PMP Advisory Committee

Chair: Sarah Pointer, Pharm D.

PMP Admin: Craig Berberet

September 20, 2017

PMP Advisory Committee
September 20th, 2017
12:00 to 1:30 PM

I. Roll Call of Voting Members

II. Meeting Minutes from June 21st , 2017 meeting

III. Illinois Health and Hospital Association's Patient Family Advisory Committee feedback on the unsolicited patient letter (Helga Brake)

IV. Peer review meeting reschedule

V. Prescriber Risk Equation (Chris Herndon)

VI. Unsolicited Letters to Prescribers - including DPH data

VII. Governor's Executive Order signed September 6th, 2017

a. Naloxone Standing Order

i. DHS approved training

ii. Tracking Naloxone Dispensing

VIII. Increased Headcount Approved

IX. General Revenue Funding

X. Technical Update

XI. Legislative Update

XII. Miscellaneous Issues

XIII. Reminder of Next Meeting – proposal to move time

XIV. Call for Motion to Adjourn

DRAFT NOTIFICATION LETTER FOR PATIENTS IDENTIFIED BY THE ILLINOIS PRESCRIPTION MONITORING PROGRAM DATABASE

Patients are identified to receive a letter if he/she has a controlled substance prescription filled at 3 different pharmacies or written by 3 different physicians within 30 days.

Original:

Dear Patient's Name:

This letter of concern to you comes from the members of the Illinois Prescription Monitoring Program. This is an electronic statewide monitoring program of all prescriptions for controlled substances in Illinois. These are prescriptions for medications with the potential for abuse, misuse, addiction, over dosage, and accidental death.

You are receiving this letter because of our concerns for your safety. You have received .... prescriptions for …. different controlled substances over the previous …. months. We are fully aware that there may be legitimate health reasons for each prescription. However, it is our responsibility to contact you and your providers to ensure that there is coordination of care if, in fact, there is a legitimate medical need. These medications alone or in combination with each other have significant risks and awareness of all of the patient's prescriptions is paramount to ensuring safe care.

It is also our responsibility to investigate this situation to the extent of sending these letters to both you and your providers to verify that you are not developing an unhealthy relationship with the medication. The risk of developing a substance abuse disorder with these controlled substances has been estimated to be as high as 20% of individuals exposed to them for medical care. Such a condition is associated with compulsive rather than controlled use of these medications and a growing psychological dependence on the medication. If this is a concern, please seek help as soon as possible with a substance abuse center, an addictionologist, or at least your primary care provider.

Post-IHA Patient/Family Advisory Committee Feedback:

Dear Patient's Name:

The Illinois Prescription Monitoring Program is an electronic statewide monitoring program of all prescriptions for controlled substances in Illinois. These medications have the possibility for abuse, mis-use, addiction, over dosage, and accidental death.

You are receiving this letter because you received .... prescriptions for …. different controlled substances over the last .... months.

We are aware that there may be valid health reasons for each prescription. It is our responsibility to contact you and your medical team out of concern for your safety to ensure your care is coordinated while your medical needs are addressed.

These medications alone or with each other have serious risks, including the risk of developing a physical dependence on them. If you find yourself having an unhealthy desire for any of these medications, please get help as soon as possible by contacting your primary care provider or a substance abuse center**.**

It was also suggested that contact information be included for additional questions.

Peer Review Meeting

- August 10th 2017 meeting
  - To be reschedule due to lack of a quorum
  - New Doodle Pole today

Prescriber Risk Equation

$$\frac{\left(\frac{ADS}{30}+\frac{AOME}{90}+\frac{\left[\frac{(PBO-PBOH)}{n}\right]}{0.1}+\frac{\left(\frac{PBOH}{n}\right)}{0.05}\right)}{4}$$

ADS = 30
AOME = 90
Patients on opioids also receiving benzos = 10%
Patients on opioids also receiving benzos and hypnotics = 5%

- Validate with DPH overdose data?
- How to address possible high risk prescribers?

Unsolicited Letters to Prescribers

- Held pending risk equation discussion
- Include DPH data on fatal and non-fatal overdoses
- Addition of taxonomy to data
- Suggestions?

Executive Order

- Signed September 6th, 2017

- **Synopsis As Introduced**

Creates the Governor's Opioid Prevention and Intervention Task Force to develop, approve, and implement an Opioid Action Plan. Contains provisions regarding: purposes and duties of the Task Force; establishment of policies and programs; membership; savings; prior executive orders; severability; and other matters. Provides that the Task Force is dissolved on September 30, 2020. Effective immediately.

Naloxone Standing Order

- DPH Website Link to Standardized Procedures and Standing Order

- DHS Approved Training

(c) Before dispensing an opioid antagonist pursuant to this
Section, a pharmacist shall complete a training program
approved by the Department of Human Services pursuant to
Section 5-23 of the Alcoholism and Other Drug Abuse and
Dependency Act. The training program shall include, but not be
limited to, proper documentation and quality assurance.

- PMP to track Naloxone Dispensing
- Notification to Pharmacists

MEMORANDUM

To: Pharmacists

From: Chief Medical Officer, Office of the Director, Illinois Department of Public Health

Date: September XXX, 2017

Subject: Statewide Naloxone Standing Order and Updated Naloxone Standardized Procedures

The Illinois Department of Public Health Chief Medical Officer will issue a statewide Illinois Naloxone Standing Order on September 7, 2017. The standing order is intended to ensure that all trained pharmacists may dispense naloxone hydrochloride to individuals at risk for opioid overdose as well as those who may be in a position to assist another person during an opioid overdose. The standing order is authorized under the Alcoholism and Other Drug Abuse and Dependency Act (20 ILCS 301/5-23) and Executive Order 17-05.

Eligible pharmacists dispensing naloxone under the Illinois Naloxone Standing Order must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85).

In addition, the Illinois Naloxone Standardized Procedures have been updated and can be found here (Insert IDFPR website).

The following is required to dispense naloxone under the Illinois Naloxone Standing Order:

- Signed standing order must be kept on pharmacy premises
- Pharmacists have complete understanding of all content in the updated Naloxone Standardized Procedure
- Pharmacists have completed training in opioid overdose reversal (examples of training resources may be found at http://www.dph.illinois.gov/)
- Naloxone Patient Pamphlet must be distributed with naloxone rescue kits (example pamphlet may be downloaded at http://www.dph.illinois.gov/)

Pharmacies should report naloxone dispensing to the Illinois Prescription Monitoring Program at https://www.ilpmp.org/. Additional information will be released in the coming weeks with further instruction on naloxone reporting.

To obtain the Illinois Naloxone Standing Order please register at http://www.dph.illinois.gov/

For more information please visit http://www.dph.illinois.gov/.

Illinois Naloxone Standardized Procedure

This updated Naloxone Standardized Procedure outlines how entities may become authorized to obtain, dispense, and administer naloxone hydrochloride for the purpose of reversing an opioid overdose. This Procedure also presents the educational requirements for obtaining the Illinois Naloxone Standing Order and the technique for administering naloxone.

Introduction

In September 2015, Illinois enacted Public Act 99-0480 (Act), expanding access to the opioid antagonist, naloxone. Naloxone may be used to reverse opioid overdoses, including those caused by heroin, fentanyl, and certain prescription pain medications. The law authorizes trained pharmacists and first responders to dispense naloxone as an opioid antagonist intervention.

Pursuant to the Act, the Illinois Department of Financial and Professional Regulation (IDFPR) – in consultation with the Illinois Department of Public Health (IDPH) and Illinois Department of Human Services (IDHS) – has issued a standardized procedure for appropriately trained professionals to obtain, dispense, or administer naloxone.

Naloxone Entity

Naloxone Entities may include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs.

- Participating pharmacies and pharmacists must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85), complete training approved by IDHS pursuant to Public Act 99-0480, and have knowledge of this document, the Illinois Naloxone Standardized Procedure. Pharmacies/pharmacists should report naloxone dispensing to the Illinois Prescription Monitoring Program at https://www.ilpmp.org/.
- Any non-pharmacy OEND program must be registered as a Drug Overdose Prevention Program with the IDHS's Division of Alcoholism and Substance Abuse, at http://www.dhs.state.il.us/. This may include law enforcement agencies, drug treatment programs, local health departments, hospitals or urgent care facilities, or other for-profit or not-for-profit community-based organizations.

Educational Requirement

Under this standardized procedure, eligible entities must complete training in opioid overdose reversal, which includes the following:

- Opioid overdose recognition and prevention
- Naloxone administration techniques
- The importance of calling 911 for the care of the overdose victim after naloxone administration

Naloxone Hydrochloride

Naloxone is indicated for the reversal of opioid overdose, induced by natural or synthetic opioids, relative to respiratory depression or unresponsiveness. It should not be given to anyone known to be allergic to naloxone hydrochloride. It may be delivered subcutaneously or intramuscularly using an auto-injector, or needle and syringe, or intranasally.

Signs of Symptoms of Opioid Overdose

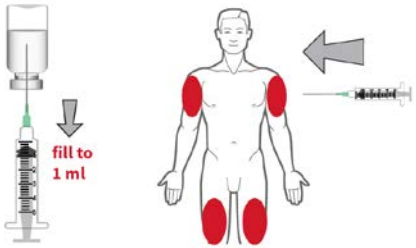
- Slowed, irregular, or no breathing
- Skin, nails turn blue
- Extreme sleepiness
- Unresponsive to sternal rub or when shaken
- Pinpoint pupils

Standardized Procedure for Naloxone Administration

1. Confirm signs and symptoms of potential opioid overdose

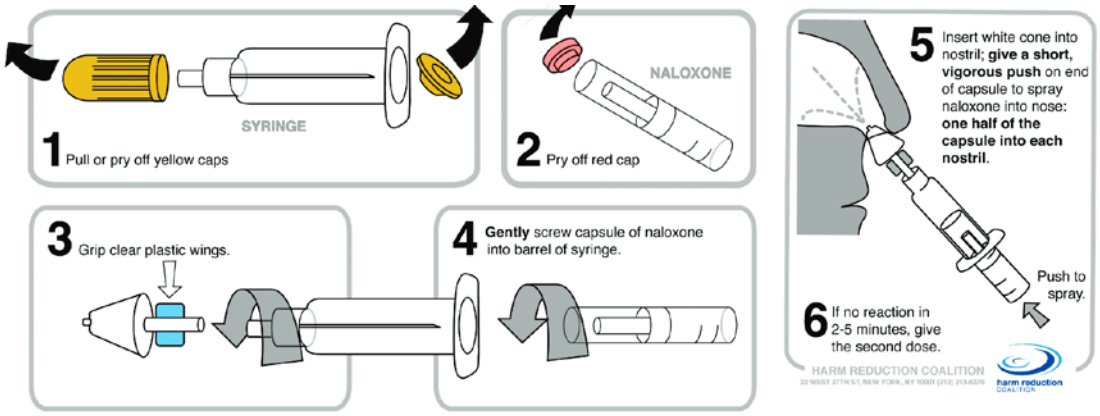
2. Call 9-1-1 and administer naloxone as follows **(select dispensed dosage form):**

   Intramuscular Naloxone**:**
   - Uncap the naloxone vial and uncap the muscle needle-syringe
   - Insert the muscle needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1 ml of naloxone liquid, and withdraw the needle
   - Insert the needle into the muscle of the upper arm or thigh of the victim, through clothing if needed, and push on the plunger to inject the naloxone
   - Repeat the injection if there is no response after three minutes



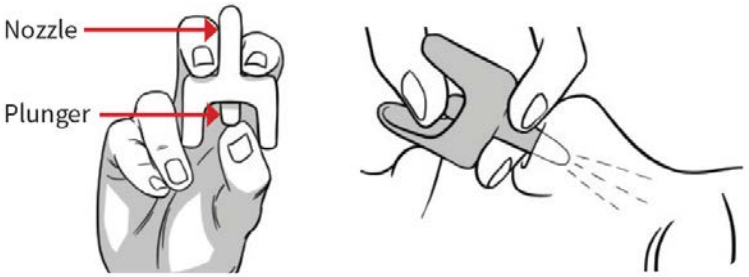
   Multi-Step Intranasal Naloxone:
   - Pop off two colored caps from the delivery syringe and one from the naloxone vial
   - Screw the naloxone vial gently into the delivery syringe
   - Screw the mucosal atomizer device onto the top of the syringe

- Spray half (1 mL) of naloxone in one nostril and the other half (1 mL) in the other
- Repeat if there is no response after three minutes



Single-Step Intranasal Naloxone:

- Peel back the package to remove the device
- Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle
- Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose
- Press the plunger firmly to release the dose into the patient's nose
- Repeat if there is no response after 3 minutes



Auto-injector Naloxone:

- Pull auto-injector from outer case and pull off red safety guard
- Place the black end of the auto-injector against the outer thigh, through clothing if needed, press firmly and hold in place for 5 seconds
- Repeat if there is no response after 3 minutes

1. Provide rescue breathing using a disposable rescue breathing device, chest compressions, or full cardiopulmonary resuscitation (CPR) based on the training and abilities of the responder[1] or follow the instructions of the 911 dispatcher.

2. If person becomes unresponsive again, administer another dose of naloxone. Stay with the person until emergency help arrives.

Contraindications

- Patient is known to be hypersensitive to naloxone hydrochloride

Precautions

- Pre-existing cardiac disease or seizure disorder
- Person is suspected to be physically dependent on opioids including newborns of mothers with opioid dependence (Reversal of opioid effect will precipitate acute abstinence syndrome)
- Use in Pregnancy:
    1. Teratogenic Effects: Pregnancy category C, no adequate or well-controlled studies in pregnant women
    2. Non-teratogenic Effects: Pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms
    3. Naloxone should only be used in pregnant women with opioid dependence in situations of life-threatening overdose
- Nursing Mothers: Caution should be exercised when administering to nursing women due to transmission in human milk
- Geriatric Use**:** Caution should be exercised for potential decreased hepatic, renal and cardiac function, as well as concomitant disease and other pharmacotherapies

Adverse Reactions

- Adverse reactions are related to precipitating opioid withdrawal. They include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgias, diaphoresis, abdominal cramping, yawning, and sneezing.
- These symptoms may appear within minutes of naloxone administration and subside in approximately 2 hours.
- The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
- Adverse effects beyond opioid withdrawal are rare

[1]As there is insufficient data to recommend one resuscitation method over another, naloxone entities will need to determine whether rescue breathing, chest compressions, both, or neither, is most appropriate for inclusion in their training curricula. (New York State Technical Working Group on Resuscitation Training in Naloxone Provision Programs. 2016)

PMP Update

- Approved additional headcount

1. Executive I: **Temporarily Assigned** (as of 9/15/16)
2. Executive I: **Temporarily Assigned** (as of 1/17/17)
3. Administrative Assistant I: **Vacant** (as of 4/16/2013)
4. Office Assistant: **Vacant** (as of 3/16/2014)
5. Executive II: **Vacant** (as of 8/1/2013)

PMP Update

- General Revenue Funding
  - $259,800
- CDC Grant
  - $917,661
- CDC Supplemental Grant
  - $499,152
- CDC Expansion Grant
  - $734,129
- Harold Rogers Grant
  - $399,961
- SAMHSA/DASA
  - $440,847

PMP Update

- Technical Update
  - LogiCoy Contract
  - EHR integration
  - Designee Page

Legislative Update

- Review of current legislation affecting the PMP
  - HB313
    - Nurse Practice Act- Various
  - HB524
    - Safe Pharmaceutical Disposal
  - HB3161
    - DHS Opioid Abuse-Website
  - HB1607
    - Proposed language and status

HB313

NURSE PRACTICE ACT-VARIOUS (FEIGENHOLTZ S) House Committee Amendment No. 2 - Replaces everything after the enacting clause. Amends the Regulatory Sunset Act. Extends the repeal date of the Nurse Practice Act from January 1, 2018 to January 1, 2028. Amends the Nurse Practice Act. Eliminates the position of Assistant Nursing Coordinator. Eliminates the Advanced Practice Nursing Board. Provides that the Department of Financial and Professional Regulation may provide notice to a licensee or applicant by certified or registered mail to the address of record or by email to the email address of record. Provides provisions for change of address of record and email address of record, application for license, confidentiality of any information collected by the Department in the course of an examination or investigation of a license or applicant, and disposition by a consent order. Changes references to "advanced practice nurse" to references to "advanced practice registered nurse" throughout the Act and in other Acts. Changes references to "Illinois Center for Nursing" to references to "Illinois Nursing Workforce Center". Makes changes concerning definitions, application of the Act, unlicensed practice, prohibited acts, Department powers and duties, nursing delegation, qualifications for licensed practical nurse, registered nurse, and advanced practice registered nurse licensure, registered nurse education program requirements, registered nurse scope of practice, grounds for disciplinary action, intoxication and drug abuse, the Nursing Dedicated and Professional Fund, investigations, notices, hearings, use of stenographers and transcripts, review under the Administrative Review Law, certification of records, the Center for Nursing Advisory Board, and medication aide licensure requirements. Repeals provisions concerning registered nurse externship permits, rosters, liability of the State, hearing officers, and orders for rehearings. Makes other changes. Effective immediately.

House Floor Amendment No. 3 - In provisions amending the Nurse Practice Act concerning definitions, defines "comprehensive nursing assessment", makes changes to various definitions, and removes the definition of "monitoring". In provisions concerning prohibited acts, provides that no person shall discipline or take adverse action against a nurse who refused to delegate a nursing intervention based on patient safety. In provisions concerning nursing delegation by a registered professional nurse, removes references to "advanced practice registered nurses". Makes changes to actions a registered professional nurse is authorized to take. Makes changes to the scope of practice for a licensed practical nurse and registered professional nurse. Makes other changes.

Senate Floor Amendment No. 1 - Amends the Medical Practice Act of 1987. In provisions concerning physician delegation of authority, provides that the provisions apply to advanced practice registered nurses who have not been granted full practice authority. Provides that a licensee under the Act may not directly or indirectly divide, share, or split any professional fee or other form of compensation for professional services with anyone in exchange for a referral or otherwise. Further amends the Nurse Practice Act. Defines "full practice authority". Adds language concerning the scope of practice of advanced practices nurses with full practice authority, including provisions concerning prescriptive authority. Makes changes to continuing education requirements for advanced practice registered nurses. Amends the Illinois Controlled Substances Act. Expands the definition of "prescriber" to include full practice authority advanced practice registered nurses and makes a conforming change in the definition of "prescription". In provisions concerning mid-level practitioner licenses, provides that the mid-level practitioner license applies to advanced practice registered nurses who do not have full practice authority. Makes other changes. Effective January 1, 2018, except that some provisions take effect immediately.

Current Status:
9/18/2017 - Added as Alternate Co-Sponsor Sen. Jacqueline Y. Collins

Recent Status:
7/24/2017 - Sent to the Governor
6/25/2017 - Passed Both Houses

State Bill Page: HB313

SB1607 **CONTROLLED SUBSTANCES MONITOR** (BUSH M) Senate Committee Amendment No. 1 - Replaces everything after the enacting clause. Amends the Illinois Controlled Substances Act. Before issuing a prescription for a Schedule II, III, IV, or V controlled substance, a prescriber or his or her designee shall access the prescription monitoring program to determine compliance with the pharmacy and medication shopping provisions of the Act. Provides that within one year of the effective date of the bill, the Department shall adopt rules requiring all Electronic Health Records Systems to interface with the Prescription Monitoring Program application program on or before January 1, 2021 to ensure that all providers have access to specific patient records during the treatment of their patients. These rules shall also address the electronic integration of pharmacy records with the Prescription Monitoring Program to allow for faster transmission of the information required under the Act. Provides that the Department shall establish actions to be taken if a prescriber's Electronic Health Records System does not effectively interface with the Prescription Monitoring Program within the required timeline. Provides that the Department of Human Services, in consultation with the Advisory Committee, shall adopt rules allowing licensed prescribers or pharmacists who have registered to access the Prescription Monitoring Program to authorize a designee to consult the Prescription Monitoring Program on their behalf. The rules shall include reasonable parameters concerning a practitioner's authority to authorize a designee, and the eligibility of a person to be selected as a designee.

Senate Floor Amendment No. 2 - Restores language of the law that when a person has been identified as having 3 or more prescribers or 3 or more pharmacies, or both, that do not utilize a common electronic file for controlled substances within the course of a continuous 30-day period, the Prescription Monitoring Program may (rather than shall) issue an unsolicited report to the prescribers, dispensers, and their designees informing them of the potential medication shopping.

Senate Floor Amendment No. 3 - Replaces everything after the enacting clause. Amends the Illinois Controlled Substances Act. Reinserts the provisions of the bill as amended by Senate Amendments Nos. 1 and 2. Deletes provision that a prescriber who receives the report from the Prescription Monitoring Program concerning a person who has been identified as having 3 or more prescribers or 3 or more pharmacies, or both, either personally or through an agent at his or her place of practice, shall be prohibited from issuing a controlled substance to that same person unless the prescriber signs a statement on the prescription acknowledging receipt of the report. Deletes that if a pharmacy or pharmacist receives a prescription for a person he or she knows or should know to be the subject of the report, and the prescriber fails to provide the required acknowledgement, the pharmacy or pharmacist must contact the prescriber and obtain a signature on the acknowledgement before filling the prescription. Provides that if an unsolicited report is issued to a prescriber or prescribers, then the report must also be sent to the applicable dispensing pharmacy. Restores provision that nothing in this provision shall be construed to create a requirement that any prescriber, dispenser, or pharmacist report any patient activity, or prescribe or refuse to prescribe or dispense any medications. Also provides that a prescriber who prescribes a Schedule II, III, IV, or V controlled substance in the course of oncology treatment, a condition associated with oncology, or hospice care is exempt from having to check the Prescription Monitoring Program prior to prescribing the controlled substance.

Current Status: 7/6/2017 - Rule 19(a) / Re-referred to Rules Committee

Recent Status: 7/6/2017 - Senate Bills on Second Reading
7/5/2017 - Senate Bills on Second Reading

State Bill Page: SB1607

Miscellaneous Issues

- Open Discussion
  - New meeting time?

Next Meeting
December 20th, 2017

Meeting adjourned