

Colorado State Board of Pharmacy Approved Statewide Protocol for Prescribing Hormonal Contraceptive Patches and Oral Contraceptives

(Appendix A)

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to perform the pertinent physical assessments and prescribe hormonal contraceptive patches and oral contraceptives under the conditions of this protocol and according to and in compliance with all applicable state and federal laws and rules.

Definitions

- (1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.
- (2) "Hormonal contraceptive patch" means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.
- (3) "Oral hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

Training Program

Only a Colorado-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 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 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 Colorado Self-Screening Risk Assessment Questionnaire;
 - (b) Utilize and follow the Colorado Standard Procedures Algorithm to perform the patient assessment;
 - (c) Prescribe, if clinically appropriate, the hormonal contraceptive patch or self-administered oral hormonal contraceptive, 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 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) Require a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive patch or self-administered oral hormonal contraceptive;
 - (b) 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
 - (c) Prescribe in instances that the Colorado Standard Procedures Algorithm requires referral to a provider.
- (4) 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.

STANDARD PROCEDURES ALGORITHM FOR COLORADO RPH DISPENSING OF CONTRACEPTIVES

1) Health and History Screen
 Review Hormonal Contraceptive Self-Screening Questionnaire.
 To evaluate health and history, refer to USMEC or Colorado MEC.
1 or 2 (green boxes) – Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes) – Hormonal contraception is contraindicated --> Refer

2) 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?
 b. Have you had a baby in the last 4 weeks?
 c. Did you have a miscarriage or abortion in the last 7 days?
 d. Did your last menstrual period start within the past 7 days?
 3. Have you abstained from sexual intercourse since your last menstrual period or delivery?
 f. Have you been using a reliable contraceptive method consistently and correctly?

If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step.
If NO to ALL of these questions, pregnancy can NOT be ruled out -- Refer

3) Medication Screen (Questionnaire #20)?
Caution: anticonvulsants, antiretrovirals, antimicrobials, barbiturate, herbs & supplements, including:

Carbamazepine	lumacaftor/ivacaftor	primidone	topiramate
Felbamate	oxcarbazepine	rifampin / rifabutin	
Griseofulvin	phenobarbital	ritonavir	
Lamotrigine	phenytoin	St John's Wort	

4) Blood Pressure Screen
 Is blood pressure <140/90?
 Note: RPH may choose to take a second reading, if initial is high.

5) Evaluate patient history, preference, and current therapy for

5a) Choose Contraception
Initiate contraception based on patient preferences, adherence, and history for new therapy

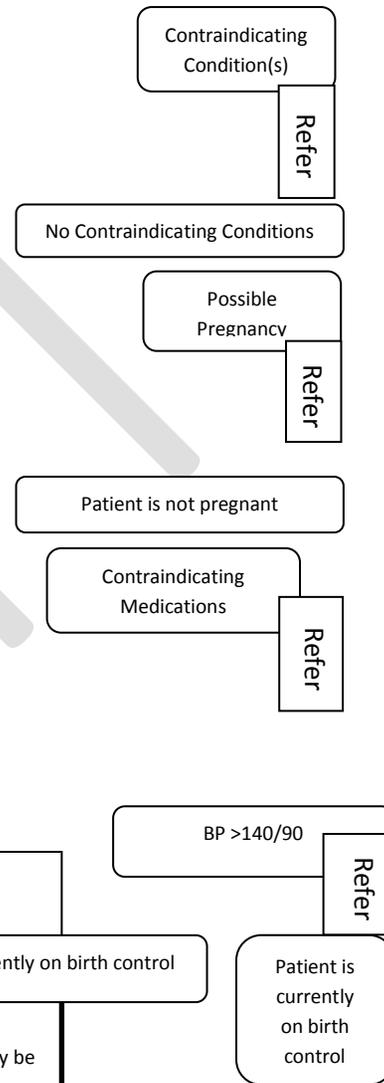
 -Prescribe up to 12 months of desired contraception and dispense product (quantity based on professional judgment and patient preference)

5b) Choose Contraception
Continue current form of pills or patch, if no change is necessary
 -or-
Alter therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate

 -Prescribe up to 12 months of desired contraception and dispense product. (quantity based on professional judgment and patient preference)

6) Discuss Initiation Strategy for Initial Treatment/Change in Treatment (as applicable)
 a) Counseling - Quick start - Instruct patient she can begin contraceptive today; use backup method for 7 days.
 b) Counseling – Discuss the management and expectations of side effects (bleeding irregularities, etc.)
 c) Counseling – Discuss adherence and expectations for follow-up visits

7) Discuss and Provide Referral / Visit Summary to patient
Encourage: Routing health screenings, STD prevention, and notification to care provider
 If patient consumes tobacco/smokes: refer to QuitLine



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

Pages 1,2Color coded in the left column to match the corresponding question of the Oregon Self-Screening Risk Assessment Questionnaire.

Pages 3,4Arranged alphabetically by disease state

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

Corresponding to the order of the Colorado Self-Screening Contraception
Risk Assessment Questionnaire:

Condition	Sub-condition	Combined pill, patch		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
a. Age		Menarche to <40=1		Menarche to <18=1		Yes
		>40=2		18-45=1		Yes
				45=1		Yes
b. Smoking	a) Age < 35	2		1		Yes
	b) Age > 35, < 15 cigarettes/day	3		1		Yes
	c) Age > 35, >15 cigarettes/day	4		1		Yes
c. Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA*
d. Postpartum (nonbreastfeeding women)	a) < 21 days	4		1		Yes
	b) 21 days to 42 days:					
	(i) with other risk factors for VTE	3*		1		Yes
	(ii) without other risk factors for VTE	2		1		Yes
	c) > 42 days	1		1		Yes
e. Breastfeeding	a) <21 days postpartum	4*		2*		Yes
	b) 21to <30 days postpartum					
	(i) with other risk factors for VTE	3*		2*		Yes
	(ii) without other risk factors for VTE	3*		2*		Yes
	c) 30-42 days postpartum					
	(i) with other risk factors for VTE	3*		1*		Yes
	(ii) without other risk factors for VTE	2*		1*		Yes
	d) >42 days postpartum	2*		1*		Yes
f. Diabetes mellitus(DM)	a) History of gestational DM only	1		1		Yes
	b) Non-vascular disease					

	b) Other abnormalities:				
	(i) non-insulin dependent	2	2	Yes	
	(ii) insulin dependent‡	2	2	Yes	
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*	2	Yes	
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*	2	Yes	
g. Headaches	a) Non-migraine (mild or severe)	1*	1	Yes	
	b) Migraine:				
	i) without aura (includes menstrual migraine)	2*	1	Yes	
	iii) with aura	4*	1	Yes	
h. Hypertension	a) Adequately controlled hypertension	3*	1*	Yes	
	b) Elevated blood pressure levels (properly taken measurements):				
	(i) systolic 140-159 or diastolic 90-99	3	1	Yes	
	(ii) systolic ≥160 or diastolic ≥100‡	4	2	Yes	
	c) Vascular disease	4	2	Yes	
i. History of high blood pressure during pregnancy		2	1	Yes	
j. Hyperlipidemias		2/3*	2*	Yes	
k. Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function:				
	(i) < 6 months	4	1	Yes	
	(ii) > 6 months	3	1	Yes	
	b) Moderately or severely impaired cardiac function	4	2	Yes	
l. Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*	2*	Yes	
m. Ischemic heart disease‡	Current and history of	4	2	3	Yes
n. Valvular heart disease	a) Uncomplicated	2	1	Yes	
	b) Complicated‡	4	1	Yes	
o. Stroke‡	History of cerebrovascular accident	4	2	3	Yes
p. Thrombogenic mutations‡		4*	2*	Yes	
q. Deep venous thrombosis (DVT) & Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy				
	i) higher risk for recurrent DVT/PE	4	2	Yes	

	ii) lower risk for recurrent DVT/PE	3	2	Yes	
	b) Acute DVT/PE	4	2	Yes	
	c) DVT/PE and established on anticoagulant therapy for at least 3 months				
	i) higher risk for recurrent DVT/PE	4*	2	Yes	
	ii) lower risk for recurrent DVT/PE	3*	2	Yes	
	d) Family history (first-degree relatives)	2	1	Yes	
	e) Major surgery				
	(i) with prolonged immobilization	4	2	Yes	
	(ii) without prolonged immobilization	2	1	Yes	
	f) Minor surgery without immobilization	1	1	Yes	
r. History of bariatric surgery‡	a) Restrictive procedures	1	1	Yes	
	b) Malabsorptive procedures	COCs: 3	3	Yes	
s. Breast disease & Breast Cancer	a) Undiagnosed mass	2*	2*	Yes	
	b) Benign breast disease	1	1	Yes	
	c) Family history of cancer	1	1	Yes	
	d) Breast cancer:‡				
	i) current	4	4	Yes	
	ii) past and no evidence of current disease for 5 years	3	3	Yes	
t. Viral hepatitis	a) Acute or flare	3/4*	2	1	Yes
	b) Carrier/Chronic	1	1	1	Yes
u. Cirrhosis	a) Mild (compensated)	1	1	Yes	
	b) Severe‡ (decompensated)	4	3	Yes	
v. Liver tumors	a) Benign:				
	i) Focal nodular hyperplasia	2	2	Yes	
	ii) Hepatocellular adenoma‡	4	3	Yes	
	b) Malignant‡	4	3	Yes	
w. Gallbladder disease	a) Symptomatic:				
	(i) treated by cholecystectomy	2	2	Yes	
	(ii) medically treated	2	3	Yes	
	(iii) current	3	2	Yes	
	b) Asymptomatic	2	2	Yes	
x. History of Cholestasis	a) Pregnancy-related	2	1	Yes	
	b) Past COC-related	3	2	Yes	
y. Systemic lupus	a) Positive (or unknown) antiphospholipid antibodies	4	3	Yes	

erythematous‡	b) Severe thrombocytopenia	2	2	Yes
	c) Immunosuppressive treatment	2	2	Yes
	d) None of the above	2	2	Yes
z. Rheumatoid arthritis	a) On immunosuppressive therapy	1	1	Yes
	b) Not on immunosuppressive therapy	2	1	Yes
aa. Blood Conditions & Anemias	a) Thalassemia	1	1	Yes
	b) Sickle Cell Disease‡	2	1	Yes
	c) Iron-deficiency anemia	1	1	Yes
bb. Epilepsy‡	(see also Drug Interactions)	1*	1*	Yes
cc. Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*	1*	Yes
	b) Pelvic	1*	1*	Yes
dd. HIV	High risk	1	1	Yes
	HIV infected (see also Drug Interactions)‡	1*	1*	Yes
	AIDS (see also Drug Interactions)‡	1*	1*	Yes
	Clinically well on therapy	If on treatment, see Drug Interactions.		
ee. Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*	1	Yes
	b) Non-nucleoside reverse transcriptase inhibitors	2*	2*	Yes
	c) Ritonavir-boosted protease inhibitors	3*	3*	Yes
ff. Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*	3*	Yes
	b) Lamotrigine	3*	1	Yes
gg. Antimicrobial therapy	a) Broad spectrum antibiotics	1	1	Yes
	b) Antifungals	1	1	Yes
	c) Antiparasitics	1	1	Yes
	d) Rifampicin or rifabutin therapy	3*	3*	Yes
Anemias	a) Thalassemia	1	1	Yes
	b) Sickle cell disease‡	2	1	Yes
	c) Iron-deficiency anemia	1	1	Yes
Benign ovarian tumors	(including cysts)	1	1	Yes
Breast disease/ Breast Cancer	a) Undiagnosed mass	2*	2*	Yes
	b) Benign breast disease	1	1	Yes
	c) Family history of cancer	1	1	Yes
	d) Breast cancer‡			
	i) current	4	4	Yes

	ii) past and no evidence of current disease for 5 years	3	3	Yes
Cervical cancer	Awaiting treatment	2	1	Yes
Cervical ectropion		1	1	Yes
Cervical intraepithelial neoplasia		2	1	Yes
Cirrhosis	a) Mild (compensated)	1	1	Yes
	b) Severe (decompensated)	4	3	Yes
Cystic Fibrosis		1*	1*	Yes
Deep venous thrombosis (DVT) / & Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy			
	i) higher risk for recurrent DVT/PE	4	2	Yes
	ii) lower risk for recurrent DVT/PE	3	2	Yes
	b) Acute DVT/PE	4	2	Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months			
	i) higher risk for recurrent DVT/PE	4*	2	Yes
	ii) lower risk for recurrent DVT/PE	3*	2	Yes
	d) Family history (first-degree relatives)	2	1	Yes
	e) Major surgery			
	(i) with prolonged immobilization	4	2	Yes
	(ii) without prolonged immobilization	2	1	Yes
	f) Minor surgery without immobilization	1	1	Yes
Depressive disorders			1*	Yes
Diabetes mellitus (DM)	a) History of gestational DM only	1	1	Yes
	b) Non-vascular disease			
Diabetes mellitus (cont.)	(i) non-insulin dependent	2	2	Yes
	(ii) insulin dependent	2	2	Yes
	c) Nephropathy/ retinopathy/ neuropathy	3/4*	2	Yes
	d) Other vascular disease or diabetes of >20 years' duration	3/4*	2	Yes
Endometrial cancer		1	1	Yes
Endometrial hyperplasia		1	1	Yes
Endometriosis		1	1	Yes
Epilepsy	(see also Drug Interactions)	1*	1*	Yes
Gallbladder disease	a) Symptomatic			
	(i) treated by cholecystectomy	2	2	Yes
	(ii) medically treated	3	2	Yes
	(iii) current	3	2	Yes

	b) Asymptomatic	2	2	Yes		
Gestational trophoblastic disease	a) Decreasing or undetectable s-hCG levels	1	1	Yes		
	b) Persistently elevated s-hCG levels or malignant disease	1	1	Yes		
Headaches	a) Non-migrainous	1*	2*	1*	1*	Yes
	b) Migraine					
	i) without aura, age <35	2*	3*	1*	2*	Yes
	ii) without aura, age >35	3*	4*	1*	2*	Yes
	iii) with aura, any age	4*	4*	2*	3*	Yes
History of bariatric surgery	a) Restrictive procedures	1	1	Yes		
	b) Malabsorptive procedures	COC2: 3	3	Yes		
		P/R: 1				
History of cholestasis	a) Pregnancy-related	2	1	Yes		
	b) Past COC-related	3	2	Yes		
History of high blood pressure during pregnancy		2	1	Yes		
History of pelvic surgery		1	1	Yes		
HIV	High risk	1*	1*	Yes		
	HIV infected (see also Drug Interactions)	1*	1*	Yes		
	AIDS (see also Drug Interactions)	1*	1*	Yes		
	Clinically well on therapy	If on treatment, see Drug Interactions.				
Hyperlipidemias		2/3*	2*	Yes		
Hypertension	a) Adequately controlled hypertension	3*	1*	Yes		
	b) Elevated blood pressure levels					
	(i) systolic 140-159 or diastolic 90-99	3	1	Yes		
	(ii) systolic >160 or diastolic >100	4	2	Yes		
	c) Vascular disease	4	2	Yes		
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*	2	Yes		
Ischemic heart disease	Current and history of	4	2	3	Yes	
Liver tumors	a) Benign					
	i) Focal nodular hyperplasia	2	2	Yes		
	ii) Hepatocellular adenoma	4	3	Yes		

	b) Malignant‡	4	3	Yes
Malaria		1	1	Yes
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*	2*	Yes
Multiple sclerosis	a) with prolonged immobility	3	1	Yes
	b) without prolonged immobility	1	1	Yes
Obesity	a) >30 kg/m ² body mass index (BMI)	2	1	Yes
	b) Menarche to < 18 years and > 30 kg/m ² BMI	2	1	Yes
Ovarian cancer‡		1	1	Yes
Parity	a) Nulliparous	1	1	Yes
	b) Parous	1	1	Yes
Past ectopic pregnancy		1	2	Yes
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)			
	(i) with subsequent pregnancy	1	1	Yes
	(ii) without subsequent pregnancy	1	1	Yes
	b) Current			
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function			
	(i) < 6 months	4	1	Yes
	(ii) > 6 months	3	1	Yes
	b) Moderately or severely impaired cardiac function	4	2	Yes
Postabortion	a) First trimester	1*	1*	Yes
	b) Second trimester	1*	1*	Yes
	c) Immediately post-septic abortion	1*	1*	Yes
Pregnancy		NA*	NA*	NA*
Rheumatoid arthritis	a) On immunosuppressive therapy	2	1	Yes
	b) Not on immunosuppressive therapy	2	1	Yes
Schistosomiasis	a) Uncomplicated	1	1	Yes
	b) Fibrosis of the liver‡	1	1	Yes
Severe dysmenorrhea		1	1	Yes
Sexually transmitted infections (STIs)	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1	1	Yes
	b) Other STIs (excluding HIV and hepatitis)	1	1	Yes
	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	Yes
	d) Increased risk of STIs	1	1	Yes
Smoking	a) Age < 35	2	1	Yes

	b) Age > 35, < 15 cigarettes/day	3	1	Yes	
	c) Age > 35, >15 cigarettes/day	4	1	Yes	
Solid Organ transplantation‡	a) Complicated	4	2	Yes	
	b) Uncomplicated	2*	2	Yes	
Stroke‡	History of cerebrovascular accident	4	2	3	Yes
Superficial venous thrombosis	a) Varicose veins	1	1	Yes	
	b) Superficial thrombophlebitis	2	1	Yes	
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4	3	Yes	
	b) Severe thrombocytopenia	2	2	Yes	
	c) Immunosuppressive treatment	2	2	Yes	
	d) None of the above	2	2	Yes	
Thrombogenic mutations‡		4*	2*	Yes	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid.	1	1	Yes	
Tuberculosis‡ (see Drug Interactions)	a) Non-pelvic	1*	1*	Yes	
	b) Pelvic	1*	1*	Yes	
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	2*	2*	Yes	
	a) Uncomplicated	2	1	Yes	
Uterine fibroids	b) Complicated‡	4	1	Yes	
	a) Irregular pattern without heavy bleeding	1	2	Yes	
Vaginal bleeding patterns	b) Heavy or prolonged bleeding	1*	2*	Yes	
	a) Acute or flare	3/4*	2	1	Yes
	b) Carrier/Chronic	1	1	1	Yes
DRUG INTERACTIONS					
Antiretroviral therapy (All other ARVs are 1 or 2 for all methods)	Fosamprenavir (FPV)	3*	2*	Yes	
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*	3*	Yes	
	b) Lamotrigine	3*	1	Yes	
Antimicrobial therapy	a) Broad spectrum antibiotics	1	1	Yes	
	b) Antifungals	1	1	Yes	
	c) Antiparasitics	1	1	Yes	
	d) Rifampicin or rifabutin therapy	3*	3*	Yes	
SSRIs		1	1	Yes	
St. John's Wort		2	2	Yes	

Hormonal Contraceptive Self-Screening Questionnaire

Name _____ Health Care Provider's Name _____ Date _____
 Date of Birth _____ Age* _____ 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: _____

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 taken birth control pills, or used a birth control patch, ring, or injection? Have you previously had contraceptives prescribed to you by a pharmacist?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- 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 <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, which one do you use?	
4	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Medical History:

6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Are you currently breastfeeding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Do you get migraine headaches? If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Have you ever had a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	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"/>
18	Do you have cystic fibrosis, multiple sclerosis, lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	
20	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	

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

A pill you take each day **A patch that you change weekly** **Other (ring, injectable, implant, or IUD)**

Internal use only verified DOB* with valid photo ID BP Reading ____/____.

Pharmacist Name _____ Pharmacist Signature _____

Drug Prescribed _____ Rx# _____ -or- Patient Referred-circle reason(s)

Sig: _____ Pharmacy Phone _____ Address _____

Notes: _____ Date _____

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 course 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

- 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 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.