to administer injectable drugs in 30 states. I have included with my testimony documents outlining experiences in other states and guidelines adopted by the American Pharmaceutical Association for pharmacy-based immunization activities that will 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.

Rep. Cleary: How do we ensure that the authorization is on record - where somebody knows?

Galen Jordre: The pharmacy would have to keep a record.

Rep. Niemeier: This protocol implies there are going to be some risks involved - what about liability?

Galen Jordre: It is included as a part of the pharmacy - it is part of the package.

Howard Anderson: Executive Director of the N.D. State Board of Pharmacy. (See written testimony.) The Board of Pharmacy has been in support of the changes in this legislation for some time. This initiative would be a good example of increased utilization of competent and well trained health professionals to improve the access and the care for the public in North Dakota.

David Peske: N.D. Medical Association. Our Commission supports the bill for three reasons: It furthers the physician/pharmacist relationship by requiring the injectable drug be prescribed by and administered under protocol with an authorized prescriber; it is permissive, in that the prescriber is not required to collaborate with the pharmacist but may work with a pharmacist on a patient-by-patient basis, considering the best interests and care for the patient; and the bill requires additional safeguards and education for the pharmacist, and specified the rules and

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House Human Services Committee
Bill/Resolution Number SB 2350
Hearing Date February 20, 2001

requirements to insure the protection of the patients and the appropriate collaborative process
between pharmacists and physicians.

Chairman Price: Close hearing on SB 2350.

COMMITTEE WORK:

Rep. Klein: Do Pass.

Rep. Tieman: Second.

12 YES 0 NO 2 ABSENT CARRIED BY REP. GALVIN

Date: 2-20-01
Roll Call Vote #: 1

2001 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2350

House Human Services Committee

Subcommittee on _____
or
 Conference Committee

Legislative Council Amendment Number _____

Action Taken DO PASS

Motion Made By Rep. Klein Seconded By Rep. Tieman

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price - Chairman			Audrey Cleary	✓	
William Devlin - V. Chairman	✓		Ralph Metcalf	✓	
Mark Dosch	✓		Carol Niemeier	✓	
Pat Galvin	✓		Sally Sandvig	✓	
Frank Klein	✓				
Chet Pollert	✓				
Todd Porter	✓				
Wayne Tieman	✓				
Dave Weiler	✓				
Robin Weisz	✓				

Total (Yes) 12 No _____

Absent 2

Floor Assignment Rep. Galvin

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

REPORT OF STANDING COMMITTEE (410)
February 20, 2001 11:58 a.m.

Module No: HR-31-3980
Carrier: Galvin
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2350: Human Services Committee (Rep. Price, Chairman) recommends DO PASS
(12 YEAS, 0 NAYS, 2 ABSENT AND NOT VOTING). SB 2350 was placed on the
Fourteenth order on the calendar.

2001 TESTIMONY

SB 2350

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JUDY SWISHER, R.Ph.

President

BONNIE THOM, R.Ph.

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METLINE, R.Ph.

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**Testimony on SB 2350
Senate Human Services Committee
January 30, 2001**

Galen Jordre, R.Ph. – Executive Vice President

Chairperson Lee, 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 North Dakota Pharmaceutical Association (NDPhA) represents the 670 pharmacists licensed to practice pharmacy in this state. These pharmacists provide services to patients through 175 community retail pharmacies and 56 institutional pharmacies located in 73 different communities of our state.

The purpose of Senate Bill 2350 is to allow qualified pharmacists to administer immunizations and other medications by injection when authorized and following rules established by the Board of Pharmacy. The pharmacists of North Dakota support this legislation because they feel that by using this authority they will improve the health of the citizens of the state. About 55 % of our pharmacists are in retail pharmacies, 30 % are in hospitals, and the remaining 15% are in clinic pharmacies or other specialized locations. 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 these injectable drugs.

At the present time, pharmacists have authority to administer oral drugs, topical drugs and home infusion drugs in emergency situations when 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 13 – This addition to the definition of administration authorizes immunization and vaccination by injection to persons more than 18 years in age. These immunizations are only authorized when the pharmacist receives an order from a physician or nurse practitioner authorized to prescribe the immunization or vaccination. This order would be separate from a prescription that authorizes a pharmacist to dispense a drug to a patient.

Page 1, Line 17 – This new definition authorizes a pharmacist to provide drugs by subcutaneous, intradermal, and intramuscular injection to persons more than 18 years in age. Once again the pharmacist is required to have a specific order to administer the drug. It

It is important to note that the authority does not extend to a pharmacist providing intravenous drugs.

Page 2, Line 1 – This new section outlines the process that a pharmacist would follow to be authorized by the Board of Pharmacy to administer drugs under this Act. The Act requires the Board to establish rules setting forth educational and operational requirements. The rules would cover specific areas to insure patient safety.

- Twenty hour educational requirement with specific areas of course content;
- Requirement that pharmacist be current in CPR or Basic Life Support;
- Requirement that authorized pharmacists maintain continuing competency with six hours of education every two years;
- Specific requirements for orders and protocols;
- Reporting requirements; and
- Requirements for the environments where injections may be administered.

The ability of pharmacists to provide immunizations and other injections will be beneficial as more drug therapy is instituted and administered outside institutional settings. Trained pharmacists 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 30 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. 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 - most 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.

What safeguards will be in place to assure safety?

- The ability of pharmacists to administer immunizations, vaccinations, and other injections will be dependent upon a physician order just like all other health care providers. The bill specifically authorizes only qualified pharmacists to administer and that pharmacists cannot 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 course of education for active practitioners will follow the same format.
- 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 approved by the Centers for Disease Control. Pharmacists would also be required to be certified in CPR or BCLS.
- 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. Pharmacists will be required to report in the same manner as all other health care providers.

We are proposing this legislation for those pharmacists who are in practices where it is appropriate for them to administer medications. The professional marketplace will dictate who participates. 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 providing immunizations and administering medications will enhance delivery of care to their patients and the patients of their communities or organizations.

I have included with my testimony documents outlining experiences in other states and guidelines adopted by the American Pharmaceutical Association for pharmacy-based immunization activities that will 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.

Immunization Process

In the immunization delivery process, pharmacists and pharmacy students can play several roles: to advocate, to facilitate, and to immunize. All three roles are equally important in facilitating immunization delivery to needed populations. Thirty states currently allow pharmacists to immunize. The other twenty states, however, also have a mission to fulfill. Pharmacists and pharmacy students are encouraged to actively advocate and facilitate the immunization process in order to help increase immunization awareness and delivery.

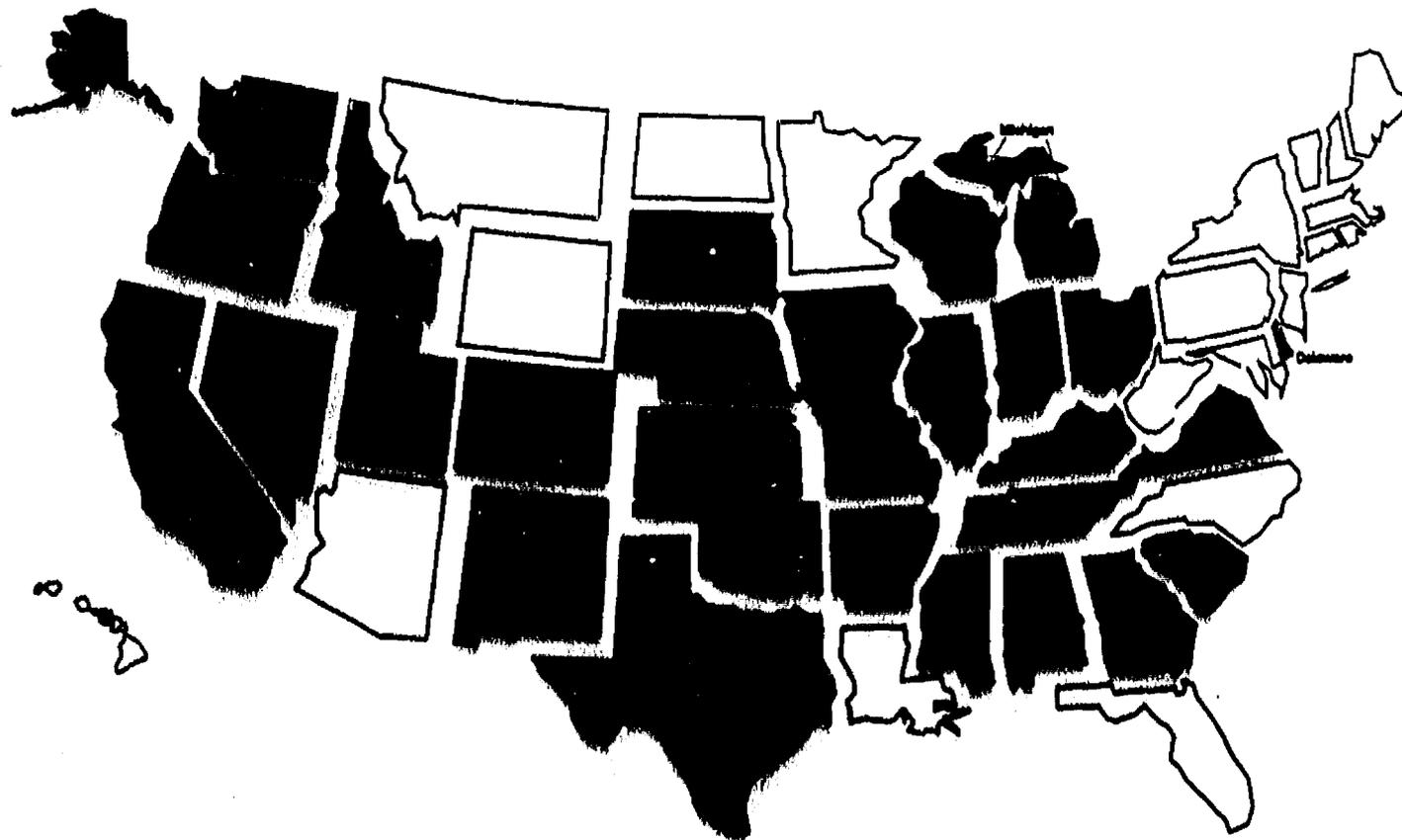
Immunization advocacy spans the life-cycle from newborns to the elderly. Pharmacy's impact can involve educating parents and caregivers on the importance of maintaining immunization records and adhering to immunization schedules. Pharmacists can help communities meet their immunization goals. Currently pharmacy's activities focus on providing vaccinations and immuniza-

tion information to adolescents and adults. The adult community is currently the population most likely not to receive immunizations for several reasons. For example, many adults may find it difficult to schedule appointments at a clinic because it takes them away from work and other obligations they have. In today's society, people are more likely to partake in an activity if it is convenient to them.

Pharmacies are avenues that are noted to be more accessible and convenient than other offices or public health clinics for some people. Extended hours in the evenings and on the weekends and locations in the same proximity as the patients' neighborhoods help make pharmacists readily available to the public. People also depend on pharmacists, known to be one of the most trusted healthcare professionals, for information and advice. Therefore, pharmacists possess a great opportunity to provide patients with resources they need to become active in preventative healthcare.

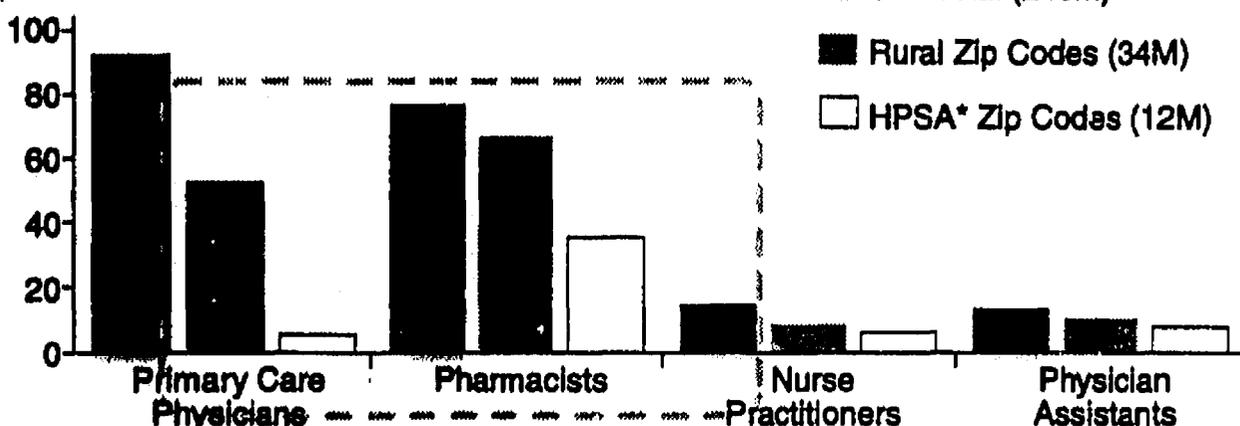
States Where Pharmacists May Immunize

■ Black = Authorized (30)



National Distribution of Provider Groups

Providers per
100,000
population



Source: JAPhA 1999; 39:127-35.

*HPSA: Health Provider Shortage Area

Many people may be more apt to receive immunizations if they can do so at their own convenience. This especially includes those who struggle with transportation problems. By expanding the scope of immunization delivery to include pharmacists, more adults are reached and are given information on immunizations. Increasing the number of adults immunized is the ultimate result.

Pharmacists do possess a unique opportunity to reach populations. A National Vaccine Advisory Committee report on Adult Immunization Programs in Nontraditional settings (March 24, 2000) stated that many adults are not receiving immunizations. Therefore, in order to increase the number of adults being immunized, vaccine delivery and information must be readily available. Pharmacists have the ability to provide these services. By examining patients' medication profiles, pharmacists may identify high-risk patients who would benefit from receiving immunizations. For example, adults 50 years and older should be vaccinated against influenza. Patients who are taking medications for congenital or adult heart disease, diabetes, chronic pulmonary disease, or other similar disease states are also high risk patients who should be informed about the importance of being immunized.

During the 1999 flu season, an estimated 1500 immunizing pharmacists provided over 200,000 immunizations.

Pharmacists' access to patients provide an excellent opportunity to reach at-risk patients through the use of reminders, bag inserts, and other educational materials.

As an advocate, pharmacists should identify high-risk patients and offer them immunization information that will help patients protect their health.

People Who Need Influenza and Pneumococcal Vaccines

Influenza and pneumococcal vaccines are indicated for people in these groups:^{3,4,17,18}

- Adults, adolescents, and children with chronic disorders of the pulmonary or cardiovascular systems. For influenza vaccine, this includes children with asthma.
- Adults, adolescents, and children who needed regular medical follow-up or hospitalization during the previous year for chronic metabolic diseases—including diabetes mellitus, renal dysfunction, problems related to hemoglobin, or any form of immunosuppression, including that caused by medications.
- Residents of nursing homes and other chronic care facilities housing people of any age with chronic medical conditions.
- People aged 65 years or more should get both vaccines, even if otherwise healthy. In addition, influenza vaccine is recommended for everyone 50 years and older. Patients older than 65 account for >80% of pneumococcal and influenza deaths. About two-thirds of those who died had been hospitalized in the previous year but were not vaccinated. More than 90% had visited an outpatient clinic or private physician in the preceding year. But again, their clinicians did not take advantage of these opportunities to protect them from deadly infection.⁴¹⁻⁴³

For influenza vaccine only:

- Children and teenagers (6 months to 18 years of age) who receive long-term aspirin therapy and therefore may be at risk of developing Reye's syndrome if they contract influenza.
- Staff and visitors at nursing facilities with residents at increased risk of influenza.

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.

Pharmacy-Based Immunization Delivery A National Certificate Program for Pharmacists

Special Program Offering for Affiliated State Pharmacy Associations

Program Overview

"Pharmacy-Based Immunization Delivery: A National Certificate Program for Pharmacists" will teach pharmacists the skills necessary to become a primary source for vaccine information and administration. Pharmacists who participate in this program and become vaccine advocates can improve immunization rates in communities throughout the United States and establish the role of the pharmacist as a source for immunization and related information.

Pharmacists learn the basics of immunology and vaccine administration. Issues such as legal and regulatory requirements and strategies for developing a profitable pharmacist driven vaccine administration program are highlighted.

Overall Program Goals

- Provide comprehensive immunization education and training;
- Provide pharmacists with the skills, resources and materials necessary to establish and promote a successful immunization specialty service;
- Train pharmacists to identify at-risk patient populations needing immunizations; and
- Train pharmacists to maintain necessary immunization records.

Program Components

I. *The Foundation: Self-Study Learning Modules* (0.8 CEU – 8 hours of continuing pharmacy education credit)

Several weeks prior to the seminar, participants receive a complete set of self-study learning modules designed to prepare them to take an active role in immunization delivery. Participants must carefully review these materials and complete an assessment examination prior to attending the seminar.

- **Module 1 – Implementing a Pharmacy-Based Immunization Program**
- **Module 2 – Clinical Considerations**
- **Module 3 – Practice Considerations**
- **Module 4 – Pharmacists Guide to CDC's *Epidemiology & Prevention of Vaccine-Preventable Diseases***

*II. The Tools: 1 ½ day Training Seminar
(1.2 CEUs – 12 hours of continuing pharmacy education credit)*

The training seminar is designed to deliver an active learning experience that focuses on pharmacy practice implementation. It highlights epidemiology of vaccine-preventable diseases, interprofessional communications, social marketing and reimbursement, documentation and record keeping, patient care strategies, and vaccine administration training.

Participant Pre-requisite

Participants in the program should be practicing pharmacists who are community leaders committed to implementing an immunization delivery service in the context of a patient-focused practice.

All participants should have current certification in Cardiopulmonary Resuscitation (CPR)/Basic Cardiac Life Support (BCLS).

Copyright of Program Materials

APhA retains all rights to the materials developed for this program throughout the world, including claim to copyright. No part of any of the program materials may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or other without written permission from APhA.

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NEXT FICHE

Figure 1. Example: Standing Order and Protocol for Administration of Influenza Vaccine

THE PHARMACY
MAIN ST.
RURAL, IA

Authorizing Prescriber Statement for Influenza Vaccination

J. Doe of The Pharmacy, and other licensed pharmacists or visiting nurses employed by The Pharmacy, acting as delegates for Dr. Physician according to and in compliance with Article 155A.3 and Article 155A.4 of the Iowa Pharmacy Practice Act, will administer injectable influenza vaccination on the premises of The Pharmacy only, and for a fee.

Influenza Virus Vaccine 0.5 mL IM may be given to consenting individuals at The Pharmacy. Vaccine may be given as early as September if necessary, but preferably late October/November.

Criteria

1. The vaccine is available to:
 - a. Adults with chronic disorders of cardiovascular or pulmonary system, or
 - b. Healthy individuals 60 years of age or older, or
 - c. Persons who have contact with high risk persons.
2. Each recipient will be made aware of the benefits and risks, and shall sign informed consent.
3. A standard form will be utilized to document immunizations and The Pharmacy will maintain a patient record of administration.
4. The Pharmacy will inform the prescribing physician of vaccinated individuals on a regular basis.

Contraindications

1. Febrile illness.
2. Severe allergy to eggs.

Emergencies

Use The Pharmacy Protocol and Standing Order for Management of Allergic and Anaphylactic Reactions for emergencies.

Date

Physician, MD
Medical Director, County Health Department

Date

J. Doe, PharmD
Chief Pharmacist, The Pharmacy

This authorization will be in effect for one year unless rescinded earlier in writing by either party. Any changes in protocol must be agreed upon by both parties.

Adapted with permission from Black Hawk County Health Department, Waterloo, Iowa.

Figure 2. Example: Standing Order and Protocol for Treatment of Emergencies

THE PHARMACY
MAIN ST.
RURAL, IA

Protocol for ALLERGIC and ANAPHYLACTIC REACTIONS to Injectable Medications Administered at The Pharmacy

If an allergic reaction to injectable medication occurs at The Pharmacy, the following protocol will be followed.

Standing orders for management of ALLERGIC REACTION and ANAPHYLAXIS:

I. Supplies to stock

- A. Epinephrine Injection, USP, 1:1000. Preferably, this will be in pre-drawn syringes with 0.1 mL gradations on the barrel (Ana-Kit or equivalent). If pre-drawn syringes are not used, 1 cc tuberculin syringes with 1/2-inch or 5/8-inch 26 ga. needle will be used.
- B. Diphenhydramine hydrochloride injection.
- C. Blood pressure cuffs, ped-size and adult regular, with stethoscope.

II. Recognition of anaphylactic reaction

- A. Sudden onset of itching, redness, with or without hives, within several minutes after injecting a vaccine. The symptoms may be localized or generalized.
- B. Angioedema (swelling of the lips, face, throat), anxiety, difficulty swallowing, syncope, fall in blood pressure, lightheadedness, paresthesia, flushing, sweating, palpitations.
- C. Bronchospasm, wheezing, tightness in chest, shock.

III. Emergency treatment

- A. If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for 30 minutes, watching for generalized symptoms. If none occur, go to III. (G).
- B. If symptoms are generalized, activate the emergency response system (911) and notify the ordering physician. This should be done by another person, while the agent treats and observes the patient.
- C. Administer epinephrine according to dose in the table below, subcutaneously or intramuscular. Site of administration can be the anterior thigh or deltoid muscle.
- D. Administer diphenhydramine by IM injection according to the dose in the table below. DO NOT administer diphenhydramine or anything else by mouth if the patient is not fully alert or if patient has respiratory distress.
- E. Monitor the patient until EMS arrives; perform CPR and maintain airway if necessary.
 - 1. Keep patient in supine position unless there are breathing difficulties. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness.
 - 2. Monitor vital signs frequently.
- F. If EMS has not arrived and symptoms are still present, repeat the dose of epinephrine every 15 minutes.
- G. Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later.

Testimony in support of Senate Bill 2350
Senate Human Services Committee
January 30, 2001

The North Dakota Medical Association supports SB 2350. Our Commission on Legislation voted to support this bill, which was modified at our request before introduction by the pharmacists. We support the bill for three main reasons:

1. SB 2350 furthers the physician/pharmacist collaborative relationship (already existing in the area of initiating and modifying drug therapy) by requiring the injectable drug be prescribed by and administered under protocol with an authorized prescriber;
2. It is permissive, in that the prescriber is not required to collaborate with the pharmacist but may work with a pharmacist on a patient-by-patient basis, considering the best interests and care for the patient; and
3. The bill requires additional safeguards and education for the pharmacist, and specifies the rules and requirements to insure the protection of patients and the appropriate collaborative process between pharmacists and physicians. NDMA has received assurances from the pharmacy representatives that we will have an opportunity for full involvement in the initial development of the rules called for in the bill, before they are promulgated for additional public comment.

David Peske
North Dakota Medical Association



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

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Wahpeton, Treasurer
HOWARD C. ANDERSON, Jr., R.Ph.
Turtle Lake, Executive Director

Senate Bill No. 2350
January 30th, 2001 - 10:45 AM
Senate Human Services Committee - Red River Room

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

The Board of Pharmacy has been in support of the changes in this legislation for some time. One of our strongest supporters is Dr. Harvey Hanel, Pharm.D., R.Ph. and one of our professors at NDSU College of Pharmacy. As Galen Jordre, R.Ph., Executive Vice President of the North Dakota Pharmaceutical Association stated, The College currently trains all our pharmacy school graduates in the proper administration of injectable medications.

You have already heard that many states around the country allow immunizations and administration of injectable medications by pharmacists.

There is excellent training available for pharmacists. The American Pharmaceutical Association runs a national course offered at several locations throughout the country which is developed in cooperation with the Center for Disease Control. It teaches pharmacists the additional information and techniques that they may not have received during their education or upon which they are not current.

We currently require separate training for those wishing to participate in Disease State Management such as Anticoagulation, Diabetes, Asthma and Dyslipidemia. We would institute a similar certificate program for those wishing to participate in immunizations.

This initiative would be a good example of increased utilization of competent and well trained health professionals to improve the access and the care for the public in North Dakota.

We encourage you to support this bill.

Thank You.

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Testimony on SB 2350

House Human Services Committee

February 20, 2001

Galen Jordre, R.Ph. – Executive Vice President

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 2350 is to allow qualified pharmacists to administer immunizations and other medications by injection when authorized and following rules established by the Board of Pharmacy. The pharmacists of North Dakota support this legislation because they feel that by using this authority they will improve the health of the citizens of the state. At the present time, pharmacists have authority to administer oral drugs, topical drugs and home infusion drugs in emergency situations when there is no nursing service available. The language of this legislation sets out a method to expand this authority while protecting the public. Presently pharmacists are authorized to administer injectable drugs in 30 states.

The legislation proposes additions to the definition of administration that:

- authorizes immunization and vaccination by injection to persons more than 18 years in age. These immunizations are only authorized when the pharmacist receives an order from a physician or nurse practitioner authorized to prescribe the immunization or vaccination. This definition also allows protocols to authorize immunization programs.
- authorizes a pharmacist to provide drugs by subcutaneous, intradermal, and intramuscular injections to persons more than 18 years in age. The pharmacist is required to have a specific order to administer the drug. It is important to note that a prescription authorizing a pharmacist to dispense a drug would not authorize administration unless noted on the prescription.

This legislation provides key safeguards that:

- prohibit administration to patients under the age of eighteen,
- do not allow pharmacists to administer intravenous drugs, and
- prohibit pharmacists from delegating the authority to any other person.

Pharmacists are authorized to administer drugs under this Act when they follow rules established by the Board of Pharmacy. The Act requires the Board to establish rules setting forth educational and operational requirements. The rules would cover specific areas to insure patient safety.

- Twenty hour educational requirement with specific areas of course content;
- Requirement that pharmacist be current in CPR or Basic Life Support;
- Requirement that authorized pharmacists maintain continuing competency with six hours of education every two years;
- Specific requirements for orders and protocols;
- Reporting requirements; and
- Requirements for the environments where injections may be administered.

The ability of pharmacists to provide immunizations and other injections will be beneficial as more drug therapy is instituted and administered outside institutional settings. Trained pharmacists will enhance the efforts of the health care team to provide drugs to patients in the most effective manner. 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 and injectables but feel that they offer another point of access where patients can obtain these medications.

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. Pharmacies – most with private consultation rooms – offer professional locations for administration.

We are proposing this legislation for those pharmacists who are in practices where it is appropriate for them to administer medications. The professional marketplace will dictate who participates. 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 providing immunizations and administering medications will enhance delivery of care to their patients and the patients of their communities or organizations.

I have included with my testimony documents outlining experiences in other states and guidelines adopted by the American Pharmaceutical Association for pharmacy-based immunization activities that will 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.



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

OFFICE OF THE EXECUTIVE DIRECTOR

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Senate Bill No. 2350
February 20th, 2001 - 9:00 AM
House Human Services Committee - Fort Union Room

Committee 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 in support of the changes in this legislation for some time. One of our strongest supporters is Dr. Harvey Hanel, Pharm.D., R.Ph. and one of our professors at NDSU College of Pharmacy. As Galen Jordre, R.Ph., Executive Vice President of the North Dakota Pharmaceutical Association stated, The College currently trains all our pharmacy school graduates in the proper administration of injectable medications.

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We encourage you to support this bill.

Thank You.

Howard C. Anderson, Jr, R.Ph.

Testimony in support of Senate Bill 2350

House Human Services Committee

February 20, 2001

The North Dakota Medical Association supports SB 2350. Our Commission on Legislation voted to support this bill, which was modified at our request before introduction by the pharmacists. We support the bill for three main reasons:

1. SB 2350 furthers the physician/pharmacist collaborative relationship (already existing in the area of initiating and modifying drug therapy) by requiring the injectable drug be prescribed by and administered under protocol with an authorized prescriber;
2. It is permissive, in that the prescriber is not required to collaborate with the pharmacist but may work with a pharmacist on a patient-by-patient basis, considering the best interests and care for the patient; and
3. The bill requires additional safeguards and education for the pharmacist, and specifies the rules and requirements to insure the protection of patients and the appropriate collaborative process between pharmacists and physicians. NDMA has received assurances from the pharmacy representatives that we will have an opportunity for full involvement in the initial development of the rules called for in the bill, before they are promulgated for additional public comment.

David Peske

North Dakota Medical Association