

NoDak PHARMACY

Volume 25, No. 5

December 2012



Be Great Nominate!

NDPhA and NAPT
are now accepting
Nominations.

NDPhA
NORTH DAKOTA
PHARMACISTS
ASSOCIATION

Don't Forget Your
2013 NDPhA
Membership Dues
now being collected...

Invoice for NDPhA Membership

January 1 – December 31, 2013

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

LICENSE #

ND License # _____

Full Name: _____

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Email: _____

Would you like to receive email updates from NDPhA?

☐ Yes

☐ No

Legislative District _____

Practice Setting

- | | |
|--------------------------------------|---------------------------------------------------|
| <input type="checkbox"/> Chain | <input type="checkbox"/> Manufacturer/Distributor |
| <input type="checkbox"/> Educator | <input type="checkbox"/> Non-Pharmacy |
| <input type="checkbox"/> Hospital | <input type="checkbox"/> Other |
| <input type="checkbox"/> Independent | |
| <input type="checkbox"/> Owner | |
| <input type="checkbox"/> Employee | |

Academies

Select one:

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

I am interested in an academy for:

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

Membership Categories

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

Optional Association Support

- ☐ Contribution to NDPhA Political Action Committee (PAC)
(Cannot be Corporate Checks AND must be a Separate Check)
Amount _____
- ☐ Contribution to the Pharmacy Advancement Corporation (PhAC) NDSU Scholarship Fund (These funds are used entirely to provide scholarships to NDSU College of Pharmacy Students. Personal or Corporate Checks are accepted.)
Amount _____

Payment

Mail to:

NDPhA

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

☐ Check Enclosed Amount _____

Name on Card: _____

Street Address & Zip code billing address for card

Type (check one): ☐ Visa ☐ MasterCard

Credit Card # _____

Expiration Date _____

CVV

(3 digit code on the back of card)

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

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COLLEGE OF PHARMACY,
NURSING, AND
ALLIED SCIENCES



CALENDAR

2012/2013

DECEMBER

ASHP

Dec 2-6 Midyear Clinical Meeting
Las Vegas NV

JANUARY 2013

ND Legislature

Jan 8 ND 63rd Legislative
Assembly Convenes
Jan 21 Deadline for ND
Representatives to introduce
Bills
Jan 28 Deadline for ND Senators to
introduce Bills

FEBRUARY

Old Fashioned Ice Cream Social

February 14 Pharmacy Legislative Day &
Ice Cream Social , ND State
Capitol

MARCH

ND Legislature

March 1 Crossover

NASPA

March 1-3 JW Marriott, Los Angeles,
CA

APhA 2013

March 1-4 JW Marriott, Los Angeles CA

APRIL

NACDS

April 20-23 The Breakers, Palm Beach FL

NDPhA 128th Annual Convention

April 26-28 Grand Dakota Lodge
Dickinson ND

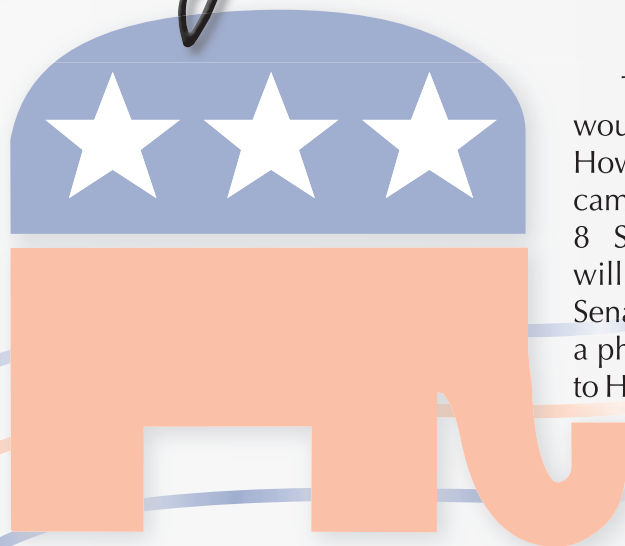
Message from the NDPhA President

Greetings to all of my fellow pharmacy enthusiasts. In the last issue, I wrote an article about fair reimbursement and finding new opportunities in your practice. I recently attended the NCPA convention in San Diego. Many new ideas were presented, and I was impressed by all the technology that is available to make our practices more efficient and patient friendly. "About The Patient" was also present at the convention to show our MTM Express system to groups interested in adding MTM and/or DSM to their practice or PBM. We should be proud of what we have created and our vision. Once again the small state of North Dakota is proving that we are leaders in the profession of pharmacy. Dr. Wendy Brown, NDSU professor and About The Patient Clinical Coordinator, was educating our profession on our product and the detail our MTM Express system provides. She did a great job of promoting our system and sharing new ideas of providing clinical pharmacist services and accurately measuring detailed responses. NDPhA is very fortunate to have this partnership with Wendy and the NDSU College of Pharmacy, Nursing and Allied Sciences. She is an expert in MTM and DSM, and really knows how to get meaningful results and outcome measurements to show the positive impact of pharmacist interventions in patient care.

I returned from San Diego wishing the warm weather could follow. I came back to work with a renewed energy that everyday practice and challenges can take from you. I have fresh new ideas about my practice. I would encourage everyone involved in the profession of pharmacy in North Dakota to make an effort to attend a national convention. NDPhA's convention is only 6 months away and provides a professional atmosphere to get that boost of energy and time to share ideas and frustrations. I know it helps give me a jumpstart, and I am sure it will do the same for you.

May we find opportunities about the patient,
Shane Wendel Pharm.D.

Congratulations!



The ND Pharmacists Association would like to congratulate Mr. Howard Anderson on a successful campaign and winning the District 8 Senate seat. Senator Anderson will be a great addition to the ND Senate and it doesn't hurt that he is a pharmacist either! Congratulations to Howard, his family and his district!

2013 NDPHA Award Nominations

Fax to: (701) 258-9312 or email to: ndpha@nodakpharmacy.net by January 4, 2013. A list of past recipients can be found on our website at www.nodakpharmacy.net.

Nominations should be submitted **along with biographical information**. The following awards will be presented:

AWARDS NOMINATIONS CRITERIA

AL DOERR SERVICE AWARD

The recipient must: be a pharmacist licensed to practice in North Dakota, The recipient must be a member of the North Dakota Pharmacists Association, be living (not presented posthumously); not have been a previous recipient of the award; has compiled an outstanding record for community and pharmacy service.

Nominee: _____ Submitted by: _____

UPSHER-SMITH LABORATORIES EXCELLENCE IN INNOVATION AWARD

- ❖ The recipient should be a practicing pharmacist within North Dakota and a member of NDPhA who has demonstrated Innovative Pharmacy Practice resulting in improved patient care.

Nominee: _____ Submitted by: _____

PHARMACISTS MUTUAL DISTINGUISHED YOUNG PHARMACIST AWARD

- ❖ The goal of this award is to encourage the newer pharmacists to participate in association and community activities. The award is presented annually to recognize one such person for involvement and dedication to the practice of pharmacy. The recipient must: have received his/her entry degree in pharmacy less than nine years ago; be a pharmacist licensed to practice in North Dakota; a member of NDPhA; have practiced community, institutional, managed care or consulting pharmacy and who has actively participated in national pharmacy associations, professional programs, state association activities and/or community service.

Nominee: _____ Submitted by: _____

APHA/NASPA BOWL OF HYGEIA

- ❖ The recipient must: be a pharmacist licensed to practice in North Dakota; a member of NDPhA; be living (not presented posthumously); not have been a previous recipient of the award; is not currently serving, nor has he/she served within the immediate past two years as an officer of the association in other than an ex-officio capacity or its awards committee; have compiled outstanding record of community service, which apart from his/her specific identification as a pharmacist, reflects well on the profession.

Nominee: _____ Submitted by: _____

Message from the NAPT President

Greetings,

As we are busy preparing for Christmas it is important to take a few minutes and put some thought into a few Pharmacy Technicians topics at hand.

The time is upon us to start thinking about NAPT award nominations for the upcoming NDPhA Annual convention. Take a minute and review the criteria for the different awards and determine if you know of someone that merits one of these awards. Send in a nomination with a letter of recommendation of the individual's outstanding achievements.

The Executive Board will have several positions open for the upcoming 2013-2014 term. If you are interested in serving as a NAPT Executive Board member or have any questions regarding a position, please contact me by email at dkisse@thriftywhite.com. The offices of Vice-President and Secretary will be open for nominations for the upcoming term. This is a great opportunity for anyone interested in becoming involved with NAPT. NAPT is an Association for Pharmacy Technicians run by Pharmacy Technicians.

Our 20th Annual NAPT Fall Conference was held the beginning of October in Bismarck and was a big success. A BIG Thank You to the fall conference committee for all their hard work and time planning a successful conference!

Happy Holidays!

Donna Kisse, NAPT President

Celebrate Technicians!

Pharmacists, store managers, and technicians celebrate your technicians. We continually hear about the great technicians working in North Dakota. Every year the Northland Association of Pharmacy Technicians wants to recognize those great technicians that are working assisting in the pharmaceutical care of our patients.

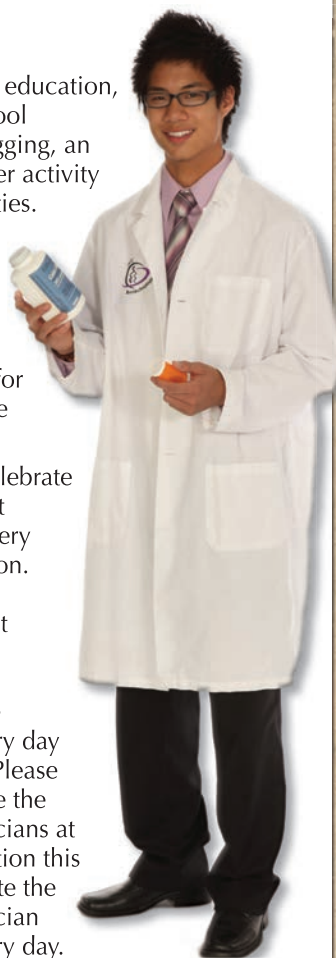
Do you have a technician who is new to the profession who is doing an outstanding job? One that goes above and beyond any expectations you had for them when you hired them. One who has taken on some leadership in your pharmacy? One not only doing a great job in the pharmacy but also gives time to those important community activities. There is an award for that technician. The *Distinguished Young Technician of the Year*

Do you have a technician who simply does a flawless job? Is willing to take on whatever responsibility you have? One who assists and trains others? Has been a Registered Technician longer than 10 years? There is an award for that technician. The *Technician of the Year*

Do you have a technician you work with that is outstanding not only in their professional life, but personal life as well? They are the Girl Scout leader, the Cub Scout or Boy Scout leader. They

help with religious education, PTA and other school activities. Sandbagging, an increasing volunteer activity in many communities. That technician that gives and gives professionally and personally. There is an award for that technician. The *Diamond Award*

We need to celebrate the technicians that are contributing every day to this profession. Pharmacists and Technicians it is not too early to begin nominating those outstanding people you work with every day for these awards. Please help us to celebrate the outstanding technicians at the annual convention this spring and nominate the outstanding technician you work with every day.



NAPT

Board of Directors

NAPT President

Donna Kisse
Employer: Thrifty White Drug, Fargo
Work #: 701.269.8747
Email: dkisse@ThriftyWhite.com

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Vacant

NAPT Secretary

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Employer: Workforce,
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Work #: 701.570.3148
Email: dkupper@wil.midco.net

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Work #: 701.483.4858

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Email: barbara.lacher@ndscs.edu

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Immediate Past President

Kristina Foster
Employer: White Drug #62, Mohall
Work #: 701-756-6000
Email: kristinafoster23@yahoo.com

The 20th Annual Fall Conference was held in Bismarck, October 4 & 5. The two day event provided 10 hours of continuing education for the technicians. In celebration of 20th anniversary, there were trivia questions and a reduced fee for attending. There were over 60 in attendance! There were two sponsors, St. Alexius Medical Center and James Feeney of Ferring Pharmaceuticals, that helped cover some of the costs.

The CE topics were about sleep, chiropractic care, respiratory therapy, home care and hospice, post-partum depression, customer service, ND Medicaid changes, ND law, and the teamwork involved with the OR. Unfortunately, Howard was not able to present, but Diane Halvorson and Barb Lacher were gracious enough to step in and help!

So on behalf of the Fall Planning Committee and my co-chair, Jodi Hart, I would like to thank everyone who was able to come and enjoy the conference! We also thank the Board for their support and direction when needed, Barb Lacher for helping us secure the CE credit, and for all the speakers that came to help support our education! Of course it was not the same without Howard; we wish him well and look forward to his next presentation!

Sincerely,
Nicole Gerjets



NAPT Annual Awards Nominations

Now is the time to start thinking about nominations for the NAPT Annual Awards to be presented at the NDPhA 2013 Annual Convention in Dickinson. We have many outstanding technicians in the state that are dedicated to patient care and the Pharmacy Technician profession.

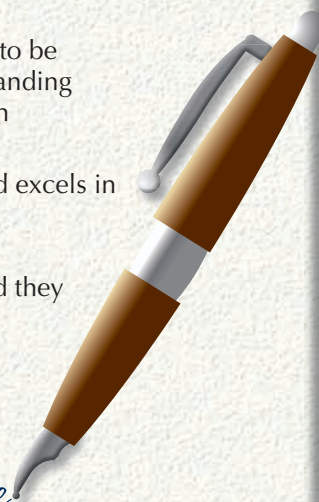
This individual should be an outstanding achiever in the Practice of Pharmacy and excels in the criteria of the award nominated.

The nominator shall prepare a letter of recommendation listing the outstanding achievements of the nominee. The nominator shall also include the name of the award they are making the nomination for.

The nominator shall send a letter of recommendation to the attention of the NAPT President Donna Kisse via email: ndpha@nodakpharmacy.net or mail to NDPhA 1641 Capitol Way, Bismarck, ND 58501. You may also contact Donna by phone at 701-269-8747.

The deadline for nominations is March 1, 2013.

I nominate.



NAPT Minutes On-line

The NAPT General Business and Executive Board minutes are available on-line. You will find a listing of minutes available on the NDPhA website. For access, go to www.nodakpharmacy.net >about us > academies > Northland Association of Pharmacy Technicians. It is an excellent way to stay in touch with Pharmacy Technician updates.



2013 NAPT Award Nominations

Please enter the name of the candidate and place of employment under the title of the award. The nominator must prepare a letter of recommendation listing the outstanding achievements of the nominee and send the letter to the Selection Committee, attention chairperson of such committee. such letter must arrive within the determined due dates as posted yearly by the Selection Committee. The criterion for each award is listed below.

DISTINGUISHED YOUNG PHARMACY TECHNICIAN

Minimum Selection Criteria/ Nominations will be accepted from any member of NAPT, NDPhA or NDSHP

1. Practicing as a Pharmacy Technician for less than 10 years.
2. Registered as a Pharmacy Technician in North Dakota.
3. Practice sites shall include but are not limited to; Institutional, Managed Care, Retail, or consulting pharmacy in the year selected.
4. Nominee should demonstrate an outstanding work experience in the Profession of Pharmacy. Participation in national technician association, professional programs, state association activities, and or community services is not required but would be good examples of dedication to the profession.

Nominee: _____

Submitted by: _____

Place of Employment _____

DIAMOND AWARD

Minimum Selection Criteria/ Nominations will be accepted from any member of NAPT, NDPhA or NDSHP

1. Current or past registration as a N.D. pharmacy technician is required.
2. The nominee must be living, awards are not posthumously.
3. The nominee is not a past recipient of this award.
4. The nominee is not currently serving as an officer of the NAPT Association.
5. The recipient has demonstrated an outstanding record of community service such as; involved in church, community (scouts, school, PTA, Jaycees or other organizations). The recipient also demonstrates an outstanding service to the Profession of Pharmacy.

Nominee: _____

Submitted by: _____

Place of Employment _____

FRIEND OF NAPT

Minimum Selection Criteria/ Nominations will be accepted from any ND Registered Pharmacy Technicians

1. The nominee has not been a previous recipient of this award.
2. The nominee has been an advocate of NAPT and the Profession of Pharmacy Technicians.
3. The nominee may include but are not limited to; Registered Pharmacy Technician, Registered Pharmacist, or any related Pharmacy Business. The recipient is not limited to a specific person; a company can also be noted as a recipient.

Nominee: _____

Submitted by: _____

Place of Employment _____

NAPT PHARMACY TECHNICIAN OF THE YEAR AWARD

Minimum Selection Criteria/ Nominations will be accepted from any member of NAPT, NDPhA or NDSHP

1. The nominee shall be a Registered Pharmacy Technician in North Dakota.
2. No nominee shall be a member of the Selection Committee or past recipient of the award.
3. Each nominee shall be actively practicing as a Pharmacy Technician in North Dakota. However, need not be actively involved with NAPT.

Nominee: _____

Submitted by: _____

Place of Employment _____



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AHRQ Launches Regional Partnership Development Initiative to Promote Comparative Effectiveness Research

The Federal Agency for Healthcare Research and Quality (AHRQ) recently launched efforts to promote comparative effectiveness research (CER), a type of patient-centered outcomes research, in patient and professional communities in all 50 states, Washington, D.C., and the U.S. territories. AHRQ has established five Regional Partnership Development Offices that are cultivating sustainable partnerships with hospitals and health systems, patient advocacy organizations, businesses, and other groups that serve clinicians, consumers, and policymakers. You're invited to learn more about CER and to partner with AHRQ by using and encouraging others to use free CER reports and materials, which support efforts to improve the quality of health care in communities.

What is comparative effectiveness research?

Comparative effectiveness research provides information that helps clinicians and patients work together to treat an illness or condition. CER compares drugs, medical devices, tests, surgeries, or ways to deliver health care. The research findings don't tell clinicians how to practice medicine or which treatment is best, but they provide evidence-based information on the effectiveness and risks of different treatments. Clinicians and patients can use this information to support their treatment decisions based on each individual's circumstances.

AHRQ's Effective Health Care Program works with researchers, research centers, and academic organizations to conduct the research and focuses on 14 priority health conditions, including: cardiovascular and related diseases, diabetes, arthritis, mental health disorders, and pregnancy. The full research reports are made available, and findings are translated into practical patient and clinician materials, that include:

- Patient treatment comparison summaries (English and Spanish)
- Clinician research summaries
- Executive Summaries
- Faculty Slide Sets
- Continuing education (CME/CE) Modules
- Podcasts



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Partners can participate in a range of scalable activities such as distributing guides at meetings and in medical offices, placing articles in newsletters, and hosting Web conferences that highlight CER findings. Organizations that are using these materials or the CER findings include Mayo Clinic, the American Academy of Nurse Practitioners, and AARP, among many others.

Findings from comparative effectiveness research can be helpful to everyone participating in health care decisionmaking:

Patients are often faced with complicated decisions, such as which test is best, which medicine will help most with the least side effects, or whether surgery is the best option. Every patient is different, and each should make informed choices based on individual needs. By providing Effective Health Care Program products that summarize evidence-based, comparative effectiveness research findings, you can help patients work with their health care professionals to make a more informed decision among many treatment options.

Health care professionals can use CER to keep current on comparisons of medications and treatments. The products developed by the Effective Health Care Program help distill the information so health care professionals and consumers can review treatment options together. When research is not available to answer clinical questions, AHRQ publications highlight research gaps.

Policymakers, business leaders, and others want to make health care policy decisions based on reliable, objective information about effectiveness. Comparative effectiveness research helps decisionmakers plan evidence-based public health programs.

To learn more about comparative effectiveness research, order free materials, access our free continuing education modules or to become part of this growing partnership network, please contact Kate Stabrawa in AHRQ's Denver Regional Partnership Development Office at 303-382-2444 or kate.stabrawa@ahrq.hhs.gov. You can also learn more about CER by visiting www.effectivehealthcare.ahrq.gov.

PHARMACY MARKETING GROUP, INC



AND THE LAW

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

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

CONTRACTS

Contracts are a fact of life in the modern world. We are faced with all types of contracts in both our professional and personal lives. These include leases of real property, agreements to sell real estate or to buy a car, or even the terms and conditions that we click on a website in order to proceed to the whatever product or service that we want to purchase. Contracts provide stability and certainty in the business world, but occasionally the terms contained in them can come back to haunt us.

A contract is defined as a promise, or set of promises, for breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty.¹ A contract can require a party to do some act and/or prohibit them from doing some other act. It can also set mutual expectations for quality and quantity of goods, price, delivery, etc. A contract essentially sets out the rules that will govern a particular transaction. Contracts can be either oral or written, although the written contract is easier to review and interpret later. Except in some special circumstances, oral contracts are every bit as valid and enforceable as a written one. Don't be fooled by thinking that all contracts must be written. When things proceed as agreed, which is usually the case, the stability of our commerce and society is enhanced. The problem, of course, occurs when things don't go as planned. The key is to be informed before a contract is signed.

The law of contracts has developed over centuries and the parts of a contract are legally well-defined. Many of the words and phrases are words of art, i.e., they have a particular meaning in the world of contract law. This makes it difficult for a pharmacist, or any layperson, to effectively and efficiently interpret a contract without the help of an attorney who is knowledgeable about contracts. It will not be an effective defense in a lawsuit over a contract to state that either you didn't understand or didn't read the contract that you signed. By signing the contract, you have agreed to the terms of that contract. Absent a showing of fraud or deceit (for instance, that the contract was altered after you signed it), the contract will be binding.

The pharmacist should initially review a contract to assure that it accurately sets out what the parties have agreed to. However, when reviewing a contract, a pharmacist should be aware that the words in the contract are there for a reason and should not assume that they are fluff, boilerplate or other mumbo jumbo. The old adage about

reading the fine print is true and is derived from previous experiences with contracts. The pharmacist should seek professional help for any confusing or unfamiliar terms. The time to clarify and change terms is before the contract is signed and not after.

While there is a cost to obtain this help up front, it will usually be less costly than trying to get out of an unfavorable contract. As the attorney, there will be fewer tools available and much more work to do in trying to undo a contract than in reviewing it prior to execution.

As noted at the beginning, we are all faced with many types of contracts in our lives and not all of them will justify this type of expense. However, when it comes to our profession and our businesses, contracts are an area where an ounce of prevention is definitely worth a pound of cure.

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

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



¹ 1 Williston, Contracts § 1

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Getting Techy With It

By Andrea Stan, PharmD

It is estimated that 35 percent of the U.S. population owns a smartphone (such as an iPhone, Android, or BlackBerry). Marketing firms predict a rapid growth over the next few years and some estimates report as much as 65 percent owning a smartphone and/ or tablet device by 2015.

Smartphone applications ("Apps") enable users to have a multi-use device, and the types are limitless. Pharmacists more commonly use drug information apps, but could we use this avenue to increase our patients' medication adherence? Yes, there are initiatives explored by universities and health care associations to help develop the best adherence app for patients. While we are waiting for those apps, let's look at a few which are patient-centered and currently available.

Dosecast is a free app that has iPhone and Android capabilities and can operate without an Internet connection. Users will program medication information such as drug name, type, dose strength, dosing schedules, and start/stop dates. Reminders can be set for a specific time and are accompanied by sounds and push notifications. This means a message will pop up whenever a phone is on to notify user it is time to take the dose. Dosecast will adjust to time zone changes when traveling, allow users to program bedtime to prevent late night notifications, and will log doses as taken on time, taken late, or skipped. Lastly, a log can be emailed to any user with a record of the last 30 days of medication history. There is a "Premium" edition available for a cost, which allows you to program dosage forms other than pills, track refills and multiple family members' medication, compliance information, doctor, and pharmacy information.

MedCoach is also free, and essentially provides the Dosecast Premium edition features. However, it does require an Internet connection. Some additional features include a drug database where the user can enter a drug name and the information will automatically populate fields such as the dosage form and strength. Along with using stock clip art, users may take a picture of the drug so the image will pop up alongside the reminder notification. Entries are linked to the software's drug information database, which answers questions about missed doses and basic drug information.

This technology is best utilized on a device with phone or cellular data network capabilities, instead of an iPod touch or tablet, to allow the seamless ease of calling the pharmacy for refills, contacting a physician office, looking up drug information, and staying on top of scheduled medications. The apps available are quite impressive and provide our patients a way to manage their prescriptions and over the counter medications as a supplement to visiting their pharmacist and other health care professionals. The next step in adherence app advancements will be synching medication information directly from the pharmacy to the patient. In the meantime, in our efforts to increase medication adherence, let's help make our patients more accountable for their medication use. Do you know a patient who could benefit from this technology?

Reprinted with permission from National Community Pharmacists Association in the September 2012 issue of *America's Pharmacist*. For more information about NCPA, visit www.ncpanet.org.

Learning from the New England Compounding Center

Alan Yan, Jr, Pharm D Candidate

Over the past month, there has been a lot of negative news stirring around the New England Compounding Center. It is believed that the company had unknowingly shipped contaminated vials of methylprednisolone which is commonly used for intrathecal injection for chronic back and joint pain. The New England Compounding Center has been linked to over three hundred *Aspergillus meningitis* and joint infections which has resulted in twenty three deaths in the United States so far. As a result of this outbreak, the company has agreed to voluntarily recall all their compounded products and is coordinating closely with the CDC and FDA in their investigation of the outbreak. Along with recalling their products, the company has also surrendered their pharmacy license in Massachusetts. With the investigation as ongoing and surrendering their license, there have been some troubling issue that have come to light. In preliminary findings of the investigation, reports have shown the company of shipping vials of injectable steroids (methylprednisolone) before the sterility test came back, proper cleaning procedures, and practicing outside the laws of their own pharmacy license.

When looking into the issues that surround this preventable outbreak from occurring, it is crucial to take a step back and try to learn from the mistakes that caused this tragic occurrence. One issue that is very alarming would be that the company did not wait for sterility test to come back before shipping their products out. Due to this lack of follow through by the company, it is possible that it had shipped products that were contaminated to the public. Taking a step back even further, these products were most likely contaminated as a result of using improper aseptic techniques and unsanitary work conditions. With that being said, it is important to follow some type of guideline such as USP 797 and the rules and laws described by the board of pharmacy. As of this year, the board of pharmacy has updated the rules and laws which now contain a comprehensive overview of pharmaceutical compounding standards for both sterile and non-sterile compounding.

Another issue that came up was that this company was operating outside of their pharmacy license in Massachusetts. During the initial investigation, it was shown that the company may have been acting more of a wholesale distributor/manufacturer by distributing their products without a patient prescription for use. Instead, the company was allegedly labeling their product for office use without one specific patient in mind. In this aspect, it is important to realize how important it is to follow the rules and laws laid out by their board of pharmacy since they are not all the same in every state. North Dakota laws and rules allow a compounding pharmacy to make products for a physician to administer at their office but that product cannot be dispensed or sold to others. The ND Board expects the pharmacist compounding the "Office Use" product to ensure the practitioner understands and complies with this. Bulk sales to other pharmacies, clinics, or hospitals would be considered manufacturing and is not allowed for compounded medications. The rules and regulations laid out by each state may vary but ultimately are there for the protection and safety of the public.

It is vital we realize that this one outbreak could lead to a very negative perception towards compounding pharmacies. It is important that we relay the message that in most cases, compounding pharmacies are very safe and offer medications that are not commercially made or available. In closing, it is imperative that we learn from this event that is unfolding as it will be continue to be a source of much discussion.



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Ready for Part D in 2013? Key changes explained

Diana Yap

CMS released final rules and guidance in 2011 and 2012 with revisions to Medicare Part D that beneficiaries will see taking effect in the coming year. Of interest to pharmacy, key changes include improving the Part D medication therapy management (MTM) program; requiring that pharmacies provide patients whose Part D claim is denied with a printed, revised, standard notice describing their options; and continuing to close the Part D “doughnut hole.”

MTM program

On April 2, 2012, CMS released its annual advance notice and call letter, a subregulatory guidance document, to Medicare Advantage and Part D plans for 2013. According to the call letter,

- Part D plans must start using a standardized format for patients' action plans and summaries as part of the MTM benefit.
- Pharmacies must provide a standard, printed notice of Part D appeals options.

Part D sponsors must begin using a standardized format no later than January 1, 2013 for an action plan and summary that plan sponsors must provide to targeted MTM-eligible beneficiaries after their comprehensive medication review (CMR).

The call letter also provided the following clarifications based on Part D sponsor and industry questions:

- Targeted beneficiaries are auto-enrolled when they meet the eligibility criteria, so sponsors should not wait for program acceptance from the patient to offer the required minimum MTM services.
- The provision of the action plan and written summary in CMS's standardized format requires certain minimum service levels for the CMR.
- Sponsors should offer to provide a

CMR to newly targeted patients as soon as possible after enrollment into the MTM program, but no later than 60 days after being enrolled in the MTM program.

- Sponsors are expected to use more than one approach when possible to reach all eligible targeted patients.

The MTM program annual cost threshold in 2013 will be \$3,144. CMS designated two additional core chronic diseases for its list of core chronic diseases for which beneficiaries should be targeted for MTM: Alzheimer disease and end-stage renal disease requiring dialysis. CMS also added atrial fibrillation and chronic noncancer pain to the list of non-core chronic diseases. Plans are expected to target at least five of nine core chronic conditions, which modifies the current criteria of at least four of seven chronic diseases.

Finally, plans are required to have information on their website about their MTM program.

MTM description

A description of the MTM benefit appears in the 2013 *Medicare & You* handbook that is mailed to all beneficiaries and is available online. A reference to MTM also appears online in the Part D section of the Medicare website. The description first appeared in 2012.

In comments on the draft 2013 advance notice and call letter, APhA wrote, “We are very encouraged by CMS's efforts to increase beneficiary awareness about MTM programs,” citing the 2012 *Medicare & You* handbook and a link on



the Medicare Plan Finder to MTM program eligibility information, which has continued.

Appeals notice

On February 2, 2012, CMS finalized a revised, standard notice, Medicare Prescription Drug Coverage and Your Rights, to provide to Medicare patients when a prescription cannot be filled by Part D at the pharmacy. The notice describes options for coverage determinations and appeals.

While CMS has required pharmacies to provide the notice since January 1, 2012, the requirement was enforced starting May 1, 2012, and most plan years start in 2013. Before this change, pharmacies could communicate the patient's options by either providing a notice or displaying a poster. Pharmacies generally chose to put up the poster. Meanwhile, CMS revised the standard notice to be clear that pharmacists don't determine coverage—the Part D plan does.

Pharmacists may see a message on their computer screen telling them to provide a printed notice to patients whose claims have been denied by Part D. The message will likely be accompanied by one of two codes: 569 if the claim is denied, or 018 if the claim is denied by Part D but covered by a secondary payer. The codes will be visible to the pharmacist if the pharmacy management system already shows other codes. The changes don't need to be programmed into pharmacy management systems.

In comments on CMS's April 15, 2011, final rule implementing the changes, APhA wrote, “Pharmacists are committed to the needs of patients but are concerned with the potential administrative burden and cost shift to pharmacy. We also urge CMS to consider ways to ensure that plans are also

providing this information to patients.”

Coverage gap

On April 12, 2012, CMS issued a final rule that implements Medicare Advantage and Part D technical and program changes. Among the final rule’s provisions was the continued narrowing of the Part D coverage gap, or doughnut hole. In 2013, Medicare patients in the doughnut hole (who don’t qualify for the low-income Extra Help program) will pay 47.5% of the cost for brand-name drugs and 79% of the cost for generic drugs.

By 2020, Medicare patients in the doughnut hole will pay 25% of the cost for both brand-name drugs and generic drugs. The doughnut hole is closing gradually under the Medicare Coverage Gap Discount Program in the Affordable Care Act. Drug manufacturers pay for a 50% discount on brand-name drugs, and the federal government is

Table 1. Standard Medicare Part D benefit: 2012 vs. 2013

Standard benefit	2012	2013
Deductible	\$320	\$325
Initial coverage limit	\$2,930	\$2,970
Out-of-pocket threshold	\$4,700	\$4,750
Minimum cost sharing		
Generic/preferred multisource medications	\$2.60	\$2.65
Other	\$6.50	\$6.60

Source: CMS announces 2013 payment and policy updates for Medicare drug and health plans to ensure choice and improve quality. www.cms.gov/apps/media/fact_sheets.asp

gradually subsidizing to an increasing extent both brand-name and generic drugs for patients in the gap until it is closed.

In November 2010, CMS released a coverage gap tip sheet to help pharmacists answer questions about the discount program (www.cms.gov/partnerships/downloads/11522-P.pdf).

Earlier enrollment

Medicare’s annual Fall Open Enroll-

ment Period started October 15 and ends December 7—the same as last year. During these weeks, people with Medicare can change their Medicare health and drug coverage options such as their Part D plan. Pharmacists can remind Medicare patients of the dates and speak with them about which plan covers their particular medications.

Diana Yap

Senior Assistant Editor, *Pharmacy Today*

Hub in brief

Fungal meningitis outbreak: Members of Congress react

U.S. House of Representatives Energy & Commerce Committee Chair, Rep. Fred Upton (R-MI), and senior Democrat of the committee, Rep. Henry Waxman (D-CA), have sent letters to FDA and CDC requesting briefings regarding the fungal meningitis outbreak linked to contaminated spinal steroid injections from the New England Compounding Center (NECC). Several lawmakers cosigned the letter.

Sen. Richard Blumenthal (D-CT) and Rep. Edward Markey (D-MA) each sent letters to the U.S. Department of Justice requesting a criminal investigation into how NECC distributed potentially contaminated spinal steroid injections to patients in 23 states.

Blumenthal also sent a letter to the U.S. Department of Defense, calling on the department to explain details of its contract with NECC.

APhA has been meeting with congressional staff on this issue. The Association will continue to monitor developments related to the outbreak and work with colleague pharmacy organizations. For more information on the outbreak, see page 50.

FDA’s BeSafeRx campaign to educate public about risks of buying meds online

On September 28, FDA announced a national campaign, BeSafeRx—Know Your Online Pharmacy, to raise awareness about the high risk of buying medications from an illegal online drug seller and to help patients buy medications online safely.

Resources for patients and caregivers are available on FDA’s BeSafeRx website (www.fda.gov/BeSafeRx). These resources can help patients know the dangers of buying from sellers posing as pharmacies, identify a fake online pharmacy, and find a safe and legitimate online pharmacy. Such safe and legitimate online pharmacies require a valid prescription from a physician or other health professional, are located in the United States, have a licensed pharmacist available for consultation, and are licensed by the patient’s state board of pharmacy.

Pharmacists can share campaign resources with their patients and consider becoming a campaign supporter. APhA supports the new campaign.

A new FDA survey showed that al-

most one in four Internet users has purchased prescription medication online, according to the FDA news release. The National Association of Boards of Pharmacy reported that less than 3% of online drug sellers meet state and federal laws. Products purchased from these illegal online drug sellers may contain the wrong ingredients; the wrong amount of, or no, active ingredient; or other harmful ingredients.

Signs that a patient may consider buying medications online include patients lacking adequate prescription coverage; lower-income and older patients needing long-term maintenance medications; patients seeking lifestyle medications; patients used to home delivery who have met their coverage limits; and more, according to FDA’s BeSafeRx website.

Health professionals should consider counterfeit or substandard medications as a potential explanation for patients not responding to treatment or experiencing an unexpected adverse effect or new symptoms; discuss risks and benefits of buying medications online; educate patients with BeSafeRx resources; and more, according to the website.

Message from the Dean

Charles D. Peterson, Pharm.D., FASHP
Dean and Professor / College of Pharmacy,
Nursing, and Allied Sciences
NORTH DAKOTA STATE UNIVERSITY

NDSU College of Pharmacy, Nursing, and Allied Sciences

A Message From the Dean

The College hosted a pharmacy national advisory board meeting on October 5th during Homecoming. New members were welcomed to the Board including Mark Hardy, Assistant Executive Director of the North Dakota Board of Pharmacy; Mark Aurit, Owner/Pharmacist of Gateway Health Mart Pharmacy in Bismarck; and Brent Solseng, Marketing Pharmacy Manager of Blue Cross & Blue Shield of North Dakota. Fred Paavola and Gary Boehler were recognized as advisory board emeritus members. Other members of the advisory board include Bob Biberdorf, Vice President Pharmacy, Renal & Transplant Services at Sanford Health in Fargo; Terry Dahl, Vice President of Commercial Manufacturing, Gilead Sciences, Inc., Foster City, CA; Scott Johnson, Director of Pharmacy Procurement, Supervalu, Phoenix, AZ; Jim Normark, (Advisory Board Chair), retired Colonel in United States Air Force, resides in Seeley Lake, MT; MerriKay Oleen-Burkey, retired Director of Health Economics and Outcomes Research for Teva Neuroscience, resides in Leawood, KS; Dawn Pruitt, Pharmacist, ND Pharmacy, Inc. and Pharmacist, Osco Drug, Dickinson, ND; Melissa Rohrich, Specialty Care/ICU Pharmacist VA Health Care System, Fargo, ND; Tina Schlecht, Senior Director of Long Term Care Division and Pharmacy Affairs at NCPA, Alexandria, VA; Wendy Weber, (Advisory Board Vice Chair), Strategic Health Solutions, LLC, Omaha, NE; Tim Weippert, Executive Vice President of Pharmacy Operations, Thrifty White Pharmacy, Maple Grove, MN; Tony Welder, currently owns six pharmacies with varied practices and former President of NCPA, resides in Bismarck, ND; John Wold, retired Vice President Lilly Research, Eli Lilly & Co, resides in Marco Island, FL; and Gayle Ziegler, (Advisory Board Secretary), Pharmacy Coordinator at Sanford Health South University, Fargo, ND. These are the current members of our pharmacy national advisory board.



The Accreditation Council for Pharmacy Education sent a five member Evaluation Team on April 3-5, 2012 to evaluate our pharmacy program for the purposes of continued accreditation. The Evaluation Team report found us compliant with all 30 standards with a few requiring continued monitoring. Recommendations for program improvements were given and included: addressing space needs of the program; strengthening faculty and staff in areas such as experiential program, ambulatory care, pre-pharmacy advising, career planning, and residencies; accelerating implementation of the new curriculum; revising the strategic plan; and enhancing program financial resources. An interim progress report was submitted by the Dean on October 15th to address the program's progress in addressing these areas. cdp

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APhA-ASP Midyear Regional Meetings Held in Fargo, ND!

The APhA-ASP Midyear Regional Meetings (MRMs) are held every fall in each of the eight APhA-ASP regions across the country. The APhA-ASP MRMs are the only meetings in the U.S. designed exclusively for student pharmacists. These meetings offer great networking, professional development, educational programming, and much more! In addition, the APhA-ASP Policy Process begins and Regional Officers are elected.

NDSU College of Pharmacy, Nursing and Allied Sciences hosted the Region V MRM at the Fargo Holiday Inn the weekend of October 19 – 21. The NDSU chapter had 21 students at this meeting. All Region V Pharmacy Schools were represented at the meeting. Dean Charles Peterson opened up the meeting with a hearty welcome and explanation of the ABCs of pharmacy (Association, College and Board) working well together in North Dakota. Mike Schwab, Executive Vice President of the ND Pharmacists Association and Dr. Mark Hardy, Assistant Executive Director of the ND Board of Pharmacy also provided greetings and further explained why the ABC's of pharmacy are so important and effective.

Sponsorships were provided from some of the following: NDPhA, NDPSC, NDSU College of Pharmacy, Nursing, and Allied Sciences, Thrifty White Pharmacy, Southpointe Pharmacy, Lexicomp, McKesson, Gavis Pharmaceuticals, Polaroid, and others.





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