# NoDak Pharmacy

Volume 27, No.2 March 2014

# Invoice for NDPhA Membership

## January 1 – December 31, 2014

**Or Renew On-line at www.nodakpharmacy.net, select the Join tab on the Right**

**LICENSE #**

ND License #_____

Full Name: _____

Home Address: _____

City, St, Zip:_____

_____

Email:_____

Would you like to receive email updates from NDPhA?

❒ Yes ❒ No

Legislative District _____

### Practice Setting

- ❒ Chain
- ❒ Educator
- ❒ Hospital
- ❒ Independent
  - ❒ Owner
  - ❒ Employee
- ❒ Manufacturer/Distributor
- ❒ Non-Pharmacy
- ❒ Other

### Academies

Select one:

- ❒ Community Practice Academy (CPA)
- ❒ Health-system Practice Academy (HPA)

I am interested in an academy for:

- ❒ Long-term Care/Consultant
- ❒ Nuclear
- ❒ Compounding
- ❒ Student
- ❒ Other _____

### Membership Categories

- ❒ Active Member (ND Licensed Pharmacists) $150
- ❒ Corporate Member (Having a business interest in Pharmacy, up to 5 Active memberships) $750
- ❒ Associate $50
- ❒ Student (No Fee)

### Optional Association Support

❒ Contribution to NDPhA Political Action Committee (PAC)
**(Cannot be Corporate Checks AND must be a Separate Check)**
Amount _____

❒ Contribution to the Pharmacy Advancement Corporation (PhAC) NDSU Scholarship Fund (These funds are used entirely to provide scholarships to NDSU College of Pharmacy Students. Personal or Corporate Checks are accepted.)
Amount _____

### Payment

Mail to:

**NDPhA**
1641 Capitol Way
Bismarck ND 58501-2195
Fax: 701-258-9312

❒ Check Enclosed Amount_____

_____

Name on Card:

_____

Street Address & Zip code billing address for card

**Type (check one):** ❒ Visa ❒ MasterCard

_____

**Credit Card #**

_____ _____

**Expiration Date** **CVV**
(3 digit code on the back of card)

**PLEASE MAKE A COPY FOR YOUR RECORDS AND MAIL OR FAX TO:**
**NDPhA, MEMBERSHIP BENEFITS, 1641 CAPITOL WAY, BISMARCK ND 58501-2195 FAX: 701-258-9312**

# Table of Contents



## Support Our Advertisers



# 2014 Calendar

**MARCH 2014**

**NACDS RxImpact Day on Capitol Hill**
March 12-13 — Washington, D.C.
www.nacds.org

**NASPA Meeting**
March 28-29 — Orlando, FL
*In conjunction with APhA's Annual Meeting
www.naspa.us

**APRIL 2014**

**NDPhA 129th Annual Convention**
April 4-6, 2014 — Ramada Plaza Suites, Fargo, ND

**MAY 2014**

**NCPA Government Affairs Conference**
May 7-8, 2014 — Grand Hyatt Washington, Washington, D.C.

Voice for Pharmacy since 1885

# North Dakota Annual Pharmacy Convention

April 4-6, 2014 in Fargo, North Dakota - Registration Form

Name: Guest/Spouse Name:

Mailing Address: City/State: Zip Code:

Phone: Email Address:

**Registration Fees** (Entire Convention) **Make Checks Payable to: NDPhA 2014 Convention**

| **POSTMARKED** | **Before March 21** | **After March 21** |
|---|---|---|
| Member Pharmacist | $150 | $200 |
| Member Technician | $75 | $100 |
| Student (pharmacist/technician) | $50 | $75 |
| Non-Member Pharmacist | $300 | $350 |
| Non-Member Technician | $150 | $200 |
| Spouse/Guest | $50 | $75 |
| Spouse/Guest Meals | Lunch $15 | Dinner $25 |
| Student Sponsor | $50 per student | |

*** Member Pharmacist Rates apply to NDPhA, NDPSC or NDSHP Members**

**Registration Total: $_____**

Registration includes all meals. Please note any special meal considerations or accommodations here or call 701-258-4968:

Type of Card (circle one) Visa or Mastercard

_____/____/_____

Credit Card Number Expiration Date CVV (3 digit code)

Name on Card: Billing Address, City, State, Zip Code

Signature: Date:

**Mail Completed Forms and Payment to:** **NDPhA, 1641 Capitol Way, Bismarck, ND 58501**


## FRIDAY, APRIL 4

| | |
|---|---|
| 7:00 AM to 3:00 PM | *Registration* |
| 7:00 AM to 8:00 PM | *Breakfast* |
| 8:00-9:00 AM | Management of Hypertension in 2014, Rick Clarens, Pharm.D. (0.1 CEU) |
| 9:00-10:00 AM | Prescription Drug Take Back Program and Street Drug Abuse, Kelly Wimer, Special Agent/Drug Task Force Coordinator (0.1 CEU) |
| 10:00 AM-10:30 AM | *Coffee Break* |
| 10:30 AM-12:00 PM | The Treatment of Venous Thromboembolism (VTE): Has Warfarin Met Its Match?, Mike Gulseth, Pharm.D., BCPS, FASHP (0.15 CEU)<br>Integrating Nutritional Supplements into a Pharmacy Practice, R. Baylor Rice Jr. RPh, FIACP (0.15 CEU) |
| 12:00 PM-1:00 PM | *Lunch* |
| 12:00 PM-4:00 PM | *Exhibitors* |
| 1:00-4:00 PM | Public Health Poster Session (0.3 CEU) |
| 3:30-4:00 PM | *Ice Cream Social* |
| 4:00 - 5:00 PM | *My Life as a Resident (Student Programming)* |
| 4:00-6:00 PM | *First NDPhA Business Session* |
| 6:00-7:00 PM | *Social* |
| 7:00-10:00 PM | *NDPhA Opening Banquet/ Entertainment* |

## SATURDAY, APRIL 5

| | |
|---|---|
| 7:00 AM -8:00 AM | *Registration/Breakfast* |
| 8:00 AM -9:00 AM | Provider Status, Tom Johnson, Pharm.D., MBA, BCPS, FASHP, FCCM (0.1 CEU) |
| 9:00-10:00 AM | Pharmacy Practice Model Initiatve, Tom Johnson, Pharm.D., MBA, BCPS, FASHP, FCCM (0.1 CEU)<br>Updates on Treatment of Rheumatic Disease, Donald Miller, Pharm.D., FASHP (0.1 CEU) |
| 10:00-10:15 AM | *Coffee Break* |
| 10:15-11:15 AM | *2nd NDPhA Business Meeting* |
| 11:15 AM -12:00 PM | *NAPT/NDSHP/NDPhA Meetings* |
| 12:00-1:00 PM | *Lunch* |
| 1:00-2:15 PM | USP 795 and USP 797: The Why Behind the USP Compounding Chapters, Eric Kastango, B.S. Pharm, MBA, FASHP (0.125 CEU) |
| 2:15-3:00 PM | Overview of USP 795 (Nonsterile Compounding), Eric Kastango, B.S. Pharm, MBA, FASHP (0.075 CEU) |
| 3:00-4:00 PM | Overview of USP 797 (Sterile Compounding), Eric Kastango, B.S. Pharm, MBA, FASHP (0.1 CEU)<br>More Than the Sniffles: an Update on the Treatment of Pediatric Respiratory Infections, Amy Crawford, Pharm.D. (0.1 CEU) |
| 4:00-5:00 PM | *NDBOP Rule Hearing/NDSCS Accreditation Changes/Town Hall Meeting* |
| 5:00-6:00 PM | *Past President's Social/Phun Run* |
| 6:30-7:00 PM | Pre-Supper Social |
| 7:00-11:00 PM | *NDPhA President's Awards Banquet/ Scholarship Auction* |

*Current CE's Approval Pending*

## SUNDAY, APRIL 6

| | |
|---|---|
| 7:00-8:00 AM | *Breakfast* |
| 8:00-8:45 AM | *Memorial Service* |
| 8:45-9:45 AM | *3rd NDPhA Business Meeting* |
| 9:45-10:00 AM | *Coffee Break* |
| 10:00 AM - 12:00 PM | |

**Practice Pearls in Community and Health System Pharmacy Practice**
(0.2 CEU)

North Dakota State University College of Pharmacy, Nursing, and Allied Sciences is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Attendance at the session and completion of the evaluation form will be required to receive CE credit.

An ACPE statement of credit will be mailed upon request. Pharmacy professionals can now obtain CE statements of credit on the CPE Monitor website.

Non-pharmacists will receive a noncredit transcript within 4-6 weeks of receipt of all evaluation materials.

# Practice Pearls

### Daily work WHILE giving Immunizations

Objective: *Demonstrate how to operate an immunization clinic*

Presenter: *Steve Boehning: Steve is the pharmacy owner and manager at Linson Pharmacy in Fargo, ND. They operate a successful immunization practice to their patients*

### Improving Care for Sepsis Patients

Objective: *Apply at least two evidence based guidelines to the care of patients with sepsis*

Presenter: *Nicholas (Cole) Helbling: Cole is a pharmacist at Sanford Health Medical Center Fargo Pharmacy. Cole works on the Internal Medicine Teaching time and also is a pharmacist in the ICU. Improving Care for Sepsis patients was a research project Cole accomplished during his residency, as well as continued Medication Use Evaluations.*

### Admission Medication Reconciliation: The Snowball Effect

Objective: *Explore at least three effects admission medication reconciliation has on a patient admission*

Presenter: *Jena Schwieger, PharmD: Jena is a health system pharmacist at Sanford Medical Center Fargo Pharmacy. She participates in medication reconciliation for patient care and makes significant interventions during this process.*

## 340B in Health System Pharmacy: Navigating the hoops

Objective: *Indicate three or more items that have proved important in successful 340B implementation*

Presenter: *Jesse Breidenbach, PharmD: Jesse is the Director of Pharmacy at Sanford Health Medical Center Fargo Pharmacy. He has past experience as a health system pharmacist and pharmacy informatics. A recent successful 340B implementation within this health system has occurred.*

## 340B Contract pharmacy: Life as an aspiring 340B Provider

Objective: *Discover at least four "tips" to starting a 340B Contract Pharmacy*

Presenter: *Dave Olig: Dave practices as a pharmacist, owns and operates multiple community pharmacies in Fargo, ND. Recent expansion into 340B retail contract pharmacy has been a major initiative*

## Inter-departmental relationships: Getting Buy-in

Objective: *Demonstrate two or more methods for building relationship with other departments in your facility*

Presenter: *Brian Ament, PharmD, MBA: Brian is the pharmacy director at Jamestown Regional Medical Center in Jamestown, ND. Brian and his staff have successfully implemented many changes with other departments, improving patient care and staff relationships.*

## Medication Therapy Management and Patient Outcomes

Objective: *Discover two or more significant outcomes of MTM in daily practice*

Presenter: *Faith Wentzel, PharmD: Faith is a pharmacist at Ye Olde Medicine Center in Park River, ND. She is certified in the About the Patient's Diabetes and Pain Management Programs.*

## The Patient Impact of Discharge Medication Reconciliation

Objective: *Discuss two or more impacts discharge medication reconciliation can make in patient care*

Presenter: *John Savageau: John is the Clinical Pharmacy Manager at Sanford Medical Center Pharmacy Bismarck. This team has successfully implemented discharge medication reconciliation that has seen significant results in patient care.*

## Preceptor Pearls

Objective: *Identify best practices in incorporating pharmacy students into patient care activities.*

Speakers: *Wanda Roden, Experiential Education Director of Outreach and Assessment, NDSU and Teri Undem, Associate Director of Advanced Pharmacy Practice Experiences, NDSU.*

## Nursing Home Consulting in the Daily Grind

Objective: *Review two or more workflow tips that have resulted in a successful nursing home consulting business*

Presenter: *Bonnie Thom, RPh: Bonnie is a nursing home consultant pharmacist and former owner of Velva Drug. She also is a current board member of the North Dakota Board of Pharmacy.*

## Telepharmacy Tips

Objective: *Review at least two ways telepharmacy is changing pharmacy practice*

Presenter: *Shelley Doherty-Johnsen,RPh: Shelley is the Pharmacy Director of ePharmacist Direct for Virtual Health Services – Catholic Health Initiatives. She has successfully implemented many telepharmacy projects and is a pioneer in giving this service to the patients in our region.*

## FRIDAY, APRIL 4

**8:00-9:00 AM** Management of Hypertension in 2014, Rick Clarens, Pharm.D. (0.1 CEU)

1. *Discuss the clinical use of diuretics, beta blockers, ACE inhibitors, ARBs, and calcium channel blockers in managing patients with hypertension.*
2. *Describe recent clinical trials that have clinical implications on BP goals and the choice of antihypertensive agent.*
3. *Compare and contrast BP goals and first-line therapy options from recent clinical practice hypertension guidelines (e.g., JNC 8, ADA, AHA).*

**9:00-10:00 AM** Prescription Drug Take Back Program and Street Drug Abuse, Kelly Wimer, Special Agent/Drug Task Force Coordinator (0.1 CEU)

1. *Describe prescription drug and street drug abuse.*
2. *Identify street drugs.*
3. *Discuss current trends of prescription controlled substances & street drugs in the Fargo/Moorhead area.*
4. *Explain how to dispose of unwanted/unused prescription controlled substances and medications.*

**10:30 AM -12:00 PM** The Treatment of Venous Thromboembolism (VTE): Has Warfarin Met Its Match?, Mike Gulseth, Pharm.D., BCPS, FASHP (0.15 CEU)

1. *Describe the pathophysiology and epidemiology of venous thromboembolism (VTE).*
2. *Identify how VTE is currently recommended to be medically managed.*
3. *Compare and contrast the novel oral anticoagulants being studied for VTE treatment.*
4. *After reviewing the novel oral anticoagulant studies, assess how you would treat an individual patient through case study examples.*

Integrating Nutritional Supplements into a Pharmacy Practice, R. Baylor Rice Jr. RPh, FIACP (0.15 CEU)

1. *Discuss the benefits of integrating science-based nutritional therapies in your pharmacy practice.*
2. *Describe how to select the best nutritional products for your pharmacy practice.*
3. *Identify supplements and lifestyle changes that may help patients with health issues.*
4. *Describe how to increase pharmacy revenues with therapeutic nutraceuticals.*
5. *Discuss science-based educational resources that can be used to grow your nutraceutical pharmacy practice.*

**1:00-4:00 PM** Public Health Poster Session (.01/.02/0.3 CEU)

1. *Discuss public health topics and identify interventions that can be made to improve healthcare within a variety of patient populations.*

## SATURDAY, APRIL 5

**8:00 AM -9:00 AM** Provider Status, Tom Johnson, Pharm.D., MBA, BCPS, FASHP, FCCM (0.1 CEU)

1. *Describe the current efforts surrounding obtaining Provider Status for pharmacists.*
2. *Recognize how obtaining Pharmacist Provider Status will affect the practice of pharmacy.*
3. *Globally describe how the various viewpoints on provider status are gaining consensus.*

**9:00-10:00 AM** Pharmacy Practice Model Initiatve, Tom Johnson, Pharm.D., MBA, BCPS, FASHP, FCCM (0.1 CEU)

1. *Review the self-assessment and planning tools available through the PPMI.*
2. *List the resources available through ASHP and other organizations to help manage medication shortages.*
3. *Describe how the recently passed compounding legislation will likely affect practice.*
4. *Discuss the professional resources available for pharmacists through ASHP in both education opportunities and member resources.*

## SATURDAY, APRIL 5 CONTINUED

**9:00-10:00 AM** Updates on Treatment of Rheumatic Disease, Donald Miller, Pharm.D., FASHP (0.1 CEU)

1. *Explain how and why rheumatologist use aggressive treatment goals in managing rheumatic disease patients.*
2. *Describe the pharmacology of JAK inhibitors,TNF-alpha inhibitors and newer biologic treatments.*
3. *Choose a drug regimen appropriate for a rheumatic disease patient, based on safety and efficacy.*
4. *Describe appropriate monitoring parameters for new drug and biological therapies.*
5. *Evaluate the drug therapies as to their appropriateness for individual patients.*

**1:00-2:15 PM** USP 795 and USP 797: The Why Behind the USP Compounding Chapters, Eric Kastango, B.S. Pharm, MBA, FASHP (0.125 CEU)

1. *Describe the evolution of the practice of sterile compounding including misadventures that shaped pharmacy regulation.*
2. *Explain current and upcoming national and state laws and standards as it pertains to compounding.*

**2:15-3:00 PM** Overview of USP 795 (Nonsterile Compounding), Eric Kastango, B.S. Pharm, MBA, FASHP (0.075 CEU)

1. *Describe essential elements of performance described in USP Chapters 795 as they relate to nonsterile compounding.*

**3:00-4:00 PM** Overview of USP 797 (Sterile Compounding), Eric Kastango, B.S. Pharm, MBA, FASHP (0.1 CEU)

1. *Describe the elements of performance described in USP Chapters 797 as they relate to sterile compounding.*
2. *List the performance elements required of healthcare personnel performing limited sterile compounding outside of a controlled pharmacy compounding environment.*
3. *Define the importance of achieving and maintaining a state of control as it relates to sterile compounding.*

More Than the Sniffles: an Update on the Treatment of Pediatric Respiratory Infections, Amy Crawford, Pharm.D. (0.1 CEU)

1. *Describe treatment strategies for pediatric respiratory infections.*
2. *Choose an antibiotic regimen for a pediatric patient: including appropriate drug/formulation and dose.*
3. *Distinguish patients eligible for shorter courses of antibiotic therapy.*
4. *Analyze current literature evaluating the PK/PD parameters and therapeutic goals of vancomycin in children.*

## SUNDAY, APRIL 6

**10:00 AM - 12:00 PM** Practice Pearls in Community and Health System Pharmacy Practice (0.2 CEU)

1. *Demonstrate how to operate an immunization clinic.*
2. *Apply at least two evidence based guidelines to the care of patients with sepsis.*
3. *Discuss at least three effects admission medication reconciliation has on patient admission.*
4. *Indicate three or more items that have proved important in successful 340B implementation.*
5. *Discuss at least four "tips" to starting a 340B Contract Pharmacy.*
6. *Demonstrate two or more methods for building relationships with other departments in your facility.*
7. *Discuss two or more significant outcomes of MTM in daily practice.*
8. *Discuss two or more impacts discharge medication reconciliation can make in patient care.*
9. *Identify best practice incorporating pharmacy students into patient care activities.*
10. *Review two or more workflow tips that have resulted in successful nursing home consulting business.*
11. *Review at least two ways telepharmacy is changing pharmacy practice.*

# 2014 Annual Pharmacy Convention
## Friday April 4, 2014 to Sunday April 6, 2014

**Ramada Plaza & Suites**
**1635 42nd Street South, Fargo, ND 58103**

Please make reservations by Tuesday, March 4, 2014 by calling (701) 277-9000
Rooms available for $125.00 to $135.00 per night

# NDPhA 129th Annual Convention

NDPhA NORTH DAKOTA PHARMACISTS ASSOCIATION

**April 4 – 6, 2014**
**Ramada Plaza Suites**
**1635 42nd Street South, Fargo, ND**

ND PHARMACY CONVENTION 2014 ONE VOICE. ONE VISION.

## STUDENT AUCTION DONATION FORM

***PLEASE PRINT THE INFORMATION REQUESTED BELOW AND RETURN TO:***

***PhAC AUCTION, NDPhA, 1641 Capitol Way, Bismarck, ND 58501-2195***
***Fax: 701-258-9312 Ph: 701-258-4968 email: ndpha@nodakpharmacy.net***

**DONOR Name**

**ADDRESS (City, St, Zip)**

**EMAIL ADDRESS** **PHONE**

**ITEM QUANTITY** **DOLLAR VALUE**

**ITEM QUANTITY** **DOLLAR VALUE**

**DELIVERY IS THE RESPONSIBILITY OF THE DONOR.**
Items are appreciated by 10:00 AM-Saturday, April 5.
The auction will be held on **Saturday, April 5, 2014.**

***The Pharmacy Advancement Corporation Scholarship Annual Auction will be held Saturday April 5, 2014 after the President's Banquet during the NDPhA convention at the Ramada Plaza Suites, Fargo. The auction committee would like to invite everyone to participate by donating items. The North Dakota Pharmacists Association is celebrating 129 years so come on you woodcrafters, quilters, and other artisans help us celebrate this momentous occasion. As in years past, several items will be placed on a silent auction with the highlight of the evening being the "live" auction.***

***Please forward any questions to Lorri at ndpha@nodakpharmacy.net or call 701-258-4968.***

***Thank you for your participation in the past and we look forward to another outstanding auction.***

# Note from the President

Greetings Fellow Technicians,

The new Board of Pharmacy Technician certification requirement is in full force. All ND registered technicians will need to maintain an active PTCB certification to practice in the pharmacy, with the exception of technicians registered prior to August 1st, 1995.

The NAPT Executive Board would like to extend a "BIG" thank you to NDSU student Corey Melroe for his assistance in helping technicians prepare for the PTCB exam.

I would like to encourage all technicians to join the Executive Board members at the North Dakota Annual Pharmacy Convention on April 4-6, 2014 in Fargo, North Dakota. The convention is a great opportunity to receive continuing education, meet fellow technicians and grow in the profession of pharmacy. It is your involvement that makes the convention a great success!

The NAPT Executive Board has several officer positions open for the upcoming term. This is a great opportunity for technicians to become involved and provide leadership in the organization. The open positions for the upcoming term are Vice-President/President Elect, Secretary and Treasurer. I encourage all North Dakota NAPT members to vote, fill out the ballot by 3/31/14 and return to:

NDPhA
Attention: NAPT Election
1641 Capital Way
Bismarck, ND 58501

Donna Kisse
NAPT President

## *NAPT Executive Officer Ballot*

*Vote once for each postion*

Northland Association of Pharmacy Technicians

**VICE PRESIDENT/PRESIDENT ELECT**

_____ Brittany Butler

_____ _____
(Write in candidate)

**SECRETARY**

_____ Tamara Link

_____ _____
(Write in candidate)

**TREASURER**

_____

_____ _____
(Write in candidate)

Please complete this form and return to:
NDPhA
Attention: NAPT Election
1641 Capital Way
Bismarck, ND 58501

**MUST BE POSTMARKED BY 3/31/2014**

## NAPT Board of Directors

**NAPT President**
Donna Kisse
Employer: Thrifty White Drug, Fargo
Work #: 701.269.8747
Email: dkisse@thriftywhite.com

**NAPT Vice-President**
Sharon Kupper
Employer: Workforce Safety & Insurance, Bismarck
Work#: 701.570.3148
Email: dskup@wil.midco.net

**NAPT Secretary**
Tamara Link
Employer: Gateway Pharmacy, Bismarck
Work#: 701.224.9521
Email: taktlink@me.com

**NAPT Treasurer**
Bobbie Hauck
Employer: Irsfeld Pharmacy, Dickinson
Work#: 701.483.4858
Email: bobbiehauck@yahoo.com

**NAPT Parliamentarian**
Barbara Lacher
Employer: NDSCS, Wahpeton
Work#: 701.671.2114
Email: barbara.lacher@ndscs.edu

**NAPT Member-At-Large**
Brittany Butler
Employer: Tara's Thrifty White, Oakes
Work#: 701.742.3824
Email: brit_j_smith@hotmail.com

**NAPT Member-At-Large**
Kiah Erdmann
Employer: Sanford Health-South University, Fargo
Work#: 701.280.4466
Email: Kiah.Erdmann@Sanford-Health.org

**Immediate Past President**
Kristina Larson
Employer: White Drug #50, Rugby
Work#: 701.776.5741
Email: kristinafoster23@yahoo.com

# Advisory Committee

The Technician Advisory Committee attended the annual meeting with the ND Board of Pharmacy members in Fargo to discuss various topics for ND Technicians.

The main topic of discussion was on the upcoming changes with the new certification requirements for ND technicians. The NAPT Executive Board members reached out to ND technicians, offering assistance with preparation for the PTCB exam. With response back from interested technicians, NDSU student Corey Melroe presented a PowerPoint assisting technicians in preparing for the exam.

Another topic of discussion was on the importance of technicians setting up their NABP e-profile and registering for CPE Monitor. Technicians don't want to miss out on valuable CPE Credit. Registering for CPE Monitor allows the Board of Pharmacy and technicians to view and track CPE credits through ACPE-accredited providers.

## E-MAIL ADDRESSES

**Technicians**: Please ensure that the Board of Pharmacy has your current e-mail address which can be updated on the Board of Pharmacy website. It is important to maintain your e-mail address as this is becoming the way to communicate important updates and changes.

## Pharmacy Technician Wanted:

Professional Pharmacy of Bismarck is looking for a full time technician. We have great hours - Monday through Friday 8:30 am to 5 pm. No weekends - and closed the major holidays! If interested or have questions can call Curt at 701-223-6854 ext. 105 or email curt.mcgarvey@ppltc.com

PHARMACY MARKETING GROUP, INC

# Rx AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

## THE DRUG QUALITY AND SECURTIY ACT

Most pharmacists are aware that the Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Most are also aware that the law provides additional regulatory oversight over the compounding of sterile products. This comes from the Compounding Quality Act (CQA) portion of the DQSA. However, many pharmacists are unaware of the other provision in the DQSA, the Drug Supply Chain Security Act (DSCSA). This portion will increase the ability to track and trace products from manufacturers downstream to the ultimate users.

The CQA creates a new entity in the drug distribution model; the Outsourcing Facility. An Outsourcing Facility compounds sterile products and elects to register as an Outsourcing Facility under the act. A facility that compounds only non-sterile preparations cannot register as an Outsourcing Facility. An Outsourcing Facility is not required to be a licensed pharmacy. In addition, the Outsourcing Facility may or may not obtain prescriptions for identified individual patients. Registration and abiding by the provisions of the CQA allow the products compounded by the Outsourcing Facility to be exempt from the requirements of the New Drug Application process. Section 503A of the Food, Drug and Cosmetic Act contains another avenue for exemption when there is an identified individual patient who is the recipient of the compounded item, whether it is sterile or non-sterile.

The CQA provides a broad definition of compounding. Compounding includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering a drug or bulk drug substance to create a drug. The inclusion of the words diluting and reconstituting show the intent to cover everything sterile that is compounded, no matter how simple the action. Note that the inclusion of admixing shows that IV admixture programs are considered compounding.

Outsourcing Facilities will have to register with the FDA annually. The list of registrants will be public information. Outsourcing Facilities will also have to file with the FDA reports of their activities twice per year. The contents of these reports will not be public information. Outsourcing Facilities will be subject to FDA inspection on a risk-based schedule.

The CQA will also require the implementation or completion of some lists of products/components in order for Outsourcing Facilities to be able to comply with the section. An Outsourcing Facility cannot compound a product if it is on a list of drugs that have been withdrawn or removed from the market for reasons of safety or effectiveness. Also, an Outsourcing Facility cannot compound a product that is on the Demonstrable Difficulties for Compounding list. In addition, bulk substances without an USP/NF monograph must not be used unless they are on an approved list of bulk substances. None of these lists are currently complete, but the FDA will be convening a Pharmacy Compounding Advisory Committee to help compile these lists.

The second part of the DQSA is the Drug Supply

Chain Security Act. This provision will impact many more pharmacies than does the CQA. This act creates a drug product history, starting with the manufacturer that must be passed on with the product as is it sold or distributed down the supply chain. This encompasses wholesalers, third party logistics providers, trading partners, repackagers, and dispensers. The drug product history is not required to be provided by the dispenser to the prescribed patient. But the dispenser is required to have policies and procedures in place to quarantine suspect or illegitimate products, return them as necessary and notify any patients who may have received them from the dispenser.

Another provision of the act will require that a product identifier be affixed to the packaging of prescription drugs. This identifier will need to be readable by both humans and machines. The act also specifically outlines the content of the drug histories. Implementation of the different requirements of the act varies according to the type of entity involved, but many items will need to be implemented no later than July 1, 2015.

The DQSA has been covered in the media primarily as a compounding law, but the tracking and tracing requirements will apply to all participants in the drug distribution chain. So it behooves all pharmacists to review the act and determine which provisions impact their practice and when that impact will occur.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

# When a Small Reminder Makes a Big Difference

Have you ever had one of those little warning icons light up on your car's dash and you don't know what it means? You know that some signals require attention right away and others can wait. The thing is, most of the time you have to look up the icon to make that decision.

When it comes to medicines and people's lives, there is no substitute for being clear about a warning, and for injectable drugs the stakes are particularly high. Beginning December 1st, manufacturers of injectable drugs will have to comply with new labeling standards that help ensure that important warnings — warnings that can help prevent life-threatening situations — are obvious and clear. The standards were established by the U.S. Pharmacopeial Convention (USP). USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's mission is to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

In short, this USP standard states that warning messages – for example, "Warning – Paralyzing Agent" or "Dilute Before Using" – are the only markings that should appear on ferrules and cap overseals of injectable drugs. The ferrules and cap overseals must remain clear of any markings, including logos, except for markings intended to prevent an imminent life-threatening situation. The standard goes on to say that warnings must be printed in contrasting color and clearly visible under ordinary conditions of use. Finally, products that do not require cautionary statements should be free of information, so that those with cautionary statements are immediately apparent.

With the new USP labeling standard, if a healthcare provider sees a warning on a ferrule or cap overseal, he or she will know immediately that it is a vital, possibly life-saving piece of information that must be observed and acted upon before administering the drug to the patient.

Warning messages on ferrules and cap overseals may go a very long way to helping practitioners protect their patients from harm.

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# NASPA finds state-level provider status is widespread, but not necessarily linked to payment

KRYSTALYN WEAVER

Thirty-four states recognized pharmacists as providers or practitioners in at least one section of their state statute or in their state Medicaid program, according to a recent analysis conducted by the National Alliance of State Pharmacy Associations (NASPA). But little correlation existed between the recognition of pharmacists as providers within state law or the Medicaid program, and payment for pharmacists' patient care services.

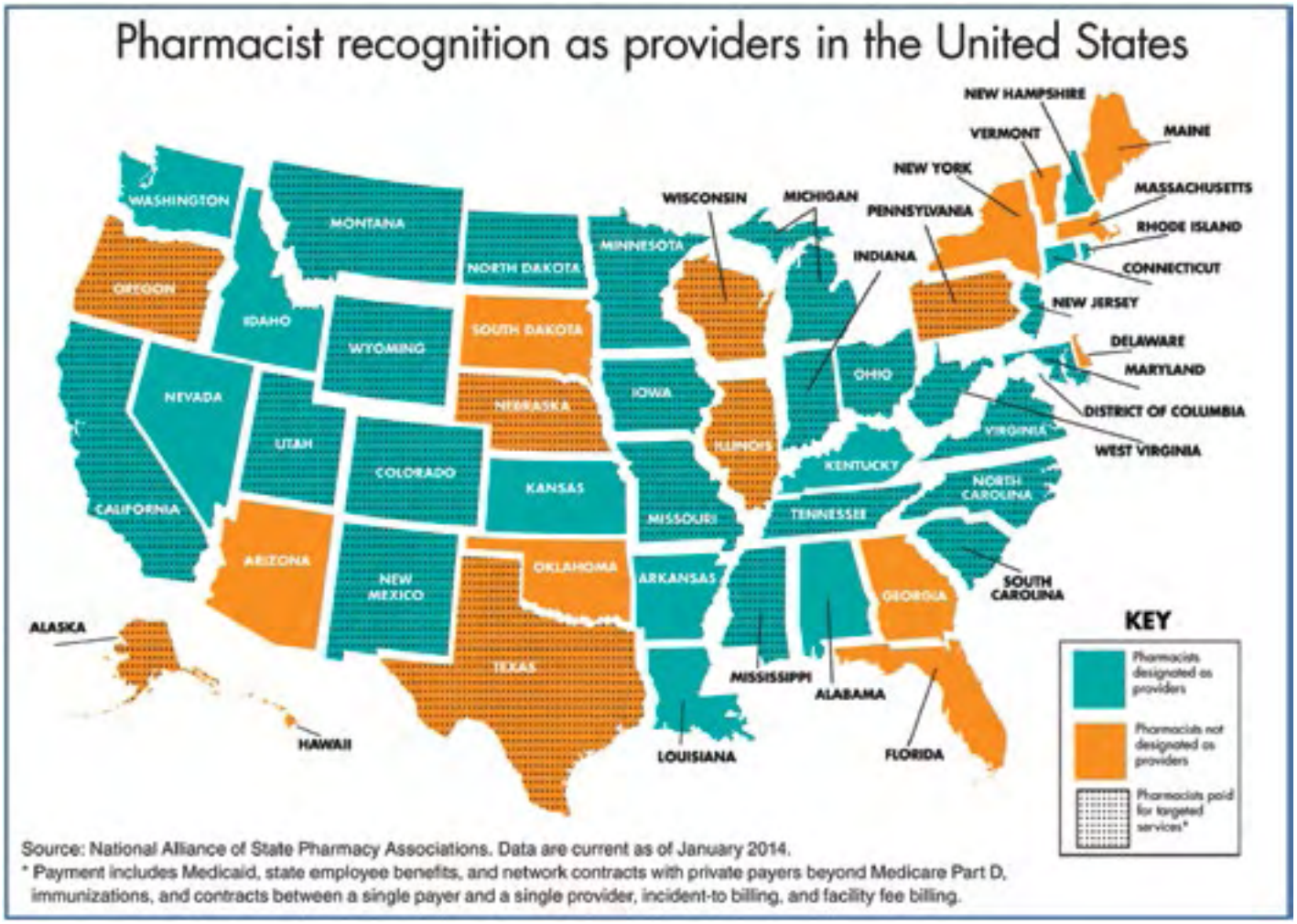
The actual framework and positioning of the language in state law varied greatly from state to state, as did the payment implications of having provider status.

"The large number of states who already have recognized pharmacists as providers or practitioners is both exciting and sobering news," Rebecca P. Snead, BSPharm, NASPA Executive Vice President and CEO, told ***Pharmacy Today***. "It's exciting because it shows us that there are fewer statutory barriers to payment for pharmacists' patient care services, but also is a reminder that there is much work to be done beyond legislative advocacy."

### Overview of results

To determine which states have designated pharmacists as providers or practitioners, NASPA staff looked at state statutes, specifically the insurance code, the business and professional codes, and the pharmacy practice act; looked at the Medicaid provider manuals; and surveyed the state pharmacy association executives.

NASPA staff also collected information on states where pharmacists are being paid for the patient care services they are providing. The analysis included the collection of information on payment for pharmacists' patient care services from Medicaid, state employee benefits, and network contracts with private payers; instances of network contracting opportunities were captured from a survey of state pharmacy association executives. The analysis didn't include contracts between a single payer and a single provider, in-



cident-to billing, and facility fee billing.

Of the 34 states that recognized pharmacists as providers or practitioners, the majority do so through state statute, but a handful also recognize pharmacists within their state Medicaid provider manuals. In a couple of cases, pharmacists are recognized in their Medicaid provider manual but not within state law.

In at least 28 states, pharmacists' patient care services (other than immunization administration) are covered by either the state or private payers. Included in the 28 were 15 states where pharmacists can be paid for services by their Medicaid program for at least one specified service, and 6 states with a state employee MTM benefit.

In at least six states, pharmacists are not formally recognized as providers in the state's statute or Medicaid provider manual, but are compensated for providing targeted patient care services.

One of the reasons for the lack of correlation between payment and a state's designation of pharmacists as providers or practitioners is likely due to pharmacists not being federally recognized as providers. Because Medicaid and private payers often follow precedents set by Medicare, federal provider status for pharmacists within the Social Security Act would likely make coverage for pharmacists' patient care services easier and more widespread.

See the map on the previous page for more information on pharmacist recognition as providers in the United States.

### State pathways to provider status

A state can take various pathways to designate pharmacists as providers.

**Insurance code**. The insurance code is one of the most common places within state statutes for pharmacists to be formally recognized as providers. The insurance code is the set of laws with which insurance companies in the state must comply. But because state insurance laws do not apply to publicly funded programs (Medicare, Medicaid, state employee plans) or to plans for self-funded employers, the insurance code affects only a small portion of the insurance market—so changes to these laws may have less impact.

Although some states have seen positive effects from recognizing pharmacists as providers under the insurance code, others have seen little change. For example, pharmacists in Virginia have been recognized as practitioners in the insurance code for more than a decade but have not seen scalable payment from private insurers for their services.

**Other sections in state codes**. In a handful of states, pharmacists are recognized as providers in the pharmacy practice act. With this approach, the statute may include in the definition of the word "pharmacist" a provider designation. Such is the case with Connecticut and Tennessee, which also both recognize pharmacists as health care providers in the insurance code.

Some states, such as California and Nevada, define pharmacists as health care providers in their business, professional, or occupation codes. A handful of states, such as Minnesota and Michigan, recognize pharmacists in their public health provisions; Minnesota also recognizes pharmacists as providers in the insurance code.

**Recognition by Medicaid**. At least nine states recognize pharmacists as providers in the state Medicaid provider manual, including two states where pharmacists are not recognized in statute. Although recognition as providers in Medicaid doesn't always result in payment for the provision of patient care services, it does help to remove a barrier to implementing new programs that include pharmacists.

**Recognition by private payers**. Because the end goal of achieving provider status is to provide patients with access to coverage for pharmacists' patient care services, another approach is to work directly with private payers. This approach has been used in states such as New Mexico, where pharmacists are recognized by many of the health maintenance organizations and health plans, and in Tennessee, where pharmacists are recognized and being paid as providers of patient care services through a program developed by the Blue Cross Health Foundation and the Tennessee Pharmacists Research and Education Foundation.

> **"The large** number of states who already have **recognized pharmacists** as providers is … exciting because it shows us that **there are fewer** statutory barriers to payment for **pharmacists' patient care services,** but also is a reminder that **there is much work** to be done beyond **legislative advocacy."**

### Every pharmacist can make an impact

The NASPA analysis showed that legislative changes are not the only way—and never the final step—to effect change in the pharmacy practice model. Practicing pharmacists collectively can make a huge impact on the national and state level provider status initiatives by doing what they do best: taking care of their patients. Pharmacists need to share their impact on patients' health outcomes and costs. As public demand increases for pharmacists' patient care services, there will be more pressure on payers to cover them. Pharmacists should continue to support APhA and other national and pharmacy associations to ensure the success of provider status initiatives.

**Krystalyn Weaver, PharmD,** Director of Policy and State Relations, National Alliance of State Pharmacy Associations, Richmond, VA

### Call to action

Please note that it was not possible for the National Alliance of State Pharmacy Associations (NASPA) to do a comprehensive analysis of all potential contracts between pharmacists and payers for the provision of patient care services. If you are a pharmacist who is currently participating in such a contract, APhA and NASPA want to hear about it! Please send information about your program to Michael Ghobrial, PharmD, JD, APhA Associate Director of Health Policy, at mghobrial@aphanet.org.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# Considering the Utility of a Universal Medication Entering System

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Have you ever had a patient come to your pharmacy that is unsure whether they have insurance, any medication allergies, or even if they are taking any other medications? When these all-too-common situations arise, several problems can occur. First, if they are not filling other prescriptions at their pharmacy, the pharmacist has no way of knowing what other medications they are currently taking. Additionally, medication interactions are not flagged because the computer does not have the information necessary to identify them. Pharmacy Benefit Management programs can do some of this, but lack patient-specific information. Second, patients could be filling a prescription for a controlled substance at your pharmacy, even though they got the same medication from a different pharmacy earlier in the day. The Prescription Drug Monitoring Program will eventually catch up with that person, but only after they have been identified as a controlled substance "frequent flier." Third, if they do not have their insurance information with them, the time used to call their primary pharmacy to get that information, just for this one fill, is time-consuming and thereby costly. All of these scenarios could be resolved by one solution, a universal medication entering system.

The healthcare system in the United States is in an era of sweeping reform. One of the most significant reforms in the recent years is the widespread use of electronic health records (EHR). In fact, according to a recent report from the Centers for Disease Control and Prevention, North Dakota health care providers have the highest rate of electronic medical record use in the country, followed by Minnesota[a]. A universal medication entering system linking all pharmacies in the United States would be a natural extension of this healthcare innovation. If pharmacy as a profession were to come together to agree upon a digital platform to support a universal system of record-keeping patient care would improve and the efficiency and safety of pharmacists would be enhanced.

There are many benefits illustrating the utility of such a universal medication entering system. The health issues this intervention would address include drug-drug interactions, opioid abuse, and time management of the pharmacy staff. According to the FDA, **every year, more than 2 million patients suffer serious Adverse Drug Reactions (ADRs) in the US; of those, 100,000 of which are fatal[2].** This makes ADRs the fourth leading cause of death in the United States. The average number of prescriptions filled per person-year in the U.S. is 15.5 and rising[3]. With this rate of usage it is difficult for individuals to get all of their prescriptions at the same pharmacy. This makes it difficult for a given pharmacy to know what other medications the patient is normally taking if they are only filling one prescription with them. With this many medications having been consumed, each individual also has increased risk of an adverse drug reaction.. By having a universal entering system, every pharmacy would be able to see what each patient has filled at any other pharmacy.

A universal entering system will also allow pharmacists to identify the adherence level of their patients by having access to the information necessary to calculate the proportion of days covered metric (number of days' supply obtained and number of days between fills). In time Medicare Advantage reimbursement levels

will be decided based on the Five-star Quality Rating System, requiring the reporting of adherence rates, so this innovation will prepare the way[4].

The universal entering system being proposed will also allow hospital pharmacies to connect with community pharmacies. When a patient is hospitalized for surgery, or for emergency care, the pharmacists at the hospital administering the medication will be able to tell whether or not the antibiotics or pain medications the patient is receiving will interact with any medications they are currently on, or if they have been tried with this patient and shown to be ineffective. A universal pharmacy entering system would allow ease of access to all healthcare providers to better meet the needs of their patients, and help decrease the rate of adverse drug reactions. Models such as the North Dakota Health Information Network (HIN) have the potential to take us in the right direction, but it is far from being implemented, and is too narrow in scope for the needs proposed here.

Having a universal pharmacy entering system would also help decrease painkiller abuse in the United States by decreasing ease of access to these medications. Pharmacists would now be able to track each individual patient and what prescriptions they are picking up, including date and location, as well as their insurance status. Patients would no longer be able to conceal that they had already picked up that specific medication elsewhere, because pharmacy staff would be able to pinpoint exactly what medication was received, when it was picked up and the pharmacy it was purchased from. According to the CDC, 12 million people used painkillers illicitly in 2010, that is, using them for nonmedical purposes[5]. Although a universal pharmacy entering system would not address abuse in those individuals getting these drugs illegally, it would decrease the number of individuals abusing the system by using legal pharmacies to obtain opiods to use for illegal and dangerous purposes. Having this system would also allow ease of access to all pharmacy employees and decrease the need to contact other pharmacies. By optimizing time, it leaves more time to focus on the patient and meeting their needs.

There are many barriers to be overcome in order to realize the dream of a universal medication entering system. There are barriers to erecting such a system. The cost and maintenance of the platform would be significant. The security of the patient information would have to be insured. Individuals with access to patient information would need to be licensed in digital security and HIPAA regulations. Limited use policies would need to be created, so that large retail pharmacies could not use the information for solicitation or direct sales. But pharmacy is a health profession with a commitment to patient-centered care and the highest ethical standards. The respective boards of pharmacy and pharmacy associations are well prepared to write the policy need to insure that a universal medication entering system is designed which will serve the purpose for which it is intended and minimize the opportunity for abuse. Although it would be difficult to require all pharmacies to join the network, the benefits it brings would quickly outweigh any reluctance some pharmacists might feel.

Many of the challenges and frustrations faced by practicing pharmacists today could be addressed by the implementation of a universal medical entering system. Innovations such as a system like this are needed in order to continually improve the effectiveness and efficiency of pharmacy. The sort of unity this system would create would be incredible. Furthermore, implementing this system would improve individual health care and our country's healthcare as a whole.

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# "Jingles for Shingles"

Kelsey Wolfe

At least one million individuals each year will get shingles. Herpes Zoster or "shingles" is a virus which lays dormant in adult and elderly populations who have had the chicken pox infection. These individuals are at a greater risk of developing shingles as the virus still lives within their body and can be triggered at any time into shingles. Other individuals at high risk include people 50 years of age and older, as well as those who are immunocompromised due to HIV infections, diseases such as cancer, or medication use such as steroids or chemotherapy. These individuals have a weakened immune system which increases the risk of a shingles infection to occur. The purpose of this article is to address the need for increased awareness about the shingles virus and its relevance to pharmacy practice in preventing a shingles outbreak.

In order to prevent an outbreak, individuals at high risk may be eligible to receive the shingles vaccine, known as Zostavax, which was licensed in the United States in 2006. Clinical trials show the shingles vaccine reduces the risk of contracting shingles by 50% and has shown effective in reducing the severity of pain associated with a shingles outbreak.[1] As such, the vaccine provides a form of protection against the extremely painful shingles virus. By vaccinating individuals at risk of developing shingles, it lessens the probability of having a serious outbreak that could lead to hospitalizations, increased medical costs, and spreading of the virus to those individuals who have not had the chicken pox.

The purpose of this intervention is to increase awareness and disease protection against shingles within a community pharmacy setting by screening individuals ages 50 years and older who may be at risk of developing shingles. The most important piece of this intervention will be the pharmacist, who will be responsible for screening patients and determining their risk level for shingles. The pharmacist would also be in charge of properly administrating the vaccine to the patient and providing documentation for the patient's chart. Furthermore, pharmacy technicians and interns would be responsible for initially screening the patient for age eligibility and providing those patients with an informational brochure in their prescription bags. The time frame would include November – February of each year; with screenings and immunizations for shingles to be completed within a local community pharmacy. In order to promote this health intervention, a bell will be rung for each patient who receives the shingles vaccine in an effort to enhance interest and/or entice other patients to also get the shingles vaccine. Since the time frame revolves around the holidays, 'ringing of the bells' would adequately be within season. Hence, the slogan for this intervention is "Jingles for Shingles".

Within the community pharmacy, individuals would first be recruited based on their age by checking their date of birth when filling a prescription. Should the patient meet the eligible age requirement, the pharmacist would then communicate with the patient and ask if they have heard of the shingles virus or if they have had the chicken pox. An informational brochure would be handed to the patient that provides additional information about the shingles virus and the vaccine that is now available for prevention of shingles. The informational brochure would also be sent to all patients who initially qualify for a shingles vaccine by placing the brochure in their medication bags upon picking up a prescription. Upon receiving the informational brochure, patients interested in receiving the vaccine would come back to the pharmacy


to complete the second step of the intervention. This step includes a health screening questionnaire to determine if the patient has any precautions or contraindications to the vaccine. If the patient was still eligible at this point for the shingles vaccine, direct treatment (i.e. receiving the vaccine) could be administered within the pharmacy. Upon approval from the physician or via standing orders already established, the pharmacist would then administer the vaccine to the patient in a closed consultation area.

The overall goal for this intervention is to prevent an outbreak of shingles in those populations at highest risk. Although this goal cannot be measured on a numeric scale, one could assess whether or not the vaccine was successful in preventing an outbreak. This intervention was designed to serve the Fargo/Moorhead area, with an ideal number of participants per intervention time frame being 300 individuals. However this goal is for a single community pharmacy only; should additional local pharmacies within the state of North Dakota adopt this intervention into practice, then the number of participants per intervention time frame would increase to a larger goal.

The total cost of the shingles vaccine will vary with each individual patient. Some insurance companies will pay a percentage of the overall cost incurred for administration of the vaccine versus out of pocket expenses when the vaccine is not covered. Typical expenses that would be covered by insurance companies include doctor visit copays and the copay for the vaccine, which would be an estimated $10-$50 after insurance. However, insurance coverage may be limited to persons older than 60 years of age. For those patients not covered by health insurance, the cost of getting a shingles vaccine is going to be more expensive at $200-$250.[2] Nevertheless, patients can take a proactive measure in disease prevention by getting immunized against the extremely painful shingles virus.

In conclusion, this intervention serves to increase awareness and disease protection against the shingles virus within a North Dakota community pharmacy by screening individuals who may be at increased risk of developing shingles. This intervention is relevant to pharmacy practice in that immunizations play an essential role in overall patient care. Pharmacists are educated in screening patients in order to determine if they are eligible candidates for vaccines and they are also trained on how to effectively administer vaccines to patients. Instead of going to the clinic or physician's office for a vaccine, pharmacies can provide a quick, convenient alternative for their patients in comparison to the traditional clinic setting. By vaccinating against shingles, it lessens the probability of an individual having a serious outbreak that could lead to hospitalizations and increased medical costs. Overall, pharmacists are able to communicate with their patients on a personalized level and evaluate the patient's medication profile for any concerns they have regarding the patients overall health.



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