Pharmacist Prescribing of Self-Administered Oral Contraceptive Therapy STATEWIDE PROTOCOL Arkansas State Board of Pharmacy

I. Background

This protocol has been developed to provide guidance for an Arkansas licensed pharmacist who is currently practicing within the state to initiate oral contraceptive therapy, either by administering or dispensing, or both, in a patient who is eighteen (18) years of age or older. This protocol is issued pursuant to Act 408 of 2021 (HB1069)(Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to initiate oral contraceptive therapy in accordance with the provisions of Arkansas Code § 17-92-115 and the guidance provided therein.

II. Purpose:

To set criteria for properly trained pharmacists to prescribe hormonal contraception directly to eligible patients of Arkansas. This prescriptive authority of pharmacists will increase access to effective contraception. It is expected that increased access may improve contraceptive use and therefore increase individuals' ability to plan and space pregnancies and decrease the high rate of unintended pregnancy in Arkansas.

III. Screening Assessment, Questionnaire and Algorithm

The Board of Pharmacy shall adopt screening assessment procedures and questionnaires (Appendix A) to be used by pharmacists throughout the state. When a patient requests oral contraception or when a pharmacist, in his or her professional judgement, decides to initiate oral contraception therapy and counseling, the pharmacist shall assess, at a minimum, the following patient criteria in determining the appropriate therapy to initiate and should refer to the most recent edition of the United States Medical Eligibility Criteria for Contraceptive Use (US MEC) (Appendix B) for further detail regarding the patient's medical eligibility for contraceptive use:

- 1. <u>Background information</u>, i.e., pregnancy screening, history of smoking, current contraceptive use, etc.
- 2. <u>Medical history</u>, i.e., diabetes, migraine headache, inflammatory bowel disease, myocardial infarction and or stroke, deep vein thrombosis or pulmonary embolism, hypertension, liver disease, breast cancer, etc.

Pharmacists should follow the CDC guidelines and the standard procedures algorithm for deciding when to proceed with prescribing or when to refer the patient. (See Appendix C)

IV. Procedure:

Under this statewide protocol, when initiating therapy and administering or dispensing, or both, oral contraceptives in persons eighteen (18) years of age or older, a pharmacist shall:

1. Complete a training program related to the provision of oral contraceptives that has been approved by the Arkansas State Board of Pharmacy. (See Appendix D)

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- 2. Notify the primary care provider of the patient of any oral contraceptive furnished to the patient or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. (See Appendix D)
- 3. Provide the patient with a written record of the oral contraceptives furnished and advise the patient to consult a primary care provider of the patient's choice if the patient does not have a healthcare provider. (Appendix E)
- 4. Provide the patient with a standardized fact sheet (Appendix E) that shall include without limitation:
 - I. The indications and contraindications for the use of the oral contraceptive.
 - II. The appropriate method for the use of the oral contraceptive.
 - III. The need for medical follow-up.
 - IV. Other appropriate information.
- 5. Screen a patient seeking oral contraceptives to assess whether the patient has been seen by a primary care provider or women's healthcare provider within the previous six (6) months.
 - I. If the patient has NOT been seen by a primary care provider or women's healthcare provider within the previous six (6) months, the pharmacist shall:
 - i. Provide the patient with a referral to a local primary care provider or healthcare provider. (Appendix E)
 - ii. Not dispense more than a six (6) month supply of oral contraceptives or the equivalent number of refills to the patient until the patient has been seen by a primary care provider or healthcare provider.
 - iii. Not provide the patient with a referral to a licensed abortion provider.
- 6. Explain verbally to the patient the possible effects of an oral contraceptive including without limitations the death of an unborn child and possible health complications and adverse reactions as printed by the United States Food and Drug Administration. (Appendix F)
- 7. Provide the patient with an informed consent form that documents the explanation described in subdivisions (1-6), to which both the pharmacist and patient must sign, and place the form in the patient's medical record. (Appendix G)
- 8. Report the following information to the Department of Health:
 - I. The number of women who receive oral contraceptives as initiated by a pharmacist.
 - II. The age of the women who receive oral contraceptives as initiated by a pharmacist.

BIRTH CONTROL SCREENING FORM This information is strictly confidential.							
Name:	Date of birth: / Ag	Today's	Today's date:				
					, ,		
Email:		<u> </u>	Phone:		//		
ciliali.			Priorie.				
Primary care or women's health pro	vider:	Provider's contact	t info:				
A summary of today's visit will be se	ent to your provid	ler, if you agree.	☐ Yes	□ No □	☐ No prov	ider'	
First date of your last menstrual period:	Date of your las	t STD/HIV tests:		our last re	•	'e	
/	/_	/	_	/	/		
Birth control method(s) you are curr ☐ Pills ☐ Patch ☐ Ring ☐ Shot	ently using:						
Birth control method(s) you would I							
☐ Pills ☐ Patch ☐ Ring ☐ Shot		-					
ALLERO	GIES (List name of ea	ch medicine and your re	action to it)				
RIPTH CONTROL	LISTORY (List one	h birth control type and	vour ovporior	oco with it)			
DIKTI CONTROL	LIIISTONI (List eac	in birtir control type and	your experier	ice with it)			
	HEALT	H HISTORY					
Have you had a hysterectomy ?					☐ Yes		No
Have you had unprotected sex in the	e last 5 days?				☐ Yes		No
Do you think you might be pregnant now?					☐ Yes		No
Have you abstained from sex or used a reliable form of birth control since your last period?					☐ Yes		No
					☐ Yes		No
Have you given birth within the last (6 months?				☐ Yes		No
					No		
Do you smoke cigarettes ?					☐ Yes		No
Do you have or have you ever had br	east cancer?				☐ Yes		No
Have you ever been told by a medica	ıl professional not	to take hormones	?		☐ Yes		No
Do you have vaginal bleeding for an unknown reason?					No		

Do you have migraine headaches , or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?		Yes		No
Have you had bariatric surgery or stomach reduction surgery?		Yes		No
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
Do you have diabetes?		Yes		No
Do you have high blood pressure, hypertension, or high cholesterol?		Yes		No
Have you ever had a heart attack or stroke, or been told you had any heart disease?		Yes		No
Have you ever had a blood clot in your leg or in your lung?		Yes		No
Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?		Yes		No
Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?		Yes		No
Do you have lupus, rheumatoid arthritis, or any blood disorders?		Yes		No
Do you take medication for seizures, tuberculosis, or human immunodeficiency virus (HIV) ? If yes, list them here:		Yes		No
Do you have any other medical problems or take any other medications , including herbs or supplements? If yes, list them here:		Yes		No
am requesting a birth control consultation and prescription from the pharmacist. I understand t	he t	follov	ving	<u> </u>

- The pharmacist is providing care based on the information I provide.
- If the pharmacist is unable to provide my desired method of birth control, I will be given a referral to another healthcare provider.
- No method of birth control is 100% effective at preventing pregnancy.
- Hormonal birth control does not start working right away to prevent pregnancy. After using hormonal birth control for 7 days, it will prevent pregnancy.
- Hormonal birth control does not protect against sexually transmitted diseases (STDs). Condoms protect against STDs.
- The pharmacist will review my birth control options. For my selected birth control method, the pharmacist will review how to use it and what to expect. The pharmacist is available to answer all my questions.
- I will contact my pharmacist, primary care provider or women's health provider regarding any side effects,

 problems, or changes to my health status or medication It is advised to have regular visits with a primary care or recommended tests and screenings. 		ceive
Signature:	/ Date:// _	

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Appendix B: *United States Medical Eligibility Criteria for Contraceptive Use* (Updated 2020).

Condition	Sub-Condition	Cu-IUD	LNG-IUD	Implant	DMPA	POP	СНС
		I C	I C	I C	I C	I C	I C
Age		Menarche	Menarche	Menarche	Menarche	Menarche	Menarche
		to	to	to	to	to	to
		<20 yrs:2	<20 yrs:2	<18 yrs:1	<18 yrs:2	<18 yrs: 1	<40 yrs:1
		≥20 yrs: 1	≥20 yrs:1	18-45 yrs:1	18-45 yrs:1	18-45 yrs:1	≥40 yrs: 2
		,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	>45 yrs:1	>45 yrs:2	>45 yrs:1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Anatomical	a) Distorted uterine cavity	4	4				
abnormalities	b) Other abnormalities	2	2				
Anemias	a) Thalassemia	2	1	1	1	1	1
	b) Sickle cell disease‡	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 [‡]	_	_			-	
	i) Current	1	4	4	4	4	4
	ii) Past and no evidence of current	1	3	3	3	3	3
	disease for 5 years		3				
Breastfeeding	a) <21 days postpartum			2*	2*	2*	4*
	b) 21 to <30 days postpartum						
	i) With other risk factors for VTE			2*	2*	2*	3*
	ii) Without other risk factors for VTE			2*	2*	2*	3*
	c) 30-42 days postpartum						
	i) With other risk factors for VTE			1*	1*	1*	3*
	ii) Without other risk factors for VTE			1*	1*	1*	2*
	d) >42 days postpartum			1*	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 [‡] (decompensated)	1	3	3	3	3	4
Cystic fibrosis‡		1*	1*	1*	2*	1*	1*
Deep venous thrombosis	a) History of DVT/PE, not receiving						
(DVT)/Pulmonary embolism (PE)	anticoagulant therapy i) Higher risk for recurrent DVT/PE		2	2	2	2	
embolism (FE)	, ,	1	2	2	2	2	3
	ii) Lower risk for recurrent DVT/PE		2	2	2	2	_
	b) Acute DVT/PE c) DVT/PE and established anticoagulant	2	2	2	2	2	4
	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*

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)					

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Condition	Sub-Condition	Cu-	IUD	LNG	IUD	Implant	DMPA	POP	CHC
		- 1	С	- 1	С	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	2
	ii) Insulin dependent	1		2	2	2	2	2	2
	c) Nephropathy/retinopathy/neuropathy [‡]	1		2	2	2	3	2	3/4*
	 d) Other vascular disease or diabetes of >20 years' duration[‡] 	1	1	2	2	2	3	2	3/4*
Dysmenorrhea	Severe	2	2	1		1	1	1	1
Endometrial cancer [‡]		4	2	4	2	1	1	1	1
Endometrial hyperplasia		1	ı	1		1	1	1	1
Endometriosis		2	2	1		1	1	1	1
Epilepsy [‡]	(see also Drug Interactions)	1		1		1*	1*	1*	1*
Gallbladder disease	a) Symptomatic								
	i) Treated by cholecystectomy	1		2	2	2	2	2	2
	ii) Medically treated	1		2	2	2	2	2	3
	iii) Current	1		2	2	2	2	2	3
	b) Asymptomatic	1		2		2	2	2	2
Gestational trophoblastic disease [‡]	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	ı	1	1	1	1	1	1*
	b) Migraine								
	i) Without aura (includes menstrual migraine)	1	ı	1	ı	1	1	1	2*
	ii) With aura	1		1		1	1	1	4*
History of bariatric	a) Restrictive procedures	1	I	1		1	1	1	1
surgery [‡]	b) Malabsorptive procedures	1	1	1	ı	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	2	3
History of high blood pressure during pregnancy		1	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	i	1
	b) HIV infection					1*	1*	1*	1*
	i) Clinically well receiving ARV therapy	1	1	1	1	_	-	e Drug Inter	_
	ii) Not clinically well or not receiving ARV								
	therapy [‡]	2	1	2	1	if on tr	eatment, se	e Drug Inter	actions

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; LNC-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/contraception_guidance.htm.

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Condition	Sub-Condition	Cu-	IUD	LNG	-IUD	Implant	DMPA	POP	СНС
		_	С	-1	С	ı	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*	1*	2*	1*	3*
	ii) Systolic ≥160 or diastolic ≥100‡	·	1*	2	2*	2*	3*	2*	4*
	c) Vascular disease	•	1*	2	2*	2*	3*	2*	4*
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	1	1	1	1	1	2	2	2/3*
Ischemic heart disease‡	Current and history of	,	1	2	3	2 3	3	2 3	4
Known thrombogenic mutations [‡]			1*	2	2*	2*	2*	2*	4*
Liver tumors	a) Benign								
	i) Focal nodular hyperplasia	1	1	2	2	2	2	2	2
	ii) Hepatocellular adenoma‡	,	1	3	3	3	3	3	4
	b) Malignant [†] (hepatoma)	·	1	3	3	3	3	3	4
Malaria		,	1	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	1	2	2	2*	3*	2*	3/4*
Multiple sclerosis	a) With prolonged immobility	1	1	1	1	1	2	1	3
	b) Without prolonged immobility	•	1	1	1	1	2	1	1
Obesity	a) Body mass index (BMI) ≥30 kg/m²	•	1	1	1	1	1	1	2
	b) Menarche to <18 years and BMI ≥ 30 kg/m²	1		1	1	1	2	1	2
Ovarian cancer [‡]		•	1	1	1	1	1	1	1
Parity	a) Nulliparous	- 1	2	2	2	1	1	1	1
	b) Parous		1	1	1	1	1	1	1
Past ectopic pregnancy		1	1	1	1	1	1	2	1
Pelvic inflammatory	a) Past								
disease	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 [‡]	a) Normal or mildly impaired cardiac function								
	i) <6 months		2		2	1	1	1	4
	ii) ≥6 months	- 7	2	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*
	b) Second trimester		2*		2*	1*	1*	1*	1*
5	c) Immediate postseptic abortion	4	4	4	4	1*	1*	1*	1*
Postpartum (nonbreastfeeding	a) <21 days					1	1	1	4
(nonoreastreeaing women)	b) 21 days to 42 days								P. U
	i) With other risk factors for VTE					1	1	1	3*
	ii) Without other risk factors for VTE					1	1	1	2
Destruction	c) >42 days					1	1	1	1
Postpartum (in breastfeeding or non-	a) <10 minutes after delivery of the placenta		1 *		14				
breastfeeding women,	i) Breastfeeding		1*		2*				
including cesarean	ii) Nonbreastfeeding b) 10 minutes after delivery of the placenta		1*		*				
delivery)	to <4 weeks	•	2*	_	2*				
	c) ≥4 weeks		1*		1*				
	d) Postpartum sepsis	4	4	4	4				

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Condition	Sub-Condition	Cu-	IUD	LNG	-IUD	Implant	DMPA	POP	СНС
		-	С	- 1	С	I C	I C	I C	I C
Pregnancy		4	*	4	*	NA*	NA*	NA*	NA*
Rheumatoid	a) On immunosuppressive therapy	2	1	2	1	1	2/3*	1	2
arthritis	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 [‡]		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	1	2
	b) Age ≥35, <15 cigarettes/day	,	1	1	1	1	1	1	3
	c) Age ≥35, ≥15 cigarettes/day	1	1	1	1	1	1	1	4
Solid organ	a) Complicated	3	2	3	2	2	2	2	4
transplantation [‡]	b) Uncomplicated	- 2	2	- 2	2	2	2	2	2*
Stroke [‡]	History of cerebrovascular accident	•	1	- 2	2	2 3	3	2 3	4
Superficial venous	a) Varicose veins	1	1		1	1	1	1	1
disorders	b) Superficial venous thrombosis (acute or history)	1	1	1	1	1	1	1	3*
Systemic lupus erythematosus‡	 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	1	1
Tuberculosis [‡]	a) Nonpelvic	1	1	1	1	1*	1*	1*	1*
(see also Drug Interactions)	,	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	a) Uncomplicated	1		1	<u> </u>	1	1	1	2
disease	b) Complicated [‡]		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) All other ARVs are 1 or 2 for all methods.	1/2*	1*	1/2*	1*	2*	2*	2*	3*
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone,		1		1	2*	1*	3*	3*
	topiramate, oxcarbazepine)								
	b) Lamotrigine		1		1	1	1	1	3*
Antimicrobial	a) Broad spectrum antibiotics		1	_	1	1	1	1	1
therapy	b) Antifungals		1	•	1	1	1	1	1
	c) Antiparasitics	_	1	1	1	1	1	1	1
	d) Rifampin or rifabutin therapy	1	1	1	1	2*	1*	3*	3*
SSRIs		1	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-guidance.htm. Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condomreduces the risk of STDs and HIV.

STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING OF ORAL CONTRACEPTIVES

1) Health and History Screening Contraindicating Review the Birth Control Screening Form Condition(s) Refer to USMEC to evaluate health and history 1 or 2 (green boxes) -Birth Control is indicated, proceed to next step 3 or 4 (red boxes)-Birth Control is contraindicated----Refer NO CONTRAINDICATING CONDITIONS 2) Pregnancy Screen Did your last menstrual period start within the past 7 days? Have you had a miscarriage or abortion within the last 7 days? Have you abstained from sexual intercourse since your last menstrual period or delivery? **Possible** Have you had a baby within the last 4 weeks? **Pregnancy** ☐ Did you have a baby less than 6 months ago, are you breastfeeding, AND have you had no menstrual period since the delivery? 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 patient must be referred NOT PREGNANT **Blood Pressure Screening** $BP \ge 140/90$ Take and document patient's current blood pressure. Is BP <140/90 Note: RPH may choose to take a second reading if initial is high. **BLOOD PRESSURE <140/90** 4) Medication Screening Caution: anticonvulsants, antiretrovirals, antimicrobials, barbiturates, herbs & supplements ☐ Anticonvulsants (pheynytoin, carbamazepine, barbiturates, primidone,topiramate, Contraindicating oxcarbazepine, lamotrigine) Medications ☐ Antiretrovirals (for prevention-PrEP or (*PLEASE ALWAYS REFER TO CURRENT MEC*) Treatment of HIV) ☐ Antimicrobial therapy (broad spectrum antibiotics, antifungals, antiparasitics, rifampin or rifabutin therapy) ☐ Herbs & Supplements **NO CONTRAINDICATING MEDICATIONS** Evaluate patient history, preference, and current therapy for selection of treatment Not currently on birth control Patient is currently on birth control 5a) Choose Contraception 5b) Choose Contraception **Initiate** contraception based on patient **Continue** current form of pills if no change is necessary preferences, adherence, and history for therapy. -If the patient has not been seen by a PCP or **Alter** therapy based on patient concerns, such as side effects WHP within the previous 6 mo. provide patient patient may be experiencing or refer if appropriate with referral and not dispense more than 6 mo supply. If under care, may dispense quantities or refills up to date of next yearly visit. 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: Routine health screenings, STD prevention, and notifications to care provider

TRAINING PROGRAM FOR THE PROVISION OF ORAL CONTRACEPTIVES

ONLINE AND LIVE PROGRAMS



Curricular Outline:

- I. Introduction
- II. Screening Assessment and Questionnaire
 - a. Background information
 - b. Medical history
- III. Primary Care notification and referral
 - a. Limits on refills
 - b. No referrals to abortion providers
- IV. Possible side effects and adverse reactions
 - a. Informed Consent Form
- V. Instructions for use
 - a. Warning that O.C. do not protect against STD or infections
- VI. Reporting requirements
- VII. Educational Resources

DOCUMENTATION FORM To be completed by pharmacist.								
Patient Name:		Date of Birth:	/ Age	Today's Date:				
		, ,	ı	/ /				
	SUBJECTIVE							
		OBJECTIVE						
Blood Pressure M	easurement(s):	mmHg		_ / mmHg				
Pregnancy Screen	/			_ /				
Health History								
Other (eg., pulse,	weight)							
	A	SSESSMENT						
	PLAN / IMPI	LEMENT / FOLLOW-	UP					
	osage, effectiveness, how to start/ eventative health screenings, cond			otential side effects, safety	/,			
Patient Education Handouts Given:								
Patient Referred For:	Patient ☐ LARC evaluation/placement Referred ☐ related preventative health screenings (cervical cancer, breast cancer, STD/HIV)							
Prescription(s) Issued:								
Medication Administered:	Med: Lot #:							
Pharmacist Name:			License Number:					
PCP Notified:	□ yes, PCP/practice: notified by: □ phone □ fax □ o		□ no, no P0 :e: /	CP/referred □ no, declin /	ed			

APPENDIX F



fact sheet

The combined oral contraceptive (COC), or "the pill," is a method of hormonal birth control. The pill contains estrogen and progestin hormones. Brands include Loestrin, Ortho Tri-Cyclen, Yaz, and Yasmin. The pill has many benefits beyond birth control. Many people use it to help with acne, premenstrual syndrome (PMS), or their periods. The pill does NOT protect against sexually transmitted diseases (STDs).

How does it work?

The hormones in the pill prevent pregnancy in several ways. Estrogen prevents ovulation while progestin increases the thickness of cervical mucus and thins the uterine lining. These actions hinder sperm travel, egg release, and implantation in the uterus.

How well does it work?

When used correctly, the pill is over 99% effective in preventing pregnancy, but missing pills or taking them late is common, so the overall effectiveness drops to 91% with typical use.

How do I take it?

The pill is taken by mouth at the same time every day with or without food. Most combination pills come in packs of 28, where the last four or 7 days are placebos ("sugar pills") that do not contain any hormone. You should expect to get your period during the hormone-free days.

What if I forget to take it on time?

It's very important to take all the hormone pills on time.

- If you are late or miss one pill and remember before your next pill is due, take the late pill as soon as possible and resume your normal pill schedule. It is okay to take 2 pills in one day.
- If you miss 2 or more pills, take the most recent missed pill as soon as you remember and resume your normal pill schedule. Throw away any other pills that were missed. Use backup birth control, like condoms, for the next 7 days.
- If pills from the last week of hormones (days 15-21 for 28-day pill packs) were missed, skip the hormone-free period by finishing the hormone pills in the current pack and starting a new one the next day.

You may also consider using emergency contraception like Plan B One-Step (levonorgestrel), but not Ella (ulipristal acetate).

Missing any or all of the placebo pills is okay; no further action is needed to prevent pregnancy, but it is good practice to take them as regularly as the hormone pills so that you can maintain the habit and routine.

What if I want to get pregnant soon?

The pill is a great option if you plan to become pregnant within the next year. It is possible to get pregnant as soon as you stop taking the pill.

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What are some side effects I might experience?

Though rare, there are serious side effects that can occur when using the pill. These include blood clots, heart attacks, and strokes. If you experience sudden and/or severe pain in your stomach, chest, head, or legs with or without dizziness, nausea, vomiting, difficulty breathing, or changes in vision or mental status, call your healthcare provider right away and/or get to an emergency room. Other possible side effects are headaches, breast tenderness, changes in mood, sex drive, and bleeding patterns. These usually improve after a few months. On the bright side, the pill may help with acne and make periods lighter and more regular.

Is it right for me?

The pill is safe for many people. Some health conditions (history of blood clots, high blood pressure, migraine, smoking, and age over 35) make it unsafe to use the pill, so the progestinonly "minipill" can be used instead. (Find the minipill fact sheet here.) Another consideration is the ability to remember to take the pill on time all the time. If you travel often and find it difficult to schedule your doses while keeping time zones in mind, the pill may not be the best option for you.

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Progestin-Only Pills: The "Minipill"

fact sheet

The "minipill," or progestin-only pill (POP), is a method of birth control that contains only one hormone, a progestin. There are 2 types of minipills: norethindrone and drospirenone. The minipill is different from the combined oral contraceptive (COC or "the pill"), which contains progestin and estrogen hormones (find "the pill" fact sheet here). The minipill does NOT protect against sexually transmitted diseases (STDs).

	Norethindrone	Drospirenone
Brands	Micronor, Camila, Errin, etc.	Slynd
Are generics available?	Yes	No
Any hormone-free days?	No	Yes; 4
How late can I take a pill (since the scheduled time)?	Up to 3 hours	Up to 24 hours
Available since	The 1970s	2019

How does it work?

The hormone in the minipill acts like the body's natural hormone progesterone. It causes thickening of the mucus in the cervix and thinning of the uterine lining. It can also prevent the release of an egg but not consistently. Together, these effects make it hard for sperm to get to an egg (if there is one) and for an egg to implant in the uterus.

How well does it work?

When taken correctly, the minipill is more than 99% effective, but missing pills or taking them late is common, so the overall effectiveness drops to 91% with typical use. Overall, the minipill is slightly less effective at preventing pregnancy than COCs.

How do I take it?

Take the minipill by mouth on the first day of your period. If you are using the norethindrone minipill, you may take the first pill on any other day, but use backup birth control, like condoms, for 48 hours. Consistency is key with the minipill. Aim to take it at the same time every day. For the norethindrone minipill, all pills in the 28-day pack contain hormone. Because of this, it must be taken every single day with no skipping. For the drospirenone minipill, 24 pills in the 28-day pack contain hormone, and the last 4 are placebo ("sugar pills"). You may get your period during these 4 days.

What if I forget to take it on time?

If you are more than 3 hours late for the norethindrone minipill or more than 24 hours late for the drospirenone minipill, you should take the late or most recently missed pill as soon as you remember and resume the regular schedule. You may need to use a backup birth control, like condoms, for the next 48 hours until the minipill continues to reliably prevent pregnancy. If you are on the drospirenone minipill, it is okay to miss any of the 4 placebo pills; no further action is needed to prevent pregnancy, but it is good practice to take them as regularly as the hormone pills so that you can maintain the habit and routine.

What if I want to get pregnant soon?

The minipill is a good option if you are planning to get pregnant within the next year. It is possible to get pregnant right after stopping the minipill.

Updated July 2020 Page 2 of 2

What are some side effects I might experience?

The most common side effect of the minipill is changes in bleeding patterns. These can include bleeding between periods or not having a period at all. (If you miss 2 periods in a row while on the drospirenone minipill, call your health care provider.) The minipill may also cause changes in mood, skin (acne), or appetite. If you do experience some side effects, do not despair; they typically go away after 2 to 3 months of using the minipill.

Is it right for me?

The minipill is a safe option for most people, and it is especially appropriate for those who have recently given birth or are breastfeeding. The drospirenone minipill is a good option for those who are looking for birth control with fewer side effects of oily skin, weight gain, and hairiness. Some health conditions (history of blood clots, high blood pressure, migraine, smoking, and age over 35) make it unsafe to use COCs, so the minipill can be used instead. Talk to your healthcare provider for further guidance. Another consideration is the ability to remember to take the minipill every day at the same time. If you travel often and find it difficult to schedule your doses while keeping time zones in mind, the minipill may not be the best option for you.

ORAL CONTRACEPTIVE CONSENT FORM

The following statements include important information about oral contraceptives (birth control pills) and should be read before taking oral contraceptives.

You are required to have been seen by a primary care provider or women's healthcare provider within the past six (6) months. ***If not, then the patient must be referred to a local primary care provider or women's healthcare provider AND shall not receive more than a six-month supply of birth control pills until the patient has been seen by a primary care provider or women's healthcare provider***

Birth control methods, including birth control pills, are **NOT 100% effective** and some women may become pregnant while taking the pill.

Birth control pills **DO NOT** prevent or protect you from sexually transmitted infections or HIV (human immunodeficiency syndrome).

Taking certain medications along with birth control pills may **decrease the effectiveness** of the birth control pill which may increase your chance of becoming pregnant.

Please be aware there are possible side effects of taking oral contraceptives to include the death of an unborn child and possible health complications and/or adverse reactions as printed by the United States Food and Drug Administration

Cigarette smoking increases the risk of serious cardiovascular side effects while taking some oral contraceptives (risk increases with age-individuals older than 35 years and with heavy smoking.) It is strongly recommended not to smoke while taking birth control pills.

It is important to tell your health care provider if you have any of the following conditions **BEFORE** taking birth control pills: unexplained vaginal bleeding, a history of blood clots or any type of clotting disorder, breast cancer or cancer of reproductive organs, heart disease, stroke, and liver disease.

The following **symptoms (A.C.H.E.S)** are serious and indicate a possible blood clot. If any of the following occur, you should seek medical attention immediately.

A-Abdominal pain (severe), C-Chest pains or shortness of breath, H-Headaches (severe), dizziness, numbness, weakness, E-Eye problems (blurred or double vision, loss of vision, speech problems, S-Severe leg pain

me to ask questions.	,
Patient's Signature	Date
Pharmacist Signature	Date

I understand the information as presented above. The pharmacist has explained the information and allowed

Terms Definitions

	An Arkaneae pharmacist with a valid license and in good
	An Arkansas pharmacist with a valid license and in good
Properly trained pharmacist	standing with the Arkansas State Board of Pharmacy who
Troperty trained priarmatise	has completed the board approved training program for
	oral contraceptive prescribing.
Eligible Patients	Females ages 18 years of age or older
0 10 1 11 71	Refers to combined oral contraceptive(COC) and/or
Oral Contraception Therapy	progestin-only pills (POP)
Primary Care Physician (PCP)	A healthcare professional who practices general medicine
	or specializes in women's health to include Nurse
Women's Healthcare Professional (WHP)	Practitioners and Physician Assistants
	Suggests patient should follow-up and be seen by PCP or
Referral	WHP. Routine health screenings by either a PCP or WHP
	are encouraged
	Patient records should be kept in an electronic health
Medical record	record or must be kept in such a manner that all data is
iviedical record	readily retrievable and shall be retained as a matter of
	record by the pharmacist for two years

Frequently Asked Questions

1. What type of training must be completed by pharmacists to initiate therapy of oral contraceptives?

Pharmacists are required to complete a training program that has been approved by the Arkansas State Board of Pharmacy. Additional educational resources will also be available to pharmacists. Continuing education hours on contraception will be encouraged as it is important for pharmacists to be up to date on knowledge and standards of care.

2. Can the pharmacist initiate therapy if the patient has not been seen by a PCP or WHP within the previous six (6) months?

Yes, however, the pharmacist must provide the patient with a referral to a local primary care physician or women's healthcare professional. The pharmacist can dispense no more than a six (6) month supply of oral contraceptives or the equivalent number of refills to the patient until the patient has been seen by a PCP or WHP.

3. If the patient requests a different type of birth control other than oral contraceptives, can the pharmacist initiate therapy?

No. The patient must be referred to a local PCP or WHP if they choose a different birth control method, or if contraindications exist to oral contraceptives.