

SECTION VIII PHARMACEUTICALS

A. OVERVIEW

1. Each delegate program registered with the Colorado State Board of Pharmacy must have its own "Other Outlet License" at each clinic location.
2. Each delegate program will comply with the Pharmacy Practice Act.
3. A Pharmacy Protocol must be utilized: The Protocol must be reviewed and signed annually by a Registered Pharmacist and the Family Planning Program Coordinator.
4. Nurse Practitioners and Physician Assistants select medications utilizing protocols reviewed and signed annually by a physician.
 - a. Nurse Practitioners with Prescriptive Authority must follow the Board of Nursing Rules and Regulations regarding Prescriptive Authority. In addition, they must comply with the employing clinic's treatment protocols.
 - b. Registered Nurses give medications per chart order.
 - c. Non-nursing staff, with appropriate training, can be delegated the task of filling medication orders, including refills, at the discretion of the consulting pharmacist. This staff, however, cannot dispense from standing orders.

B. DRUG STOCKS

1. Ordering (All delegate agencies are eligible to purchase drugs at the 340B PHS pricing)
 - a. A written order signed by the program coordinator is necessary when ordering prescription items. Prescription items may be ordered through:
 - 1) Arrangements with pharmaceutical supply companies or distributors.
 - 2) Wholesale distributors participating in the 340B Prime Vendor Program
<https://www.340bpvp.com/public/>
 - 3) Region IX Cooperative Purchasing Agreement
<http://www.fpcpp.org/default.asp>
 - b. Purchase records shall be maintained in program files for a period of two years from the last date of an entry.
2. Storage
 - a. All prescription items shall be maintained in cabinets or drawers that can be locked. Pharmaceuticals must be kept under continuous observation or locked.
 - b. Proper temperatures and storage conditions applicable to individual prescription items will be maintained.
 - c. Program personnel will inventory drug stocks every three months. Stock will be rotated at that time as well as on receipt of new supplies. Out-of-date stock will be returned to pharmaceutical companies or destroyed by the consultant pharmacist, or his/her delegate with proper recording of destroyed medication.
 - d. In the event a recall of pharmaceutical supplies occurs, program personnel will inventory stock for recalled items and return these to the pharmaceutical supply company. Clients who received any recalled pharmaceutical supplies will be properly identified through the dispensing logs and notified as appropriate.
3. Controlled Substances: Controlled substances will not be stocked or dispensed/administered

SECTION VIII PHARMACEUTICALS

by Family Planning Programs.

C. ADMINISTERED AND/OR DISPENSED

1. Methods

- a. Medications are administered and/or dispensed utilizing medical protocols reviewed and signed by the program physician.
- b. Medications are administered and/or dispensed utilizing chart orders.
- c. Medications are administered and/or dispensed utilizing Standing Orders, which have been approved and signed off by the program physician and other appropriate staff, with the exception of non-licensed personnel.
- d. Retention of client records indicating medication administered and/or dispensed is subject to the same recommendations as all client records. (See Section II.004).
- e. Pharmacy logs shall be maintained for two years from the last date of entry.

2. Containers: Containers utilized will be child-proof.

3. Labeling: Each prescription item will be labeled with the following information:

- a. Lot number
- b. Expiration date of medication
- c. Name and address of clinic
- d. Date
- e. Name of medication, strength, quantity
- f. Directions for use and cautionary statements, if any
- g. Client's name
- h. Name of practitioner prescribing
- i. Name of physician/nurse practitioner with prescriptive authority

4. Repackaging

- a. A licensed pharmacist or his delegate will repackage those medications purchased in bulk quantity, according to local policies.
- b. These medications will be labeled as previously outlined, including an expiration date which is the lesser of six months from the date of repackaging or one fourth of the remaining time until the date the bulk bottle expires.

D. CONSULTANT PHARMACIST

Each program will have a consultant pharmacist whose responsibilities will be:

1. To serve as a consultant for any pharmaceutical related issue.
2. To review protocols and sign annually along with the program coordinator.
3. To make on-site inspections quarterly to ascertain that there is compliance with the protocols and the Pharmacy Practice Act.
4. To make follow-up visits in the event of non-compliance until compliance is assured.

**SECTION VIII
PHARMACEUTICALS**

E. FORMULARY

1. A list of some basic family planning pharmaceutical supplies is given at the end of this policy. All medications on the list need not be maintained by each program, nor is this list all-inclusive.
2. Each program should keep a list, on-site, of prescription medications maintained at the site.
3. Programs no longer need to notify the Pharmacy Board of any drugs added to the formulary.

F. WRITING PRESCRIPTIONS FOR CONTRACEPTIVE METHODS

1. **Contraceptives are a required “service” of Title X, and therefore must be offered on a sliding scale which slides to zero cost for clients at or below 100% of the Federal Poverty Level (FPL). It would be out of compliance to write a prescription for a client’s contraceptive method and expect her to fill that prescription at a pharmacy unless the clinic can assure that the client pays no more than she would be expected to pay according to that clinic’s sliding fee schedule (approved by CDPHE). Medicaid clients who are prescribed a method that is stocked by the Title X clinic should have that method dispensed in the clinic and not via prescription at a pharmacy, unless the client requests a brand of oral contraceptives not carried by the clinic or requests a prescription because the pharmacy is more accessible than the clinic. Contraceptive continuity relies on the easiest access to one’s chosen method.**
2. **In the case of oral contraceptives, the clinic is expected to stock at least three varieties of formulation: a monophasic, a multiphasic, and an ultra low dose. If a client presents requesting a particular brand name that is not carried by the clinic, then the client should be offered the opportunity to change to one of the formulations that the clinic does carry. If the client requests a prescription for the oral contraceptive that she currently uses, or has used successfully in the past, a prescription may be written for the appropriate number of cycles for one year of that brand of oral contraceptives as long as the following conditions are met:**
 - a. **The client has been offered and refused a brand of oral contraceptives that the clinic stocks,**
 - b. **The client has been offered the opportunity and refused to change to a different method of contraception (NuvaRing, Evra, Depo, IUD, etc.) that the clinic stocks,**
 - c. **The client understands that she will have to pay full pharmacy charges for the prescription for oral contraceptives at the pharmacy, and has been informed what the charge would be for oral contraceptives available through the clinic,**
 - d. **The client is informed that if she changes her mind and wants to return to the clinic to obtain a method of contraception that the clinic stocks, she may do that at any time,**
 - e. **The client’s chart is flagged so that anytime she presents to or calls the clinic, her contraceptive continuity with the pharmacy prescription is assessed, and**
 - f. **All Title X requirements regarding counseling, consents, physical exams, client’s health history, etc. have been met.**
3. **Additionally, a client may be given a prescription for her method if it is less expensive for her to obtain the method using her insurance through a pharmacy.**

**SECTION VIII
PHARMACEUTICALS**

- 4. If a client resides out of the area (e.g., away at college, transportation difficulties to the clinic, etc.) every effort should be made to give her an adequate supply to meet her needs until she can return to the clinic. An alternative would be to mail her supplies as she requests them, and until her next clinic visit is due.**
- 5. If the provider does not have prescriptive privileges, arrangements should be made with the consulting physician for alternative means of providing prescriptions. This may include such things as calling prescriptions into the pharmacy, using pre-printed and signed (by the consulting physician) prescription pads, etc. The midlevel provider and the consulting physician must develop a policy and a procedure to cover offering prescriptions according to the above guidelines in cases where the midlevel provider does not have prescriptive privileges.**

The following is a sample of a Pharmacy On-Site Evaluation Form. This form can be downloaded from the Women's Health Unit website at:

<http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html>.

**SECTION VIII
PHARMACEUTICALS**

**COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
FAMILY PLANNING PROGRAM • PHARMACY ON-SITE EVALUATION**

Program _____ Staff Contact _____

Clinic Location _____ Date _____

Recommended Next Inspection _____

EVALUATION FORM

CRITERIA	COMPLIANT	NON-COMPLIANT
1. Handling of Medications		
• Purchase records available		
• Medication logged as received		
2. Inventory		
• Rotation		
• Locked		
3. Dispensing of Medication		
• Charts signed		
4. Labeling		
• Lot # / expiration date		
• Client name		
• Clinic name		
• Date		
• Name of practitioner		
5. Chart inspection		
• Charts signed		
• Documentation of medication (how much, when)		
• Compliance with plan notes		
6. Charts inspected (Name/Birthdate)	Comments (Recommended Corrective Action)	
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Pharmacist

Program Coordinator

**SECTION VIII
PHARMACEUTICALS**

SUGGESTED FORMULARY

1. Contraceptives

Hormonal Contraceptives

- a. Ortho-Novum: Modicon, 1/35, 7/7/7, Ortho Cyclen, Tri-Cyclen, Tri-Cyclen Lo, Orthocept, Micronor, Evra
- b. Wyeth: Ovral, Triphasil, Alesse,
- c. Watson: Necon 1/35, Reclipsen, Levora, Microgestin1/20, Lutera, Quasense
- d. Akrimax: Lo-ovral
- e. Berlex: Yasmin
- f. Schering/Plough: Mircette, NuvaRing, Implanon
- g. Pfizer: Depo-Provera (DMPA) Injection, depo subQ104 provera injection
- h. Greenstone or Sicor: generic Medroxyprogesterone 150 mg
- i. Barr and Barr generic Laboratories: Plan B, Jolessa, Lo-estrin 1.5/30, 1/20

2. Barriers

- a. Ortho All Flex 55-90

3. IUD's

- a. ICS/Paragard - Paragard
- b. Berlex - Mirena

4. Non-prescription

- a. Encare Oval Suppositories
- b. Intercept Suppositories
- c. Emko Foam
- d. Delfen Foam
- e. Ortho-Gynol Jelly & Cream
- f. Condoms
- g. VCF Film

5. Therapeutics

- a. Mycelex G Cream and/or Vaginal Tablets
- b. Terazol Cream or Suppositories
- c. Mycostatin Cream & Vaginal Tablets
- d. Monistat 7 Cream and/or Suppositories or the equivalent - non-prescriptive
- e. Gynelotrimin Vaginal Tablets - non-prescriptive
- f. Metronidazole 250 mg & 500 mg
- g. Tetracycline 250 mg & 500 mg
- h. Erythromycin 250 mg & 500 mg

**SECTION VIII
PHARMACEUTICALS**

- i. Ceftriaxone 250 mg/ml
- j. Ampicillin 500 mg
- k. Amoxicillin 500 mg
- l. Ofloxacin 200 mg & 400 mg
- m. Doxycycline 100 mg
- n. Azithromycin 250 mg. tablets or 1 Gm powder for oral suspension
- o. TCA 80%
- p. Adrenalin 1:1000 solution for emergencies
- q. Imiquimod 5% Cream

**SECTION VIII
PHARMACEUTICALS**

PHARMACY PROTOCOL REVIEW

The Pharmacy Protocols have been reviewed and found appropriate for use in the

_____ Family Planning Program.

_____ **Agency Name**

_____ **Registered Pharmacist**

_____ **Date**

_____ **Nurse Consultant**

_____ **Date**