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### Mark Your Calendar

### August Calendar Events

**August 18-20** 

Tri-state Young Pharmacist Leadership Conference

### September Calendar Events

September 15-16

NDSHP-NAPT Fall Seminar in Bismarck

September 15-18

APhA Legislative Conference

September 20

ND Opportunities Night at NDSU

September 21 - NDSU Career Fair

September 23 & 30

PQC Training: Bismarck & Fargo

September 29 & 30

Immunization Training Program:

Bismarck & Fargo

### October Calendar Events

October 7-11 - NCPA Annual Conference

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and on.

Dennis Johnson, RPh

### **Step Up to the Political Plate:** It's Every Pharmacist's Job!

If we don't provide

input decisions will be

understand pharmacy or do not

your profession, your

Pharmacy is among one of the most regulated professions around. The government regulates your professional qualifications, the medication products dispensed or sold, the limits and responsibilities of dispensing and selling medications, the records maintained, your relationship with insurance companies and PBMs, reimbursement and policies for patients enrolled in government programs, compounding, safe hold the same priorities as pharmacy. environments, quality of care, taxes you pay, and the list goes on

patients, your job and The government is involved in a pharyour future. macists' life daily and year-round, no matter where you practice. During the 2006 Interim, numerous state legislative committees have been meeting to discuss pharmacy issues and decide your future. The debate in Congress over Medicare and Medicaid is going to directly impact the future of hospitals, clinics, and community pharmacies across the nation.

Today, healthcare is at the heart of so many political discussions and decisions, we just can't ignore this reality. If we don't provide input, decisions will be made by people who do not understand pharmacy or do not hold the same priorities as pharmacy.

Not long ago, a colleague was concerned by the statement "get into politics or get out of pharmacy." As much as we may wish otherwise, the political process in this country leaves us no choice; either you get involved or you live with the consequences.

You can provide extraordinary pharmacy care, in any practice setting, but it does not guarantee that your work will be recognized or rewarded by public policies that provide incentives to do more, and focus on improved patient outcomes. More importantly, no one can understand or speak to the pharmacy perspective on these issues better

than pharmacists, but historically we have not done well in the political arena.

What's next? Financing our legislative activities is important. You may not like the way it works, but there is a component of the political process that requires giving money to support political activities and candidates. And the pharmade by people who do not

macy PAC fund needs replenishing.

It's a fact of life – doing Step up to the plate! This is about nothing requires no money, but moving forward to improve and safeguard our profession requires money. I'm in favor of moving forward and will need your help.

> How can YOU help make a difference? There are several things we must do, and by choosing a couple for yourself we can collectively make progress:

- Donate to the PAC fund so we can host legislative meetings to share the pharmacy perspective with legislative leaders
- Become knowledgeable on the relevant pharmacy issues in North Dakota
- KNOW YOUR DISTRICT LEGISLATORS and take a few minutes on a regular basis to visit about the issues impacting your profession and your patients
- Ask the candidates how they stand on pharmacy issues and patient access to care
- Attend the legislative meetings this fall that are sponsored by the Association
- Testify, and participate in the audience, in support of pharmacy issues during committee hearings
- Respond to email and FAX Alerts that ask you to contact your local legislator on specific issues

Step up to the plate! This is about your profession, your patients, your job and your future.

### Dr. Patricia Hill

### A Silver Lining?

It appears we have survived the implementation of Medicare Part D, or at least the first phase. Regardless of your political persuasion, your social/economic status or how, when and where you interfaced with the new program the feedback was negative. Whether or not you agreed with the sentiment that it was a monumental change and problems were unavoidable, or you were of the opinion that the program was ill-conceived from the start there was consensus that it was complicated and confusing — with an overabundance of bureaucratic red tape.

Pharmacy took the brunt of this debacle on its collective chin. While that heroic effort has been recognized and praised by everyone from Secretary of Health Leavitt to individual patients, the profession continues to reel from the adverse impact of this implementation process. Even so, there just might be a silver lining to this fiasco, if we have the insight and motivation to take advantage of it.

Over the last 10-15 years pharmacy has struggled under the yoke of the PBM driven prescription benefit. Take it or leave it contracts; reimbursement fees that do not cover the cost to dispense; 30 to 45 day payment cycles from the PBM while pharmacies have to pay their wholesaler bill in 7-10 days; uncompensated time for formulary management, insurance coordination, benefit management and the list goes on and on. While pharmacy has struggled with these issues for years the implementation of Medicare Part D exacerbated these problems and shed a very public light on them for the first time.

The question that we should be asking ourselves is, "What should we do with this opportunity?" Pharmacy's reimbursement paradigm has been outdated for a number of years and the current PBM business model is unsustainable. Both public and private payers are clamoring for transparency in an effort to determine actual cost of product and services. Wouldn't this be a good time for pharmacy to re-engineer its business and reimbursement model?

Since the current business model has driven most pharmacies to the brink of financial instability wouldn't

this be the most opportune time to really think outside the box? For instance...rather than the pharmacy purchasing the inventory have that inventory placed in the pharmacy on consignment. A cost of dispensing study could be used to determine an appropriate dispensing fee. When the prescription is filled product cost would be determined via the point of sale system and the payer/PBM would then pay the manufacturer for the product and the dispensing fee to pharmacy.

Or what about all those medication therapy management services we are always talking about. Instead of waiting for some third party payer to decide that they will pay us usual and customary less 15% for our medication management expertise why not go to patients and payers directly. With the confusion and complexity of the Medicare Part D benefit don't you think that Medicare eligible individuals or their caregivers would pay a pharmacist willing to help them review their medication regimen and help them pick the appropriate plan for them?

With the cost of nursing homes and skilled nursing facilities continuing to escalate wouldn't it be more cost effective for a family to pay a pharmacist to manage/monitor grandma and grandpa's medication usage so that they could remain at home? With employers beginning to understand the negative impact of smoking, obesity, poor control of chronic diseases on their bottom line wouldn't it seem reasonable that they would be willing to invest in programs to help their employees change that behavior? What about wellness, prevention and screening programs?

I'm sure you can come up with numerous examples of care and services that could be incorporated into a new business model for pharmacy. Pharmacists have the education, expertise, accessibility and public trust to make these new opportunities a reality yet very few ever take the risk. Some say we will only change when it becomes too painful to stay where we are. It seems the negative impact of the Medicare Part D implementation and the continued devaluing of our dispensing function may be the culmination of the perfect storm which will make it too painful to



Personal visit to Congressman
Pomeroy's office in DC on May
23 (1 to r): Tony Welder, Dr. Hill,
Congressman Pomeroy, Kathy and
Terry Kristensen. Pomeroy spoke
earlier at the NCPA Legislative
Conference and was presented with
the mortar and pestal as a gift.

stay where we are.

The pharmacy profession in North Dakota has a tradition of providing education, tools and networking opportunities designed to facilitate the exchange of innovative ideas and implementation of new practice models. Are you interested in exploring new opportunities or practice models? Are you up to the challenge? We need to hear from you now.

### **Introducing iRx: Your Information Prescription**

There is a new service available on the NDPhA website called iRx: Your Information Prescription. iRx provides information on newly introduced medications, including statistics, answers to commonly asked questions, even cost information. The service is provided free of charge and is updated monthly. Check it out today at www.nodakpharm-cy.net.

### THANK YOU

Special word of "thanks" to all the pharmacists who took the time to complete the cost of dispensing survey and the economic impact survey. I realize the time and energy required to participate, and I truly appreciate the commitment you have made to these projects. Thank you.

Parriai G. Dile

### **Pharmacists Visit Congressional Delegation**

In late May nearly 500 pharmacists from around the country gathered in Washington DC and made personal visits to their Senators and Congressmen. North Dakota was represented by Tony Welder, Terry Kristensen and Patricia Hill who shared with Senators Dorgan and Conrad, and Congressman Pomeroy the concerns about patient access to quality pharmacy care in our state.

If you fail to understand the importance of a united effort keep in mind the phenomenal results: 34 new cosponsors joined on to HR 5182 bringing the total to 95; three more Republicans signed onto Senate Bill 2563; and HR 1671 now includes bipartisan support from 84 representatives. These are impressive numbers, and should convince any skeptic that lobbying in support of pharmacy is a highly effective tool.

YOU can make a huge impact right here at home! Your next best chance is during the Independence Day recess from June 30-July 10, when the North Dakota delegation will likely be traveling around the state. Call now - get them to come to your pharmacy and tell them the consequences with Part D and BCBS cuts. THEY PREFER TO HEAR DIRECTLY FROM YOU because that is where patient care happens.

# Long-Term Care Pharmacy Caring for North Dakota's Aging Population



Curt McGarvey visits with a resident at Missouri Slope Care Center.

By Stacy Fiedler, Clearwater Communications

### "Medications are probably the single most important health care technology in preventing illness, disability and death in the geriatric population."

- J. Avorn, 'Medication Use and the Elderly: Current Status and Opportunities'

Pharmacists throughout North Dakota practice longterm care (LTC) consultation, primarily among the state's elderly population, with the belief that medication therapy and consultation over the long term can dramatically improve patients' health and quality of life.

In both urban and rural settings, pharmacists in North Dakota perform patient chart reviews and therapy assessments, monitor facility compliance, and provide professional recommendations regarding patients' long-term healthcare at nursing homes, assisted living centers, hospitals and vocational living centers throughout the state. While duties differ for LTC pharmacists in different settings across the state, pharmacists involved in LTC

consulting care about the health and well-being of their patients over the long term and are a primary source of information on medication, healthcare and druginteractions.

According to studies by the American Society of Consultant Pharmacists (ASCP) the total annual direct medical cost of medication-related problems in the United States is \$104.2 billion, and adverse drug reactions are among the top five greatest threats to the health of seniors. Given these statistics, it is understandable why pharmacists believe medication counseling and LTC are vital to the health of the country, where every day another 6,000 people reach age 65.



Shelly Peterson, president of the North Dakota Long-Tern Care Association.

"Pharmacy plays a key role in long-term care in North Dakota," says Shelly Peterson, president of the North Dakota Long-Term Care Association. "We understand the importance of the pharmacy profession on the success of LTC. We often ask pharmacists to sit on our boards, and seek their knowledge and experiences on a number of LTC issues. The N.D. Long-Term Care Association will continue to look to the pharmacy profession for guidance in LTC issues."

### The Role of Pharmacists in LTC

Curt McGarvey works for Valley View Pharmacy in Bismarck, where he is a pharmacy manager and LTC consulting pharmacist. Professional Pharmacy, Inc. serves and dispenses medication only for LTC facilities, so all of McGarvey's work is in LTC pharmacy practice. As such, he provides medication and consultation to around 500 patients of assisted living centers, nursing homes and institutional facilities throughout Bismarck. "To me, LTC is pharmacy in its truest form," says McGarvey. "I look very specifically at medications and how they interact with each other. When I catch problems with medications or possible drug interactions, I see firsthand the importance of the pharmacy profession."

Because of Centers for Medicare and Medicaid

(CMS) rulings during the 1990s, pharmacists must perform chart reviews at nursing homes and institutional facilities on a monthly basis. Pharmacists review charts, checking for possible drug interactions, and draft reports for doctors and nurses of the facility. In 24-hour nursing care centers, hospitals and institutional facilities, these chart reviews and recommendations go to facility doctors and nurses.

The chart reviews and facility monitoring done in assisted living centers is a bit different from reviews in hospitals and 24-hour nursing care centers. "Assisted living consultations quite often take more time," says McGarvey. "We work directly with the patients rather than the doctors or nurses. Assisted living patients are typically elderly and, as a whole, the elderly are on a lot of medications. In the most simple chart review, it can take as long as 30 minutes to review a patient with multiple medications."

Assisted living centers also require less-frequent consultation than hospitals or nursing homes, as there aren't mandates on LTC in assisted living centers.

According to Tim Carlson, pharmacy manager and long-term care consultant at Thrifty White Drug in Minot, "The



Curt McGarvey, pharmacy manager and LTC consulting pharmacist.



McGarvey completes paperwork for a LTC consultation.

state and federal governments are still working on the rules and regulations for assisted living centers. Assisted living is still evolving with grey areas in terms of the level of necessary regulation. As of now, I go into assisted living centers on a quarterly basis to review charts, drug storage, and facility compliance, but in general, the review isn't as detailed as a hospital or care center review, because there aren't any mandates yet."

In his position with Thrifty White Drug, Carlson provides LTC consultation for more than 600 beds in two nursing homes, two assisted living centers and one vocational facility. As a pharmacist involved full-time in LTC, Carlson says technological advances have done a lot to improve the efficiency of the practice. "Full-time consulting pharmacists earn their money based on the number of beds they consult, so it's important to do the job effectively and efficiently, provide the best service to patients, and to remain a profitable, viable business."

According to a study, published by the ASCP, the consultant pharmacist's drug regimen review services in U.S. nursing home facilities improve therapeutic outcomes in patients by 43 percent and save as much as \$3.6 billion annually in costs associated with medication-related

problems. The LTC consultant's role in chart review, assessing the interrelationship between disease states, nutrition, medications and dispensing and storage practices is truly an essential part of LTC healthcare.

"Consulting pharmacists are continuing to do more and get more involved, and we are a lot better educated," says Carlson. "Unlike other parts of pharmacy practice, we really get to know our patients with interactive, hands-on work. There is a huge diversity of practice compared to some other forms of pharmacy."

For Laurie Larson, owner of Ye Olde Medicine Center in Park River, diversity of practice is balancing the retail side of her pharmacy and providing LTC services to two basic and three long-term care centers in Park River and the surrounding area. Larson schedules LTC consultations after her retail pharmacy has closed, and attends quality assurance and facility monitoring meetings in the morning before the pharmacy opens. "My favorite part of LTC is working with people," says Larson. "I get to visit with people who used to be pharmacy customers, but are now in nursing care centers. It's great to see those people and to visit with the nurses about the patient's care."

### Changes in LTC Practice

In the ever-changing world of pharmacy practice, LTC is no exception. Medicare Part D, reimbursement rates, an aging population and changes in technology are all affecting LTC practice.

Larson says new nursing home billing cycles, coupled with lower reimbursement rates, are seriously affecting the bottom line in LTC. Larson's pharmacy in Park River used to fill and deliver prescriptions every 30 days and receive payment every 30 days. Now, because of the nursing home's new prescription cycle, Larson fills and delivers prescriptions every seven days, but still receives payment every 30 days. "We are still only getting \$2.50 per script," says Larson, "but now that's split four times so we are getting less than 70 cents per script. You can't fault LTC centers for getting newer, fancier systems for prescriptions, but because of the low reimbursement rates, it's hard on us. Basically, we're spending more time, but getting less money."

Larson says the implementation of Medicare Part D and the reimbursement rates that accompany it are seriously affecting small pharmacies. "Most of my patients are elderly, so are on Medicare or some form of welfare. Pharmacy is always in jeopardy to some degree, but Medicare Part D is particularly detrimental."

Kim Essler, partner in Chase Pharmacy in Garrison, agrees that Medicare Part D and North Dakota's changing demographics are affecting LTC practice. "I spend more consultation time talking about alternatives to drug coverage. People are looking for alternative drugs that work the same as the medications they are used to, but are covered under their new, specific drug plans."

In Bismarck, McGarvey says he's noticed an increase in the amount of time he spends on billing. "The implementation of Medicare Part D has definitely changed our business. Most of our patients used to be on Medicaid, but now are dually eligible. We are now billing multiple places instead of one or two. There's been a huge increase in the amount of time spent on billing."

Despite the increasing regulations and decreasing reimbursement rates, pharmacists across the state engaged in LTC agree that long-term care pharmacy is one of the most rewarding, diverse forms of practice. "In LTC consulting, I feel more involved in the medical care of patients," says Essler. "In retail, I have some input during consultation with patients, but in LTC I get to be a lot more hands-on with my patients and help them control their health for the long-term."



McGarvey visits with a LTC patient.

### ND State Board of Pharmacy





Recently I received a letter asking about a clarification in the law or regulations speaking to when a pharmacist clarifies an order from a physician or a nurse practitioner and then relays it to the nurse, as to what the procedure should be from there. I would like to share with you the response I provided to this individual.

When the pharmacist or other professional takes an order from a practitioner, that individual must be the one to record the order in the chart for the order to be valid. When the pharmacist takes the order and then relays it to a nurse, the nurse must clarify the order directly with the prescriber before entering it as an executable order. A note could be entered asking the prescriber to review the order or the nurse could confirm with a telephone call to the prescriber. One of these should be done before the next dose is due, however.

It is the opinion of our Board, that it is within the scope of practice of a pharmacist to take orders from the prescribing practitioner and record those in the patient's chart for administration or execution by another healthcare professional. In most of our institutions the pharmacist is also authorized to dispense a generic product or many times, to authorize a therapeutic substitution within that class of drugs, which has been approved by the Pharmacy and Therapeutics Committee and the medical staff of the institution.

All of these practices in hospitals or nursing homes need to comply with the facility's Medical Staff Bylaws. Typically, these Bylaws would have a provision, which says something like – "all orders for treatment must be in writing. An order will be considered to be in writing if dictated to authorized personnel and signed by the attending practitioner. Authorized personnel include any

registered nurse, licensed practical nurse, pharmacist, physical therapist, occupational therapist, speech therapist, dietitian, nurse practitioner, physician assistant and respiratory therapist, to the extent that it is within their scope of practice. Orders dictated by telephone shall be dated and timed by the person, to whom dictated, with the name of the practitioner, and then signed by the accepting professional, with their title included. The attending practitioner shall sign and date the order within forty-eight hours." Joint Commission on Accreditation of Healthcare Institutions currently likes to see the language VORB or TORB, which means – Verbal Order Read Back or Telephone Order Read Back.

In instances where a pharmacist is working as a consultant or doing medication reviews in a hospital, and does not have privileges within that hospital to record orders, the pharmacist would place a note in the chart, asking the nurse to verify the order or the physician to review the order and make appropriate changes. In this case the changes would not affect the patient until after the physician review.

Most of our larger hospitals allow other healthcare professionals to enter the order on the chart, and that order to be administered to the patient, pending the physician review within the forty-eight hours. This would be true of a medication order, which was clarified or taken over the telephone by the pharmacy department. It would also include those therapeutic or generic dispensing changes authorized through the Policy & Procedures of the Pharmacy and Therapeutics Committee and the Medical Staff Bylaws.



Joel Aukes, RPh President, NDSHP

# The Importance of Documenting and Reporting Pharmacist Interventions

As medication costs escalate and pharmacist wages increase there will continue to be a growing scrutiny of a Pharmacy Department's expenditures. In response, pharmacists have become comfortable with calculating and reporting the amount of savings associated with auto-substitutions. However, one area of savings that is sometimes forgotten is pharmacist interventions. We perform these interventions multiple times per day, often times they are so ingrained in our daily routine that we don't even think about them. However, by documenting these interventions and assigning a rational amount of time required to perform the interventions, it is possible to calculate the cost avoidance, or savings, generated by these interventions. "Cost avoidance" represents the savings realized by avoiding the costs associated with preventing ADEs, recognizing ADEs prior to serious patient harm, therapeutic duplication, etc. One of a pharmacist's challenges is educating the CEOs and CFOs to recognize that the savings generated by a Pharmacy Department is a better performance indicator than the amount of its expenditures.

In 2003, our facility began tracking a predetermined set of pharmacist interventions and calculating the associated savings or "cost avoidance". The cost avoidance calculation was based on an article by Schumock, et al.1 which determined that the benefit:cost ratio for pharmacist interventions was 4.68:1, or for every dollar spent to perform interventions there were \$4.68 in avoided costs. To calculate our, institution specific, cost avoidance for each pharmacist intervention we determined the average amount of time required to perform each intervention. We then assumed that the only cost of performing pharmacist interventions was the cost of the time spent by the pharmacist performing the intervention. With this data we calculated the cost of performing the intervention by multiplying the

amount of time required (in hours) by the average pharmacist wage (\$/hr). The cost of performing the intervention was then multiplied by \$4.68 for the cost avoidance of the pharmacist intervention.

Since the beginning to document and value our pharmacist interventions the number of interventions have increased every year. This increase is partially due to the learning curve associated with remembering to document every intervention. Additionally, our Pharmacy Department has been able to offer more clinical services because of the documented cost avoidance; this resulted in more possibilities for pharmacist interventions. The following chart shows the growth in the number of our intervention and value of our cost avoidance since 2003.

	Total Interventions	Total Cost Avoidance	Cost Avoidance per patient day
2003	507	\$43,390.69	\$6.80
2004	1148	\$75,759.43	\$10.88
2005	1171	\$66,677.89	\$8.45
2006*	1320	\$65,729.35	\$8.96

<sup>\*</sup> Estimated; based on year-to-date data

When Pharmacy Departments compile these numbers, calculate the associated cost avoidance and report this saving they can help rationalize their relatively high labor cost compared to other departments. Furthermore, by reporting cost avoidance to the CEOs and CFOs of our organizations we begin to educate them on the value of pharmacy beyond the counting and dispensing of medications.

1 Schumock GT, et al. Evidence of economic benefit of clinical pharmacy services: 1996-2000. Pharmacotherapy. 2003;23(1):113-32.

### VACCINATING ADULTS AND ADOLESCENTS: AN IMMUNIZATION PROGRAM FOR PHARMACISTS

Practicum from 1 to 4 pm on September 29 in Bismarck at the Radisson Hotel and September 30 in Fargo at Sudro Hall - NDSU College of Pharmacy

Goals: This program is specifically designed to train pharmacists to immunize adults and adolescents. It is a customized version of the CDC program "Epidemiology & Prevention of Vaccine-Preventable Diseases." Completing this course earns 15 hours of CE credit, while becoming certified to administer vaccines.

#### Course Outline:

PART 1. Didactic Training ( ACPE # 130-000-04-056-H01) Participants will complete 12 hours of home study which includes DVD lectures by Dr. William Atkinson, Medical Epidemiologist, National Immunization Program, CDC, Atlanta, GA. The didactic

home study includes the text: Epidemiology & Prevention of Vaccine Preventable Diseases, published by CDC. An open-book post-test must be completed with a score of at least 70% correct responses. Participants keep the DVD and textbook for your personal library of pharmacy resources. Pharmacists receive 12 hours of continuing education credit for Part 1.

PART 2. Practicum (ACPE# 130-000-04-053-104) The practicum session involved three hours of hands-on training administering

immunizations. Participants give and receive injections and prepare for adverse effects. The practicum also covers how to establish an immunization center in your pharmacy, vaccine storage and handling and helpful tips for your immunization practice. Part 2 comes with a textbook - "Immunization: a Manual

Pharmacists are needed to enhance public health and medical preparedness efforts in North Dakota.



"Pharmacists should consider attending this immunization training... increasing the state's capacity to distribute pharmaceuticals could truly be life saving."

> Dr. Terry Dwelle ND State Health Officer

Rod Shafer, RPh. PART 3. CPR training on your own. If you are not currently certified in CPR we suggest you complete this training prior to the practicum in September. A current CPR card is required in order to issue the immunization certificate. Call

for Pharmacists." Pharmacists receive 3 hours of continuing education credit for Part 2. The Practicum is presented by

Immunization Certificate: In order to receive your certificate, you must successfully complete all three parts of the immunization certificate program. The steps do not need to be completed in a specific order. Formal Certificates will be mailed upon successful completion of the program in its entirety.

CE Credit: The Washington State Pharmacy Association is accredited with the Accreditation Council of Pharmacy Education as a provider of continuing pharmacy education.

Pharmacists will receive a total of 15 hours of continuing education credit (1.50 CEUs) upon completion of this seminar.

DIDACTIC Part 1: ACPE # 130-000-06-056-H01 (12 hours or 0.12 CEUs). PRACTICUM Part 2: ACPE # 130-000-04-053-L04 (3 hous or 0.3 CEUs)

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This immunization program is sponsored by the North Dakota Pharmacists Association in partnership with the Washington State Pharmacy Association (WSPA). All registration, training, and certification will be handled by the Washington Association. If you have questions please feel free to call NDPhA at 701.258.4968.

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  responsible for expenses incurred by anyone not confirmed and for whom space is not available at this program.

The Registration Fee of \$295 includes the CDC text and DVD lecture series by Dr. Atkinson, the Practicum Manual, CE credit certificates, and a formal immunization certificate. The Registration Fee does not include CPR training. Upon receipt of registration, each participant will receive a welcome letter, CDC text and DVD lecture series, along with the exam for Part 1- Didactic Training.

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### **Continuing Education** for Pharmacists

A New Era in the Management of Diabetes: Inhaled Insulin

Thomas A. Gossel, R.Ph., Ph.D. **Professor Emeritus Ohio Northern University** Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D. **Professor Emeritus University of Cincinnati** Cincinnati, Ohio

**Goals**. The goal of this lesson is to discuss the use of inhaled insulin in management of type 1 and type 2 diabetes mellitus.

**Objectives**. At the conclusion of this lesson, successful participants should be able to:

- 1. describe key points relative to diabetes, and patient reactions to the use of injectable versus inhaled insulin;
- 2. identify physical and chemical characteristics that define the overall action of inhaled insulin:
- 3. explain the physiologic and pharmacologic principles that define

This continuing education activity is supported by an educational grant from GlaxoSmithKline.









the therapeutic usefulness of inhaled insulin: and

4. select, from a list, important points to pass along to patients relative to correct use of inhaled insulin.

FDA has approved the first-ever inhaled insulin (Exubera), which is a new alternative to injectable insulin for the more than five million Americans who use insulin. Exubera is the first new insulin delivery option introduced since insulin was first used more than 80 years ago. It is a powder form of recombinant (rDNA) human insulin for the treatment of adult patients with type 1 and type 2 diabetes mellitus (Table 1).

#### **Background on Insulin**

The therapeutic insulin era began January 11, 1922, with the first clinical use of insulin following its discovery by Banting and Best. In the ensuing 80 years, scientists discovered the basic pathophysiology of diabetes, elucidated insulin's structure, and directed their attention to developing improved insulin formulations (e.g., NPH, Lente). These advancements led to development and availability of rapid-acting (e.g., aspart, glulisine, lispro) and basal insulin (e.g., glargine) analogs, which have resulted in routine

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#### Table 1 **Diabetes Facts**

- 20.8 million people in the U.S. (7 percent of the population) have
- An estimated 14.6 million people (of the 20.8 million) have been diagnosed with diabetes: unfortunately, 6.2 million (nearly one-third of the total) are unaware they have the disease.
- There are 41 million Americans with pre-diabetes, in addition to the 20.8 million.
- To differentiate between prediabetes and diabetes, a Fasting Plasma Glucose Test (FPG) or an Oral Glucose Tolerance Test (OGTT) can be done. The American Diabetes Association recommends the FPG because it is easier, faster, and less expensive to perform.
- With an FPG test, a fasting blood glucose value between 100 and 125 mg/dL signals pre-diabetes. A level of 126 mg/dL or higher defines diabetes.
- For the OGTT test, if the 2-hour blood glucose level is between 140-199 mg/dL, the person is prediabetic. A value of 200 mg/dL or higher means the person tested has diabetes.
- Persons with pre-diabetes do not automatically progress to diabetes. Those who lose weight and increase their physical exercise can often prevent or delay the disease.
- · Among adults with diagnosed diabetes, 16 percent take insulin only, 12 percent take both insulin and oral hypoglycemics, 57 percent take oral hypoglycemics only, and 15 percent take neither insulin nor oral hypoglycemics.

use of insulin regimens that closely approach physiological conditions.

Because insulin is essential in controlling type 1 diabetes, a

noninvasive delivery system is a more convenient alternative. The progressive decline in beta-cell function that is the hallmark in pathogenesis of type 2 diabetes means that many patients will eventually fail on oral antidiabetic therapy and require insulin at some point.

Numerous long-term prospective clinical trials have demonstrated the benefits of tight glycemic control in reducing the risk of secondary complications in persons with type 1 and type 2 diabetes. Other studies have shown that despite the benefits of tight glycemic control, which ultimately may only be achieved with insulin in type 2 diabetic patients, there is reluctance on the part of many patients, and oftentimes their physicians, to initiate insulin therapy. This reluctance may be due to the social stigma of diabetes, lifestyle restriction, sense of guilt or failure, weight gain, perception of worsening pathology, physical limitations to drawing up insulin, or needle anxiety. Physicians, therefore, often prescribe a simple regimen initially in order to assure maximum patient compliance.

It should be stressed that many individuals with type 2 diabetes have a positive regard for injectable insulin in terms of efficacy, prevention of complications, and improved overall health. For various reasons. insulin use may be reserved as a last resort for therapy after the stepwise approach of diet, exercise, and oral antidiabetic agents have failed to produce and maintain adequate glycemic control. However, many (some reports say most) patients eventually require exogenous insulin to attain glycemic control targets.

#### **Diabetes: The Disease**

Despite therapeutic advances, the incidence of both type 1 and type 2 diabetes continues to increase in the U.S. with type 2 at epidemic proportions. Type 1 disease typically develops when the body's immune system destroys the pancreatic beta

cells. Risk factors may be autoimmune, genetic, or environmental. There is presently no way to prevent type 1 diabetes.

Type 2 diabetes is associated with decreased sensitivity to insulin in muscle, liver, and adipose (i.e., fat) cells, as well as progressive decline in pancreatic insulin production. The precise causes of insulin resistance with eventual beta-cell failure remain unclear; however, it appears that both genetic predisposition and environmental factors interact. Obesity and sedentary lifestyle are closely linked to both onset and progression of type 2 diabetes; weight loss, exercise, and selective medications can often delay or prevent its onset.

The leading cause of morbidity and mortality in patients with diabetes is cardiovascular disease. A marker of insulin resistance, hyperinsulinemia, is an independent risk factor for cardiovascular disease. Diabetes treatments that decrease hyperinsulinemia and/or insulin resistance seem to protect against cardiovascular events more than treatments that do not impact these factors. Moreover, aggressive treatment of dyslipidemia is critical to effectively manage the complications of diabetes.

However, despite the more favorable time-action profiles of modern insulin analogs, which can help optimize glycemic control, many patients remain suboptimally controlled. Even in teaching institutions throughout the U.S., American Diabetes Association treatment goals are only infrequently attained. For these reasons, the development of a novel, noninvasive, dry-powder insulin delivery system for inhalation use shows promise for adults with type 1 and type 2 diabetes.

#### Exubera

Exubera is an inhaled dry powder formulation of recombinant (rDNA) human insulin with a particle diameter of 1-5  $\mu$ m. The powder is contained in blister packs and used in combination with an inhaler

device. There are two dosage strengths: each blister contains 1 mg or 3 mg of insulin brought up to a total weight of 5 mg with mannitol, glycine, sodium citrate, and sodium hydroxide. The inhalation system is designed to deliver a fine dry-powder formulation of regular human insulin deeply into the lung in a reproducible and efficient manner.

A blister pack is inserted into the inhalation device (similar to a nebulizer). A pneumatic mechanism is activated by a lever, which punctures the blister. The powder is dispersed in a discrete cloud into the air chamber. The insulin cloud is inhaled slowly, at the beginning of a deep breath. With a bioavailability of 10 to 15 percent and dose equivalence about three times greater than that of injected insulin, each administration delivers the equivalent of approximately 3 IU or 9 IU of subcutaneous (SC) insulin, respectively.

Early studies have shown promising results. Onset of action of inhaled insulin is faster than that of regular human insulin, more closely resembling onset of rapid-acting insulin analogs. Exogenously administered insulin by SC injection has several disadvantages when used in controlling prandial (mealtime) glycemia. Physiologic insulin secretion peaks 30 to 45 minutes after meals and then decreases to basal levels over the next two to three hours. Subcutaneous injection of regular human insulin causes plasma insulin to increase slowly with a peak level achieved 90 to 120 minutes following the injection, and then a slow decline to baseline approximately eight hours after injection. This leads to postprandial hyperglycemia followed by hyperinsulinemia and increased risk of hypoglycemia before the next meal. Although the rapid-acting insulin analogs have reduced some of these difficulties, another problem associated with SC insulin injections is the frequent inter- and intra-individual absorption variation. This appears more often in the

older, type 2 diabetes population, in whom absorption of rapid-acting insulin from SC sites has been shown to be slower than in patients with type 1 diabetes. Inhaled insulin is a viable alternative to prandial injectable insulin administration in patients with diabetes because of its more favorable pharmacokinetic profile and less invasive route of administration. In type 1 diabetes, inhaled insulin is used in combination with a longer-acting injectable insulin. In type 2 diabetes, inhaled insulin can be used as monotherapy. or in combination with longer-acting insulins or oral hypoglycemics.

Clinical Trials. Two 12-week clinical trials evaluated the effect of inhaled insulin in patients with type 1 or type 2 diabetes. These studies demonstrated that patient satisfaction is increased with inhaled insulin compared with injectable insulin. The data showed that improved patient satisfaction is consistently correlated with improvements in glycemic control.

The two 12-week trials were then extended to one year. Patient satisfaction and preference, along with effects on HbA1C levels with inhaled insulin, were compared with an SC insulin regimen both in patients with type 1 or type 2 diabetes. In the 12-week parent studies, patients were randomized to inhaled insulin or SC insulin regimen. In the one-year extension studies, patients were permitted to select their treatment regimen of choice. Patient satisfaction was recorded at baseline (beginning of parent studies), week 12 (end of parent studies), and one-year (extension studies).

Of the 60 patients who received inhaled insulin during the 12-week trials, 85 percent (n = 51) chose to continue treatment, 3.3 percent (n = 8) switched to SC insulin, and 1.7 percent (n = 1) did not continue in the trial. Of the 61 patients who received SC insulin in the 12-week studies, 21.3 percent (n = 13) chose to continue treatment, 75.4 percent (n = 46) switched to inhaled insulin, and 3.3 percent (n = 2) did not

continue. From baseline to one year, reductions in HbA1C of 0.8 percent were maintained, and greater improvements were noted in the subjects using inhaled insulin versus those in the SC insulin group, with overall satisfaction of 37.9 percent versus 3.1 percent, respectively.

The Lung as a Site for **Insulin Delivery.** The lung is an excellent site for drug delivery. The alveolar-capillary network, with a surface area of 140 m<sup>2</sup>, is the body's largest microvascular organ and receives the entire cardiac output. Because the lung provides a large surface area for drug absorption, inhaled insulin rapidly attains peak plasma level and metabolic effect. The primary mechanism of insulin absorption across the alveolar capillary and epithelial cells remains unknown, but is believed to be transcytosis (i.e., "across the cells") and formation of insulin vesicles. In this process, insulin molecules are taken up in vesicles by the alveolar epithelial cells. These insulin-containing vesicles are released between epithelial cells and the alveolar capillary endothelial cells. Insulin molecules are then taken up within vesicles by endothelial cells, transported across them, and released into the alveolar capillary blood.

**Pulmonary Delivery of** Insulin. Following inhalation, pulmonary delivery of insulin results in peak insulin levels within 15 to 20 minutes, with return to baseline 40 to 60 minutes later. If inhaled insulin is not administered correctly, a large portion of the dose will deposit in the upper airways and subsequently be removed from the lung via mucociliary clearance. In order to be absorbed systemically, insulin must be deposited deep within the lung. Two major factors affect its optimal deep-lung deposition: particle size and particle velocity. The optimal particle size for delivery to the alveoli is 1 to 3 µm in aerodynamic diameter. Larger particles will likely be deposited in the oropharynx and

upper airways, whereas smaller particles will be lost on exhalation. Independent of particle size, particle velocity also has a major effect on absorption. Inhaled insulin particles must have a low velocity for optimal deposition and absorption.

Safety. The safety of injected insulin is well documented. There is less data to support the safety of inhaled insulin, although in general, studies have confirmed that its safety is comparable with SC insulin. The incidence of hypoglycemia is similar. In animal studies with rats and monkeys, daily inhalation was well tolerated with no evidence of airway or pulmonary lesions.

The American Conference of Governmental Industrial Hygienists has determined that the threshold limit value for inhalation of insoluble "nuisance dust" into the lung is 30 mg/day. Inhaled insulin is rapidly absorbed from the epithelial surface of the lung and therefore will only deposit up to an average of 10 mg of insulin into the lung each day. This means that therapeutic daily doses of inhaled insulin would not be expected to adversely affect pulmonary function. In general, pulmonary function has been stable in patients with type 1 and type 2 diabetes who have been treated with inhaled insulin, and no clinically significant differences in common measures of pulmonary function (spirometry, lung volume, diffusion, capacity or oxygen saturation) have been noted.

An increase in the incidence of mild-to-moderate cough has been reported, which should be expected with inhalation devices. Cough tended to occur within seconds to minutes after insulin inhalation, and lessened with continued use.

Increased antibody formation has been reported with insulin analogs in general. The clinical impact, if any, of such increases has yet to be determined. Pooled data from Phase II and III (three- and six-month) studies of inhaled insulin in patients with type 1 and type 2 diabetes have demonstrated that

#### Table 2 Patient Advice for Exubera

- Read the *Medication Guide* provided by the manufacturer before you start using Exubera, and each time you get your prescription filled.
- This medicine should not be used if you smoke or have stopped smoking within the past six months. If you decide to start smoking, contact your doctor for a different treatment for your diabetes.
- Tell your doctor if you have unstable or poorly controlled lung disease, or are using any other inhaled medicine.
- This medicine is to be placed in the Exubera inhaler device and inhaled through your mouth into your lungs as directed. The manufacturer states that mealtime doses should be taken 10 minutes before a meal.
- Do not open the blister. The inhaler device will open it automatically. Do not swallow the powder or breathe into the inhaler.
- Follow your doctor's advice on diet, exercise, sleep, personal hygiene, and how to monitor your blood sugar.
- Tell your doctor about all other prescription and OTC medicines, vitamin/mineral supplements, natural products and herbal remedies you are taking. Some OTC medicines (decongestants, aspirin) have a warning on their label advising persons with diabetes not to take them unless directed by a doctor. If you see such a warning on the label of an OTC product, ask your doctor or pharmacist if it is okay for you to take the OTC product.
- Unopened blisters should be stored at room temperature, protected from moisture. Do not refrigerate, freeze or use them after the expiration date on the label.
- After opening the foil overwrap, follow the storage instructions in the *Medication Guide* and use this medicine within three months.
- The inhaler device can be used for up to one year from first use. The release unit should be changed every two weeks.

switching from SC insulin to inhaled insulin is associated with increased antibody levels. However, these increased antibody levels have not caused a need for increased insulin doses or allergic reactions.

### Factors that Affect Inhaled Insulin Activity

Smoking. Smoking is reported to be as common in persons with diabetes as in the general population, and is known to increase the permeability of the alveolar-capillary barrier in humans. Smoking may therefore increase absorption of inhaled insulin such that its dose requirements may be lower in smokers. In comparison, SC insulin absorption is decreased in smokers, necessitating larger SC doses. Exubera is contraindicated in patients who smoke or who have discontinued smoking less than six months prior to starting therapy.

Lung Disease. In persons with underlying lung disease such as asthma, COPD, or upper respiratory infections (URI), delivery of inhaled insulin to the blood may be affected by the overall efficiency of pulmonary function. For example, a study showed that subjects with chronic asthma absorb less insulin after inhalation than healthy subjects, resulting in less action to reduce blood glucose levels. The decreased insulin absorption is believed to be caused by a difference in the airway caliber or pulmonary vasculature as a result of chronic lung disease. The patient's physician may suggest that inhaled insulin not be used during intermittent URIs.

Counseling Patients on Inhaled Insulin. A comprehensive *Medication Guide* is provided with Exubera. Patients should understand all the information before beginning therapy. A summary of these points, which pharmacists may use in their counseling, is provided in Table 2.

#### **Overview and Summary**

The benefits of intensive insulin therapy have been demonstrated in large clinical trials. Despite such advantages, intensive insulin therapy is not widely accepted because of real or imagined barriers to invasive insulin. Inhaled insulin is a non-invasive method of supplying insulin that should alleviate some of the problems and/or fears associated with insulin injections. It has demonstrated efficacy in terms of achieving significant attainment of HbA1C targets in both type 1 and type 2 disease. Inhaled insulin is. therefore, a suitable alternative to injectable insulin to promote achievement of good glycemic control, and therefore help to prevent the microvascular, macrovascular, and neuropathic complications of diabetes and decrease the risk of premature death.

Once inhaled insulin is made available, it may be of particular benefit in patients who are unreceptive to multiple daily insulin injections. It represents a promising and novel diabetes therapy that offers the benefit of noninvasive administration, along with a time-action profile that combines the advantages of both rapid-acting insulin analogs and regular human insulin.

### **Continuing Education Quiz**

### A New Era in the Management of Diabetes: Inhaled Insulin

1. All of the following are rapid-acting insulin analogs EXCEPT:

a. aspart.b. glargine.c. glulisine.d. lispro.

2. With a fasting plasma glucose (FPG) test, the lowest level that defines diabetes is:

a. 26 mg/dL. c. 126 mg/dL. b. 99 mg/dL. d. 199 mg/dL.

- 3. Which of the following is a marker of insulin resistance and an independent risk factor for cardiovascular disease?
  - a. Hyperinsulinemia
  - b. Hypoinsulinemia
  - c. Hyperglycemia
  - d. Hypoglycemia
- 4. All of the following statements about Exubera are true EXCEPT:
  - a. it is a dry powder formulation.
  - b. it is recombinant (rDNA) human insulin.
  - c. it comes in a blister pack to be used in combination with an inhaler device.
  - d. it comes in five dosage strengths.
- 5. Compared to injectable insulin, the dose equivalence of Exubera is about:
  - a. three times greater than that of injectable insulin.
  - b. three times less than that of injectable insulin.
- 6. The onset of action of Exubera is:
  - a. faster than that of regular human insulin.
  - b. slower than that of regular human insulin.
- 7. The primary mechanism of insulin absorption across the alveolar capillary and epithelial cells is:

a. active transport.

c. passive diffusion.

b. iontophoresis.

- d. unknown.
- 8. Following inhalation, pulmonary delivery of insulin results in peak insulin levels within:
  - a. 1 to 5 minutes.
  - b. 15 to 20 minutes.
  - c. 30 to 35 minutes.
  - d. 40 to 45 minutes.
- 9. Which of the following OTC medicines has a warning on its label advising persons with diabetes not to take them unless directed by a doctor?
  - a. Antihistamines
  - b. Decongestants
  - c. Expectorants
  - d. Laxatives
- 10. Unopened blisters of Exubera should be stored:
  - a. in the freezer.
  - b. in the refrigerator.
  - c. at room temperature.

### A New Era in the Management of Diabetes: Inhaled Insulin

July 2006 ACPE # 129-047-06-004-H01

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Learning objectives on first page were addressed.

 1 Disagree - 5 Agree

 Objective 1
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 Objective 2
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 Objective 3
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Material was well organized and clear. 1 2 3 4 5 Content sufficiently covered the topic. 1 2 3 4 5

Material was non-commercial in nature. 1 2 3 4 5

#### **Answer Sheet:**

 1. a b c d
 6. a b c d

 2. a b c d
 7. a b c d

 3. a b c d
 8. a b c d

 4. a b c d
 9. a b c d

 5. a b c d
 10. a b c d

### Study Confirms Health Monopoly Fears Market Domination in North Dakota Cited as Disadvantage

By Russ Britt

LOS ANGELES (Dow Jones) -- Consolidation among health insurers is creating near-monopolies in virtually all reaches of the U.S. - with the most dominant firms grabbing more market share by several percentage points a year - according to a study released Monday.

Data from the American Medical Association shows that in each of 43 states, a handful of top insurers have gained such a stronghold that their markets are considered 'highly concentrated' under Department of Justice guidelines, often far exceeding the thresholds that trigger antitrust concerns.

The study also shows that in 166 of 294 metropolitan areas, or 56%, a single insurer controls more than half the business in health maintenance organization (HMO) and preferred provider networks (PPO) underwriting.

'This problem is widespread across the country and it needs to be looked at,' said Dr. Jim Rohack, an AMA trustee and physician in Temple, Texas. 'The choices that patients have now are more difficult.'

The AMA study cited a Justice Department benchmark in citing antitrust concerns, the Herfindahl-Hirschman Index, or HHI. A score above 1,000 shows 'moderate' concentration. Those scoring above 1,800 yield a 'high' concentration.

Figures show that 95% of the 294 HMO/PPO metropolitan markets studied were above 1,800. Raise that HHI bar even higher to 3,000 and yet more than half, or 67%, rise above it.

The AMA study is the latest piece of evidence -- and most comprehensive to date -- showing the market power of a few companies, and a large number of regional non-profit Blue Cross operations, is formidable and growing. And it comes at a time when premiums continue to grow at near double-digit rates.

Critics say that carriers are not only creating monopolies and oligopolies in many regions, they also control the other side of the equation in what is known as monopsony power. That means in addition to having the most enrollees, they're also the biggest purchasers of health care and can dictate prices and coverage terms.

It also makes it harder for new carriers to emerge as pricing already has been set by the dominant carrier.

That's particularly true in North Dakota, where the state's Blue Cross Blue Shield provider has, by various estimates, a roughly 90% share of the market, said Insurance Commissioner Jim Poolman. New carriers would have to pay more to health-care providers and charge less to policyholders to gain a foothold.

In North Dakota, there isn't much incentive for that, he added. "It's difficult in a market of 640,000 people to write new insurance policies," Poolman said.

The AMA says there have been more than 400 mergers among health-care insurers in the past decade. As they've consolidated and presumably eliminated duplicative functions, they're not passing the savings in personnel and administrative costs on to consumers. Rate increases, though slowing, are higher than ever and growing at a near double-digit pace.

Studies by the Kaiser Family Foundation show double-digit premium hikes from 2001 to 2004 -- peaking with a 13.9% jump in 2003 -- have soared well above inflation and wages. Those categories have risen at rates less than a half to less than one-fifth that of insurance premiums, Kaiser says.

Last year, the string of double-digit jumps was broken but was close to that level with a 9.2% increase, the Kaiser study said. The foundation is not affiliated with the nonprofit HMO of the same name.

Some health insurance analysts have said the recent uptick in premiums is part of an 'underwriting cycle' in which carriers go through a period of boosting profits, and then ease up on premium increases for several years.

But Gary Claxton, vice president at the Kaiser Family Foundation, contends fewer insurers mean the need for underwriting cycles has diminished. And it's likely that carriers will settle on the high side when it comes to premium increases.

'They won't get down to cost,' he said. 'They see it as their collective right not to cut prices too much.'

David Colby, chief financial officer for WellPoint Inc. (WLP), the nation's largest carrier, disagreed. He said medical cost increases have forced his company to hike premiums, adding the percentage his company spends on actual medical care has remained constant in recent years.

'Our premiums are pretty much tracking what medical costs are doing,' he said.

The AMA says it has taken up this antitrust issue with the U.S. Department of Justice but says it has run into roadblocks with regulators. AMA officials say regulators seem uninterested, even though government officials are more than willing to target doctors' groups and hospitals on antitrust matters.

Justice Department officials did not respond to requests for comment.

A former Justice official says, however, that the health insurance market doesn't operate by normal rules. Constance K. Robinson, the department's former director of operations, says there are a number of issues to consider when deciding if competition is hampered in a particular market.

A single carrier may have naturally accumulated huge market share as more consumers became less enchanted with rivals or a dominant carrier could be keeping medical costs down. Managed care plans have fallen into disfavor in many cases as well.

So if numbers show a high concentration of market power, there may be more to the story, she said.

'The answer any antitrust lawyer should tell you is, it depends,' said Robinson, who left the department in late 2003 to become an antitrust lawyer in the private sector. 'Health care is not a so-called normal market. You have different drivers.'

WellPoint's Colby disputes the numbers in the AMA study, but acknowledges that the market shares of the largest companies have grown tremendously. WellPoint and UnitedHealth Group Inc. (UNH) are the two biggest carriers and are expected to dominate the for-profit landscape.

He expects other health-care mergers with any number of companies possible targets, including such giants as Cigna Corp. (CI), Aetna Inc. (AET) and Humana Inc. (HUM)

Still, he says that in some cases, health mergers create economies of scale. Some insurers are able to initiate new medical programs off the savings from combining operations. WellPoint's recent merger with Anthem created direct savings of \$250 million alone, Colby said.

The Justice Department has looked into health-care mergers sporadically in the past. It forced Aetna to divest some of its holdings in Dallas and Houston when it acquired Prudential Insurance's health care business in 1999.

It also seeks divestiture of some properties in Boulder, Colo., and Tucson, Ariz., before UnitedHealth completes its buyout of Pacificare Health Systems. (PHS)

Other key mergers have gone through unscathed, though. Regulators deemed that the 2004 marriage of Blue Cross giants WellPoint (WLP) and Anthem posed no antitrust threat. Regulators found there were few overlapping markets between the two.

The AMA has studied the issue of growing health insurer monopolies for several years, and has a vested interest in the subject. It's trying to protect its doctors, who are concerned about declining reimbursements from carriers.

Yet other independent studies have shown similar findings in other health insurance circles.

The Government Accountability Office twice looked at the issue this decade, in 2000 and 2004, examining small-group insurers in roughly 41 states that submitted data. Small-group insurers cover companies with two to 50 employees.

The GAO found that heavy consolidation among small-group insurers has increased the average market share of each state's largest firm from 36.9% to 43.3%. That represents a 17.7% increase.

At the same time, the collective market share of the five largest small-group insurers in each state went up an average 12.5%. And findings show that in the four-year period, the number of carriers has dropped by 17.6% on average per state.

There's more. James Robinson, a health economics professor at the University of California at Berkeley, examined in late 2004 how many states had a high concentration of market share in the hands of a few.

Citing figures from Goldman Sachs Global Equity Research and insurer consultant InterStudy, Robinson found that in 42 states and the District of Columbia, antitrust concern was 'high.' Eleven more states triggered a 'moderate' antitrust concern, under the HHI index used by the AMA.

'Further consolidation, and a further increase in entry barriers, is to be expected, as small local plans continue to sell out to the dominant carriers,' he wrote in the industry journal Health Affairs in late 2004. Some states are trying to take matters into their own hands.

Poolman, North Dakota insurance commissioner, says he faces challenges 'every day' when it comes to contending with the vast 90% market share of Blue Cross Blue Shield.

Although the local Blue Cross plan is operated by a notfor-profit firm, Noridian Mutual Insurance Co., it still often flexes its muscles, Poolman said. And it still can make money; it's just that such operations reinvest profits back into the business instead of paying shareholders.

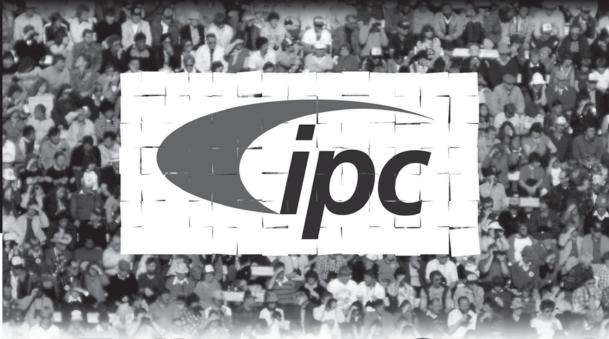
'Their reserve rate is growing astronomically,' Poolman said. The company's reserves now stand at 600% of its risk-based capital, triple what is needed to remain solvent, he said.

Noridian's huge market share appears to be a sore subject with the company. When asked to discuss the subject, spokesman Larry Gauper asked: 'What advantage would that provide us, talking to you?' He then declined to comment.

Poolman said Noridian last fall proposed cutting reimbursements to a group of pharmacies by 40% to 80%. The company's powerful market position put pharmacies in a bind, forcing many to close. That would have cut services to roughly 4% of the state's residents.

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### HIPAA Privacy and Security Compliance Program Version 4.0 WITH INSURANCE CERTIFICATION



Insurance companies are now paying claims for improper disclosures of Protected Health Information (PHI). With this in mind, PRS has developed an **update** to our industry leading HIPAA Compliance programs. *PRS HIPAA Compliance Program Version 4.0 With Insurance Certification* maintains the previous versions' easy to use features that include a complete HIPAA Compliance Privacy and Security Program, which customizes to your pharmacy within minutes and offers simple to use, easy to find forms.

The PRS HIPAA Version 4.0 Compliance Program CD offers these **NEW FEATURES**:

- PRS HIPAA Compliance Program Version 4.0 has a Certification Check feature that will automatically check the pharmacy's HIPAA compliance activities to ensure that HIPAA Privacy and Security Policies and Procedures have been modified to meet federal regulations at the pharmacy level.
- Upon successful completion of the certification check, the PRS HIPAA Compliance Program will generate a <u>certification letter</u> to be signed by the pharmacy owner, which states that the pharmacy's HIPAA program is current and complete. This certification letter can then be forwarded to the pharmacy's liability carrier. Documentation of HIPAA compliance may result in discounted insurance premiums!
- If the certification check fails, the program will indicate which policies, procedures and/or forms need to be reviewed and modified to become compliant.
- The global search and replace feature will permit the change of Privacy Officers, Security Officers and vendors.
- The entire HIPAA policy and procedure manual can now be printed.

PRS Pharmacy Services has been recognized as *the industry leader* in HIPAA Compliance Programs by over 70 pharmacy organizations, buying groups, wholesalers, and pharmacy software providers.

Note: All programs come with a detailed instruction manual on how to implement the program.

### System requirements are:

- Windows 95 or greater
- ➤ MS Word 97 or greater
- ➤ 16 Megabytes of RAM
- > 133 MHz processor or greater
- Adobe Acrobat Reader
- Web Browser (recommended for updates releases)

PRS continues to keep independent retail pharmacy owners as our primary concern. Whether by establishing new pharmacies and/or adding to your current pharmacy operations, PRS brings its 23 years of experience in pharmacy operations and developed best practices to streamline and save valuable pharmacy resources.

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### HIPAA Privacy and Security Compliance Program Version 4.0 WITH INSURANCE CERTIFICATION



	Product	Price	Qty	17	Γotal
1	NCPA Security Handbook + PRS HIPAA Version 4.0 Compliance Program PRS Compliance Program CD (Privacy and Security Rules) With Insurance Certification	\$897.00			
2	PRS HIPAA Version 4.0 Compliance Program PRS Compliance Program CD (Privacy and Security Rules) With Insurance Certification	\$747.00			
3	Current Users Of: PRS HIPAA Compliance Program, Privacy Rule CD OR PRS HIPAA Compliance Program, Security Rule CD UPGRADE TO THE COMPLETE PRS Compliance Program CD (Privacy and Security Rules) With Insurance Certification	\$497.00			
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# PHARMACY News Briefs

### **Victory for Compounding Pharmacists**

A federal district court judge in Texas ruled that compounded preparations are not new, unapproved drugs as the FDA has suggested and used as a basis for enforcement actions against compounding pharmacies since the 1980s.

This landmark ruling stops FDA encroachment on the authority of state boards of pharmacy and ensure that patients and physicians will continue to have access to compounded medicines on which they rely. For years the FDA has told pharmacists that compounding medicines to fill doctors' prescriptions was illegal. This ruling removes any uncertainty from pharmacy compounding and allows pharmacists to serve their patients.

The case is Medical Center Pharmacy et al. v. Gonzalez, filed by nine pharmacies in 2004.

### **PCAB Accepting Applications for Accreditation**

The Pharmacy Compounding Accreditation Board is accepting applications for accreditation from all compounding pharmacies. You can obtain more information at www.pcab.info or contact Ken Baker at 515-341-1250.

Accredited pharmacies will receive advertising and marketing materials designed to provide an advantage in this very competitive field. Accreditation provides a positive, quality-based message to patients, prescribers and the public. It also provides a basis to insure adherence to strict quality standards which minimize errors and lead to fewer liability claims, therefore motivating lower premiums.

### Less than One Year to get Required National Provider Identifier (NPI)

Don't wait to get your NPI number, which is required by May 2007and will be the only way to get reimbursed for health care transactions, as specified in HIPAA. The NPI is replacing your NCPDP number (formally your NABP number). Legacy identifiers will not be accepted after May 22, 2007. You must have completed all pretesting activities prior to May 2007 to ensure that you will continue to receive payment on claims.

For more information or to apply for your NPI go to

www.cms.hhs.gov/NationalProvidentStand or you can obtain your NPI through NDPCP – go to http://www.ncpdp.org or call Kristal Deininger at 480-477-1000, extension 112.

### **MedGuides: Pharmacy Responsibility**

Although MedGuides are technically the responsibility of the manufacturer to produce and distribute IT IS THE PHARMACIST who hands them out to patients. There are FDA guidelines about distribution of Consumer Medicine Information (CMI) - the patient information provided at the pharmacy counter. As of March 2006 there are 31 approved MedGuides, required to be dispensed with all new and refill prescriptions. MedGuides are required for all antidepressants and NSAIDS.

Failure to dispense required MedGuides is considered to be dispensing a mislabeled drug. It is important that every pharmacist is familiar with MedGuides and is able to counsel patients appropriately.

www.fda.gov/cder/Offices/ODS/labeling.htm

### **CMS and Pharmacy Quality Alliance**

CMS Administrator, Dr. Mark McClellan, enthusiastically endorsed the creation of the PQA – a coalition of health insurance plans, NCPA, NACDS, and CMS – with a primary goal to develop strategies for defining and measuring pharmacy performance. The expectation is that these efforts will lead to new pharmacy payment models for optimizing patient health outcomes. Focusing on improved patient outcomes is a fundamentally new policy approach for Medicare and Medicaid.

McClellan said the PQA is the first step toward a pharmacy model that rewards real value delivered rather then just volume of prescriptions dispensed.

### American Society of Health-System Pharmacists endorses Cochran legislation on MTM services

ASHP commends Senator Thad Cochran of Missouri, Mike Enzi of Wyoming, Jim Talent of Missouri, and Mike DeWine of Ohio for introducing S. 2563 – The Pharmacist Access and Recognition in Medicare (PhARM) Act of 2006.

S.2563 requires the Dept of Health and Human

Services to create MTM guidelines and develop a 2-year demonstration project based on best practices. The bill also provides for guarantees of prompt payment of Part D claims by the prescription drug plans to pharmacies and eliminates co-branding on Medicare cards.

Senator Kent Conrad of North Dakota, and Max Baucus of Montana also introduced S. 2664 to improve beneficiary access to pharmacies under Medicare Part D, including specific assistance for 340B facilities.



Mark your Calendar! Tuesday, Sept. 12, 2006 Joint meeting of the Interim Committees on Healthcare and Human Services at the State Capitol in Bismarck

NDPhA has arranged for a presentation by Dr. Stephen Schondelmeyer, Director of the PRIME Institute at

the University of Minnesota on the truth about rising healthcare costs and pharmacy reimbursement. Dr. Schondelmeyer is a leading expert on Medicaid rates and has been invited to provide expert testimony for various Congressional committees and numerous state legislatures. North Dakota faces potential reimbursement reductions in the wake of federal Medicaid cuts, and the consequences will certainly impact community pharmacies. PLAN TO ATTEND.....

### Supreme Court Denies PBM Industry Request to Review Maine's Law - Court of Appeals uphold First-in-Nation PBM Law As Enacted

On June 5, 2006 the U.S. Supreme Court denied a request by the PBM industry to review Maine's PBM transparency law - denying an appeal to reconsider the First Circuit Court of Appeals decision to uphold Maine's PBM regulatory law.

"It verifies what I felt all along, that this is a constitutional measure. By allowing the state to address pricing issues by middlemen, we can have a real impact on prescription drug prices. This is good news for Maine's consumers, and I hope it acts as a green light for other states who were waiting for this decision to enact similar laws," said Maine State Senator Arthur Mayo III.

"Other states can now be assured that they are on firm legal footing in regulating the business practices of pharmacy benefit managers to insure pricing transparency, ban kickbacks and enforce ethical standards," said Sharon Treat, former Senate Majority Leader who served in 2003 when the legislation first passed in Maine. "This is a win for consumers and a win for state legislators seeking to make medicines more affordable. Of particular note is the right of states to impose fiduciary duty - a duty of care and fair dealing that ensures that PBMs will act to reduce costs for consumers instead of cutting deals that benefit the pharmaceutical manufacturers or the bottom line of the PBMs at the expense of consumer pocketbooks and health."

In South Dakota where PBM legislation was enacted in 2004, Insurance Commissioner Deborah Bowen estimates well over \$800,000 has been saved in state health insurance costs in a single year as the direct result of a more transparent business model required by their law.

Some provisions of the Maine PBM regulatory bill include:

- \* preventing conflicts of interest and requiring disclosure of activities such as drug switching
- \* requiring that benefits of special drug pricing deals negotiated by PBM companies be passed through to health plans
- \* protecting against unethical behavior by requiring duty of due care between PBMs and health plans (fiduciary duty)

Other states enacting PBM transparency legislation include North Dakota, District of Columbia and Mississippi. Legislation similar to Maine's is pending in New Jersey, New York, Pennsylvania and Rhode Island. North Dakota's 2005 PBM legislation was modeled after South Dakota's, but the original version was more extensive and similar to Maines'. The legislation includes an interim study of PBMs by the IBL committee, which can recommend amendments to current law that would strengthen the law and include some of the components in the Maine law that have been upheld by the Supreme Court.

### **Prompt Pay Legislation Tops 100 Cosponsors**

Congress is increasingly acknowledging that the Medicare Part D prescription drug benefit has serious flaws that threaten patient access to their local community pharmacy. The Fair and Speedy Treatment (FAST) of Claims Act, H.R. 5182, has nearly 120 bipartisan cosponsors. H.R. 5182 represents the most comprehensive approach in addressing some of the problems caused by the Part D program that began January 1, 2006.

Data from two recent Part D surveys show Medicare Part D has caused cash flow problems for more than 90 percent of family-owned pharmacies, and more than 60 percent say they have been forced to obtain outside funding to cover their financial shortfalls.

### **Topics for Technicians**

### **NAPT Updates**

By Danika Braaten - NAPT Presidnet

I kicked off my year with NAPT at the 2006 NDPhA convention in Dickinson, ND. Seeing all the technicians that were in attendance really got me excited about the support and involvement that the pharmacy technicians in North Dakota have. I hope to see it rise and continue in the future.

Some of the happening that is going on in NAPT is: The Fall convention is set for September 15, 16, 2006 in Bismarck – remember to mark your calendar! I am planning on attending the PTEC convention in Pittsburgh July 13-16. I will also begin the yearly travel meetings with the different districts soon.

My goal for myself this year, while serving as president for NAPT, was to get more technician involvement. If anyone has any comments or concerns, please contact any member of the board so we can continue to make strides for the future of Pharmacy technicians. I hope everyone has a great summer!

### Meet Barb Kalloch, **NAPT** secretary

Hi, my name is Barb Kalloch. I have served on the board for the Northland

Association of Pharmacy Technicians for several years – since the beginning.

Currently, I am the secretary. I have seen many changes in the Technicians field and I look forward to all the new changes for us in pharmacy. I work for Mercy Medical Center in Williston where I have worked for just about 25 years.

# Congratulations to the Newly Certified Pharmacy Technicians!

Michael P. Nelson, Fargo Ashley M. Hanen, Lefor Stacy M. Larson, Fargo Lydia N. Moll, Garroson

Patricia J. Foertsch, Mantador Shayla M. Schmitz, Dickinson Hope A. Nelson, Minot Melinda K. Hove, Trenton

### **Topics for Technicians**

### More About Technicians and Pharmacists; Matching Up

By Danielle Dresden Feature Writer

Count, lick, stick and pour.... That's one way to describe a pharmacy technician's role. But, like so many aspects of the field these days, that may be open to change, along with the way pharmacists and technicians relate.

Renee Acosta, R Ph, MS and Program Coordinator of the Pharmacy Technician Program at Austin Community College in Texas, likens the situation to the relationship between physician assistants (PAs) and physicians. When PAs first came on the scene, many MDs were threatened and concerned about how much PAs would do and how that would affect salary levels. "Now," Acosta said, "the majority of MDs embrace PAs as a great benefit to the medical team."

Acosta thinks the same kind of process will evolve in pharmacy. "With the national trend in pharmacy to embrace pharmaceutical care and disease state management, done by pharmacists, our profession needs someone to do the technical aspects of pharmacy," she said.

With technicians on hand to take on appropriate tasks, pharmacists should be freed up to do more patient counseling and other clinical work.

Katrin Fulginiti, RPh, trains technicians at Kaiser Permanente and has witnessed a lot of changes during her 20 years in the field. She expects that pharmacies will get even busier in the future. "Now with pharmacists working in ambulatory care clinics providing disease state management for diabetes, asthma and other illnesses, technicians will be needed to do the clerical work involved in these practices," Fulginiti said. Technicians in these settings are helping to pull charts, remind patients of appointments and more.

Acosta also sees increased responsibility for technicians as a way to free up pharmacists for more disease state management work. For example, in Texas, where pharmacists are allowed to administer injections, one new trend is for stores to offer immunizations, such as flu shots.

Texas requires certification of technicians, effective this January. Once certified, technicians in the Longhorn State can take on tasks like labeling prescriptions, although some RPh's have reservations on this matter.

Fulginiti reports a new development in the evolution of the technician's role which reflects the realities of health care today. A lead technician is paired with a social worker to try and find funds for patients who don't have the money to pay for their prescriptions.

Increased use and expanded roles for technicians do not seem to be taking jobs away from pharmacists. Instead, there are shortages of both. Acosta said she gets 2-3 calls a week from pharmacists looking for experienced, certified technicians.

Sometimes the most unlikely matches are the most successful. As the demand for pharmacy services increases and diversifies, practitioners throughout the field might find technicians to be just what the doctor ordered.

### **NAPT - NDSHP Fall CE Conference**

This year the **Fall CE Conference** will be held in **Bismarck** on **September 15 – 16**. This conference will offer a wide variety of topics. Watch the mail for the agenda and registration form. The conference is open to all pharmacists and technicians.

- Topics will include: Home Infusion, Tech Law topic, Round Table discussions, Medication Errors, Pharmacy Automation, Drug Task Force, Compounding
- Option to attend Neuroscience Center CE Program on Saturday for Pharmacists
- Displays by Sponsors Street Fair Weekend

For more information contact Joan Johnson 530-6924 or Robin Nelson 530-6912



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### DEPARTMENT OF INSURANCE STATE OF NORTH DAKOTA

Jim Poolman Commissioner of Insurance

June 26, 2006

Dr. Patricia Hill ND Pharmacists Association 1661 Capitol Way, Suite 102 Bismarck, ND 58505

Dear Patricia, North Dakota Pharmacists!

On behalf of the Senior Health Insurance Counseling (SHIC) program I want to personally thank you for the work you did helping North Dakotans get expert, one-on-one assistance selecting a Medicare Part D plan.

Our partnership with private organizations, interested parties, and other government agencies allowed us to leverage resources and conduct effective outreach and enrollment sessions all across the state. In fact, our joint efforts were so successful that North Dakota achieved the highest signup percentage in our CMS region! At 81%, our signup rate surpassed Minnesota, South Dakota, Montana and Wyoming!

Your dedication and conscientious hard work paid off, not only in the successful launch of the Medicare Part D program in North Dakota, but for so many Medicare recipients who turned to you for help selecting a plan. You and your organization were invaluable to the success of the initial Medicare Part D launch. Please accept the enclosed pen as a token of my appreciation. I commend your Themb Past! efforts!

With warmest regards,

Jim Poolman

Commissioner of Insurance

JP:ls

#### **SURVEY RESULTS**

### Medicare Part D Hard on Pharmacists

Nationwide survey looks at program's first 90 days

iabolical and dastardly are words usually saved for the dramatic, and both were used by pharmacists who participated in a nationwide survey on the start of the Medicare Part D plan. Nearly 6,000 pharmacists completed the survey conducted by the Pharmacy Society of Wisconsin on behalf of the National Alliance of State Pharmacy Associations (NASPA). Few had positive marks for the new Medicare program.

Although the new program brought forth needed assistance for millions of Americans and up to 20 million Medicare beneficiaries may receive financial assistance with their medications for the first time, the start of the program has taxed the pharmacists serving the program—both literally and figuratively. The NASPA survey found that the new Part D programs had created significant operational and financial problems for the participating pharmacists.

ing pharmacists.

"We conducted this survey to identify and quantify what Part D was doing to and for the nation's pharmacy providers,"

said PSW's CEO Chris Decker. "There is no group of individuals more vested in this program's success than the nation's pharmacists. Based upon the findings of this survey, things better improve in the coming months or the program may col-

coming months or the program may collapse from its own weight," said Decker.

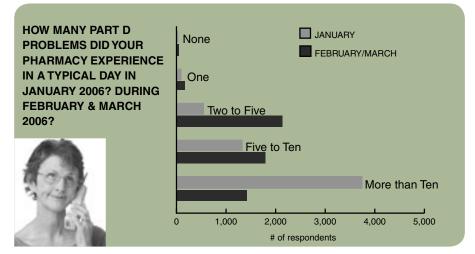
The web-based survey captured the opinions of 5,859 pharmacists, inclusive of pharmacists in every state, during the final two weeks of March. The survey was a true cross-cut of U.S. pharmacies. Approximately one-third of respondents were from communities with populations less than 10,000, one-third were from cities with a population between 10,000 – 100,000, and one-third were from cit-

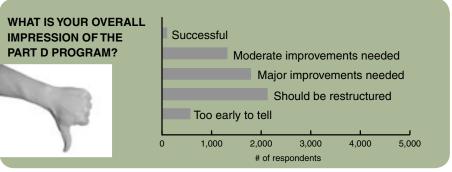
ies larger than 100,000. Fifty percent of respondents practiced in pharmacies that dispensed an average of 100-250 prescriptions each day, 30% dispensed 250-500 prescriptions/day and about 10% dispensed less than 100 prescriptions/day or more than 500 prescriptions/day.

Survey respondents reported enormous implementation problems with Medicare Part D. Sixty-four percent of the pharmacists said that they had more than ten Medicare beneficiary problems each day during the month of January. Although the number of problems reported in February and March declined, 23% of pharmacists reported that they still had ten or more problems each day and 55% of

pharmacists said they had more than five problems each day.

The intensity of the problems, and the difficulty associated with resolving them, added to pharmacists' fury with the system. Sixty percent of pharmacists reported that each problem took more than 30 minutes to address, with over half of those problems taking more than one hour during the first month of the program. Twenty percent of the problems took more than thirty minutes to resolve in February and March and another 25% took between 20-30 minutes. In total, the survey respondents reported spending a staggering one million hours resolving Medicare Part D problems during the first three months of the program! Extrapolated to all Medicare pharmacy providers, that's 20 million hours spent by pharmacists resolving Part D problems - an average of more than 200 hours for each Medicare provider pharmacist over the 90-day period. The time spent addressing Part D problems was in addition to the time spent by pharmacists dispensing medications to Part D beneficiaries.



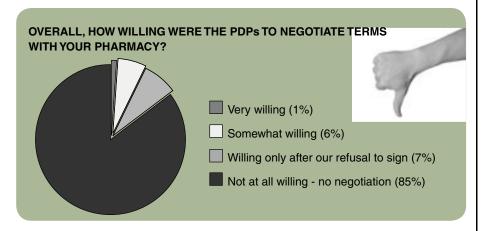


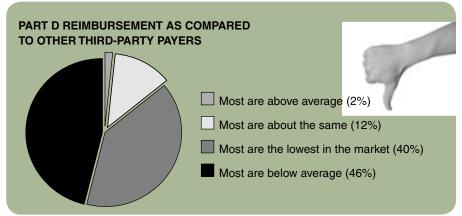
Not only were pharmacists forced to spend millions of hours of uncompensated time addressing problems associated with obtaining coverage for Part D prescriptions, the compensated time was rated poorly by most of the pharmacist respondents as well. Of the 4,000 pharmacist respondents familiar with contracting terms for Part D plans, 86% (3,356) reported that Part D reimbursement rates were below average and often the lowest in the market. Equally significant was the survey finding that the vast majority (85%) said that the prescription drug programs (PDPs) responsible for administering the benefit refused to negotiate terms satisfactory to the pharmacists. "What can we do?" asked one pharmacist. "This program has created a new, big space between the rock and the hard place. We are going to be squished to death."

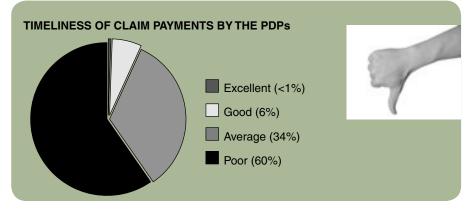
Timeliness of payments was also reported as substandard. Over half of the pharmacists familiar with the payment cycles said that PDPs were taking more than four weeks to pay submitted and approved claims. "I can't believe PBMs are getting away with this," said one respondent. "They are making money on the spread, they are making money on the float, they are making money by denying drug coverage and they are making money through hidden deals with drug companies. Where's the Inspector General?" The discontent among pharmacists was widespread.

While 10% of the pharmacists responded that they believed Part D would have a positive impact upon their business over the coming year, 60% believed it would be negative and 28% were not in a position to know.

Congress expected that Medicare Part D plans would negotiate fair and reasonable terms with the pharmacies tasked with the responsibility of dispensing medications to Medicare recipients. According to the NASPA survey results, that hasn't happened. It's time for Congress to see that the companies responsible for administering this program are held accountable for doing it right. Every pharmacist who has been taken advantage of by this program should share a copy of this article and the complete survey results at www. NCSPAE.ORG with both of their U.S. Senators and the members of the House of









### WHAT HAS BEEN THE IMPACT OF IMPLEMENTING PART D ON YOUR BUSINESS? (BASED ON 5,859 RESPONDENTS)

	Number	Ratio
Negative cash flow	3079	53%
Positive cash flow	74	1%
Increased debt load for pharmacy (required lines of credit)	2086	36%
No impact upon debt load	116	2%
Lowered profit margins	3829	65%
Improved profit margins	61	1%
More staff hired to help resolve issues	1124	19%
Support staff working longer hours (overtime)	3061	52%
Pharmacists working longer hours	3442	59%
Interrupted workflow	4737	81%
Increased numbers of patients	1111	19%
Increased prescription volume	1381	24%
Decreased prescription volume	674	12%
Reduced support staff levels due to reduced reimbursement	377	6%
Quality of care has decreased	2286	39%
Quality of care has increased	44	1%
Less time available to spend in patient care	3852	66%
Pharmacist hiring freeze	372	6%
I don't know	344	6%
Other	446	8%

Representatives from their congressional district, together with a question of what the members of Congress will do to see that the system will be corrected.

### LEGISLATION INTRODUCED IN CONGRESS

Subsequent to the NASPA survey, legislation was introduced in both the U.S. Senate and the House of Representatives to correct some of the problems faced by pharmacy providers due to the structure and implementation of the Medicare Part D program. HR 5182, introduced by U.S. Rep. Walter Jones (NC) and co-sponsored by more than 60 House members, would address inadequacies with the payment for dispensing prescription drugs to Medicare beneficiaries, eliminate co-branding on Part D program cards and enhance the medication therapy management provisions called for in the Medicare programs. Pharmacy organizations at the state and national level are advocating adoption of the legislation, as well as further improvements to the program. Pharmacists across the country are being asked to encourage their representatives to support the legislation. Go to www.NCPANET.ORG for up-todate information on the legislation and to contact your representatives.

### Significant Changes Made to Medicaid/Senior Care Preferred Drug List

In March, PSW learned of significant changes planned for the current Medicaid and Senior Care Preferred Drug List. Most notably, Nexium® and Prevacid® have taken the place of Prilosec OTC™ as preferred proton pump inhibitors. These changes took effect May 1. Originally the changes were set to take place on April 3, but due to concerns expressed by PSW to DHFS regarding the end of the Medicare Part D transition policy on April 1, the implementation date was changed to May 1.

Prilosec OTC™ is therefore no longer covered by Medicaid for Medicare Part D dual eligible patients as it has currently been. Proton pump inhibitors will be covered according to individual PDP formularies.

Other notable classes that have been changed include the two lipotropic classes.

Both Zetia® and Lipitor® have been removed from the preferred list and will now require prior authorization. Changes in these classes, in addition to changes in the bladder relaxant preparations class, took effect May 1.

The other changes (most of which were effective April 3) are accessible via the PSW website [Changes to Preferred Drug List] or the Medicaid website WWW.DHFS.STATE.WI.US/MEDICAID/PHARMACY/PDL/INDEX.HTM.

The process of converting patients to preferred products creates an opportunity



REFER TO THE MEDICAID
PHARMACEUTICAL CARE BILLING
HANDBOOK FOR SPECIFICS.

HTTP://DHFS.WISCONSIN.GOV/MED-ICAID2/HANDBOOKS/PHARMACY/PDF-FRAME.HTM for pharmacists to bill for their time using the Medicaid Pharmaceutical Care Billing program. For formulary interchanges, it is appropriate to bill using the following code combination:

Reason: PS (Product Selection Opportunity) Action: TH (Therapeutic Product Interchange; requires prescriber authorization) Result: 1E (Filled, Different Drug)

#### **ENHANCED DISPENSING FEES**

Level 11: 1-5 minutes: \$9.45 Level 12: 6-15 minutes: \$14.68 Level 13: 16-30 minutes: \$22.16 Level 14: 31-60 minutes: \$40.11 Level 15: 61+ minutes: \$40.11

To ensure payment, each claim submitted must include the ICD-9 diagnosis code for the patient's condition.





### Products and Services to Help Pharmacies Improve Quality and Reduce Prescription Errors

Welcome to Pharmacy Quality Commitment®, a product of the National Alliance of State Pharmacy Associations, LLC. We have created what we consider to be the most complete quality improvement program for pharmacy. If you haven't seen the Sentinel<sup>SM</sup> system and Quality Manager<sup>SM</sup> program in action, contact North Dakota Pharmacists Association, or call 866-365-7472 for more information that will allow you to answer questions such as:

- O Why, in today's litigation environment is it critical for ALL pharmacies no matter how large or small to have a written, functional quality improvement system in place?
- How can you easily implement a quality improvement system into your current workflow?
- How can using the Sentinel<sup>SM</sup> system allow you to have more time to spend with your patients?

In less than 5 minutes per day, the Quality Manager<sup>SM</sup> audit system allows you to track errors and "successes" according to the day of the week, type of error, name of drug and where the errors most often occur – thereby enabling you to continuously adjust workflow to prevent such errors from happening again!



### PQC Training available in September in Bismarck and Fargo

Sponsored by the ND Telepharmacy Project, the NDSU College of Pharmacy, Nursing, and Allied Sciences, and the ND Pharmacists Association

Saturday, September 9; Bismarck State College, Bismarck; 3:30 to 5:30 p.m. (training) – 5:30 to 6:30 complimentary dinner provided

Saturday, September 23; NDSU, Fargo; 3:30 to 5:30 p.m. (training) — 5:30 to 6:30 complimentary dinner provided

Participants earn 2 hours of CEUs for completing the training. The cost of the CEUs is \$ 7. Ken Baker will present the program, which includes classroom training followed by hands-on computer practice. Pharmacists and technicians are encouraged to attend, especially those who are currently using the PQC or have recently purchased the program.

#### REGISTER FOR THE PQC TRAINING IN SEPTEMBER AND RESERVE YOUR SPACE!!

Select ONE location:	K	
Bismarck on S	September 9	
Fargo on Sep	tember 23	
Name of Pharmacist (contact person	):	
Pharmacy:		
Address:		
City/State/Zip:		
Phone:	Email:	
Number of pharmacists from your ph	armacy attending: Number of technician	ns attending:
Fax or mail by August 4, 2006 to:	Ann Rathke, Telepharmacy Coordinator	
	NDSU, 120 Sudro Hall, Fargo, ND 58105	FAX - 701.231.7606

# State Convention Student Auction 2006



Harvey Hanel filling in as auctioneer.

was. Thank you to all who helped. The many items donated were wonderfully varied and interesting, the help setting up was appreciated, and our auctioneers - Jim Carlson, Harvey Hanel, and Gary Dewhirst - you were pure entertainment! It could not have been more fun...Dave Olig commented that he laughed until the tears were flowing...I think that is how we all felt. And most of all...thank you to all of you who spent your money so generously to provide scholarships for our students and gave us a record-breaking year. The students who attended Convention came back amazed and impressed that through all the difficult challenges faced this year, North Dakota pharmacists put it all aside for one night and enjoyed the companionship of each other and the friendly rivalries in bidding and still more, gave beyond measure to make it an evening they and the students will always remember. You are the best!"

"What a great event the 2006 Student Auction at Convention

- Cynthia Hanson, Director of Advancement College of Pharmacy, Nursing, and Allied Sciences



Jim Carlson was the auctioneer.

The auction raised over \$16,000 - an all time record - for scholarships for students in the NDSU College of Pharmacy! Thanks to the generosity of pharmacists from across the state! An endowment has been established to ensure scholarships for many years to come.





Amy Noeske,
Past President
- NDSHP and son
Samuel (Amy won
Distinguished Young
Pharmacist of the
Year).



Lorri Giddings and Bob Treitline.



Legislative Panel from D.C.: (L to R) Maria Spencer, ASHP, Tony Lee, NCPA, Kristina Lunner, APhA.





NDPhA Officers sworn in - (l to r): Lance Mohl, Jerry Wahl, Dennis Johnson.



NDAC College of Pharmacy Class of 1954 (L to R) Jerry and Jane Dufault, Grand Forks, Odell and Marge Krohn, Harvey, Fred and Irene Baillie, Rugby. Not pictured: Dean and Joyce Long.



Lifetime Awardss: (L to R) Jerry Dufault, Tim Carlson - NDPhA President, Odell Krohn.

Charles Peterson, Dean NDSU College of Pharmacy A Message from the Dean

# **Student and Faculty Awards Presented at Graduation Hooding Ceremony**

It is the tradition of the College to present the various awards honoring students and faculty for outstanding performance during the 2005-2006 academic year. This year's recipients received recognition at the College of Pharmacy Hooding and Honors Convocation on May 12, 2006 held on NDSU campus at the Bentson-Bunker Fieldhouse. Approximately 800 attended the ceremony to join in the celebration. The keynote speaker this year for our Graduation Hooding Ceremony was Dr. Joseph T. DiPiro, Executive Dean of the South Carolina College of Pharmacy. Dr. DiPiro is the senior editor for Pharmacotherapy: A Pathophysiologic Approach, a textbook very familiar to all our pharmacy students. Graduating senior, Trichia Dissmore (Lisbon, ND) introduced Dr. DiPiro. It was a great day and great celebration!

### STUDENT AWARDS

**Teryn B. Ebert, Spearfish, SD**, received the APhA-ASP Mortar and Pestle Professionalism Award – a hand turned, wooden replica of an early American mortar & pestle sponsored by McNeil Consumer Products Company, to a student who exhibits the ideals of professionalism and excellence in patient care in all aspects of his/her academic pharmacy career.

**Teryn B. Ebert, Spearfish, SD,** received the APhA-ASP Senior Recognition Certificate – ASP presents this award to honor a student for advancing the profession of pharmacy through outstanding service to the APhA-ASP Chapter at NDSU.

Erin R. Westby, Lovington, NM, received the Facts & Comparisons Award of Excellence in Clinical Communication – a complete library of Facts & Comparisons publications awarded to a graduating senior

based on academic achievement and outstanding clinical communication skills.

Elise R. Carlson, Raymond, SD, received the Glaxo SmithKline Beecham Pharmaceuticals Patient Care Award – a certificate and reference books awarded by SmithKline Beecham Pharmaceuticals to a graduating senior who has demonstrated superior patient care skills in both hospital and community practice rotations.

Christy L. Erickson, Bowman, ND, received the Lilly Achievement Award - a gold medal and a copy of the USPDI, awarded by Eli Lilly & Company for superior achievement, leadership and professional qualities.

Catherine M. Wieser, Moorhead, MN and Kaila B. Wilner, Hillsboro, ND, received the Merck & Company, Inc., Award – the Merck Manual and the Merck Index published by Merck Sharp and Dohme Company given on the basis of high scholarship.

**Tracy J. Nogowski, Fargo, ND,** received the Mylan Pharmaceuticals Excellence in Pharmacy Award – a certificate and a \$250 stipend presented to a graduating senior for superior scholastic and professional achievement.

Katy A. Vesel, Fargo, ND, received the Perrigo Award for Excellence in NonPrescription Medication Studies – a \$200 stipend and a plaque awarded by the Perrigo Company to a graduating senior who has demonstrated exceptional competence in patient assessment, interpretation of the patient profile, recommendation of appropriate product and knowledge of specific counseling advice in the area of nonprescription medications.

**Brody J. Maack, Alexandria, MN,** received the Roche Pharmacy Communications Award – a plaque awarded to a graduating senior who demonstrates effectiveness in



Dr. Joseph DiPiro, 2006 Guest Speaker at the 2006 Graduation Hooding Ceremony.

communications with patients and health care providers.

Kimberly J. Ault, Moorhead, MN received the Teva Pharmaceuticals, USA Outstanding Award Program – a plaque and \$200 stipend awarded to an outstanding member of the graduating class who excels in the study of pharmacy.

### **FACULTY AWARDS**

Dr. Stephen O'Rourke, Associate Professor of Pharmaceutical Sciences, received the 2006 College of Pharmacy Teacher of the Year Award - a faculty member who has been chosen by the students for their outstanding performance and commitment to teaching. Each year students from all four years of the professional program are invited to nominate through a written essay their choice for the College of Pharmacy Teacher of the Year Award. A student selection committee, which has representatives from each class, reviews the essays and then make the selection for teacher of the year based on student nominations.

**Dr. Cynthia Naughton,** Assistant Professor of Pharmacy Practice and clinical specialist at the Family Practice Health Center in Fargo, received the 2006 Faculty Preceptor of the Year Award – students in the fourth professional year of the program vote on their choice for Faculty Preceptor of the Year which represents outstanding performance and commitment in instruction of pharmacy students on clinical rotations by a full-time faculty member.

**Mr. Steven D. Boehning**, a community pharmacist practicing at Linson's Pharmacy in Fargo, received the



Dr. Hill with graduate and former NDPhA intern Stacey Christ.

2006 Adjunct Preceptor of the Year Award - graduating seniors choose an Adjunct Preceptor of the Year which represents outstanding performance and commitment in instruction of pharmacy students on clinical rotations by a practicing pharmacist who volunteers their time to provide clinical instruction of pharmacy students.

**Dr. Marjorie McCullagh,** Associate Professor of Nursing, received the 2006 College of Pharmacy Researcher of the Year Award – which recognizes an individual faculty member within our College who has demonstrated outstanding achievements in research including excellence and innovation in their scholarly work.

Please join me in congratulating these students and faculty on their recent awards!

### Classifieds



### **Relief Pharmacist Wanted**

- July 3, 2006
- Week of August 7 11, 2006
- October 19-20, 2006
- November 24, 2006
- Week of December 25-29, 2006

Holly Rudnick

Human Resource Administrator SCCI-Central Dakotas 1000 18th Street NW, Mandan, ND 58554 701-667-2000 Ext. 3130

Fax: 701-667-5944

### **Pharmacy For Sale**

#### Econo Pharmacy, Inc.

1190 W. Turnpike, Bismarck, ND 58501

Contact: Bill 701-224-1858 Work Phone: 701-224-0339

Established pharmacy; OTC's included Great location inside large grocery store

### **Pharmacists Needed**

Part-time Pharmacist Position Available Immediately

24 hr/week and every 3rd weekend.

Involves nursing home duties.

Here's an opportunity to use your education.

Contact Dan Mayo at 223-2424

#### **Immediate Position for Full-Time Pharmacist**

ND Pharmacy Inc. 20 East 26th St.

Williston, ND 58801

Contact: Jenny Peterson (1-800-735-4923)

or Bob Treitline (1-800-767-3632)

Call for salary and benefit package.

### **Pharmacy Technician Needed**

### Hospital Pharmacy Technician needed for 32-40 hours a week.

IV experience preferred.

Holly Rudnick Human Resource Administrator SCCI-Central Dakotas 1000 18th Street NW Mandan, ND 58554 701-667-2000 Ext. 3130

Fax: 701-667-5944

hrudnick@triumph-healthcare.com

### **NDPhA Endorses Pharmacy Compounding Accreditation**

NDPhA recognizes that compounding is an integral part of the practice of pharmacy. We have been working hard to protect pharmacists' rights to compound within the law. We have been alarmed by the attacks on this professional service that is so necessary to so many patients. In recent years, the federal government has raised issues related to FDA regulation; several property and causality insurance companies have indicated they will no longer insure compounding pharmacies; and some sensationalized news reports and others have questioned pharmacy's right to compound.

As part of our commitment to pharmacy, NDPhA, along with fifty other state pharmacy associations, have been leading a positive, quality approach to ensuring that pharmacy can continue to serve its patients who rely on compounding. Our efforts helped to form the Pharmacy Compounding Accreditation Board (PCAB), a national, voluntary organization through which compounding pharmacies can prove they meet the highest quality standards. In this effort, the state pharmacy associations have been joined by some of the most prestigious names in pharmacy – National Association of Boards of Pharmacy, American College of Apothecaries, American Pharmacists Association, International Academy of Compounding



Pharmacists, United States Pharmacopeia, and National Community Pharmacists

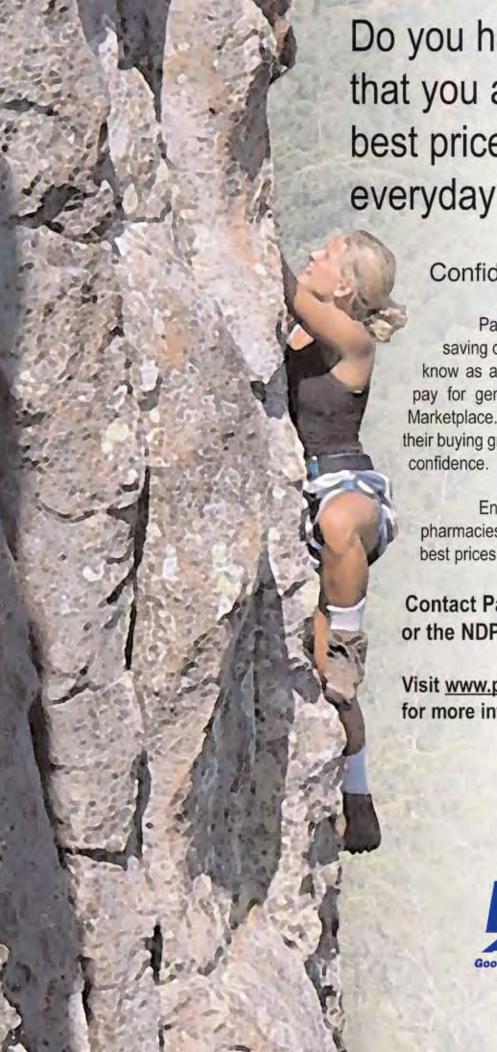
Association. PCAB is now taking applications for accreditation – it is now time for your pharmacy to act.

Compounding pharmacies in North Dakota are asked to immediately apply for PCAB accreditation. Many of our critics think that the federal government should pass laws for compounding pharmacies. We disagree – we think the

profession of pharmacy is in the best position to set rules for accreditation, standards of quality and principles of compounding. If you agree, you need to act by applying for accreditation now. Many pharmacies across the nation have already applied. We need you to join this elite first year group of your colleagues.

PCABTM is now accepting applications for compounding accreditation. NDPhA urges the leadering pharmacies in compounding to apply now. You may do so by visiting the PCABTM Website at www.pcab.info, click on "apply".

Thank you for your prompt reply to this opportunity!



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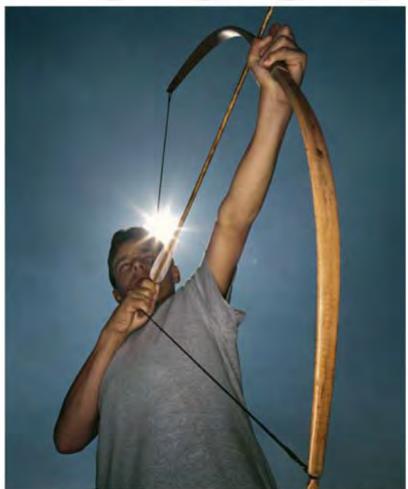
Enroll in Pace Alliance and join thousands of pharmacies that enjoy the confidence of buying at the best prices every time they order.

Contact Pace Alliance at 888.200.0998 or the NDPhA.

Visit <u>www.pacealliance.com</u> for more information



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