Pharmacy Examining Board Regulatory Digest

A Publication of the Wisconsin Pharmacy Examining Board 2015; Volume 1

Chair's Corner

***By** Thad Schumacher, PharmD.*

In the profession of pharmacy we have become accustomed to change. Every January, retail pharmacists and their staff work through issues of Medicare Part D plan changes. It seems like every day pharmacists in every practice setting conquer formulary changes to take care of their patients. That is what our profession is about, taking care of patients and creating positive outcomes. I have said many times since moving to Wisconsin several years ago and practicing in four other states that there is no other state where pharmacists are as progressive and ready for change as the current and future pharmacists of Wisconsin.

For the past year, your Pharmacy Examining Board has been hard at work. We have worked through the challenges of implementing the Prescription Drug Monitoring Program. Already we have rewritten several rules to address unforeseen issues that have arisen. This would not have been possible without the hard work and dedication of Chad Zadrazil, PDMP Project Manager and Andrea Magermans, PDMP Program Analyst. I am proud to say that, as of the writing of this message, 10,421 providers have registered for PDMP access and 82,134 PDMP inquiries are made on a monthly basis. The PDMP will not only help quantify the dispensing of controlled substances in Wisconsin, but can be used in the provider's office or at the pharmacy to thwart early refills, doctor shopping, and fraudulent prescriptions. I am proud that the Wisconsin PDMP and the following states are sharing PDMP data: Arizona, Colorado, Kansas, Illinois, Indiana, Michigan, Minnesota, New Mexico, North Dakota, South Dakota, South Carolina and West Virginia. In the upcoming months, we will be adding Iowa, Idaho, Nevada and Utah to the list of states sharing data with Wisconsin.

With the prescription drug abuse epidemic that we are faced with here in Wisconsin and nationally, the Board was involved in many additional initiatives to curb abuse. We testified during the hearing for the Heroin, Opiate Prevention and Education (HOPE) legislation that was passed last April that has multiple provisions that touch pharmacy, which will be discussed later in this regulatory update.

Additionally, there have been many changes to the existing rules. Links to the updated rules can be found on the Pharmacy Examining Board website at http://dsps.wi.gov/Boards-Councils/Board-Pages/Pharmacy-Examining-Board-Main-Page/

The PEB also started one of our biggest challenges in recent months, the decision to perform total rewrites of both Chapters 7 Pharmacy Practice and 15 Sterile Pharmaceuticals. In light of the tragedies that took place with the New England Compounding Center Pharmacy's sterile compounds and the movement of the Federal Government on compounding, we thought it prudent to update and clarify our rules regarding compounding. At the same time over the years the Board has developed a list of changes that need to be made to update or clarify pharmacy practice. It was decided that a full revision would be the most efficient way to proceed. It is our intent to produce a set of rules that allows the free flow of ideas and practice while setting boundaries that will protect the citizens of Wisconsin. There is no better time to engage your Board of pharmacy than now. All of our rule meetings are open to the public, and those that have attended meetings thus far have had the opportunity to speak directly to the Board's rule writing committee, often seeing their ideas incorporated into draft rules language. The Board continues to look forward to working with the stakeholders involved in the process.

These are just a few of the things that the Board has been actively pursuing. Change is something we spend a lot of our time and effort on in pharmacy. We tirelessly work with patients to improve their medication adherence. We communicate recommendations to providers in an effort to change therapy to a more appropriate or cost effective treatment. Now the Board has opened up the rules for practice and you have the opportunity to change the profession. What will you do?

Inside this Issue:

Heroin, Opiate Prevention and Education

On April 7th, 2014, Governor Scott Walker signed into law the Heroin, Opiate Prevention and Education (HOPE) legislative package.

2013 Wisconsin Act 194 provides immunity from criminal prosecution for both the possession of drug paraphernalia and possession of a controlled substance, or controlled substance analog, under the circumstances surrounding or leading to his or her commission of acting as an "aider." A person may be considered an "aider" if both of the following apply:

- The other person is, or the person believes him or her to be, suffering from an overdose of, or other adverse reaction to, any controlled substance or controlled substance analog.
- The person did any of the following:
  - Brings another person to an emergency room, hospital, fire station, or other health care facility.
  - Summons a law enforcement officer, ambulance, emergency medical technician, or other health care provider, to assist another person.
  - Dials the telephone number "911" or, in an area in which "911" is not available, the number for an emergency medical service provider, to obtain assistance for another person.

2013 Wisconsin Act 195 requires the Department of Health Services (DHS) to create two or three new regional comprehensive opioid treatment programs to provide treatment for opiate addiction in rural and underserved, high-needs areas. Programs created under the Act may not offer methadone treatment. The Act also requires DHS to obtain and review proposals for opioid treatment programs in accordance with its request-for-proposal procedures.

An opioid treatment program created under the Act must do all of the following:

- Offer an assessment to individuals in need of service to determine what type of treatment is needed.
- Transition individuals to a licensed residential program, if that level of treatment is necessary.
- Provide counseling, medication-assisted treatment, including both of the following:
  - Long-acting opioid antagonist and partial agonist medications that have been approved by the federal Food and Drug Administration.
  - Abstinence-based treatment.
- Transition individuals who have completed treatment to county-based or private post-treatment care.

DHS must submit a progress report on the outcomes of the opioid treatment programs created under the Act to the Joint Committee on Finance (JCF) and to the appropriate standing committees of the Legislature. DHS must submit a progress report by April 1, 2106, and then annually thereafter.

2013 Wisconsin Act 199 creates several requirements applicable to the dispensing of Schedule II and III drugs.

Identification Card

The Act specifies that a Schedule II or III drug generally may not be dispensed or delivered without an identification card belonging to the person to whom it is dispensed or delivered. The pharmacist or other person dispensing or delivering a Schedule II or III drug must record the name on the identification card and maintain the record of that name for as long as is required by administrative rules promulgated by the Pharmacy Examining Board (Board), or until it is submitted to the Board through the Prescription Drug Monitoring Program, as described below, whichever is sooner. The types of identification card that are acceptable are the following: A Wisconsin motor vehicle operator's license.

- A Wisconsin state identification card issued by the Department of Transportation.
- An identification card issued by a U.S. uniformed service.
- A U.S. passport.
- A motor vehicle operator's license or a state identification card issued by another state.
- A foreign passport.

An identification card is not required under any of the following circumstances:

- When a health care practitioner administers or dispenses a drug directly to a patient for administration.
- If the pharmacist or other person dispensing or delivering a Schedule II or III drug has personal knowledge of the person to whom the drug is dispensed or delivered and knows that the person is the ultimate user or the ultimate user's authorized representative. However, the pharmacist or other person must record the name of the person and report it to the Board and the PDMP to the same extent that the name on an identification card must be reported.
- When a drug is delivered to a health care facility, if the drug is to be administered in the health care facility. The types of facilities included in this exemption are the following:
  - Hospital.
  - Nursing home.
  - Community-based residential facility.
  - Continuing care facility.
  - Mental health institution.
  - County home.
  - County infirmary.
  - County hospital.
  - County mental health complex.

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Do You Know What a Doctor Shopper Looks Like?

Americans abuse prescription drugs more than cocaine, heroin, and hallucinogens combined. The "Red Flags" video helps pharmacists identify the warning signs of prescription drug abuse and diversion.

https://m.youtube.com/watch?feature=youtu.be&v=WY9BDgcdxaM

- Veterans home.
- Center for the developmentally disabled.
- Local health department dispensary.
- Adult family homes.
- Residential care apartment complexes.

Delivery to a Person Other Than the Ultimate User

A Schedule II or III drug may be delivered to a representative of the ultimate user if the representative has an identification card as described above. In this circumstance, the person delivering the drug may, but is not required to, ask the ultimate user to designate a person who is authorized to pick up the drug on their behalf. The pharmacist may inform the person picking up the drug that his or her identification is being recorded.

Pharmacist Immunity for Sales Made in Good Faith

A pharmacist is immune from any civil or criminal liability and from professional discipline for any act he or she takes in reliance on an identification card that he or she reasonably believed was authentic and displayed the name of the person to whom the drug was being delivered, if the sale was made in good faith.

PDMP Reporting Requirements

The Act requires the name on an identification card that is presented when a Schedule II or III drug is dispensed to be reported to the Board through the PDMP.

However, this reporting requirement does not go into effect until April 9, 2016. The Board may delay the reporting requirement beyond that date after consultation with representatives of licensed pharmacists and pharmacies, subject to the approval of the Secretary of the Department of Safety and Professional Services.

Current law specifies that the Board's administrative rules governing the PDMP must identify the specific data elements to be contained in a PDMP report. The Act provides the method of payment is one of the data elements to be identified.

2013 Wisconsin Act 200 contains various provisions related to the training and agreements for administering an opioid antagonist drug; the authority of first responders and all emergency medical technicians (EMTs) to administer an opioid antagonist; the authority to prescribe and dispense an opioid antagonist; and immunity for certain individuals who administer an opioid antagonist. Under the Act, an "opioid antagonist" is defined to mean a drug, such as naloxone, that satisfies all of the following:

- The drug binds to the opioid receptors and competes with or displaces opioid agonists at the opioid receptor site but does not activate the receptors, effectively blocking the receptor and preventing or reversing the effect of an opioid agonist.
- The drug is not a controlled substance.

The Act provides that any person may possess an opioid antagonist and may deliver or dispense an opioid antagonist except that a licensed physician, licensed physician assistant, or advanced practice nurse who is certified to issue prescription orders (APRN), or licensed pharmacist may only dispense or deliver in accordance with his or her other legal authority to dispense prescription drugs, as described below.

Administration of an Opioid Antagonist by First Responders, EMTs, Law Enforcement, and Fire Fighters

The Act authorizes a certified first responder to administer a naloxone, or another opioid antagonist, if he or she has received training necessary to safely administer it, as determined by the Department of Health Services (DHS).

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Prescription Delivery

On November 1st, 2013, Clearinghouse Rule (CR) 13-018 and associated changes to Phar 7.01(1)(e) became effective allowing for delivery of a prescription(s) to a location of the patient's choice. Specifically, the revisions state to *give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a location of the patient's choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a location of the patient's choice, is not satisfied by only offering to provide consultation.*

To view a copy of the updated administrative rule, click here Phar 7.

DEA Drug Disposal Final Rule

On September 9th, 2014 the U.S. Drug Enforcement Administration's (DEA) Final Rule for the Disposal of Controlled Substances, which implements the Secure and Responsible Drug Disposal Act of 2010 (The Disposal Act), was published in the Federal Register, effective October 9th, 2014. Additional information can be found on the DEA website http://www.deadiversion.usdoj.gov/drug_disposal/ and in a DEA press release http://www.dea.gov/divisions/hq/2014/hq090814.shtml.

DEA Classifies Tramadol a Controlled Substance

Please see article from NABP for additional details. https://www.nabp.net/news/dea-classifies-tramadol-a-controlled-substance

DEA Reschedules Hydrocodone Combination Products as Schedule II

Please see article from NABP for additional details. https://www.nabp.net/news/dea-reschedules-hydrocodone-combination-products-as-schedule-ii

DHS must also permit EMTs, at all levels of training, to administer naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose. DHS must also require EMTs to undergo any training necessary to safely and properly administer naloxone or another opioid antagonist. Every ambulance service provider is required by the Act to do all of the following:

- Ensure that every EMT under the ambulance service provider's supervision who has obtained the training necessary to safely and properly administer naloxone or another opioid antagonist has a supply of naloxone or other opioid antagonist available for administration when he or she is performing his or her duties as an EMT, to the extent that naloxone or the other opioid antagonist is available to the ambulance service provider.
- Require each certified first responder and EMT under its supervision to, in the manner prescribed by DHS, keep a record of each instance in which he or she administers naloxone or another opioid antagonist.
- Submit the records described above to DHS in a manner prescribed by DHS.

The Act also authorizes a law enforcement agency or fire department to enter into a written agreement to affiliate with an ambulance service provider or a physician for all of the following purposes:

- Obtaining a supply of naloxone or another opioid antagonist.
- Allowing law enforcement officers and fire fighters to obtain the training necessary to safely and properly administer naloxone to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose.

Prescriptions for an Opioid Antagonist

The Act provides that a prescription order for a prescription opioid antagonist need not specify the name and address of the individual to whom the opioid antagonist will be administered. Instead, it must specify the name of the person to whom the drug will be delivered or dispensed.

The Act also authorizes a licensed physician, licensed physician assistant, and APRN to prescribe an opioid antagonist to a person who is in a position to assist another person who is at risk of experiencing an opioid-related drug overdose, either directly or by the use of a standing order. They may also deliver or dispense an opioid antagonist to a person who is in a position to assist another person at risk of experiencing an opioid-related drug overdose. However, if a licensed physician, licensed physician assistant, or APRN prescribes or delivers an opioid antagonist to such a person, he or she must ensure both of the following:

- The person to whom the drug will be delivered or dispensed has the knowledge and training necessary to safely administer it to an individual experiencing an opioid- related overdose.
- The person to whom the drug will be delivered or dispensed will ensure that any individual to whom the person further delivers or dispenses the drug has or receives that knowledge and training necessary to safely administer it to an individual experiencing an opioid-related overdose.

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Electronic Prescribing of Controlled Substances

2011 Wisconsin Act 159 amended § 961.38, Stats. to allow electronic prescriptions for schedule II controlled substances. On September 1st, 2014, Clearinghouse Rule (CR) 13-075 became effective to make the necessary rule changes to allow electronic prescriptions for schedule II controlled substances. Specifically, the note following Phar 7.08(1) which stated that prescription orders for schedule II controlled substances may not be transmitted electronically except in emergency was repealed. Phar 8.05(4) was modified to indicate that a prescription containing a controlled substance can only be dispensed pursuant to a written hard copy or electronic order signed by the prescribing practitioner. Phar 8.07(2) indicates the notation of the partial quantity provided is written on the hard copy of the prescription or the electronic order; and the word "emergency" is moved to solely modify oral prescriptions. Phar 8.09(1), (2), (3) and (4) removed electronic from the emergency prescriptions to reflect the provisions relate solely to oral authorizations in an emergency situation. Lastly, the reference to the "practitioner's phone number as listed in the telephone directory" was removed and instead requires pharmacists to make a reasonable effort to make sure an oral prescription came from an authorized practitioner.

To view a copy of the updated administrative rule, click here Phar 8.05(4), 8.07(2) and 8.09.

Drug Supply Chain Security Act (DSCSA)

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Over the next 10 years a variety of provisions related to product identification, tracing, verification, detection and response, notification, wholesaler licensing, and third-party logistics providers will be implemented. Please see the FDA website for further details. http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/

A licensed pharmacist is authorized under the Act to deliver or dispense an opioid antagonist upon the prescription order of a physician, physician assistant, or APRN that complies with the requirements described above. The pharmacist must provide a consultation in accordance with rules promulgated by the Pharmacy Examining Board for the delivery or dispensing of a prescription to the person to whom the drug is delivered or dispensed. A licensed physician, licensed physician assistant, or APRN who, acting in good faith, prescribes, delivers, or dispenses an opioid antagonist in accordance with the procedures created by the Act may not be subject to professional discipline for any outcomes resulting from prescribing, delivering, or dispensing that drug. Likewise, a licensed pharmacist who, acting in good faith, delivers, or dispenses an opioid antagonist in accordance with the procedures created by the Act may not be subject to professional discipline for any outcomes resulting from delivering or dispensing that drug.

Immunity from Civil or Criminal Liability

The Act provides that, in general, any person who **delivers** an opioid antagonist to another person is immune from civil or criminal liability, with the following exceptions:

- A licensed physician, licensed physician assistant, or APRN must act in good faith when prescribing, delivering, or dispensing an opioid antagonist in accordance with the procedures created by the Act, to be immune from any criminal or civil liability for any outcomes resulting from prescribing, delivering, or dispensing that drug.
- A licensed pharmacist must act in good faith when delivering or dispensing an opioid antagonist in accordance with the procedures created by the Act, to be immune from any criminal or civil liability for any outcomes resulting from delivering or dispensing that drug.
- The Act also provides that, in general any person who **administers** an opioid antagonist to another, whom the person reasonably believes to be undergoing an opioid-related drug overdose, is immune from civil or criminal liability, with the following exceptions:
- A law enforcement officer or fire fighter is only immune from civil or criminal liability for any outcomes resulting from the administration of naloxone or another opioid antagonist to another person if the law enforcement officer or fire fighter does all of the following:
  - Reasonably believes the individual is undergoing an opioid-related drug overdose.
  - Acts pursuant to an agreement with an ambulance service provider or a physician and any training obtained pursuant to the agreement, as described above.
- An employee trained in health care or a health care professional is not immune from civil liability if he or she renders emergency care for compensation within the scope of their usual and customary employment or practice at a hospital or other institution equipped with hospital facilities, at the scene of an emergency or accident, enroute to a hospital or other institution equipped with hospital facilities, or at a physician's office.

Prescription Drug Monitoring Program (PDMP)

On September 1, 2014, Clearinghouse Rule (CR) 14-003 and associated changes to Phar 18, regarding the Prescription Drug Monitoring Program (PDMP), became effective. Over the course of the PDMP implementation, a number of opportunities were identified to clarify and simplify the administrative rules governing the program.

In section Phar 18.02, the definitions of the terms dispenser, dispenser delegate, and practitioner were amended and hospital, managing pharmacist, pharmacist, and pharmacist delegate were created.

The following changes were made to Phar 18.04 regarding the compilation of dispensing data: the classification code for payment type and refill information was added; quantity prescribed was removed as a required data element; and clarifications were made to reporting of an animal patient's name, address and birthdate. The terms "dispenser" and "dispenser delegate" were replaced with "pharmacist" or "pharmacist delegate" where appropriate based upon the updated definitions in Phar 18.02. For entities requesting PDMP data, a specific statute and/or rule must be provided to support the request. Additionally, the revised rule repeals the requirement for the Board to disclose PDMP information to staff of a relevant agency in another state who are authorized to access confidential patient health care records under §§. 146.82 and 450.19, repeals the requirement to disclose the minimum amount of PDMP information necessary to health care facility staff committees or accreditation or health care services review organizations, adds that the board will disclose the minimum amount of PDMP information necessary to staff who are investigating pharmacists and pharmacist delegates, clarifies that the board may disclose de-identified PDMP information which does not identify any patient upon request, and repeals the requirements for a researcher to obtain PDMP information.

The rule revisions further clarify the following: dispenser delegates are subject to discipline for failing to compile required dispensing data; unless exempt, a dispenser shall electronically submit data; the dispenser shall submit a zero report for each 7 day period during which the dispenser did not dispense a monitored prescription drug; if incorrect dispensing data had been submitted, the dispenser shall submit the correct information within 7 days; and a dispenser is not required to compile or submit information on non-narcotics identified in schedule V of the Wisconsin Controlled Substances Act that are dispensed in an amount intended to last 7 days or less.

To view a copy of the updated administrative rule, click here: Phar 18.

WISCONSIN | PDMP

A wealth of useful information is available on the Department of Safety and Professional Services Website at: http://dsps.wi.gov

Do you have a change of name or address?
Licensees can update name or address information on the Department website at:
https://online.drl.wi.gov/UserLogin.aspx

Please note that confirmation of change is not automatically provided. Legal notices will be sent to a licensee's address of record with the Department.

Telephone Directory:
Call the Department of Safety and Professional Services toll-free (877) 617-1565, or (608) 266-2112 in the Madison area to connect to the service you need.

Pharmacy Examining Board Membership and Staff Assignments

The Pharmacy Examining Board consists of 7 members. The members are appointed by the Governor and confirmed by the Senate.

Board Members:

Thaddeus Schumacher, Chairperson (Fitchburg)

Franklin LaDien, Vice Chairperson (Menomonee Falls)

Philip Trapskin, Secretary (Fitchburg)

Cathy Winters, Pharmacist Member (Wausau)

Charlotte Rasmussen, Public Member (Stanley)

Terry Maves, Pharmacist Member (Appleton)

Kristi Sullivan, Public Member (Fitchburg)

Information on how to apply for appointment to the Wisconsin Pharmacy Examining Board can be found through the Office of the Governor:
http://walker.wi.gov/governor-office/apply-to-serve/boards-commissions

Department of Safety and Professional Services (DSPS)

Administrative Staff:

Dan Williams, Executive Director

Gretchen Mrozinski, Legal Counsel

Nilajah Madison-Head, Bureau Assistant

Executive Staff:

Dave Ross, Secretary

Jay Risch, Deputy Secretary

Eric Esser, Assistant Deputy Secretary

The dates and times of the Pharmacy Examining Board meetings are announced on the DSPS website at http://dsps.wi.gov. Meeting agendas are posted approximately one week prior to the meeting.

Enforcement Actions of the Pharmacy Examining Board

The Pharmacy Examining Board, with help from staff at the Department of Safety and Professional Services, can take action against licensees around the state to help protect the profession and the citizens of Wisconsin. You may search for any of the Board Orders listed below on the Department's website by using this link:

Board Order Search: ***http://dsps.wi.gov/Other-Services/Lookup-Orders-Disciplinary***

Disciplinary options available to the Board:

Reprimand - A public warning of the licensee for a violation.

Limitation of License - Imposes conditions and requirements upon the licensee, imposes restrictions on the scope of practice, or both.

Suspension - Completely and absolutely withdraws and withholds for a period of time all rights, privileges and authority previously conferred by the credential.

Revocation - To completely and absolutely terminate the credential and all rights, privileges and authority previously conferred by the credential.

Non-disciplinary options available to the Board:

Administrative Warning - Issued if violation is of a minor nature, a first occurrence and the warning will adequately protect the public. The issuance of an Administrative Warning is public information, however the reason for issuance is not.

Remedial Education Order - Issued when there is reason to believe that the deficiency can be corrected with remedial education, while sufficiently protecting the public.

Board Orders

January 2015 – April 2015

Profession	Order No	Order Date	Respondent
Pharmacist	LS0602082PHM	4/22/2015	Jernegan, James L
Pharmacist	LS9903102PHM	4/1/2015	Osness, Craig R
Pharmacist	ORDER0003853	3/25/2015	Hapka, David J
Pharmacy (out of state)	ORDER0003854	3/25/2015	New Era Pharmaceuticals, LLC
Pharmacist	LS0907232PHM	2/23/2015	Ivey, Michael Steven
Pharmacist	ORDER0001108	2/17/2015	Nelson, Ryan J
Pharmacist	LS0909235PHM	2/17/2015	Orth, Erin K
Pharmacist	ORDER0002830	2/17/2015	Bosnjak, John J
Pharmacist	ORDER0001108	2/17/2015	Nelson, Ryan J
Pharmacist	LS0610191PHM	1/20/2015	Isaacson, Scott D
Pharmacist	ORDER0003027	1/20/2015	Hubeler, Robert W