HB 178 DRAFT PROPOSED RULES-6/16/2021

R156-17b-627 Operating Standards-Prescription of drugs or devices by a pharmacist-

(1)In accordance with Subsections 58-17b-601(1) and 58-17b-627(3), a pharmacist who issues a prescription for a legitimate medical purpose designated in Subsection 58-17b-627 (3(a)(i) through (v), shall:

(a) follow guidance adopted xx,xx, 2021 by the Division, as posted on the Division's website https://dopl.utah.gov/pharm/;

(b)Conduct a patient **assessment** to include;

(i) patients health status

(ii_ rationale for care; and

(iii) current medication

(c)follow prescribing drug or device **guidance for health care providers** by

(i) the CDC; or

(ii)the Department of Health and Division in collaboration with the Board, using evidence based guidelines.

(d)Develop and implement an appropriate **follow-up** care plan with the patient to include;

(1)monitoring parameters;

(2)adverse reaction; and

(3)further medical care.

(e)(i)The Pharmacist shall identify the patient's primary care or other **health care provider**, and provide **notice** of the prescription in writing, by electronic transmission or telephone within five (5) business days following the prescribing of a drug or device.

(ii) The prescription notice shall include the following

(a)patient assessment in section (1) (a);

(b) prescribing pharmacist;

(c) pharmacy name;

(d) pharmacy phone number;

(e) patient;

(f) drug or device;

(g) dispensed quantity;

(h) directions for use; and

(i) refill.

(f) Documentation of patient care provided, shall be retained in a readily retrievable form and location for 5 years following the date of the transaction and shall include:

(i) notice in section (1)(c)(i);

(ii) Identity of the primary care or other health care provider; and

(iii) Notice of contact of the primary care or other health care provider.

(2) Each prescription prescribed by a pharmacist shall be:

(a) dispensed in accordance with Subsection 58-17b-602(1)(a) through (f) and Section 58-17b-609; and

(b) dispensed from a Class A or Class B pharmacy

Utah Guidance for Pre-Exposure and Post-Exposure Prophylaxis of HIV
Approved x,xx 2021

This collaborative pharmacy practice statewide protocol authorizes qualified Utah-licensed pharmacists ("Pharmacists") to provide pertinent assessment of risk of HIV acquisition and prescribe pre-exposure and post-exposure prophylaxis medications for the prevention of HIV infection according to and in compliance with all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the US Centers for Disease Control and Prevention (CDC)[1, 2] and the United States Preventive Services Task Force (USPSTF)[3] .

Prior to prescribing and dispensing HIV prevention medication per this protocol, the pharmacist must:

1. Hold a current license to practice in Utah
2. Be engaged in the practice of pharmacy
3. Have earned a Doctor of Pharmacy degree or completed at least 5 years of experience as a licensed pharmacist
4. Carry adequate professional liability insurance as determined by the Division in collaboration with the Board (Need Board input on adequate insurance).
5. Complete a training program accredited by the Accreditation Council for Pharmacy Education, or equivalent in accordance with Utah Admin Code R156-17b-303a(2)(a) and(c).
6. Follow rules in Utah Admin Code R156-17b-627

[1] CDC Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2017 Update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

[2] Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV-United States, 2016. Available at: https://stacks.cdc.gov/view/cdc/38856

[3] USPTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

The pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality. Records:

A. Pursuant to Utah Admin. Code R156-17b-627(1)(e), a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and lab test(s) ordered, and any test results.

B. Pharmacists shall comply with all aspects of Utah Code 58-17b-611 with respect to the maintenance of proper records.

Pre-Exposure Prophylaxis (PrEP) Protocol

Under this protocol, Pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table 1 according to the following criteria:

1. Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care fingerstick blood test, taken within 7 days. Neither oral swab testing nor patient report of negative status are acceptable for evidence.

2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:

a. MSM (men who have sex with men)
- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following:

- any anal sex without condoms (receptive or insertive) in the past 6 months
- A bacterial STI (syphilis, gonorrhea or chlamydia) diagnosed or reported in past 6 months

b. Heterosexually Active Men and Women
- Adult person
- Without acute or established HIV infection

• Any sex with opposite sex partners in past 6 months
• Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following:

• Is a man who has sex with both women and men (behaviorally bisexual)
• Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be substantial risk of HIV infection (persons who inject drugs PWID or bisexual male partner)
• Is in an ongoing sexual relationship with an HIV-positive partner
• A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

c. Persons Who Inject Drugs (PWID)
• Adult person
• Without acute or established HIV infection
• Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following:

• Any sharing of injection or drug preparation equipment in past 6 months
• Risk of sexual acquisition (see above)

Patients who should NOT be prescribed PrEP under this protocol and should be referred to primary care provider for further action:

• Patients with baseline HIV tests indicating existing HIV infection
• Recent flu-like symptoms in the past month as this may suggest recent HIV infection not yet detectable (tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin)
• CRCL < 60 ml/min

TABLE 1 – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available.

Formulations, cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

Medication	Age/Weight	Frequency	Duration of Therapy	Notes
FTC/TDF emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <60 ml/min.
FTC/TAF emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women. Pharmacist must review drug/drug interaction considerations as per package insert Table 5.

TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

• PrEP cannot be started without a negative HIV test at baseline.

• Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab results.

• PrEP refills will not be authorized past the initial 30 day supply if recommended baseline testing is not done by one of the above mechanisms.

Test	Frequency	CDC recommendations	Notes
HIV	Baseline + Every 3 months	**Required**	If positive, refer
Three site STI screening (syphilis, gonorrhea, chlamydia)	Baseline + At 3 mo if symptomatic. Every 6 months if asymptomatic	Recommended	If positive – refer for care
Serum creatinine	Baseline, at 3 months, and thereafter every 6 months	Recommended	If CRCL <60 ml/min, cannot use FTC/TDF If CRCL <30 ml/min cannot use FTC/TAF
Hepatitis B screening	Baseline	Recommended	If positive – refer for care
Bone health		Optional	
Need to continue PrEP	Annually	Recommended if at continued risk	Discuss with patient

Counseling (at minimum):

• Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)

• The importance of medication adherence with relation to efficacy of PrEP/nPEP

• Signs/symptoms of acute HIV infection and recommended actions

• Consistent and correct use of condoms and prevention of STIs

• The necessity of follow up care with a primary care provider for usual care

• The importance and requirement of testing for HIV, renal function, hepatitis B, and sexually transmitted diseases

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the

pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.

- The pharmacist will also follow all rules in Utah Admin Code R156-17b-627

Referrals to primary care provider:

• If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://hivandme.com/find-a-clinic/ or https://ptc.health.utah.gov/local-health-departments/ (need confirmation from DOH that this is the best resource)

If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://ptc.health.utah.gov/local-health-departments/ (need confirmation from DOH that this is the best resource)

• If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. http://health.utah.gov/epi/diseases/hepatitisB/ (Couldn't find how to locate providers or clinics on this site) https://ptc.health.utah.gov/local-health-departments/

• Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

• If a female patient becomes pregnant while on PrEP

• Usual care for any other issues, stress importance of routine primary care and health maintenance.

Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol

Non-Occupational Post-Exposure Prophylaxis (nPEP) is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. nPEP must be started as soon as possible to be effective, and always within 72 hours of the possible exposure. This particular protocol addresses non occupational post-exposure prophylaxis (nPEP) only, those with occupational exposures are not eligible and should be referred for care.

Under this protocol, pharmacists may assess patients 13 and older for high-risk exposure to HIV and prescribe antiretroviral drugs if appropriate. Patients under 18 years of age require parental consent to access this Protocol. nPEP should only be provided for infrequent exposures.

If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be referred to another provider. PEP providers in Utah include the Department of Health (888-222-2542 is this the best number at the DOH?) and local emergency departments.

If the following criteria are met, antiretroviral agents in Table 1 are recommended:

• The exposure must have occurred within 72 hours

• A rapid antibody CLIA waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and nPEP is otherwise indicated, therapy should still be initiated.

• Exposure to a source individual known to be HIV-positive. Exposure of:

- o Vagina
- o Rectum
- o Eye
- o Mouth
- o Other mucous membranes
- o Nonintact skin
- o Percutaneous contact (e.g., injecting drugs with a contaminated needle or needle stick injury)

WITH

- o Blood
- o Semen
- o Vaginal secretions
- o Rectal secretions
- o Breast milk
- o Any body fluid visibly contaminated with blood

- Exposure types with the highest risk of transmission of HIV are:

  - o Needle sharing during injection drug use
  - o Percutaneous needle stick
  - o Receptive anal intercourse

• If exposure with a source in which the HIV status is not known, nPEP may be considered and antiretroviral agents in Table 1 may be prescribed. NPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Colorado Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

Patients who should NOT be prescribed nPEP under this protocol and should be referred to primary care provider for further action:

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP
- If a child presents to the pharmacy with a request for NPEP and is potentially a victim of child abuse, child protective services MUST be contacted.

Other Considerations:

- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). Resources may be found at https://www.ucasa.org/
- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services MUST be contacted 1-855-323-3237.

TABLE 1.A – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available. Formulations cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

Medication	Age/Weight	Dose	Duration of Therapy	Notes
PREFERRED REGIMEN				
emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic) PLUS raltegravir 400mg OR Dolutegravir 50mg	≥ 13 years	Once daily #28 no refills Twice daily #56 no refills Once daily #28 no refills	28 days	Dosing adjustments with renal dysfunction if CrCL <60 ml/min. Dolutegravir should not be used in pregnant women If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then “alternative regimens” per CDC guidelines should be referenced and used.

TABLE 2.A – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

• All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is.

• Ask the following screening question:

1. Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

In this event, pharmacist should make arrangements to refer patient for a Scr blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCL <60 ml/min).

• Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.(Is this within the scope of the pharmacist and the direction to go with the Bill?)

• Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

Test	Frequency	CDC recommendations	Notes
HIV	Baseline + Post-exposure at week 4-6, and months 3 and 6	**Required**	If positive, refer.
STI screenings (syphilis, gonorrhea, chlamydia)	Baseline	Recommended	If positive – refer for care
Serum creatinine	Baseline + @4-6 weeks.	Recommended	
ALT/AST	Baseline + @4-6 weeks.	Recommended	
Hepatitis B screening	Baseline + 6 mo	Recommended	If positive – refer. If negative and clinically appropriate, vaccinate
Hepatitis C screening	Baseline + 6 mo	Recommended	If positive - refer
Pregnancy	Baseline + @4-6 weeks.	Recommended	Pregnancy is not a contraindication to NPEP

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all rules in accordance with Utah Admin Code R156-17b-627.

Referrals:

If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at https://ptc.health.utah.gov/local-health-departments/

- The patient should be referred immediately for guideline based follow-up HIV testing and care, and follow-up testing for STIs, Hepatitis C, and Hepatitis B.
- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- If a patient tests positive for Hepatitis B or C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

- Signs of symptoms of acute drug toxicities or serious side effects

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

Information for DOPL'S website:

1. This protocol
2. CDC PREP Guidelines: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
3. CDC PEP Guidelines: https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
4. USPTF Recommendations: https://jamanetwork.com/journals/jama/fullarticle/2735509
5. DOH Providers https://ptc.health.utah.gov/local-health-departments/
6. Utah Coalition Against Sexual Assualt https://www.ucasa.org/
7. Utah Division of Child Protective Services https://dcfs.utah.gov/services/child-protective-services/

Utah Guidance for Self-Administered Hormonal Contraceptives
Approved xx,x, 2021

This guidance authorizes qualified Utah-licensed pharmacists ("Pharmacists") to perform the pertinent assessments and prescribe hormonal contraceptives under the conditions of this guidance and according to and in compliance with all applicable state and federal laws and rules.

Training Program

Only a Utah-licensed pharmacist, who has completed an Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may dispense hormonal contraceptive patches, a hormonal vaginal ring, and oral hormonal contraceptives to a patient. In addition, pharmacists shall comply with the most current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use as adopted by the U.S. Centers for Disease Control and Prevention (CDC).

Age Requirements

A pharmacist may prescribe hormonal contraceptive patches, a hormonal vaginal ring, and self-administered oral hormonal contraceptives to a person who is at least 18 years of age.

Further Conditions

(1) For each new patient requesting a contraceptive service and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:

(a) Obtain a completed Utah Hormonal Contraceptive Self-Screening Questionnaire;

(b) Utilize and follow the Standard Procedures Algorithm for Prescribing of Contraceptives to perform the patient assessment;

(c) Prescribe, if clinically appropriate, the hormonal contraceptive patch, self-administered oral hormonal contraceptive, hormonal vaginal ring, or refer to a healthcare practitioner;

(d) Provide the patient with a Visit Summary;

(e) Advise the patient to consult with a primary care practitioner or women's health care practitioner;

(f) Refer any patient that may be subject to abuse to an appropriate social services agency; and

(g) Ensure that the pharmacy provides appropriate space to prevent the spread of infection and ensure confidentiality.

(2) If the hormonal contraceptive patch, hormonal vaginal ring, or self-administered oral hormonal contraceptive is dispensed, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.

(3) A pharmacist must not:

(a) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit; or

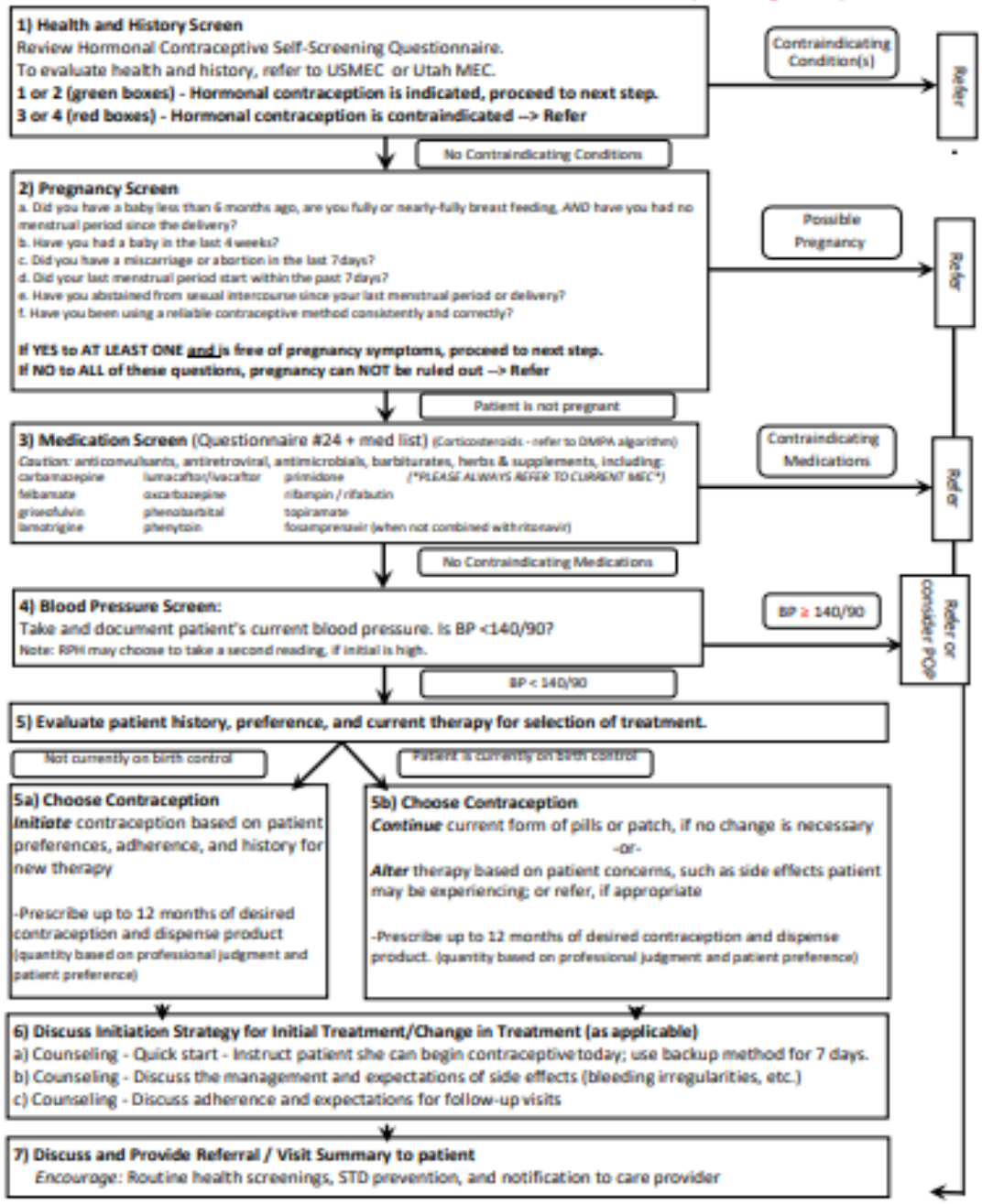
(b) Prescribe in instances that the Standard Procedures Algorithm requires referral to a provider.

(4) Records:

(a) Pursuant to Utah Admin Code R156-17b-627, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(b) Pharmacists shall comply Utah Code 58-17b-611 with respect to the maintenance of proper records.

STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING OF CONTRACEPTIVES (excluding DMPA)



Utah Hormonal Contraceptive Self-Screening Questionnaire

Name_____ Health Care Provider's Name_____ Date_____

Date of Birth_____ Age_____ (must be 18) Weight _____ Do you have health insurance? Yes / No

What was the date of your last women's health clinical visit? _____

Any allergies to Medications? *Yes / No* If yes, list them here _____

Do you have a preferred method of birth control that you would like to use?

□A daily pill □A weekly patch □A monthly vaginal ring □Injectable (every 3 mo.) □Other (IUD, implant)

Background Information:

1	Do you think you might be pregnant now?	Yes □ No□
2	What was the first day of your last menstrual period?	___/___/___
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection? Have you previously received contraceptives?	Yes □ No □ Yes □ No □
	Did you ever experience a bad reaction to using hormonal birth control?	Yes □ No □
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes □ No □
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes □ No □
5	Do you smoke cigarettes?	Yes □ No □

Medical History:

6	Have you had a recent change in vaginal bleeding that worries you?	Yes □ No □
7	Have you given birth within the past 21 days? If yes, how long ago?	Yes □ No □
8	Are you currently breastfeeding?	Yes □ No □
9	Do you have diabetes?	Yes □ No □
10	Have you ever had a migraine headaches?	Yes □ No □
11	Are you being treated for inflammatory bowel disease?	Yes □ No □
12	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes □ No □
13	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □ No □
14	Have you ever had a blood clot?	Yes □ No □
15	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes □ No □
16	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □ No □
17	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes □ No □
18	Have you had bariatric surgery or stomach reduction surgery?	Yes □ No □
19	Do you have or have you ever had breast cancer?	Yes □ No □
20	Have you had a solid organ transplant?	Yes □ No □
21	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 □ No □
22	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes □ No □
23	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes □ No □
	- If yes, list them here:	
24	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes □ No □
	- If yes, list them here:	

*Signature*_____ *Date*_____

Optional Side – May be used by pharmacy
This side of form may be customized by pharmacy –Do not make edits to the Questionnaire (front side)

Pregnancy Screen	
a. Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	Yes □ No □
b. Have you had a baby in the last 4 weeks?	Yes □ No □
c. Did you have a miscarriage or abortion in the last 7 days?	Yes □ No □
d. Did your last menstrual period start within the past 7 days?	Yes □ No □
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes □ No □
f. Have you been using a reliable contraceptive method consistently and correctly?	Yes □ No □

☐ Verified DOB with valid photo ID ☐ BP Reading _____ /_____

Note: Must refer patient if either systolic or diastolic reading is out of range, per algorithm

℞ Drug Prescribed _____ Rx_____
Directions for Use _____
Pharmacist Name _____ Pharmacist Signature _____
Pharmacy Address _____ Pharmacy Phone _____

-or-

☐ Patient Referred

Notes:
_____
_____
_____

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

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <20 yrs:2		Menarche to <20 yrs:2		Menarche to <18 yrs:1		Menarche to <18 yrs:2		Menarche to <18 yrs:1		Menarche to <40 yrs:1	
		≥20 yrs:1		≥20 yrs:1		18-45 yrs:1 >45 yrs:1		18-45 yrs:1 >45 yrs:2		18-45 yrs:1 >45 yrs:1		≥40 yrs:2	
Anatomical abnormalities	a) Distorted uterine cavity	4		4									
	b) Other abnormalities	2		2									
Anemias	a) Thalassemia	2		1		1		1		1		1	
	b) Sickle cell disease[2]	2		1		1		1		1		2	
	c) Iron-deficiency anemia	2		1		1		1		1		1	
Benign ovarian tumors	(*including cysts*)	1		1		1		1		1		1	
Breast disease	a) Undiagnosed mass	1		2		2*		2*		2*		2*	
	b) Benign breast disease	1		1		1		1		1		1	
	c) Family history of cancer	1		1		1		1		1		1	
	d) Breast cancer[2]												
	i) Current	1		4		4		4		4		4	
	ii) Past and no evidence of current disease for 5 years	1		3		3		3		3		3	
Breastfeeding	a) <21 days postpartum							2*		2*		4*	
	b) 21 to <30 days postpartum												
	i) With other risk factors for VTE							2*		2*		3*	
	ii) Without other risk factors for VTE							2*		2*		3*	
	c) 30-42 days postpartum												
	i) With other risk factors for VTE							1*		1*		3*	
	ii) Without other risk factors for VTE							1*		1*		2*	
	d) >42 days postpartum							1*		1*		2*	
Cervical cancer	Awaiting treatment	4	2	4	2	2		2		1		2	
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		1		2		2		2		1		2	
Cirrhosis	a) Mild (*compensated*)	1		1		1		1		1		1	
	b) Severe[2] (*decompensated*)	1		3		3		3		3		4	
Cystic fibrosis[3]		1*		1*		1*		2*		1*		1*	
Deep venous thrombosis (DVT)/Pulmonary embolism (PE)	a) History of DVT/PE, not receiving anticoagulant therapy												
	i) Higher risk for recurrent DVT/PE	1		2		2		2		2		4	
	ii) Lower risk for recurrent DVT/PE	1		2		2		2		2		3	
	b) Acute DVT/PE	2		2		2		2		2		4	
	c) DVT/PE and established anticoagulant therapy for at least 3 months												
	i) Higher risk for recurrent DVT/PE	2		2		2		2		2		4*	
	ii) Lower risk for recurrent DVT/PE	2		2		2		2		2		3*	
	d) Family history (*first-degree relatives*)	1		1		1		1		1		2	
	e) Major surgery												
	i) With prolonged immobilization	1		2		2		2		2		4	
	ii) Without prolonged immobilization	1		1		1		1		1		2	
	f) Minor surgery without immobilization	1		1		1		1		1		1	
Depressive disorders		1*		1*		1*		1*		1*		1*	

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Diabetes	a) History of gestational disease	1		1		1		1		1		1	
	b) Nonvascular disease												
	i) Non-insulin dependent	1		2		2		2		2		2	
	ii) Insulin dependent	1		2		2		2		2		2	
	c) Nephropathy/retinopathy/neuropathy[4]	1		2		2		3		2		3/4*	
	d) Other vascular disease or diabetes of >20 years' duration[3]	1		2		2		3		2		3/4*	
Dysmenorrhea	Severe	2		1		1		1		1		1	
Endometrial cancer[2]		4	2	4	2	1		1		1		1	
Endometrial hyperplasia		1		1		1		1		1		1	
Endometriosis		2		1		1		1		1		1	
Epilepsy[2]	(*see also Drug Interactions*)	1		1		1*		1*		1*		1*	
Gallbladder disease	a) Symptomatic												
	i) Treated by cholecystectomy	1		2		2		2		2		2	
	ii) Medically treated	1		2		2		2		2		3	
	iii) Current	1		2		2		2		2		3	
	b) Asymptomatic	1		2		2		2		2		2	
Gestational trophoblastic disease[3]	a) Suspected GTD (immediate postevacuation)												
	i) Uterine size first trimester	1*		1*		1*		1*		1*		1*	
	ii) Uterine size second trimester	2*		2*		1*		1*		1*		1*	
	b) Confirmed GTD												
	i) Undetectable/non-pregnant ß-hCG levels	1*	1*	1*	1*	1*		1*		1*		1*	
	ii) Decreasing ß-hCG levels	2*	1*	2*	1*	1*		1*		1*		1*	
	iii) Persistently elevated ß-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2*	1*	2*	1*	1*		1*		1*		1*	
	iv) Persistently elevated ß-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4*	2*	4*	2*	1*		1*		1*		1*	
Headaches	a) Nonmigraine (mild or severe)	1		1		1		1		1		1	
	b) Migraine												
	i) Without aura (includes menstrual migraine)	1		1		1		1		1		2*	
	ii) With aura	1		1		1		1		1		4*	
History of bariatric surgery[3]	a) Restrictive procedures	1		1		1		1		1		1	
	b) Malabsorptive procedures	1		1		1		1		3		COCs: 3	
												P/R: 1	
History of cholestasis	a) Pregnancy related	1		1		1		1		1		2	
	b) Past COC related	1		2		2		2		2		3	
History of high blood pressure during pregnancy		1		1		1		1		1		2	
History of Pelvic surgery		1		1		1		1		1		1	
HIV	a) High risk for HIV	1*	1*	1*	1*	1		1		1		1	
	b) HIV infection					1*		1*		1*		1*	
	i) Clinically well receiving ARV therapy	1	1	1	1	If on treatment, see Drug Interactions							
	ii) Not clinically well or not receiving ARV therapy[4]	2	1	2	1	If on treatment, see Drug Interactions							

Key:

1 No restriction (method can be used)	3 Theoretical or proven risks usually outweigh the advantages
2 Advantages generally outweigh theoretical or proven risks	4 Unacceptable health risk (method not to be used)

Abbreviations: ARV = antiretroviral; C=continuation of contraceptive method; CHC=combined hormonal contraception (pill, patch, and ring); COC=combined oral contraceptive; Cu-IUD=copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; I=initiation of contraceptive method; LNG-IUD=levonorgestrel-releasing intrauterine device; NA=not applicable; POP=progestin-only pill; P/R=patch/ring; SSRI=selective serotonin reuptake inhibitor; ‡ Condition that exposes a woman to increased risk as a result of pregnancy. *Please see the complete guidance for a clarification to this classification: https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr.html

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

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Hypertension	a) Adequately controlled hypertension	1*		1*		1*		2*		1*		3*	
	b) Elevated blood pressure levels (*properly taken measurements*)												
	i) Systolic 140-159 or diastolic 90-99	1*		1*		1*		2*		1*		3*	
	ii) Systolic ≥160 or diastolic ≥100[3]	1*		2*		2*		3*		2*		4*	
	c) Vascular disease	1*		2*		2*		3*		2*		4*	
Inflammatory bowel disease	(*Ulcerative colitis, Crohn's disease*)	1		1		1		2		2		2/3*	
Ischemic heart disease[2]	Current and history of	1		2	3	2	3	3		2	3	4	
Known thrombogenic mutations[3]		1*		2*		2*		2*		2*		4*	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	1		2		2		2		2		2	
	ii) Hepatocellular adenoma[3]	1		3		3		3		3		4	
	b) Malignant[3] (hepatoma)	1		3		3		3		3		4	
Malaria		1		1		1		1		1		1	
Multiple risk factors for atherosclerotic cardiovascular disease	(e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1		2		2*		3*		2*		3/4*	
Multiple sclerosis	a) With prolonged immobility	1		1		1		2		1		3	
	b) Without prolonged immobility	1		1		1		2		1		1	
Obesity	a) Body mass index (BMI) ≥30 kg/m²	1		1		1		1		1		2	
	b) Menarche to <18 years and BMI ≥ 30 kg/m²	1		1		1		2		1		2	
Ovarian cancer[2]		1		1		1		1		1		1	
Parity	a) Nulliparous	2		2		1		1		1		1	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		1		1		1		2		1	
Pelvic inflammatory disease	a) Past												
	i) With subsequent pregnancy	1	1	1	1	1		1		1		1	
	ii) Without subsequent pregnancy	2	2	2	2	1		1		1		1	
	b) Current	4	2*	4	2*	1		1		1		1	
Peripartum cardiomyopathy[3]	a) Normal or mildly impaired cardiac function												
	i) <6 months	2		2		1		1		1		4	
	ii) ≥6 months	2		2		1		1		1		3	
	b) Moderately or severely impaired cardiac function	2		2		2		2		2		4	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	2*		2*		1*		1*		1*		1*	
	c) Immediate postseptic abortion	4		4		1*		1*		1*		1*	
Postpartum (*nonbreastfeeding women*)	a) <21 days					1		1		1		4	
	b) 21 days to 42 days												
	i) With other risk factors for VTE					1		1		1		3*	
	ii) Without other risk factors for VTE					1		1		1		2	
	c) >42 days					1		1		1		1	
Postpartum (*in breastfeeding or non-breastfeeding women, including cesarean delivery*)	a) <10 minutes after delivery of the placenta												
	i) Breastfeeding	1*		2*									
	ii) Nonbreastfeeding	1*		1*									
	b) 10 minutes after delivery of the placenta to <4 weeks	2*		2*									
	c) ≥4 weeks	1*		1*									
	d) Postpartum sepsis	4		4									

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Pregnancy		4*		4*		NA*		NA*		NA*		NA*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2	1	2	1	1		2/3*		1		2	
	b) Not on immunosuppressive therapy	1		1		1		2		1		2	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver[3]	1		1		1		1		1		1	
Sexually transmitted diseases (STDs)	a) Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1		1		1		1	
	b) Vaginitis (*including trichomonas vaginalis and bacterial vaginosis*)	2	2	2	2	1		1		1		1	
	c) Other factors relating to STDs	2*	2	2*	2	1		1		1		1	
Smoking	a) Age <35	1		1		1		1		1		2	
	b) Age ≥35, <15 cigarettes/day	1		1		1		1		1		3	
	c) Age ≥35, ≥15 cigarettes/day	1		1		1		1		1		4	
Solid organ transplantation[2]	a) Complicated	3	2	3	2	2		2		2		4	
	b) Uncomplicated	2		2		2		2		2		2*	
Stroke[3]	History of cerebrovascular accident	1		2		2	3	3		2	3	4	
Superficial venous disorders	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial venous thrombosis (acute or history)	1		1		1		1		1		3*	
Systemic lupus erythematosus[2]	a) Positive (or unknown) antiphospholipid antibodies	1*	1*	3*		3*		3*	3*	3*		4*	
	b) Severe thrombocytopenia	3*	2*	2*		2*		3*	2*	2*		2*	
	c) Immunosuppressive therapy	2*	1*	2*		2*		2*	2*	2*		2*	
	d) None of the above	1*	1*	2*		2*		2*	2*	2*		2*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis[2] (*see also Drug Interactions*)	a) Nonpelvic	1	1	1	1	1*		1*		1*		1*	
	b) Pelvic	4	3	4	3	1*		1*		1*		1*	
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	4*	2*	4*	2*	3*		3*		2*		2*	
Uterine fibroids		2		2		1		1		1		1	
Valvular heart disease	a) Uncomplicated	1		1		1		1		1		2	
	b) Complicated[2]	1		1		1		1		1		4	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		1	1	2		2		2		1	
	b) Heavy or prolonged bleeding	2*		1*	2*	2*		2*		2*		1*	
Viral hepatitis	a) Acute or flare	1		1		1		1		1		3/4*	2
	b) Carrier/Chronic	1		1		1		1		1		1	1
Drug Interactions													
Antiretrovirals used for prevention (PrEP) or treatment of HIV	Fosamprenavir (FPV)	1/2*	1*	1/2*	1*	2*		2*		2*		3*	
	All other ARVs are 1 or 2 for all methods.												
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1		1		2*		1*		3*		3*	
	b) Lamotrigine	1		1		1		1		1		3*	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampin or rifabutin therapy	1		1		2*		1*		3*		3*	
SSRIs		1		1		1		1		1		1	
St. John's wort		1		1		2		1		2		2	

Updated in 2020. This summary sheet only contains a subset of the recommendations from the U.S. MEC. For complete guidance, see https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr.html. Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condom reduces the risk of STDs and HIV.

CS314239-A

Hormonal Contraception Information for DOPL's Website

1. This guidance
2. Utah Hormonal Contraceptive Self Screening Questionnaire https://dopl.utah.gov/pharm/hormonal_contraception_questionnaire.pdf
3. Utah Hormonal Contraceptive Self Screening Questionnaire-Spanish https://dopl.utah.gov/pharm/hormonal_contraceptive_Questionnaire_Spanish.pdf
4. Standard Procedures Algorithm for Prescribing of Contraceptives https://dopl.utah.gov/pharm/standard_procedures_algorithm_contraceptive.pdf
5. Summary Chart of U.S Medical Eligibility Criteria For Contraceptive Use https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf
6. Women's Health Resources https://mihp.utah.gov/wp-content/uploads/Womens-Health-Resources.pdf
7. Utah Maternal and Infant Health Program https://mihp.utah.gov/
8. ACOG Well-Woman Recommendations https://www.acog.org/topics/well-woman-health-care?utm_source=redirect&utm_medium=web&utm_campaign=otn
9. JCCP Pharmacist Patient Care Process https://jcpp.net/patient-care-process/

Utah Approved Statewide Guidance for Tobacco Cessation Products

Approved xx, x, 2021

This guidance is for Utah-licensed pharmacists ("Pharmacists") to prescribe and dispense safe and effective tobacco cessation products according to and in compliance with all applicable state and federal laws and rules. The pharmacists will perform an assessment and may then determine the need for and dispense a tobacco cessation product pursuant to the terms of the attached guidance. Pharmacists must have a valid Utah pharmacist license and have completed an Accreditation Council for Pharmacy Education (ACPE) accredited program in tobacco cessation.

PHARMACISTS GENERAL REQUIREMENTS:

a. All pharmacists participating in this protocol for tobacco cessation drug therapy will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update (or subsequent updates as they become available). Additionally, all product information (PI) and dosing from any products dispensed;

b. Pharmacists will implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco; and

c. Pharmacists services will include an educational component to include counseling on medication therapies and cessation strategies as well as referral to sources provided by the Colorado Quit Line program.

SCREENING AND HISTORY

a. Under this protocol, pharmacists should offer assistance to tobacco users motivated and ready to quit. Medications should be offered as appropriate.

b. A standardized screening tool will be used to assess the following for each patient intending to use medications:

1. Medical and social history including current medications;
2. Previous medication attempts, failures, intolerances;
3. Allergies and hypersensitivities;
4. Potential drug interactions with potential medication treatments (per Guidelines/Dispensing Information);
5. Precautions/contraindications of potential medication treatments (per Guidelines/Dispensing Information); and
6. Patient preferences with regards to treatment options

c. A standardized screening tool will be used to identify patients who do **NOT** qualify for specified medication therapies under this protocol and will be referred to a primary care provider for further assessment:

1. Age under 18 years (any/all medications);
2. Pregnancy or plan to become pregnant (any/all medications);
3. History of seizure disorder (bupropion);
4. History of eating disorder (bupropion)

5. History of mental illness / psychiatric disorder (bupropion or varenicline);
6. Patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs (bupropion);
7. Hypersensitivity to any previous use of nicotine, bupropion or varenicline;
8. Use of a monoamine oxidase inhibitor (MAOI) within 14 days (bupropion);
9. Recent history of myocardial infarction (within 14 days), serious cardiac arrhythmias, unstable or severe angina (nicotine replacement);
10. Known moderate/severe hepatic or renal impairment (any/all medications); and
11. Smokeless tobacco use (any/all medications).

DISPENSING

a. FDA First-Line Approved Medications which may be prescribed (dosing per Clinical Practice Guidelines/Package Inserts). This information should be updated no less frequently than every 2 years.

1. Nicotine Replacement Therapies

Patch

• Treatment of 8 weeks or less has been shown to be as efficacious as longer treatment periods. Patches of different doses sometimes are available as well as different recommended dosing regimens. Clinicians should consider individualizing treatment based on specific patient characteristics, such as previous experience with the patch, amount smoked, degree of dependence, etc.

• Step-down Dosage

4 weeks	21 mg/24 hours
then 2 weeks	14 mg/24 hours
then 2 weeks	7 mg/24 hours

Gum

• Nicotine gum is available in 2-mg and 4-mg (per piece) doses. The 2-mg gum is recommended for patients smoking less than 25 cigarettes per day; the 4-mg gum is recommended for patients smoking 25 or more cigarettes per day. Smokers should use at least one piece every 1 to 2 hours for the first 6 weeks; the gum should be used for up to 12 weeks with no more than 24 pieces to be used per day.

Lozenge

• Nicotine lozenges are available in 2-mg and 4-mg (per piece) doses. The 2-mg lozenge is recommended for patients who smoke their first cigarette more than 30 minutes after waking, and the 4-mg lozenge is recommended for patients who smoke their first cigarette within 30 minutes of waking. Generally, smokers should use at least nine lozenges per day in the first 6 weeks; the lozenge should be used for up to 12 weeks, with no more than 20 lozenges to be used per day.

Nasal Spray

• A dose of nicotine nasal spray consists of one 0.5-mg dose delivered to each nostril (1 mg total). Initial dosing should be 1–2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/day, with a maximum limit of 40 doses/day (5 doses/hour). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.

Inhaler

• A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers a total of 4 mg of nicotine over 80 inhalations. Recommended dosage is 6–16 cartridges/day. Recommended duration of therapy is up to 6 months. Patient should taper dosage during the final 3 months of treatment.

2. Bupropion

• Begin bupropion SR treatment 1–2 weeks before they quit smoking. Patients should begin with a dose of 150 mg every morning for 3 days, then increase to 150 mg twice daily. Dosage should not exceed 300 mg per day. Dosing at 150 mg twice daily should continue for 7–12 weeks. For long-term therapy, consider use of bupropion SR 150 mg for up to 6 months post-quit.

3. Varenicline

• Start varenicline 1 week before the quit date at 0.5 mg once daily, followed by 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 3 months. Varenicline is approved for a maintenance indication for up to 6 months.

Note: Patient should be instructed to quit smoking on day 8 when dosage is increased to 1 mg twice daily.

4. Evidence-Based Combination Therapies

• Bupropion + Nicotine patch (standard dosing as detailed above). If this combination is used, patient shall be monitored for treatment emergent hypertension and include a follow up blood pressure within 1-2 weeks.

• Long term nicotine patch (>14 weeks) + other nicotine replacement products (gum and spray) – doses as detailed above.

• Nicotine patch + Nicotine inhaler (doses as detailed above)

b. Duration of the above therapies, if not specifically detailed above, shall not exceed 6 months.

c. Dosing, Precautions, Contraindications and Monitoring considerations shall follow Clinical Practice Guidelines and manufacturer prescribing information.

d. Patients will be supplied with written educational information on any therapies prescribed.

e. Pharmacists will implement an appropriate monitoring and follow up plan with each patient.

f. Pharmacists may continue to provide over-the-counter smoking cessation products to tobacco users without the use of this guidance.

RECORDS

a. Pursuant to Utah Admin Code R156-17b-627, the pharmacist may communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

b. Pharmacists shall comply with Utah Code 58-17b-611 with respect to the maintenance of proper records.

Smoking Cessation Information to be posted on DOPL's Website

1. This protocol
2. Utah Tobacco Prevention and Control Program https://tobaccofreeutah.org/
3. AHRQ Treating Tobacco Use and Dependence:2008 Update-Clinical Practice Guideline https://www.ahrq.gov/prevention/guidelines/tobacco/index.html
4. CDC Smoking and Tobacco Use Resources https://www.cdc.gov/tobacco/
5. UCSF RX for Change: Clinician-Assisted Tobacco Cessation https://rxforchange.ucsf.edu/
6. JCCP Pharmacist Patient Care Process https://jcpp.net/patient-care-process/
7. National Cancer Institute https://smokefree.gov/
8. Utah Quite Line 1-800-Quit Now available 24/7 https://waytoquit.org/get-help-quitting/

STATE OF COLORADO
DEPARTMENT OF REGULATORY AGENCIES

Colorado State Board of Pharmacy Approved Statewide Protocol for Dispensing Tobacco Cessation Products

(Appendix B)

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to dispense safe and effective tobacco cessation products according to and in compliance with all applicable state and federal laws and rules.

The pharmacists will perform health screening according to this protocol and may then determine the need for and dispense a tobacco cessation product pursuant to the terms of the attached protocol.

Pharmacists must have a valid Colorado pharmacist license and have completed an Accreditation Council for Pharmacy Education (ACPE) accredited program in tobacco cessation.

The pharmacy shall ensure that appropriate space is provided to prevent the spread of infection and to ensure confidentiality.

Protocol

PHARMACISTS GENERAL REQUIREMENTS:

a. All pharmacists participating in this protocol for tobacco cessation drug therapy will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update (or subsequent updates as they become available). Additionally, all product information (PI) and dosing from any products dispensed;

b. Pharmacists will implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco; and

c. Pharmacists services will include an educational component to include counseling on medication therapies and cessation strategies as well as referral to sources provided by the Colorado Quit Line program.

SCREENING AND HISTORY

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b. A standardized screening tool will be used to assess the following for each patient intending to use medications:

    1. Medical and social history including current medications;

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    2. Pregnancy or plan to become pregnant (any/all medications);

    3. History of seizure disorder (bupropion);

    4. History of eating disorder (bupropion);

5. History of mental illness / psychiatric disorder (bupropion or varenicline);

6. Patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs (bupropion);

7. Hypersensitivity to any previous use of nicotine, bupropion or varenicline;

8. Use of a monoamine oxidase inhibitor (MAOI) within 14 days (bupropion);

9. Recent history of myocardial infarction (within 14 days), serious cardiac arrhythmias, unstable or severe angina (nicotine replacement);

10. Known moderate/severe hepatic or renal impairment (any/all medications); and

11. Smokeless tobacco use (any/all medications).

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1. Nicotine Replacement Therapies

<u>Patch</u>

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4 weeks	21 mg/24 hours
then 2 weeks	14 mg/24 hours
then 2 weeks	7 mg/24 hours

<u>Gum</u>

- Nicotine gum is available in 2-mg and 4-mg (per piece) doses. The 2-mg gum is recommended for patients smoking less than 25 cigarettes per day; the 4-mg gum is recommended for patients smoking 25 or more cigarettes per day. Smokers should use at least one piece every 1 to 2 hours for the first 6 weeks; the gum should be used for up to 12 weeks with no more than 24 pieces to be used per day.

Lozenge

- Nicotine lozenges are available in 2-mg and 4-mg (per piece) doses. The 2-mg lozenge is recommended for patients who smoke their first cigarette more than 30 minutes after waking, and the 4-mg lozenge is recommended for patients who smoke their first cigarette within 30 minutes of waking. Generally, smokers should use at least nine lozenges per day in the first 6 weeks; the lozenge should be used for up to 12 weeks, with no more than 20 lozenges to be used per day.

Nasal Spray

- A dose of nicotine nasal spray consists of one 0.5-mg dose delivered to each nostril (1 mg total). Initial dosing should be 1–2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/day, with a maximum limit of 40 doses/day (5 doses/hour). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.

Inhaler

- A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers a total of 4 mg of nicotine over 80 inhalations. Recommended dosage is 6–16 cartridges/day. Recommended duration of therapy is up to 6 months. Patient should taper dosage during the final 3 months of treatment.

2. Bupropion

- Begin bupropion SR treatment 1‑2 weeks before they quit smoking. Patients should begin with a dose of 150 mg every morning for 3 days, then increase to 150 mg twice daily. Dosage should not exceed 300 mg per day. Dosing at 150 mg twice daily should continue for 7‑12 weeks. For long-term therapy, consider use of bupropion SR 150 mg for up to 6 months post-quit.

3. Varenicline

- Start varenicline 1 week before the quit date at 0.5 mg once daily, followed by 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 3 months. Varenicline is approved for a maintenance indication for up to 6 months. Note: Patient should be instructed to quit smoking on day 8 when dosage is increased to 1 mg twice daily.

4. Evidence-Based Combination Therapies

- Bupropion + Nicotine patch (standard dosing as detailed above). If this combination is used, patient shall be monitored for treatment emergent hypertension and include a follow up blood pressure within 1-2 weeks.

- Long term nicotine patch (>14 weeks) + other nicotine replacement products (gum and spray) – doses as detailed above.

- Nicotine patch + Nicotine inhaler (doses as detailed above)

b. Duration of the above therapies, if not specifically detailed above, shall not exceed 6 months.

c. Dosing, Precautions, Contraindications and Monitoring considerations shall follow Clinical Practice Guidelines and manufacturer prescribing information.

d. Patients will be supplied with written educational information on any therapies prescribed.

e. Pharmacists will implement an appropriate monitoring and follow up plan with each patient.

f. Pharmacists may continue to provide over-the-counter smoking cessation products to tobacco users without the use of this protocol.

RECORDS

a. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

b. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

HB 178 DRAFT PROPOSED RULES-6/16/2021

R156-17b-627 Operating Standards-Prescription of drugs or devices by a pharmacist-

(1)In accordance with Subsections 58-17b-601(1) and 58-17b-627(3), a pharmacist who issues a prescription for a legitimate medical purpose designated in Section 58-17b-627 (3(a)(i) through (v), shall;

(a)Conduct a patient **assessment** to include;

(i) patients health status – more clearly defined (not so vague) specific as to what they should be looking for – relevant comorbid or potentially confounding medical conditions - current active medical problems, past medical history, allergies and hypersensitivities, potential drug interactions with potential medication treatments (per guidelines), precautions, contraindications of potential medication treatments, documented - medical and social history including current medications, previous medication attempts, failures, intolerances, a

(ii rationale for care; and

(iii) all current medications (to make very clear)

(b)follow prescribing drug or device **guidance for health care providers** by

(i) the CDC; or

(ii)the Department of Health and Division in collaboration with the Board, using evidence based guidelines. (Evidence based guidelines specific to the specialty that prescribes the medication)

(iii) FDA approved drugs – and only for the FDA indication (no off label prescribing) – Jen Plumb pushed back as did pharmacists?? Pushed back for the indication???

(c) Develop and implement an appropriate **follow-up** care plan with the patient to include;

(1)monitoring parameters;

(2)adverse reaction; and

(3)further medical care.

(d)(i)The Pharmacist shall identify the patient's primary care or other **health care provider**, and provide **notice** of the prescription in writing, by electronic transmission or telephone within three (3) ~~five (5)~~ business days following the prescribing of a drug or device.

(ii) The prescription notice shall include the following

(a)patient assessment in section (1) (a);

(b) prescribing pharmacist;

(c) pharmacy name;

(d) pharmacy phone number;

(e) patient;

(f) drug or device;

(g) dispensed quantity;

(h) directions for use; and

(i) refill.

(e) Documentation of patient care provided, shall be retained in a readily retrievable form and location for 5 years following the date of the transaction and shall include:

(i) notice in section (1)(d)(i);

(ii) Identity of the primary care or other health care provider; and

(iii) Notice of contact of the primary care or other health care provider.

(2) Each prescription prescribed by a pharmacist shall be:

(a) dispensed in accordance with Subsection 58-17b-602(1)(a) through (f) and Section 58-17b-609; and

(b) dispensed from a Class A or Class B pharmacy

(3) A provider can override the prescription given (must be very clear that the provider has ability to override the prescription)

How will medications be tracked if information is not sent to a provider – don't have a primary care provider? They have no good way of reporting back to the primary care provider.

Adverse reaction report back to provider – patient ends up in hospital, etc.

It would not be in the controlled substance database. Need a statewide database – a separate arm of the CSD????

HIV Prep – would suggest not - (Different for Community Pharmacists vs. system pharmacists for labs, etc.)

- Regular STI Screening
- Bare minimum every 90 days an HIV test and as well as a BMP
- How would Pharmacists follow up on abnormal labs if not in a closed loop system?
- Ongoing prep would be very, very difficult
- Counseling??? How would that be done in the Pharmacy – who would counsel??
- Lab monitoring

Post Exposure Prophylaxis - OK

- Maybe a 7-day course so that they can get into a clinician – refer to a clinician (list of clinicians to refer to if they are not an established patient (also Wasatch Forensic Nurses)
- Guidelines – should have baseline evaluation and HEP(C), HIV, B serologies, etc.
- Labs need to be monitored

Add must have appropriate education to cover

List out which medications because if something comes out that should not be prescribed by a pharmacist, it would automatically be added in the areas listed

Pharmacist must maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research finds that specifics the following:

Patient inclusion and exclusion criteria; and

Explicit medical referral criteria

Pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings.

Pharmacist must act in good faith and exercise reasonable care

Incorporate Indiana and Colorado best guidelines for prescribing into Utah rules

Indiana State Department of Health
An Equal Opportunity Employer

Eric J. Holcomb
Governor

Kristina Box, MD, FACOG
State Health Commissioner

INDIANA STATE DEPARTMENT OF HEALTH

Protocol for Dispensing Tobacco Cessation Products under Statewide Standing Order

Pursuant to Indiana Code 16-19-4-11, the State Health Commissioner issued a Statewide Standing Order for Tobacco Cessation Products (the Statewide Standing Order) which authorizes qualified pharmacists to dispense Food and Drug Administration (FDA)-approved medications with an indication for tobacco cessation in accordance with this Protocol. This Protocol is to be used in conjunction with the Statewide Standing Order.

A. PURPOSE

This protocol specifies the criteria and procedures to assist pharmacists in providing safe and effective tobacco cessation therapy in Indiana.

B. QUALIFICATIONS

To operate under the Statewide Standing Order, the pharmacist must:

1. Have an active Indiana pharmacist license pursuant to Indiana Code 25-26-13;
2. Have received education and training in tobacco use disorder and tobacco cessation therapies, including review of the US Department of Health and Human Services, Public Health Services (USPHS), Clinical Practice Guideline for Tobacco Use and Dependence
3. Complete continuing education on tobacco cessation counseling each biennium ; and
4. Be acting in good faith and exercising reasonable care

C. PRODUCTS COVERED

Notwithstanding any other provision of law, a pharmacist may administer or dispense any FDA-approved medication with an indication for tobacco and/or smoking cessation, including the following:

1. Nicotine gum
2. Nicotine lozenge
3. Nicotine transdermal patch
4. Nicotine oral inhaler
5. Nicotine nasal spray
6. Bupropion SR oral tablets
7. Varenicline oral tablets

D. PROCEDURE

When a patient requests a medication for tobacco cessation, or when a pharmacist in his or her professional judgment decides to ask about tobacco use and offer to initiate tobacco cessation counseling and treatment, the pharmacist shall complete the following steps, which may be reviewed and revised as necessary by the Indiana State Department of Health or when the Statewide Standing Order is reissued:

1. Assessment
    a. The pharmacist shall assess a patient's readiness to quit and apply the 5 A's approach for quitting: Ask, Advise, Assess, Assist, and Arrange, as described in the Clinical Practice Guideline for Treating Tobacco Use and Dependence, or a similar strategy based on current evidence.
    b. The pharmacist may offer tobacco cessation medication to tobacco users who are deemed ready to quit and provide behavioral counseling and/or a referral to counseling.

2. Health Screening
    a. The pharmacist shall utilize and document a health screening procedure based on the Clinical Practice Guideline for Treating Tobacco Use and Dependence to identify appropriate candidates for treatment by the pharmacist.
    b. The health screen shall include:
        i. patient history, including medical and social history
        ii. family history
        iii. current living environment
        iv. concurrent illness
        v. allergies and hypersensitivities
        vi. medication history

3. Referral of high-risk patients
    a. The pharmacist shall assess and consult with or refer high-risk patients to a primary care provider, psychiatrist, or other provider, as appropriate.
    b. For purposes of this protocol, the following patients are considered high-risk:
        i. Patient is pregnant or planning to become pregnant in the next six months
        ii. Patient has cardiovascular disease and:
            A. Has had a heart attack in the past 2 weeks
            B. Has a history of arrhythmias or irregular heartbeat
            C. Has unstable angina or experience chest pain with strenuous activity
        iii. Patient has history of mental health disorder(s) and is perceived to not be stable.

4. Dispensing eligible products
    a. The pharmacist, in consultation with the patient, may select and dispense any tobacco cessation product (alone or in combination) approved by the FDA.
    b. Combination therapy (e.g., the nicotine patch plus the nicotine gum, lozenge, inhaler or nasal spray; or bupropion SR plus the nicotine patch) may be used, per current clinical practice guideline recommendations and/or published peer-reviewed literature recommendations, and is acceptable as appropriate based on patient needs and preferences.
    c. When a tobacco cessation product is dispensed under the protocol, the pharmacist shall provide necessary information about the product pursuant to 856 IAC 1-33-2, including but not limited to:
        i. The name and description of the medicine.
        ii. The route, dosage form, dosage, route of administration, and recommended duration of drug therapy.
        iii. Special directions and precautions.

iv. Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.
v. Techniques for self-monitoring drug therapy.
vi. Proper storage.
vii. Prescription refill information.
viii. Action to be taken in the event of a missed dose.

5. Counseling
    a. Once the appropriate tobacco cessation product(s) has been determined, the pharmacist shall provide the patient with counseling on the administration, possible side effects, contraindications, and warnings associated with the therapy.
    b. The patient should be encouraged to ask questions and will be supplied with educational material on any therapies dispensed.
    c. Pharmacists shall provide appropriate behavioral counseling and/or refer the patient to other resources for assistance, including but not limited to the Indiana Tobacco Quitline 1-800-QUITNOW.

6. Follow-up
    a. To reassess the appropriateness and/or continuation of therapy, pharmacists shall follow up with patients:
        i. Within two weeks of initiating therapy
        ii. After completion of a course of therapy

E. NOTIFICATION

The pharmacist must provide the patient with a record of the drug(s) or device(s) dispensed and inform the patient to follow up with his or her primary care provider or consult a licensed provider of the patient's choice, pursuant to IC 16-19-4-11.

If the patient has a primary care provider, the pharmacist must notify the primary care provider of the prescription record and follow-up care plan within three business days.

F. DOCUMENTATION

1. Documentation of a patient's screening and the prescription record for all drugs and devices shall be maintained in the pharmacy records for seven years in accordance with Indiana Code 16-39-7-1.
2. A copy shall be made available to the patient and/or patient's provider upon request.

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