

NoDak Pharmacy

Volume 28, No.5 December 2015

TOGETHER WE CAN

ND Annual Pharmacy Convention

April 29-May 1, 2016
Bismarck, ND



Renew your
NDPhA
membership
for
2016!

2015-16 Calendar

DECEMBER

- Dec 6-10** American Society of Health-System Pharmacists
50th Midyear Clinical Meeting and Expo
- Dec 25** Christmas Day

JANUARY

- Jan 1** New Years Day

FEBRUARY

- Feb 7-9** National Association of Chain Drug Stores
Regional Chain Conference
Fort Lauderdale, FL
- Feb 10-14** NCPA Multiple Locations Conference
Hyatt, Fort Myers, FL
- Feb 12-14** Midwest Pharmacy Expo
Des Moines, IA

MARCH

- March 4-7** American Pharmacists Association Annual Meeting and Expo
Baltimore, MD
- March 16-17** RxIMPACT Day on Capitol Hill
Washington, DC

Merry Christmas & Happy New Year from Mike & Lorri at NDPhA



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COLLEGE OF PHARMACY,
NURSING, AND
ALLIED SCIENCES





Howdy everyone,

As I sit here writing this letter, I look out the window to see leaves falling from the trees, frosty mornings and average temperatures dropping. Our weather's about to change. It's inevitable. No different in the pharmacy industry. Change is inevitable. One difference, however, is unlike the weather it will not change back again in the spring. So the way I see it we have two options. We can resist the changes, refuse to evolve with the industry and soon be left in the dust, or we can face the changes, make our voices heard and do our best to stay ahead of the curve. I can't believe how things have evolved just since I have been in practice, and seem to be changing faster and faster all the time. We need to get more and more people involved, and have a say in what direction pharmacy is heading.

On the national level, provider status continues to gain sponsors, Specialty pharmacy continues to be an active topic, and of course star ratings are and will continue to be ever important. I encourage everyone to stay active and make your voices heard. Let our legislators know where you stand on issues that impact you. Get your colleagues and coworkers involved. Encourage those that aren't already to join NDPhA.

It has been a great experience working with fellow board members so passionate about our patients and dedicated to the profession. I know that passion is shared throughout North Dakota. NDPhA has been very proactive and a strong advocate for pharmacy. I believe more and more are taking note of pharmacist's worth and the value of pharmacist patient interaction. We need to continue to show that value, and make sure that we are voicing our concerns. Keep up the great patient care (second to none in my opinion), and lets meet and exceed the expectations and promises made to our patients last November! I hope everyone has a safe and enjoyable holiday season!

Sincerely,

Kyle DeMontigny PharmD RPh
President NDPhA

NDPhA Award Nominations *Criteria*

Fax to: (701) 258-9312 or

Email to: ndpha@nodakpharmacy.net by **MARCH 4, 2016.**

A list of past recipients can be found on our website at www.NodakPharmacy.net. Scoring details for nominations received can also be found on our website listed above. Nominations should be submitted **ALONG WITH BIOGRAPHICAL INFORMATION.**

NDPhA 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: _____

GENERATION RX CHAMPIONS AWARD SPONSORED BY THE CARDINAL HEALTH FOUNDATION

This award was established to recognize a pharmacist for his or her work in prescription drug abuse, which could also include recovery and education.

Nominee: _____ Submitted by: _____

President's Report:

After attending the Fall Conference, as I was driving home from Grand Forks, so many thoughts were swirling around in my mind about the great weekend I had just experienced.

- * Attendance was at an all-time high.
- * It was great to see so many new faces attending and also to have the chance to reconnect with pharmacy technicians from previous conferences.
- * Quality of speakers presenting with a total of 11 continuing education credits offered.
- * Food was delicious and plentiful.
- * The Fall Conference planning committee did an awesome job!

Thank you to everyone who had a hand in planning a successful Fall Conference and to all the attendees for making this event a priority to attend!

The general membership voted to approve the proposed changes to the NAPT (Northland Association of Pharmacy Technicians) Constitution and Bylaws. NAPT is an academy under NDPhA and our executive board will now be structured similar to the NDPhA's board. Our goal is to continue to strengthen the NAPT organization by giving the vice president an extra year of learning before leading the organization.

The proposed wording updates of the Minimum Selection Criteria for award nominations were also approved by the general membership.

Now is the time to start thinking of possible nominations for one of the pharmacy technician awards given out at the Annual Pharmacy Convention. It would be great to let a co-worker know their hard work and dedication to the profession is noticed and worthy of recognition.

NAPT will be sending more information detailing the type of awards, deadlines, and the list of Minimum Selection Criteria when nominating someone for an award in the "Winter Mailing" after the first of the year.

NAPT's **Mission Statement** continues to be:

The primary objectives of the Northland Association of Pharmacy Technicians are to provide leadership, continuing education, and interaction among technicians and other health care providers in all aspects of the profession of pharmacy.

These goals are best achieved through a process that brings technicians together in a positive manner.

The Northland Association of Pharmacy Technicians will consistently strive to meet all of the expectations of those it serves and to promote Pharmacy Technicians as an integral part of the Patient Care team.

NAPT Membership

When a pharmacy technician becomes registered with the ND Board of Pharmacy, you **are** automatically a member of NAPT (Northland Association of Pharmacy Technicians).

Email Address

Remember to update the Board of Pharmacy with any changes to your address, phone numbers, place of employment, and/or your email address.

This may be done online at the North Dakota Board of Pharmacy website, <https://www.nodakpharmacy.com/> or contact their office at 701-328-9535. When information is sent out we want to make sure all pharmacy technicians are receiving the communications.

Questions

If anyone has questions, the NAPT Executive Board contact information may be found in the NoDak Pharmacy and on the NDPhA website, <http://nodakpharmacy.net/wordpress1/about-us/academies/napt/>.

Sharon Kupper

Sharon Kupper, NAPT President



NAPT Board of Directors

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2015 NAPT fall conference was a great two day learning event offering 11 CE; including general, law and patient safety topics. This is the first year that we invited our student population, in attendance were students from NDSCS, Northland and Hibbing. It was exciting to see the next generation of Pharmacy Technicians excited to be a part of this event

Friday, October 23 kicked off at the Hampton Inn, Grand Forks, with an attendance of 104. This year's lineup of speakers for Friday included Dr. Mark Hardy with North Dakota pharmacy updates, Dr. Brendan Joyce with Medicare updates, and Judy Swisher presenting on two topics; first gave insight to current trends for pharmacy and specifically Pharmacy Technicians, her second topic offered information regarding a local project; Third Street Clinic.

Due to high volume of attendance and exceeding the capacity of the Hampton Inn for the Saturday portion, NAPT Fall Conference Planning Committee felt it best to relocate this portion of the event. We thank everyone for your patience and understanding with this move. With an attendance of 134 plus, our new venue was the UND Memorial Ballroom. Our keynote speaker, Chris Jerry, shared his story of his daughter Emily, who was lost to pharmacy error and his advocacy to society to minimize and/or eliminate medication errors. Diane Halvorson had an interactive session on communicating positively with coworkers. Zak Green, from PTCB, presented on the expanding roles with pharmacy technicians. Barb Lacher shared information regarding what accreditation changes mean to Pharmacy Technician programs. What a great morning it was.

NAPT held their general business meeting. The NAPT Executive Board brought a proposed new structure that would replace the immediate past president with a chairperson. A motion was made, seconded and then voted on and passed by the general membership. The board also went over the criteria for the yearly awards. Look for the meeting minutes to be posted on the NDPhA website. It is highly encourage for all Pharmacy Technicians and students to log onto the NDPhA website and read the minutes from the General Business Meeting, as well as keep updated on NAPT by reading the Executive Board Meeting Minutes.

The afternoon concluded with Thomas O'Keefe discussing Palliative Care and Advanced Care Planning. Tim Carlson from the PharmAssist Committee presented on the important role this committee plays for all in the profession of pharmacy. He encourages any Pharmacy Technicians who have an interest in serving on this committee to please reach out to the committee. The final speaker of the day was Sargent Travis Jacobson; his presentation topic was Drugs and Society.

It was a great fall conference! Thanks to all the attendees, speakers, and committee members that worked hard on this. Can't wait to see what next year brings.

Submitted by: Danika Braaten, Fall Conference Committee Chairperson

**Thank you to all participants that
attended the NAPT Conference.
We appreciate all of your support and
hope to see you next year.**

Fax to: (701) 258-9312 or Email to: ndpha@nodakpharmacy.net by **MARCH 4, 2016**

NAPT AWARDS NOMINATIONS CRITERIA

Nominations accepted from:

- North Dakota Registered Pharmacy Technician
- North Dakota Licensed Pharmacist
- Practicing professional in the medical field

The Executive Board of NAPT will choose the recipient from the nominations received.

DISTINGUISHED YOUNG PHARMACY TECHNICIAN SPONSORED BY PHARMACISTS MUTUAL

- The nominee shall be a practicing Pharmacy Technician of less than 10 years.
- The nominee shall be registered as a Pharmacy Technician in North Dakota.
- The nominee displays passion to the Pharmacy Technician profession and strives for excellence in the Profession of Pharmacy.
- The nominee exemplifies work ethic in the Profession of Pharmacy.

Nominee: _____ Submitted by: _____

DIAMOND AWARD SPONSORED BY THRIFTY WHITE PHARMACY

- The nominee shall be registered as a Pharmacy Technician in North Dakota.
- The nominee must be living, awards are not made posthumously.
- The nominee has not been a previous recipient of the award.
- The nominee is not currently serving as an officer of NAPT.
- The nominee has compiled an outstanding record of community and pharmacy service.

Nominee: _____ Submitted by: _____

FRIEND OF NAPT SPONSORED BY NAPT

- The nominee has not been a previous recipient of the award.
- The nominee has been an advocate of NAPT and the Profession of Pharmacy Technicians.
- The nominee can be a person (s) working in the Profession of Pharmacy; a person, group, or organization.

Nominee: _____ Submitted by: _____

Note: Nominations are only accepted from ND Registered Pharmacy Technicians. Winners are chosen by past recipients of the award.

PHARMACY TECHNICIAN OF THE YEAR AWARD SPONSORED BY DAKOTA DRUG

- The nominee shall be a Registered Pharmacy Technician in North Dakota.
- The nominee exemplifies the work ethic in the Profession of Pharmacy.
- The nominee has not been a past recipient of the award.
- The nominee demonstrates the key elements of the Pharmacy Technician Profession and demonstrates an outstanding record of pharmacy service.

Nominee: _____ Submitted by: _____

NDSHP Award Nominations *Criteria*

Fax to: (701) 234-7137 or Email to: amber.olek@gmail.com by **MARCH 15, 2016**.

NDSHP AWARDS NOMINATIONS CRITERIA

NORTH DAKOTA HEALTH-SYSTEM PHARMACIST OF THE YEAR

Established in 1998, this award is given annually to an individual of high moral character, good citizenship, and elevated professional ideals. The recipient has made significant contributions to health-system pharmacy, including sustained exemplary service, an outstanding single achievement, or a combination of accomplishments benefiting the profession and public health. These may include achievements or outstanding performance that relate to health-system pharmacy: Practice, education, or administration; Research or development; Organizational activities; Scientific or professional writing; Journalism; Public and/or inter-professional relations activities; or Law, legislation, regulation, or standards of professional conduct.

Nominee: _____ Submitted by: _____

NDSHP BEST PRACTICES AWARD

This award has recognized outstanding practitioners in health-system pharmacy who have successfully implemented innovative systems that demonstrate best practices in health-system pharmacy. Eligibility: Applicants must be practicing in a health-system setting, such as an ambulatory care clinic, chronic care, home health care, inpatient care, or outpatient pharmacy. More than one successful program from a health system may be submitted for consideration. Applicants will be judged based on the following criteria: Originality and innovative nature of the program, Significance of the program to the health system, Demonstration of improvements, Significance of the program to pharmacy practice advancement, and Quality of the descriptive report.

Nominee: _____ Submitted by: _____

AWARD OF EXCELLENCE IN MEDICATION USE SAFETY

May be conferred annually to an individual or group of individuals in recognition of a specific recent contribution or achievement that has advanced the ability of hospital and health-system pharmacists in North Dakota to serve the needs of patients through improved medication safety processes. Pharmacists and nonpharmacists are eligible. The award is intended to recognize an individual or group of individuals for a recent singular, significant achievement or contribution rather than for career-long contributions. Include the following information when submitting your nomination: Professional position of the nominee (or individuals in a group) at the time of the contribution or achievement; Current professional position of the nominee or individuals in a group; Summary of the contribution or achievement; Brief statement about how the contribution or achievement advanced the ability of hospital and health-system pharmacists to serve the needs of patients, and Brief statement about why the contribution or achievement is of significance.

Nominee: _____ Submitted by: _____

PHARMACY PRACTICE LITERATURE AWARD

The Pharmacy Practice Literature Award recognizes an outstanding original contribution to the peer-reviewed biomedical literature related to pharmacy practice in hospitals and health-systems. The award is given annually to the author(s) of an important contribution of original research relevant to health-system pharmacy practice published during the calendar year preceding the state convention. Eligibility: The article submitted for the Pharmacy Practice Literature Award must have been published in a PubMed-indexed, peer-reviewed biomedical journal in the last calendar year. This article will be included in the nomination. For this award, the applicant must be a pharmacist. The applicant must be either the first or second author listed on the nominated article. To be eligible for this award, the applicant must have participated in each of the following: Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; Drafting the article or revising it critically for important intellectual content; and Final approval of the version to be published.

Nominee: _____ Submitted by: _____

What Do I Need for *Electronic Prescribing* of Controlled Substances?

Mikayla Fick, 2016 Pharm.D. Candidate and Mark Hardy, Executive Director

The Drug Enforcement Agency (DEA) issued a rule change in 2010 allowing for electronic prescribing of controlled substances.¹ North Dakota Administrative Code (NDAC) also allows for computer transmission of all prescriptions, including controlled substances in schedules II-V.² However, both require specific electronic signatures. These electronic signatures are obtained by the prescriber via application to the DEA. But that is not the only requirement for receiving and dispensing the controlled prescriptions. Pharmacies also have a responsibility to make sure their software is capable of monitoring the prescription, any changes made to it, and the verification of the prescriber's signature. All of this can be done by a third-party provider who will also perform annual audits of authorized prescribers to ensure that only those granted access to the system are doing so.³ Thus, it is a process to be sure that all the appropriate bases are covered before allowing transmission of controlled substance prescriptions.

The prescriber will be using two-factor authentication. This is similar to an ATM machine's requirements. The individual trying to use the ATM needs to know an identification number and have a bank card in order to access any information.⁴ The same will be true for transmitting a controlled substance prescription. This is to create a more secure network and avoid unauthorized individuals from accessing the system. The thought is, since there is no handwriting or verbal communication that may help identify if an imposter is present, this would help deter diversion instead.⁴ To obtain both factors of the authentication, there is a process involving a credential service provider or a certification authority that meets specific requirements.³

After prescribers obtain authorization to send controlled substances via electronic prescription, the third-party provider audits them. The audit on authorized prescribers must be conducted annually by a qualified individual.⁵ In this case, a qualified individual is one who would also be qualified to conduct specific audits such as SysTrust, WebTrust, or SAS 70 audit. This requirement may slow the process as they obtain these accreditations if they don't already have them. The third-party providers also look at the software of each pharmacy to make sure they meet all the requirements set forth to properly import, store, and display the information as well as verify prescribers.³ Both of these are major steps and take time to process.

While the third-party provider is doing most of the work for the pharmacy to ensure that their software is capable and up to date, the pharmacy may help to set controls to limit access to prescription information so that it cannot be changed.³ After electronic prescriptions for controlled substances are capable of being received, a pharmacy still maintains all the same responsibilities required of written or oral controlled substance prescriptions. This includes making sure all information is present on the prescription and the medication is appropriate for the patient.⁵

Being able to utilize electronic prescribing for controlled substances is a process. There are many factors involved to ensure that the appropriate people have access to the system and that pharmacies have the ability to verify this information. A lot of the process relies on the individual prescriber and the third-party providers. However, pharmacies will still ultimately hold the key to insuring the right medication is reaching the right patient.

Currently, there are a few prescribers and pharmacies authorized to transmit and receive electronic controlled substance prescriptions in North Dakota. We envision many more being approved in the next year, which has prompted many questions to our office. As always, it is important to verify the integrity of a controlled substance prescription with the prescriber should there be any questions or concerns.

Should you have any questions, feel free to contact the North Dakota Board of Pharmacy office. 701-328-9535

References

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4. Drug Enforcement Administration. 21 CFR Parts 1300, 1304, 1306, and 1311: Electronic Prescriptions for Controlled Substances; Final Rule. Federal Register: Part II. 2010 March 31;75(61):16235-16319.
5. Rannazzisi JT. 21 CFR Parts 1300, 1304, 1306, and 1311 [Docket No. DEA-360]: Electronic Prescriptions for Controlled Substances Clarification. Office of Diversion Control; 2011 October 7;1-10.



North Dakota pharmacies need to have a continuous quality improvement (CQI) program to adhere to newly implemented state, third party contract and Medicare Part D requirements (if your state has a law, feel free to add to/edit).

As a North Dakota pharmacy, you are provided a discount to an enhanced CQI program - the Pharmacy Quality Commitment™ (PQC) program. This program will not only assist you in meeting your QA/CQI contractual obligations, but will also help you improve your pharmacy workflow and operations.

The PQC program provides:

- Step-by-step map to get you started
- Online manual with best practices and suggested workflow guidelines
- QA Policies and Procedures
- Patient Safety Evaluation System
- Workflow Station Checklist
- Best Practice Cards
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- PSO protection for patient safety and incident reporting
- Quarterly Newsletters with tips and recommendations
- Continuing education and learning seminars



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Questions? Call PQC's customer service at 866-365-7472 for more information or call the NDPhA office at 701-258-4968.

**"I'M ALWAYS
WATCHING OUT
FOR MY PATIENTS,
BUT WHO'S
WATCHING OUT
FOR ME?"**



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CLIA Waived Testing in the *Pharmacy Setting*

Jennelle Holt, 2016 Pharm.D. Candidate and Mark Hardy, Executive Director

Currently in the U.S. there are 10,643 pharmacies that hold a Clinical Laboratory Improvement Amendment (CLIA) certificate, and in North Dakota there are 499 facilities (which includes pharmacies) that hold a CLIA waived certificate type.^{1,2} Waived tests, as defined by CLIA, are “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”³ Many changes are being made to the CLIA waived laboratory tests section of the North Dakota Board of Pharmacy’s Laws and Rules. This will contain a list of tests and methods including those that are exempt from the provisions of the Clinical Laboratory Personnel section of the North Dakota Century Code (chapter 43-48).

In order to start performing CLIA waived tests in your pharmacy, there are several steps that need to be followed. First, you must understand the education requirements. The pharmacist(s) that will be performing the tests must successfully complete training and education related to infection control, Occupational Safety and Health Administration (OSHA) requirements, proper technique to collect laboratory specimens, recognizing screening and monitoring values, and quality control. The pharmacist(s) must also understand the manufacturer’s instructions on each waived test that will be performed.⁴ It is vital that the pharmacist be proficient in screening for the necessity of a test, evaluating results, and determining if further action needs to be taken.⁵ Next, the pharmacist-in-charge must develop a policy and procedure manual related to quality control, infection control, hazardous waste disposal, recordkeeping, and test result reporting.⁴

Finally, you must obtain a CLIA certificate of waiver. This is done by enrolling your laboratory (A.K.A. the pharmacy location where you will be performing the tests) in the CLIA program by completing the application located at www.cms.hhs.gov/clia and sending it to the specified State Agency. This certificate must be renewed every 2 years. If you have multiple pharmacies that will be performing tests, you will need to obtain a CLIA certificate of waiver for each location.³ The pharmacist-in-charge must also notify the ND Board of Pharmacy before an initial performance of any CLIA waived tests.⁵

The next question – “what can I do with the test results?” Depending on the type of test, the action will be very different. If a test, such as cholesterol or blood glucose, is performed which doesn’t require immediate medication, you may choose to simply send a copy of the results with the patient and a copy to their primary care provider. However, if a test, such as rapid Streptococcus group A, is performed which may require immediate medication you may choose to look into entering a collaborative practice agreement. Per a collaborative agreement, it might be outlined as to what action should be taken in the case of each test result in which the pharmacist may be able to prescribe medication if needed or send the patient on for further testing. The pharmacist-in-charge should also have a plan in place as to how and when they will follow up with the patient and a plan for sharing the results with the patient’s primary care provider.

The key here is to have access to the patient’s health records. It is a crucial part of performing CLIA waived tests and being in a collaborative agreement. There are several programs being developed for this access to become available, including the North Dakota Health Information Network.⁶ This allows for doctors, nurses, pharmacists, and other healthcare professionals to electronically exchange a patient’s health records. The Board encourages you to collaborate with the members of the health care community to engage in how using the enhanced opportunities in collaborative agreements and CLIA waived tests could be utilized to better and more efficiently take care of your patients.

There are still many other barriers including reimbursement, practitioner acceptance, adequate space and privacy, and workflow changes within the pharmacy.^{7,8} These are all barriers that can be overcome, but it will take time and dedication. By performing a variety of CLIA waived tests in the pharmacy setting, it may increase accessibility to care, decrease the cost, and maintain a standard of quality care for patients.

To view the modifications made to the CLIA waived laboratory tests section of the North Dakota Board of Pharmacy’s Law and Rules, visit the North Dakota Board of Pharmacy website at www.nodakpharmacy.com. The proposed changes to the ND Rules will likely be effective in early 2016.

References:

1. Centers for Medicare & Medicaid Services CLIA Database. Laboratories by Type of Facility. Division of Laboratory Services; 2015.
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FDA Moves Quickly on Narcan Nasal Spray

Today the U.S. Food and Drug Administration approved Narcan nasal spray, the first FDA-approved nasal spray version of naloxone hydrochloride, a life-saving medication that can stop or reverse the effects of an opioid overdose. Opioids are a class of drugs that include prescription medications such as oxycodone, hydrocodone, and morphine, as well as the illegal drug heroin.

Drug overdose deaths, driven largely by prescription drug overdoses, are now the leading cause of injury death in the United States – surpassing motor vehicle crashes. In 2013, the Centers for Disease Control and Prevention reported the number of drug overdose deaths had steadily increased for more than a decade. When someone overdoses on an opioid, it can be difficult to awaken the person, and breathing may become shallow or stop – leading to death if there is no medical intervention. If naloxone is administered quickly, it can counter the overdose effects, usually within two minutes.

“Combating the opioid abuse epidemic is a top priority for the FDA,” said Stephen Ostroff, M.D., acting commissioner, Food and Drug Administration. “We cannot stand by while Americans are dying. While naloxone will not solve the underlying problems of the opioid epidemic, we are speeding to review new formulations that will ultimately save lives that might otherwise be lost to drug addiction and overdose.”

Until this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector. Many first responders and primary caregivers, however, feel a nasal spray formulation of naloxone is easier to deliver, and eliminates the risk of a contaminated needle stick. As a result, there has been widespread use of unapproved naloxone kits that combine an injectable formulation of naloxone with an atomizer that can deliver naloxone nasally. Now, people have access to an FDA-approved product for which the drug and its delivery device have met the FDA’s high standards for safety, efficacy and quality.

Narcan nasal spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, and can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan nasal spray should seek further immediate medical attention on the patient’s behalf.

The FDA granted fast-track designation and priority review for Narcan nasal spray. Fast track is a process designed to facilitate development and expedite review of drugs intended to treat serious conditions and that demonstrate the potential to address an unmet medical need. The agency’s priority review program provides for an expedited review of drugs that offer a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. Narcan nasal spray is being approved in less than four months, significantly ahead of the product’s prescription drug user fee goal date of January 20, 2016.

In clinical trials conducted to support the approval of Narcan nasal spray, administering the drug in one nostril delivered approximately the same levels or higher of naloxone as a single dose of an FDA-approved naloxone intramuscular injection, and achieved these levels in approximately the same time frame.

“We heard the public call for this new route of administration, and we are happy to have been able to move so quickly on a product we are confident will deliver consistently adequate levels of the medication – a critical attribute for this emergency life-saving drug,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research.

The National Institute on Drug Abuse played a critical role in the development of Narcan nasal spray as well, forming a public-private partnership by designing and conducting the clinical trials required to determine that the intranasal formulation delivered naloxone as quickly and as effectively as an injection. NIDA then worked with its private sector partners to obtain FDA approval.

“This easy-to-use intranasal formulation will no doubt save many lives,” said Nora Volkow, M.D., director, National Institute on Drug Abuse at the National Institutes of Health. “While prevention is the ultimate goal, the drug’s successful development illustrates how public/private scientific partnerships can play an important role in responding to a national crisis right now.”

Increasing access to and the use of naloxone is part of the targeted strategy that Health and Human Services Secretary Sylvia M. Burwell put forward in March to address the opioid epidemic and save lives. In July, addiction and advocacy groups called for expanded availability of naloxone during an FDA-sponsored public workshop exploring the uptake and use of the drug.

The use of Narcan nasal spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

Narcan nasal spray is distributed by Adapt Pharma, Inc., of Radnor, Pennsylvania.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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The regional Heartland Pharmacists Recovery Network conference is at Expo. If you have ever been interested in PRN, attend a session or the entire track.



The largest technician CPE conference in Iowa is now part of Expo! It's the same one-day conference, but now includes Expo's additional programming, exhibits and networking opportunities.

www.MidwestPharmacyExpo.com



2016 Midwest Pharmacy Expo: *Learn, Connect & Be Inspired*

The 2016 Midwest Pharmacy Expo is beginning to take shape and we are excited to share what we have in store for this year! In addition to the high quality continuing education and uniquely Midwestern experience you've always enjoyed, the 2016 Expo will be enhanced with additional programming this year:

BPS Track - Expo has partnered with ASHP to host their Pharmacotherapy Intensive Studies Package which features three, 2-hour intensive sessions for board certified pharmacists to earn recertification credit (BCPS, BCACP). CPE credit will also be available for non-certified pharmacists who are interested in attending. This is a unique partnership to bring BPS programming to a state-based regional meeting!

Heartland PRN - The regional Heartland Pharmacists Recovery Network conference will take place at this year's Expo. If you have ever been interested in PRN, attend a session or the entire track.

Tech Forum - The largest technician CPE conference in Iowa is now part of the Midwest Pharmacy Expo! It's the same one-day conference, but now technicians can enjoy the Expo's keynotes, Sunday programming, exhibits and networking opportunities.

With these additions, the Midwest Pharmacy Expo now offers more unique educational opportunities and a more diverse gathering of peers from across the Midwest to connect with and network.

We will be sharing more information about keynotes, breakout sessions and other agenda items in the coming weeks, but in the meantime **mark your calendars for the 2016 Midwest Pharmacy Expo on February 12-14, 2016** in Des Moines!

The Midwest Pharmacy Expo is a collaborative partnership between 8 state Pharmacy Associations.

Please call the NDPhA office with any questions at 701-258-4968. Hopefully see you in Iowa!



November 12, 2015

ACROSS THE COUNTRY

On the plains of North Dakota, it is well known the amount of hard work and dedication it takes to harvest crops on frozen, unrelenting soil. Looking back at this past year, it is clear that North Dakota pharmacists not only know a thing or two about medication management, but also about sowing the seeds for future pharmacy practice.

Pharmacy practice in North Dakota has always had a unique presence in the country. The Pharmacy Ownership Law in North Dakota states that a pharmacy must be 51% owned by a pharmacist or group of pharmacists. This unique practice climate has thrust North Dakota pharmacy into the legislative spotlight numerous times. It is no surprise that during this past year, the profession has made great strides in implementing progressive laws.

Collaborative practice

North Dakota has had legislation supportive of collaborative practice agreements for pharmacists for almost 20 years. This past year, the state has made innovative steps to expand pharmacists' role in patient care. A new bill allows pharmacists to enter into collaborative practice agreements with either nurse practitioners or physicians. The bill eliminates the institutional setting requirement and allows pharmacists to practice with collaborative practice agreements regardless of their setting as long as they have access to the medical records of the patient.

This bill sets the groundwork for North Dakota pharmacists to initiate patient assessments and administer point-of-care testing.

Provider status

Pharmacist provider status language is being integrated into multiple state bills thanks to strenuous efforts of pharmacy supporters such as the North Dakota Pharmacists Association (NDPhA). Three bills in particular specifically list pharmacists as health care providers.

The first bill grants pharmacists, as health care providers, limited authority to prescribe, distribute, and dispense naloxone rescue kits for opioid drug overdoses. The second names pharmacists as health care providers for services provided under North Dakota worker's compensation. The third, which involves the creation of a medication therapy management (MTM) program for Medicaid-eligible patients, specifically names pharmacists as providers entitled for reimbursement for their in-person or telephone MTM services.

All three members of North Dakota's representatives on Capitol Hill have signed on to their respective national provider status bills.

Point-of-care testing

There has been a big push for the expansion of point-of-care testing for pharmacies within North Dakota. The state has allowed pharmacies more opportunities to provide these tests by removing previous language from legislation. These tests, waived under the Clinical Laboratory Improvement Amendments, provide an excellent opportunity for North Dakota community pharmacies to expand their patient care services while improving health at both the patient and population level.

Pharmacists are often the most accessible health professional in rural North Dakota communities. Considering the fact that the majority of the state is a rural environment, imagine how convenient it would be for a farmer to be screened and diagnosed for influenza instead of having to drive 1 hour to see the closest available physician. Point-of-care testing is

also a great opportunity for North Dakota pharmacists to use collaborative practice agreements. That same farmer may now receive Tamiflu on the spot because of the new North Dakota legislation for collaborative practice agreements.

The ABCs

The strong relationship between the three main practice-influencing bodies in North Dakota is the main driver for advancing the profession. We call these bodies the "ABCs of Pharmacy"—the Association, the Board, and the College. They work together to promote the progression of pharmacy practice and continue to expand the role of pharmacists in health care.

It is evident by the NDPhA vision that provider status continues to be a priority in our state. "We envision a profession that is recognized as a primary health care provider capable of responding to society's health care needs," according to the vision statement on NDPhA's website.

The Board of Pharmacy is in place to impact patient care in a positive way; they provide support to pharmacists who continually improve the care they provide to the community they serve.

Finally, student pharmacists, the seeds still yet growing, are developing a passion to promote the progression of profession. Recently, our APhA-ASP Chapter brought more than 25 student pharmacists to Bismarck to educate local legislators on pharmacy issues.

From the ABCs and beyond, pharmacists in North Dakota are united in our commitment to the mutual goal of growing pharmacy practice into a prosperous field.

Cynthia Cherucheril and **Sarah Schmidt** are third-year PharmD candidates at the North Dakota State University School of Pharmacy.



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NEWS RELEASE



FOR IMMEDIATE RELEASE
October 9, 2015

CONTACT: David Shaman
202.223.7183; dshaman@aphanet.org

Majority of U.S. House Supports Value of Pharmacists to Patients

WASHINGTON, DC – APhA is thrilled to announce that this week, The Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S. 314) reached an important milestone in the U.S. House of Representatives, having a majority of members support the legislation. The legislation, introduced earlier this year by Representatives Brett Guthrie (R-KY), G.K. Butterfield (D-NC), Todd Young (R-IN), and Ron Kind (D-WI), enables seniors in medically underserved communities to access those pharmacists' patient care services which are allowed by state scope of practice laws through Medicare Part B coverage. The companion bill in the U.S. Senate (S. 314), introduced by Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), Robert Casey (D-PA), and Mark Kirk (R-IL), has 31 co-sponsors.

With 219 of the 435 House of Representatives' members signed on as sponsors and co-sponsors to the bill, APhA looks forward to the opportunity to work with Congress to help millions of medically underserved Medicare beneficiaries access health care through pharmacist-provided services. "This is a crucial moment in the public debate on how to improve health care access and how to reduce America's health care costs," said APhA Executive Vice President and CEO, Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA. "National surveys show Americans believe pharmacists are integral members of their health care team. Now, the majority of the U.S. House has stated that they agree."

The bill seeks to increase access and improve quality by enabling pharmacists to provide patient care services consistent with their education, training and license. Menighan noted pharmacists today are providing a broad spectrum of services, including managing chronic diseases, performing medication management, administering immunizations, conducting health and wellness testing, and working in and partnering with hospitals and health systems to advance health and wellness and helping to reduce hospital re-admissions.

The bill's proponents note millions of Americans lack adequate access to primary health care and this is only expected to get worse as demand increases. Over the next 15 years, the number of Medicare enrollees will likely increase from roughly 55 million to over 80 million. In addition, millions of individuals are gaining health coverage under the Patient Protection and Affordable Care Act (PPACA).

"There is need for improving access to health care and for most Americans, pharmacists are already on the front lines of their health care," Menighan said. "The primary goal of the bill is to expand access for those seniors in medically underserved communities and our Nation's 300,000 pharmacists stand ready to help."

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About the American Pharmacists Association

The American Pharmacists Association, founded in 1852 as the American Pharmaceutical Association, is a 501 (c)(6) organization, representing more than 62,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States. For more information, please visit www.pharmacist.com.

About Pharmacists Provide Care Campaign

The Pharmacists Provide Care Campaign is dedicated to promoting patient access to health care through pharmacists' patient care services. The national campaign provides information on the value pharmacists provide to patients and the health care system. Pharmacists are highly educated and trained health care providers and as a member of the patient's health care team positively affect quality, outcomes and cost. For more information, please visit www.PharmacistsProvideCare.com.

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