

Standing Orders for Pharmacists

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Declaration

I have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

Objectives

- Explore the Role of Standing Orders in pharmacy practice.
- Identify how HB2583, HB2525, and naloxone access bills are functioning in WV to improve access to self-administered hormonal contraception, tobacco cessation, and naloxone
- Discuss opportunities for collaboration and team-based care in pharmacy

Current Pharmacist Utilized Standing Orders

- Self-Administered Hormonal Contraceptives
- Tobacco Cessation
- Naloxone
- Immunizations

Why is access for hormonal contraception important?

- 6 million pregnancies in the US a year
- 37% are unplanned and unintended
- Most of these occurring in the 20-34 year age range
- About half of the unintended pregnancies end in abortion

Goal and Methods of Contraception

- Goal: Prevention of pregnancy following sexual intercourse
- Methods
 - Barrier Method
 - Create an unfavorable uterine environment
 - Types of failure:
 - Method failure, perfect use failure, user failure, typical-use failure

Resources Currently Available

- The Selected Training for WV provides continuous access to hands-on materials for easy screening and selection
- US Medical Eligibility Criteria (US MEC) for Contraceptive Use (2016) <https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html>
- These have been tailored to the WV questionnaire and protocol for ease of use

Types of Self-Administered Hormonal Contraceptives

- Oral, Transdermal, Intravaginal Ring
- Combined Hormonal Contraceptives: estrogen and progestin
 - Estrogens available as: ethinyl estradiol (EE), mestranol, estradiol valerate
 - Doses of ethinyl estradiol (EE) range between 20-50 mcg/day
- Progestin-Only Contraceptives:
 - Norgestrel, levonorgestrel, ethynodiol diacetate, levonorgestrel, norethindrone, desogestrel and norgestimate, drospirenone

Types of Oral Contraceptives

- Monophasic
 - Three weeks with each tablet containing the same amount of medication
 - One week of inactive tablets
- Multiphasic
 - Different amount of hormone in 3 different sets of “phases” of months and then a week of inactive tablets

Considerations when Selecting Self-Administered Hormonal Contraception

- Complete medical exam and Pap smear are not required before hormonal contraception is provided
- What should be done?
 - Medical History
 - Blood pressure measurement
 - Discussion of benefits, risks, and adverse effects with each patient

Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. *MMWR* 2010;59(RR04):1–85.

Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013. *MMWR* 2013;63(RR-5):1–60.

HB 2583: The Family Planning Access Act – The Bill

- The Family Planning Access Act passed during the WV Legislative Session 2019.
- The passage of this bill made West Virginia the 10th state in the nation to permit a pharmacist to dispense a self-administered hormonal contraceptive under a standing prescription drug order by the State Health Officer.
- This bill is limited to individuals 18 years or older.
- Patients must complete a self-screening risk assessment questionnaire. The patient is then assessed for safety and appropriateness of hormonal contraceptive use by a trained pharmacist. Counseling from a pharmacist on appropriate administration and storage, potential side effects and risks, the need for backup contraception, when to seek emergency medical attention, the risk of contracting a sexually transmitted infection or disease, and ways to reduce the risk of contraction is provided.

Stakeholders

- Representatives from around the state began meeting shortly after the bill was signed by the Governor to design implementation documents.
- Bureau for Public Health, Family Planning Program, State Medical Officer, Board of Pharmacy, Board of Medicine, Schools of Pharmacy, OB/GYNs worked to tailor other state programs for WV patients.
- Evaluated appropriate screening tools and training programs.
- Program circulated to pharmacy, medical, nursing practitioners, and others for feedback.
- Met with key state payer stakeholders for implementing a process for pharmacy reimbursement.

Visual of How it works: Patient Perspective

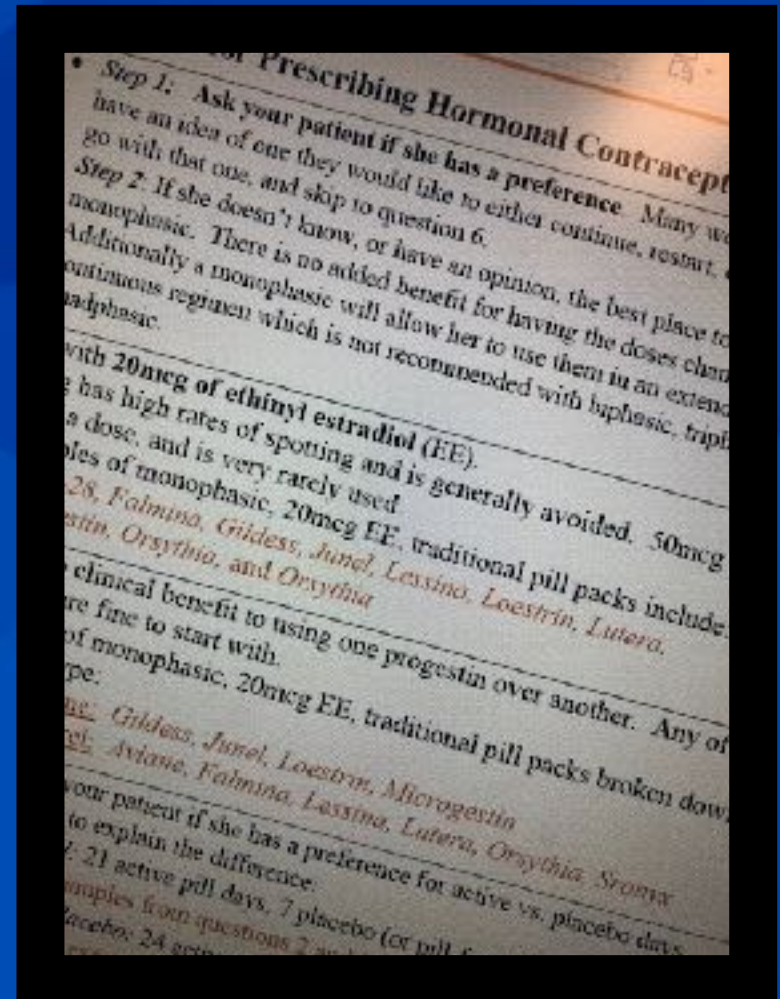
- Similar to getting an immunization at the pharmacy.
- Patient presents at pharmacy and request pharmacist-provided counseling and hormonal contraception.
- Completes Self-assessment Questionnaire for hormonal contraception.
- Consults with pharmacist regarding most appropriate hormonal contraception or applicable referral for other methods.
- If yes and a NEW type: It is recommended that the patient gets prescription for up to 3 months of new type. Then close to the end of the 3 month period there is a follow-up consult (could be via phone). If no issues, prescription is issued for remainder of 12 months. If change needed, reevaluation is done and change made with prescription issued.). It is permissible for the pharmacist, if in his or her professional judgement determining it is appropriate to do so, to provide the full 3 months with a year refills at the initial visit.
- If yes and patient been on before: Gets prescription and may get up to 3 months with refills for up to 12 months.
- If no, referral made to appropriate additional health care provider.
- Education completed regardless of path above.

Visual of How it works: Pharmacist Perspective

- Training and registration with WV Board of Pharmacy.
- Process is similar to above, Use Questionnaire as the RX.
- Counseling is vital in the assessment and selection process
- Must keep the Questionnaire on file even if no contraception is dispensed as documentation of the visit and consultation.
- Must notify PCP, if hormonal birth control provided
- Provide referrals as applicable

Training for Pharmacists

- A 4-hour web-based continuing education program.
- Developed by multiple disciplines including several OBGYN members on ACOG.
- Currently used by 9 other states as the preferred training program.
- Tailored to WV specific law and protocol.
- Continually available for reference.



The WV Questionnaire

West Virginia Pharmacy Accessible Birth Control (Pharmacist ABC) Self-Screening Questionnaire

Name: _____ Health Care Provider's Name: _____ Date: _____
 Date of Birth: _____ Age: _____ (must be 21) Weight: _____ lb _____ Do you have health insurance? Yes/No
 What was the date of your last women's health clinical visit? _____
HEALTHCARE HISTORY
 Any allergies to medications? Yes/No: If yes, list them here: _____
 Current method of birth control: _____ Types of birth control ever used: _____
What is your preferred method of birth control? *SPEAK TO YOUR PHARMACIST AFTER ANSWERING THIS QUESTION*
 A daily tablet A weekly patch A monthly vaginal ring Injection (every 3 months) OTHER (SUBJECTIVE)

Background Information:

1	Do you think you might be pregnant now?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	What was the first day of your last menstrual period?	_____
3	Have you ever been treated by a medical professional for a pelvic infection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
4	Have you ever taken birth control pills, inserted a birth control patch, ring, or injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Have you previously received birth control prescriptions to go by the pharmacist?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6	Did you ever experience an adverse reaction to using hormonal birth control? If yes, what kind of reaction occurred?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Are you currently using any method of birth control including pills, or a birth control patch, ring, or injection? If yes, which one are you using?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Medical History:

9	Have you had a recent change in vaginal bleeding that worries you?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Have you given birth within the past 21 days? If yes, how long ago?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Are you currently breastfeeding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever had a migraine headache? If so, have you ever had the onset of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or feet that comes and goes completely even before the headache starts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Are you being treated for inflammatory bowel disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Do you have high blood pressure or high cholesterol? (Please indicate yes, even if it is being controlled by medication)	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Have you ever had a heart attack or stroke or been told you have any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	Have you ever had a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
18	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Have you had recent major surgery or are you planning to have surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
20	Will you be immobile for a long period? (e.g. lying in a long airplane trip, etc.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
21	Have you had surgical surgery or abnormal uterine surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
22	Do you have or have you ever had HIV/AIDS, hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
23	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
24	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
25	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)? If yes, list them here: _____	Yes <input type="checkbox"/> No <input type="checkbox"/>
26	Do you have a medical condition that you have any education, including herbal supplements? If yes, list them here: _____	Yes <input type="checkbox"/> No <input type="checkbox"/>

Adapted from Oregon Board of Pharmacy For In-home Review/Latest Update 11/03/2020

27	Have you had any of the following vaccinations? If yes, when?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Tdap/Tdap (Td)	Yes A _____ Yes B _____
	Flu	Yes _____ No _____

Pregnancy Screen:

a.	Did you have a baby less than 6 months ago, and you fully or nearly fully breast feed? And have you had no sexual or genital skin-to-skin contact?	Yes <input type="checkbox"/> No <input type="checkbox"/>
b.	Have you had a baby in the last 6 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
c.	Did you have a test (pregnancy test, blood test, or urine test) in the last 7 days?	Yes <input type="checkbox"/> No <input type="checkbox"/>
d.	Did you feel a normal period due, with no test, in the last 7 days?	Yes <input type="checkbox"/> No <input type="checkbox"/>
e.	Have you had a normal period since your last normal or possible delivery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
f.	Have you been using a reliable contraceptive method consistently and correctly?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Question _____ Answer _____

Validated BPH without IUD or IUD BPH Pending _____ / _____ * Must be taken by RPh

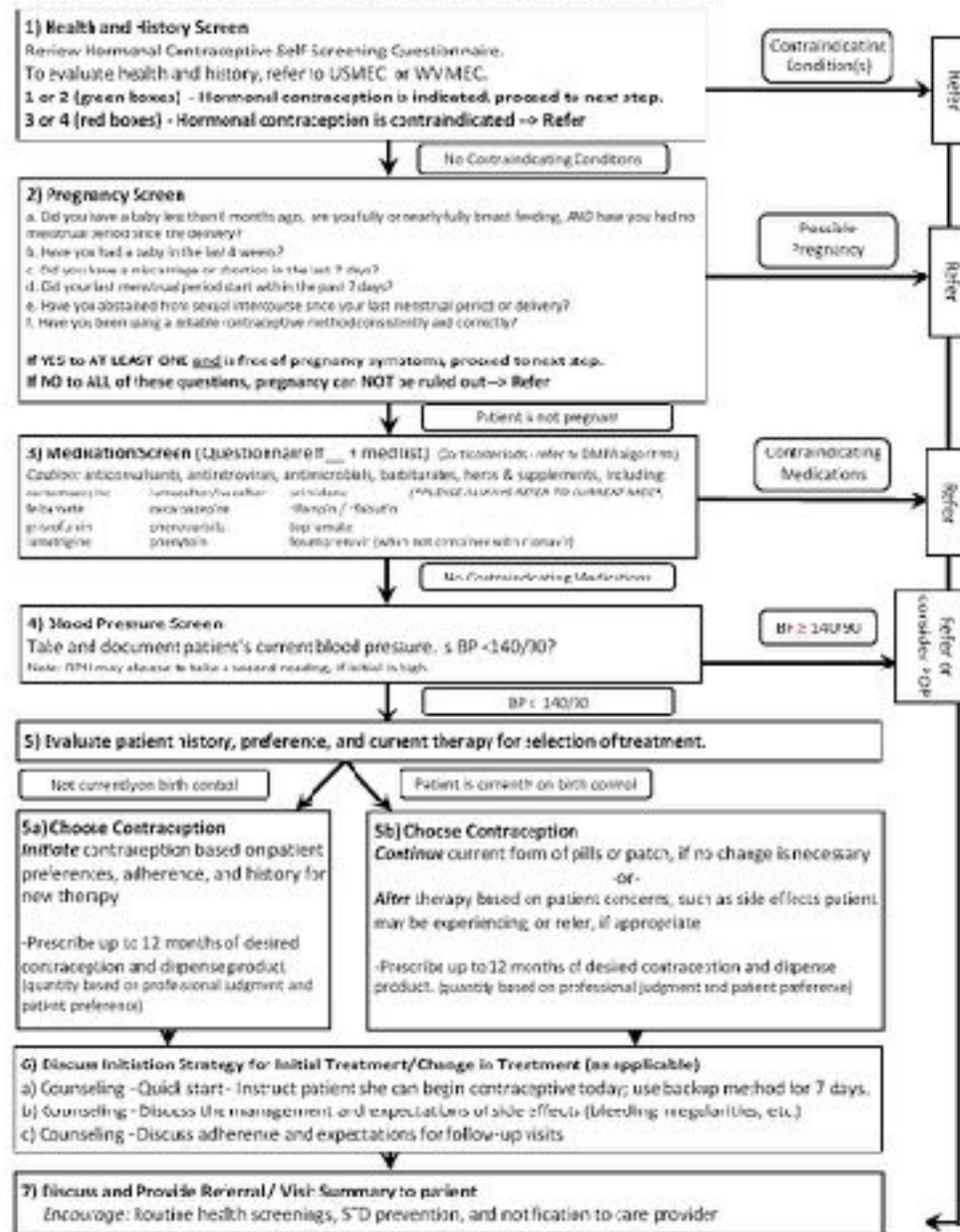
NOTE: BPH MUST REFER PATIENT TO RTU OR SUSPECTED HIV POSITIVE RESULTS TO RTU. NOT CREDITED!

Drug Prescribed: _____
 Pharmacist Name: _____ RPh Signature: _____
 Pharmacy Address: _____ Pharmacy Phone: _____
 Patient confirmed
 Patient: _____
 Medical Referral for IUD, IUD, or Further Medical Evaluation Annual reproductive health visit
 Tobacco Use/Status: _____
 Immunizations: _____

Adapted from Oregon Board of Pharmacy For In-home Review/Latest Update 11/03/2020

The WV Algorithm

STANDARD PROCEDURES ALGORITHM FOR WV PRESCRIBING OF CONTRACEPTIVES



Summary of US MEC to WV Questionnaire

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

1. This chart is a summary of the U.S. Medical Eligibility Criteria for Contraceptive Use. It is not a substitute for the full criteria. For more information, see the full criteria at www.fda.gov/oc/ohrt/contraception/contraception_mec.html.

Category	U.S. MEC	WV MEC
1. Contraceptive use	1-4	1-4
2. Contraceptive use	1-4	1-4
3. Contraceptive use	1-4	1-4
4. Contraceptive use	1-4	1-4

2. This chart is a summary of the U.S. Medical Eligibility Criteria for Contraceptive Use. It is not a substitute for the full criteria. For more information, see the full criteria at www.fda.gov/oc/ohrt/contraception/contraception_mec.html.

Comparing the West Virginia Self-Screening Risk Assessment Questions to the

Question	U.S. MEC	WV MEC	U.S. MEC	WV MEC
1. Age	1-4	1-4	1-4	1-4
2. Smoking	1-4	1-4	1-4	1-4
3. Pregnancy	1-4	1-4	1-4	1-4
4. Breastfeeding	1-4	1-4	1-4	1-4
5. Blood pressure	1-4	1-4	1-4	1-4
6. Diabetes	1-4	1-4	1-4	1-4
7. Migraine	1-4	1-4	1-4	1-4
8. History of blood clots	1-4	1-4	1-4	1-4
9. History of stroke	1-4	1-4	1-4	1-4
10. History of heart disease	1-4	1-4	1-4	1-4
11. History of liver disease	1-4	1-4	1-4	1-4
12. History of kidney disease	1-4	1-4	1-4	1-4
13. History of HIV/AIDS	1-4	1-4	1-4	1-4
14. History of tuberculosis	1-4	1-4	1-4	1-4
15. History of hepatitis	1-4	1-4	1-4	1-4
16. History of other conditions	1-4	1-4	1-4	1-4

Question	U.S. MEC	WV MEC		U.S. MEC	WV MEC
		1-4	1-4		
1. Age	1-4	1-4	1-4	1-4	1-4
2. Smoking	1-4	1-4	1-4	1-4	1-4
3. Pregnancy	1-4	1-4	1-4	1-4	1-4
4. Breastfeeding	1-4	1-4	1-4	1-4	1-4
5. Blood pressure	1-4	1-4	1-4	1-4	1-4
6. Diabetes	1-4	1-4	1-4	1-4	1-4
7. Migraine	1-4	1-4	1-4	1-4	1-4
8. History of blood clots	1-4	1-4	1-4	1-4	1-4
9. History of stroke	1-4	1-4	1-4	1-4	1-4
10. History of heart disease	1-4	1-4	1-4	1-4	1-4
11. History of liver disease	1-4	1-4	1-4	1-4	1-4
12. History of kidney disease	1-4	1-4	1-4	1-4	1-4
13. History of HIV/AIDS	1-4	1-4	1-4	1-4	1-4
14. History of tuberculosis	1-4	1-4	1-4	1-4	1-4
15. History of hepatitis	1-4	1-4	1-4	1-4	1-4
16. History of other conditions	1-4	1-4	1-4	1-4	1-4

The Referral Sheet

Patient Name _____ Date _____

Pharmacist Visit Summary

____ Today you were prescribed the following birth control: _____
(Notes: _____)

Please review this information with your primary care or women's health provider. At least one yearly visit with your doctor or health care provider is required to continue receiving this prescription for more than one year. This allows you the opportunity to talk to your doctor about your health and any necessary screenings. The visit **MUST** take place within 12 months of receiving your initial prescription.

Additional Referrals:

Tobacco Cessation Therapy

Other _____

- or -

____ I am not able to prescribe hormonal contraception to you today, because:

Pregnancy cannot be ruled out

(Notes: _____)

You have a health condition that requires further evaluation.

(Notes: _____)

You take medication(s) or supplements that may interfere with hormonal birth control.

(Notes: _____)

Your blood pressure (bp) reading is higher than 140/90 units. (BP at reading: ____ / ____)

Each requires additional evaluation by another healthcare provider. Please share this information with your provider.

If you have a question, my name is _____

Pharmacist Name _____

Pharmacy Name _____

Address _____

Phone _____

Resources:



1-800-HITHEMVV
ONE Call
ONE Text
ONE Plus
BUTANI HELP

HITHEMVV offers immediate help for any West Virginian struggling with an addiction or mental health issue.



WV Family Planning Program
What's Your Plan?
800-536-1438
<http://www.wvfamilyplanning.org>
<https://www.wvfamilyplanning.org>



The National Domestic Violence
HOTLINE
1-800-799-7233 • 1-800-785-2044



HB 2525: Tobacco Cessation Therapy Act

- The Tobacco Cessation Therapy Act Passed during the WV Legislative Session 2019
- The standing order is issued pursuant to WV Code §16-56 Tobacco Cessation Therapy Access Act which permits the State Health Officer, on a statewide basis, to prescribe tobacco cessation therapies according to the requirements of this order.
- This bill is limited to individuals 18 years or older
- Patients must complete a self-screening risk assessment questionnaire. Patients must meet the approved criteria when using the WV Tobacco Use Questionnaire to qualify to receive a selected medication. If the assessment indicates that it is safe to dispense the patient preferred tobacco cessation therapy, the pharmacist has the authority to dispense it.
- Tobacco Cessation Therapy must include both medication and behavioral coaching.

How it works

- The patient indicates to the Pharmacist that they want to quit using tobacco.
- The patient and pharmacist complete the Tobacco Cessation Self-Screening Questionnaire and if the assessment indicates that it is safe to dispense the patient preferred tobacco cessation therapy, the pharmacist has the authority to dispense it.
- Tobacco Cessation Therapy must include both medication and behavioral coaching.
- The pharmacist, in consultation with the client, may select any nicotine replacement product, bupropion SR, Varenicline, or Evidence-based combination therapies at dosing per Clinical Practice Guideline: Treating Tobacco Use and Dependence (most recent update available) and the Mayo Clinic Guidelines.
- If the patient selects nicotine replacement products supplied by the WV Tobacco Quitline, the referral will be provided using the Referral Form or online referral.
- Behavioral coaching may be provided by the Pharmacist (if qualified with CTTS) or the by the WV Tobacco Quitline.
- Follow-up monitoring and evaluation shall occur initially after 2 weeks to determine effectiveness, adverse effects, and progress with therapy. The Coaching calls and follow-up may occur via the pharmacist and/or the WV Quitline, but the method must be clearly documented. If follow-up monitoring and evaluation indicate therapy is warranted, medication refills may be authorized until the recommended duration of therapy is complete.

Training for Pharmacists

At this time there are two training programs in preparation. Pharmacists can complete either to be eligible to participate in this protocol.

- 1. A 3-hour web-based program**
- 2. A 3-hour live program**

Both programs cover the pharmacotherapy of the medications involved, the basics of motivational interviewing, epidemiology of smoking in WV and the details of the how the Tobacco Cessation Therapy Access Act works.

If a pharmacist has the CTTS certification, there is a 1 hour CE of just how the protocol works.

Naloxone

There are 3 ways that a pharmacist can provide naloxone without a physician/NP/PA prescription.

1. Pursuant to West Virginia Code §16-46-3a, there is a protocol created by the Board of Pharmacy in consultation with the Bureau for Public Health permitting a pharmacist or pharmacy intern to dispense an opioid antagonist without a prescription
2. Per the Naloxone Standing Order issued by State Health Officer
3. Per HB 4102 (session 2020) permitting pharmacist to provide to certain groups who are providing scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors provides naloxone and basic education

Immunizations

WV Law

- 18+: Permits pharmacists to order/administer and interns to administer all ACIP recommended vaccines for ages 18+
- Ages 11-17 years: Permits pharmacists/interns to administer all ACIP recommended vaccines with rx from physician

PER PREP Act 3rd Amendment – supersedes WV law

- In addition, Permits pharmacists to order and administer and interns and pharmacy technicians (properly trained) to administer all ACIP vaccines for those ages 3-17 and for ages 18+ pharmacy technicians may administer influenza

Other opportunities for team-based care

- Collaborative Pharmacy Practice
- Inpatient opportunities
- Outpatient opportunities
- Collaborating with pharmacists to improve patient outcomes
 - American Medical Associations – StepsForward Program
 - <https://edhub.ama-assn.org/steps-forward/module/2702554>

Summary

- Increased opportunities to improve access
- Team-based care across providers
- 4 programs: two getting started and two proven effective

Questions

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