

PROTOCOL FOR PHARMACIST PRESCRIPTION OF HORMONAL CONTRACEPTION

I. TITLE

New Mexico Pharmacist prescription of hormonal contraception, as intended to support and pursuant to, New Mexico Board of Pharmacy Regulations.

II. PURPOSE

This protocol will set criteria for properly trained pharmacists to prescribe hormonal contraception directly to eligible patients of New Mexico. 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 New Mexico.

III. BACKGROUND

1. The Pregnancy Risk Assessment Monitoring Systems (NM PRAMS) is an ongoing project of the New Mexico Department of Health and the National Centers for Disease Control and Prevention (CDC).¹ NM PRAMS samples over 2000 mothers each year and has determined that among NM women with a recent live birth in 2009-2010, just over half (53%) said their pregnancy was intended (wanted at that time or sooner) and the remaining (47%) were unintended (wanted later or never). Pregnancy intention is also associated with family income level, and 44% of women with a household income at 100% of the Federal Poverty Level said their pregnancy was intended while the remaining 56% of women with a household income at 100% of the Federal Poverty Level said their pregnancy was unintended. Among women who were not trying to get pregnant and giving live birth in 2009-2010, almost one-half (48%) said they were using a form of contraception at the time of conception while slightly over one-half (52%) did not report using contraception at the time of conception. Native American women were less likely to report contraception at conception compared to Hispanic and non-Hispanic White women.¹
2. For more than a decade, the World Health Organization (WHO), has advised that hormonal contraception can safely be provided to women based on a blood pressure measurement and a limited history to determine the presence or absence of risk factors for use of hormones. The same recommendation is now included in the U.S

- adaptation of the WHO guidance, the U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC) 2010.² This WHO US MEC guidance was specifically intended to apply to the United States. Blood pressure measurement and careful evaluation of a medical history are well within the capabilities of a pharmacist.
3. In 2004, pharmacists and technicians in eight Seattle area pharmacies began collaborating in the Direct Access study to provide hormonal contraception to women without the requirement of a visit to a traditional clinician (Advanced Practice Clinician or Medical Provider).³ The objective of the study was to test the feasibility of pharmacists prescribing hormonal contraception and also to decrease the rate of unintended pregnancies. Outcomes included high satisfaction for women, with 97.7% reporting being satisfied with the experience and 96.8% reporting feeling comfortable with continuing to receive prescriptions for hormonal contraceptives from the pharmacist after study completion. Higher one-year continuation rates of contraception use were observed, with 70% of participants still using the contraception at the 12 month follow-up period versus a continuation rate of 50%, with traditional contraceptive prescription prescribing practices after visit to a traditional clinician (Advanced Practice Clinician or Medical Provider).^{3,4,5}
 4. The Oregon State Board of Pharmacy explained that the ability of pharmacist prescribed hormonal contraception, passed into law as of January 1, 2016, will greatly benefit women who live in the more rural areas of Oregon and often times, must wait up to 18 weeks to see a provider. Access to birth control is a major public health concern as a contributor to the risk of unwanted pregnancies in states such as Oregon and New Mexico.⁶ New Mexico covers 121,356 square miles, with a 2014 estimated population of 2,085,572 people – 695,360 people living in rural New Mexico in which the status of health care varies as much as the terrain and people who live here.⁷ There are only 9 public health offices in rural New Mexico, leaving numerous New Mexicans without access to health care or a primary care provider for their health care needs.⁷

IV. GUIDELINES

1. All pharmacists participating in prescriptive authority for hormonal contraception should follow the Board of Pharmacy Protocol as outlined.
2. The service will be available to all patients who are capable of becoming pregnant and wish to use hormonal contraception, as detailed in the formulary section XIII.
3. The hormonal contraceptive prescribed may be written with allowable refills or refills for up to one year, as authorized by the certified prescribing pharmacist.

4. All patients who are capable of becoming pregnant and wish to use hormonal contraception must meet criteria of eligibility based on health history and blood pressure to be eligible for this service as per the US MEC.² Patients not meeting the criteria may not receive hormonal contraception, and must be referred to a primary provider or local clinic for complete evaluation.
5. All patient specific documents must be securely stored electronically or in a locked cabinet in the pharmacy, and HIPAA policies must be followed, as with other pharmacy related materials. These documents will include patient informed consent, screening documents including medical history, medications, and other relevant information.
6. All patients who are capable of becoming pregnant and wish to use hormonal contraception will receive information about the service, information about the contraceptive options available, as detailed in the formulary section XIII, and other patient education materials, as provided in the pharmacist prescriptive authority training course.
7. All patients who are capable of becoming pregnant and wish to use hormonal contraception methods not available, as detailed in the formulary section XIII, must be referred to a primary provider or local clinic.

V. PROCEDURE

When a patient requests contraception at a participating pharmacy, the patient and her pharmacist will assess the need for treatment and/or referral for hormonal contraception care by evaluating the patient's answers to the screening questions. The patient's blood pressure will be measured by the pharmacist and eligibility for the service will be determined. No further physical exams of any kind will be performed by the certified prescribing pharmacist. All patient responses to the screening questions at any time during the pharmacist/patient consultation, must be clearly consistent and confirm that use of hormonal contraception is safe. The pharmacist will refer to the hormonal contraception formulary, as detailed in the formulary section XIII, and as included in the protocol, for the contraceptive choices available. The pharmacist will provide patient information, education, and answer the patient's questions, to assist the patient in choosing the method that is right for them. After evaluation, if the patient is determined to be an eligible candidate, the patient must sign the written informed consent form provided.

VI. SCREENING QUESTIONS

Will be based on the most current version of the US MEC and clearly identified in the pharmacist prescriptive authority training course.²

VII. PHARMACIST MANDATES

1. Training will be done in accordance with the curriculum approved by the New Mexico Board of Pharmacy. The training course will be based on the current recommendations of the World Health Organization, Centers for Disease Control, Office of Population Affairs, American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, and the Association of Reproductive Health Professionals.
2. Pharmacists with prescriptive authority will document all prescription orders and advise the patient's **primary care provider** within 15 days of the prescription with patient approval as stated in the informed consent.
3. Pharmacists with prescriptive authority will follow this protocol as approved and will have on site access to a copy of the most recent New Mexico Board of Pharmacy approved protocol.
4. Pharmacists with prescriptive authority will maintain patient confidentiality and refer patients who do not meet the pharmacist prescribing criteria to a primary provider or local clinic.
5. Pharmacists with prescriptive authority will maintain patient confidentiality and refer patients wishing to obtain hormonal contraception methods not available, as detailed in the formulary section XIII, to a primary provider or local clinic.
6. Pharmacists with prescriptive authority will maintain active certification and are responsible for 2 hours of live ACPE accredited continuing education credits in the field of hormonal contraception every two years.

VIII. CONTRAINDICATIONS TO HORMONAL CONTRACEPTION

Pharmacists will refer to the screening for eligibility and appropriate selection of contraceptive method(s) guidelines in accordance with the most current version of the US MEC.²

IX. REFERRALS

1. All patients who are capable of becoming pregnant and wish to use hormonal contraception and do not meet the criteria may not receive hormonal contraception and must be referred to a primary provider or local clinic for complete evaluation.
2. All patients who are capable of becoming pregnant and wish to use hormonal contraception methods not available, as detailed in the formulary section XIII, must be referred to a primary provider or local clinic.
3. All patients who are experiencing contraception failures or symptoms of pregnancy or contraception failure will be given a referral to a primary provider or local clinic.
4. All patients experiencing side effects or symptoms, as detailed in the side effect/symptoms section X, and wishes intervention, require referral to a primary provider or local clinic for complete evaluation.
5. All patients experiencing side effects or symptoms, not detailed in the side effect/symptoms section X, require referral to a primary provider or local clinic for complete evaluation.

X. SIDE EFFECTS/SYMPTOMS

1. Symptoms that usually resolve in the first three months of use
 - A. Nausea
 - B. Breast tenderness
 - C. Irregular bleeding or spotting

Patients should be reassured that these symptoms are common and usually resolve and should be encouraged to continue careful use of their contraceptives. If the patient wishes intervention, pharmacists will refer the patient to a primary provider or local clinic for complete evaluation.

Pharmacists will refer to management guidelines in accordance with the most current version of the US MEC for proper management of side effects.²

2. Other symptoms require referral to a primary provider or local clinic.

XI. INFORMED CONSENT

The informed consent form and process will be provided during the pharmacist training course and subsequently updated.

XII. PATIENT EDUCATION

1. The pharmacist will provide all patients interested in this service with appropriate patient education as recognized by the World Health Organization, Centers for Disease Control, Office of Population Affairs, American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, and the Association of Reproductive Health Professionals.
2. Patients wishing to obtain hormonal contraception methods not available, as detailed in the formulary section XIII, must be referred to a primary provider or local clinic.
3. Patients will also be given information regarding their health care needs and referrals to local providers, including well woman care referrals.
4. Contraception failures or symptoms of pregnancy or contraception failure will be given a referral to a primary provider or local clinic.

XIII. FORMULARY

1. Hormonal contraceptive patch
2. Hormonal vaginal contraceptive ring
3. Oral contraceptives, (combined estrogen and progestin)
4. Oral contraceptives, (progestin only)
5. Depot medroxyprogesterone acetate injection
6. Emergency contraception (excluding intrauterine devices)
7. Other FDA approved hormonal contraception products, with the exclusion of implants, intrauterine devices, or devices requiring surgical training and implantation
8. Other FDA-approved non-hormonal contraceptive methods (includes over-the-counter and prescription medications)

XIV. REQUIRED ONSITE DOCUMENTS

1. Patient informed consent form
2. Pharmacist documentation, including medical history
3. Pharmacist documentation of patient education provided
4. Prescription order
5. Physician notification documentation
6. US MEC guidelines

XV. REFERENCES

1. The New Mexico Pregnancy Risk Assessment Monitoring System (NM PRAMS). New Mexico Department of Health. 2012. <https://nmhealth.org/about/phd/fhb/prams/>.
2. Department of Reproductive Health, WHO. United States Medical Eligibility Criteria for Contraceptive Use (US MEC), Fourth Edition. 2010. <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm>.
3. Gardner SG, Miller L, Downing DF, Le S, Blough D, Shotorbani S. Pharmacist prescribing of hormonal contraceptives: Results of the Direct Access Study. JAPhA. 2008; 48(2):212-221.
4. Frost JJ, Singh S, Finer LB. U.S women's one-year contraceptive use patterns, 2004. Perspect. Sex Reprod. Health. 2007; 39:48-55.
5. Wells ES, Hutchings J, Gardner JS, et al. Using Pharmacies in Washington State To Expand Access to Emergency Contraception. Family Plan Perspect. November/December 1998 :(30).
6. Gilchrist, A. How Oregon Pharmacists are Prescribing Birth Control. Pharm Times. 2016.
7. Rural Health Information Hub. 2016. <https://www.ruralhealthinfo.org/states/new-mexico>.