STATEWIDE PROTOCOLS: 
NEXT STEPS

Tuesday 
April 9, 2019

IOWA PHARMACY ASSOCIATION

STAY ENGAGED STAY INFORMED
Welcome

Kate Gainer, PharmD
Executive Vice President and CEO
Iowa Pharmacy Association
Matt Pitlick, PharmD, BCPS
Executive Fellow
Iowa Pharmacy Association
STATEWIDE PROTOCOLS:
NEXT STEPS

Mathew Pitlick, PharmD, BCPS
Executive Fellow
Iowa Pharmacy Association

April 9, 2019
Outline

• Statewide Protocols in Iowa
• Be prepared
• Statewide Protocols
  • Naloxone
  • Nicotine Replacement Therapy
  • Immunizations
• Next Steps
Statewide Protocols

• Across the U.S. states are recognizing the value of authorizing pharmacists to prescribe in order to increase access to important medications via collaborative practice, standing orders, and statewide protocols

• The term statewide protocol refers to a framework that specifies the conditions under which pharmacists are authorized to provide a clinical service or order a specified medication or category of medication

• Common examples include: tobacco cessation, immunizations, contraceptives, naloxone
Pharmacist Prescribing

Collaborative Prescribing
- Patient-Specific CPA
- Population-Specific CPA

Most Restrictive

Autonomous Prescribing
- Statewide Protocol
- Unrestricted (Category-Specific)

Least Restrictive
Statewide Protocols in Iowa

• In 2018, SF 2322 was enacted into law, authorizing the Board of Pharmacy to develop statewide protocols in consultation with the Iowa Department of Public Health

• Pharmacists are now authorized to order and administer certain medications authorized by Iowa law

• Protocols to be developed included:
  • Naloxone
  • Immunizations
  • Nicotine Replacement Therapy
Timeline

- May 2018 - SF 2322 signed by Governor
- October 2018 - Board of Pharmacy Notices Rules for Public Comment
- January 2019 – SWP Rules are Adopted and Filed
- February 2019 – ARRC Committee requests change, Emergency rules filed
- March 2019 – Protocols are approved by Board of Pharmacy
- April 2019 – Rules become effective after final ARRC approval
- July 1, 2019 – Previous immunization law set to sunset
Where?

- Both the administrative rules and protocols spell out the necessary requirements and procedure for participation

- Administrative rules
  - IAC 657-39.6 – Statewide protocols
  - IAC 657-39.8 – Statewide protocol – naloxone
  - IAC 657-39.9 – Statewide protocol – nicotine replacement tobacco cessation products
  - IAC 657-39.11 – Vaccine administration by pharmacists – statewide protocol

- Statewide Protocols
  - IPA website and Board of Pharmacy Website
What is Included?

- Definitions
- Authorized pharmacist training/education
- Assessment – patient eligibility
- Patient education
- Labeling
- Documentation and notification
- Reporting/Records
Before Participating

- Apply for personal National Provider Identifier (NPI) number – Type 1
  - https://nppes.cms.hhs.gov/

- Education/training for each statewide protocol
  - Identified in each protocol

- Ensure adequate personal professional liability insurance
Professional Liability Insurance

• Does your personal professional liability insurance cover?
  • Clinical service activities
  • Patient counseling
  • Maintenance of records
  • Immunizations

• Does the policy cover you as an individual 24 hours/day?

• Does the policy cover for patient counseling even if no prescription is filled?
Naloxone

• “Upon satisfactory assessment that the person to receive naloxone is an eligible recipient…and upon completion of training regarding recognizing and responding to suspected opioid-related overdose, the pharmacist may dispense one or more naloxone products or kits identified herein.”

• Provide naloxone to an “eligible recipient”
  • Individual at risk of opioid-related overdose
  • Family member, friend or other person in a position to assist
  • First responder if allowed
Requirements for Participation

• Complete at least one hour of ACPE-accredited continuing education related to opioid antagonist utilization prior to participation.

• Have policies and procedures (and train staff on the P&Ps) related to naloxone dispensing under this statewide protocol.

• Utilize an assessment form provided by the Board of Pharmacy to determine patient eligibility
  • https://pharmacy.iowa.gov/misc/statewide-protocols
Eligibility Assessment to receive naloxone for reversal of opioid-related overdose

<table>
<thead>
<tr>
<th>ASSESSMENT CRITERIA</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual is: 1) a person at risk, 2) a family member or friend of person at risk, 3) a person in a position to assist a person at risk, 4) a first responder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person at risk does NOT have a known allergy or sensitivity to naloxone or any component of the product to be dispensed (Answer “yes” if there is no known allergy or the person at risk is not known to the individual)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual is oriented to person, place and time and understands the essential components of opioid-related overdose, appropriate response, and naloxone administration.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual is determined to be ELIGIBLE to receive naloxone at this time (complete absence of “no” responses to above criteria)**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Even if individual is NOT eligible to receive naloxone at this time, this assessment form must be maintained with pharmacy records for at least two years, be available for inspection and copying by the board or its authorized agent, and must be submitted to the Iowa Department of Public Health.

PREVIOUS PRESCRIPTION INFORMATION

If recipient has received naloxone previously, the last dispensed product was: **CHECK**

1. Administered to reverse an opioid-related overdose
2. Lost
3. Stolen or confiscated
4. Destroyed or expired
Naloxone

• Dosage forms:
  • Intranasal naloxone with atomizer kits
  • Intranasal naloxone spray kits (Narcan®)
  • Intramuscular auto-injector kits (Evzio®)
  • Intramuscular naloxone kits

• NOT required to stock and dispense all dosage forms

• Include step-by-step instructions for administration, 911 instructions, rescue breathing, and monitoring overdose victim
Documentation

- Affix prescription label as normal in the name of the eligible participant
- Maintain original record of each assessment (regardless of eligibility) and dispensing records for at least 2 years
- Assessment form sent to IDPH within seven days of dispensing or denied eligibility
- Naloxone dispensing reported to PMP
Naloxone

• Statewide standing order still in effect if pharmacist unable to order
  • Does not provide for distribution of intramuscular naloxone kits with vial(s) and syringe(s)

• Download and print copies of the Iowa Naloxone Brochure – on Iowa Board of Pharmacy website

• [https://www.iarx.org/naloxone](https://www.iarx.org/naloxone)
Nicotine Replacement

• Order and dispense nicotine replacement tobacco cessation products
  • Gum, lozenge, transdermal patch, nasal spray, oral inhaler
  • Up to a 30-day supply

• 18 years and older

• Pharmacist’s order shall constitute a prescription

• Can continue to provide over-the-counter products without using protocol
Qualifications and Training

- Each participating Iowa-licensed pharmacist must complete at least one hour of ACPE-accredited continuing education related to smoking cessation prior to participation.
Nicotine Replacement – General Requirements

• Download and review the most current version of the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline - Treating Tobacco Use and Dependence.
  • https://www.ncbi.nlm.nih.gov/books/NBK63952/

• Implement Five A’s (ask, advise, assess, assist, arrange)
General Requirements

• Shall include an educational component to include counseling on medication therapies and cessation strategies as well as referral to sources provided by Quitline Iowa

• Have access to most current protocol

• Ensure privacy and confidentiality
Initial Patient Screening

- Current tobacco use and prior attempts to quit
- Medical and social history including current medications
- Previous medication attempts, failures, intolerances
- Allergies and hypersensitivities
- Potential drug interactions with potential medications treatments
- Precautions of medication treatments
- Patient preferences with regard to treatment options
- Other recreational substance use
Patient Screening

• Contraindications
  • Pregnancy or plan to become pregnant
  • Recent history of myocardial infarction (within 14 days), serious cardiac arrhythmias, unstable or severe angina
  • Known moderate/severe hepatic or renal impairment
  • Smokeless tobacco use
Patient Education and Follow-Up

• Follow-up monitoring and evaluation a minimum of every four weeks.

• Refill authorization as appropriate not to exceed six months

• Continuous treatment longer than six months not authorized under this protocol
Patient Education and Follow-Up

• Education to be provided:
  • Motivation to cease tobacco use
  • Drug information – dosage form, directions for use, adverse effects
  • Nicotine withdrawal symptoms
  • Lifestyle modifications
  • Techniques to prevent relapse

• Should recommend seeking additional assistance for behavior changes:
  • Quitline Iowa (https://iowa.quitlogix.org/en-US/) 1-800-quit-now
  • Health insurer/Managed care programs
  • Web-based, mobile apps
Documentation

• Prescription label affixed as normal

• Document in medication record the dispensing of NRT pursuant to the statewide protocol

• Notify patient’s PCP within a reasonable amount of time

• If patient does not have PCP, provide the patient with a written record of the dispensing and advise patient to seek one

• https://www.iarx.org/nrt
Immunizations

- Pharmacist may order and administer immunizations

- Patients 6 months and older
  - Influenza
  - Other immunizations in response to public health emergency

- Patients 11 years and older
  - Final dose(s) in a course of vaccinations for HPV

- Patients 18 and older
  - ACIP and CDC recommended immunization or vaccination
  - Travel immunization or vaccination
Immunizations - Requirements

• Each participating pharmacist must complete an approved program on vaccine administration and complete training on basic life support for health care providers which includes hands-on training.

• Ensure the completion of at least one hour of ACPE-accredited continuing education during the renewal period in which the pharmacist is engaged in vaccine administration.
Immunizations - Requirements

• Maintain current copy of the protocol at each location administering a vaccine

• Private area for administering vaccines with identified supplies and equipment

• Informed consent documented
Vaccination Record

- Must create and maintain a vaccination record for each recipient including:
  - Patient name, address, DOB, gender, telephone number
  - Copy of patient’s response to eligibility questions
  - Name, dose, manufacturer, expiration date, and lot number of vaccine administered
  - Date of the vaccine administration and location site
  - Signed and dated informed consent form
  - Record of adverse events or complications from vaccination
  - Copy of notification letter sent to patient’s PCP
Reporting

• Review the Iowa Immunization Registry Information System (IRIS) prior to ordering and administering

• As soon as reasonably possible report to:
  • IRIS
  • Patient’s PCP

• Adverse Event
  • Any clinically significant adverse event to VAERS and PCP within 24 hours
Immunizations

• The local immunization protocol regulatory authority is currently scheduled to sunset on July 1, 2019.

• IPA is working to advocate for an extension in order to work through ongoing third-party payer issues.

• https://www.iarx.org/immunization
Coverage

Will a payer accept a pharmacist NPI as the prescriber?

- Wellmark
  - Yes
- Medicare
  - Part B and D – varies
- Medicaid
  - No – pharmacists not recognized as authorized providers
  - State plan amendment may be needed
  - May 1, 2019: PA removed for NRT
Next Steps

• Obtain individual NPI
• Check professional liability insurance
• Education/Training
  • CE for each protocol

• Practice model changes
• Documentation
Resources

• IPA website
  • [https://www.iarx.org/resources](https://www.iarx.org/resources)
    • Get Ready, Get Set, GO! for each statewide protocol
  • Coverage reference

• Iowa Board of Pharmacy Website
  • [https://pharmacy.iowa.gov/misc/statewide-protocols](https://pharmacy.iowa.gov/misc/statewide-protocols)
It's easy to come up with new ideas; the hard part is letting go of what worked for you two years ago, but will soon be out-of-date.

-Roger von Oech
Questions

Iowa Pharmacy Association
515-270-0713
ipa@iarx.org
See You Next Month!

TBD Tuesday
May 14, 2019

Questions? Contact Matt Pitlick at mpitlick@iarx.org or 515-270-0713