



**Dispensing of Prepackaged Hormonal Contraceptives by
Dispensing Medical Practitioner (DMP) Clinic in Utah:**

Guidelines for FPE CAP Clinic Implementation

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Acronyms

APRN: Advanced Practice Registered Nurse

BOP: Board of Pharmacy

CA: Certification Authority

CAP: Contraceptive Access Program

DMP: Dispensing Medical Practitioner

DMPIC: Dispensing Medical Practitioner In Charge

DO: Doctor of Osteopathic Medicine

DOPL: Division of Occupational and Professional Licensing

FEFO: First-Expiry/First-Out

FIFO: First-In/First-Out

FPE: Family Planning Elevated

HCP: Health Care Professional

MD: Doctor of Medicine

OD: Doctor of Optometry

PA: Physician Assistant

PIC: Practitioner In Charge

RPh: Registered Pharmacist

Part 1: Background & Overview

There is a restricted set of health care professionals (HCPs) who are authorized to dispense prescription medications in Utah. These HCPs include registered pharmacists (RPh), pharmacy interns, allopathic and osteopathic physicians and surgeons (MD and DO, respectively), advanced practice registered nurses (APRN; “nurse practitioner”), physician assistants (PA), and optometrists (OD). A pharmacist and pharmacy intern are authorized automatically under the pharmacist scope of practice to dispense medications. Other HCPs are not automatically authorized to dispense under their scope of practice, and must obtain additional authorization. A Dispensing Medical Practitioner (DMP), is the licensing designation for a physician, nurse practitioner, or physician assistant who is authorized to dispense a defined list of medications without meeting the specific [educational and work experience requirements](#) required for a pharmacist license.

The scope of medications eligible for dispensing by DMPs remains limited; however, in November 2019, the Utah Board of Pharmacy approved a change to Rule R156-17b-623, in the [Pharmacy Practice Act Administrative Rules](#), modifying the list of drugs a DMP can dispense to include those that are currently permitted for [online dispensing](#). One notable inclusion on this list is “hormonal based contraception (except injectable or implantable methods).” This is interpreted to allow providers with a DMP license to dispense prescription hormonal contraceptives to their patients within the DMP clinic setting.

These guidelines are intended to provide an introduction and initial template of the processes for health clinics in Utah to obtain and utilize a DMP practitioner and DMP clinic license to dispense hormonal contraceptives on-site. The guidelines are for informational purposes only, and not for purposes of legal, regulatory, or business advice. Nothing in this publication creates an attorney-client relationship between FPE, the University of Utah, the Utah Board of Pharmacy, or the Utah Division of Occupational and Professional Licensing, and any other person or entity. Efforts have been made to assure the information contained herein is accurate and up-to-date according to the Pharmacy Practice Act Rule. However, laws and regulations frequently change, and clinics and practitioners should consult their own legal counsel regarding licensure, drug dispensing and storage, and other relevant requirements.

FPE CAP and other entities receiving funds or materials from the University of Utah, such as through a contract, sub-award, or receipt of these Guidelines, are further expected to comply with all applicable state laws, regulations, and other requirements related to DMP as a condition of receipt. In particular, state law conditions the receipt of state money, supplies, or materials, which includes these guidelines, upon the recipient obtaining parental consent before providing contraceptive services to an unmarried minor, unless the minor is a Medicaid recipient, emancipated, or a member of the Armed Forces.

This document has been prepared in coordination with the Board of Pharmacy (BOP) and Division of Occupational and Professional Licensing (DOPL). If you have additional specific questions, please consider contacting the Board of Pharmacy Bureau Manager Jennifer (Zaelit) Falkenrath at jzaelit@utah.gov.



Obtaining a DMP license

DOPL exists within the Utah Department of Commerce and oversees the application process for DMP licenses. There are two [applications](#) required to operate as a DMP: one application serving on behalf of the [individual provider \(“DMP”\)](#), and one application serving on behalf of the [clinic pharmacy \(“DMP clinic”\)](#) where the dispensing will take place. Both the DMP and DMP clinic applications may be submitted at the same time. If applying for a DMP license in order to dispense hormonal contraceptives, the correct dispensing subtype to indicate is “Legend, non-controlled drugs approved under Section R156-83-306 for prescribing by an online prescriber.” The individual applying for a DMP license must be licensed and in good standing as an MD, DO, APRN, PA, or OD. Applications can be completed and submitted online or a completed printed application can be submitted to DOPL in-person or by mail.

Initial application fees for a DMP license are currently \$110 per individual provider and \$200 per DMP clinic pharmacy. Clinics participating in Family Planning Elevated Contraceptive Access Program may have their initial application fees covered through FPE; please contact Caitlin Quade (caitlin.quade@hsc.utah.edu) for more information.

Once DOPL has received an application and determined that the applicant meets basic requirements for a DMP license, DOPL may issue a conditional license and schedule an inspection to confirm that the DMP and DMP clinic pharmacy meet the operating standards established by state pharmacy rules. Following a successful inspection, DOPL will issue a DMP and DMP clinic license renewable every two years, ending on September 30th of odd-numbered years. Current renewal fees are \$63 per provider and \$103 per clinic. Please note that FPE and the Utah Board of Pharmacy anticipate a change to the licensing protocol that would omit the conditional license period, instead granting full DMP licensure upon application approval, with inspection occurring at some point during the two-year licensure. Please contact FPE or DOPL for updated information.

The DMP who is responsible for the activities of the clinic pharmacy is deemed the Dispensing Medical Practitioner in Charge (DMPIC) or Responsible Dispensing Medical Practitioner (RDMP). (See Appendix B for an outline of DMPIC responsibilities). As indicated in [R156-17b-603](#), the DMPIC is responsible for establishing a unique email address to be used for formal communication with DOPL, to submit self-audits and to receive pharmacy alerts from DOPL. The DMPIC should include this unique email address in the initial application for licensure.

Part 2: DMP Dispensing Standards and Operating Procedures

The following guidelines are derived from the Dispensing Medical Practitioner Clinical Pharmacy Inspection Form, available at:

https://dopl.utah.gov/pharm/DispensingMedicalPractitionerClinicPharmacy_inv.pdf

Manuals

The facility must have current and retrievable editions of the following reference publications in print or **electronic format** and readily available to facility personnel. If the DMP clinic pharmacy is relying on online formats for these reference publications, they must be “bookmarked” to a web browser or other “readily retrievable” mechanism. Utilizing an internet search engine to locate any of these reference standards is considered non-compliant.

- [UCA 58-1 \(DOPL Licensing Act\)](#)
- [UAC R156-1 \(General Rules of DOPL\)](#)
- [UCA 58-17b \(Pharmacy Practice Act\)](#)
- [UAC R156-17b \(Pharmacy Practice Act Rules\)](#)
- [UCA 58-37 \(Controlled Substance Act\)](#)
- [UAC R156-37 \(Controlled Substance Act Rules\)](#)
- [UCA 5B-37f \(Controlled Substance Database Act\)](#)
- [UAC R156-37f \(Controlled Substance Database Act Rules\)](#)
- [Code of Federal Regulations](#)
- [FDA Approved Drug Product \(Orange Book\)](#)
- [General Drug References](#)

Staffing

The facility shall maintain a current list of licensed employees involved in the practice of the DMP clinic pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable for inspection by DOPL staff and may be maintained in paper or electronic form. Note that a DMP is able to dispense at more than one DMP clinic. For example, if a health organization has multiple clinical sites registered as DMP clinics, a DMP may dispense at each of these under the direction of the DMPIC.

The DMPIC or PIC assures that no pharmacy operates with a ratio of pharmacist or DMP to other pharmacy personnel circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare.

Note that a DMP or DMPIC can delegate another clinic employee (DMP designee) to dispense drugs under the DMP’s direction so long as the DMP is immediately available on site for consultation.

If the facility uses DMP designees, the facility must use a formal or on-the-job dispensing training program which covers topics relevant to the DMP practice. The DMPIC is responsible for developing and facilitating training, and may also wish to include an annual review of DMP designee competency and performance (e.g. through quizzes, in-service presentations, etc.). Documentation demonstrating successful completion of the training program is mandatory and shall include the following information.

- Name of the individual trained
- Name of the individual or entity that provided training
- List of topics covered during the training program
- Training completion date

All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from the pharmacy facility shall wear on their person a clearly visible and readable identification showing the individual's name and position.

When communicating by any means, written, verbal, or electronic, pharmacy personnel, including DMP designees, must identify themselves as to licensure classification.

The facility or parent company shall maintain a record for not less than 5 years of the initials or identification codes that identify each dispensing pharmacist or DMP and DMP designee by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP or DMP designee can be identified; therefore, identical initials or identification codes shall not be used.

Drug Labeling

Pre-packaged hormonal contraceptives shall have a label securely affixed to the container indicating the following minimum information:

- Name, address and telephone number of the physician prescribing and dispensing the drug;
- Serial number of the prescription as assigned by the dispensing physician;
- Filling date of the prescription or its last dispensing date;
- Name of the patient;
- Name of the prescriber;
- Directions for use and cautionary statements, if any
- Trade, generic or chemical name,
- Amount dispensed, and the strength of dosage form; and
- Beyond use date.

Many dispensing software systems and some electronic medical records (EMR) systems have an integrated label function, which will aid in the process of drug labeling and record-keeping.

Prescription files, including refill information, shall be maintained for a minimum of five years and shall be immediately retrievable in written or electronic format.

The registered DMP clinic may only process electronically signed prescriptions under the following conditions:

- the pharmacy uses a pharmacy application that meets all the applicable requirements;
- the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and
- Certification Authority (CA) has been obtained.

The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form.

Drug Recordkeeping

Inventory should be kept for each drug dispensed and a prescription dispensing medication profile for each patient receiving a drug dispensed by the DMP clinic pharmacy. Those records shall be made available to the Division upon request.

The general requirements for an inventory of drugs dispensed by a physician include:

- the DMPIC shall be responsible for taking all required inventories, but may delegate the performance of taking the inventory to another person;
- the inventory records must be maintained for a period of five years and be readily available for inspection;
- the inventory records shall be filed separately from all other records;
- the person taking the inventory and the DMPIC shall indicate the time the inventory was taken (may be taken either at the opening or the close of the business) and shall sign and date the inventory with the date the inventory was taken. The signature of the DMPIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory;
- the initial inventory shall be completed within three working days of the date on which the DMP begins to dispense a drug under Section 58-17b-309; and
- the annual inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and
- inventory shall include all stocks including out-of-date drugs.

A prescription dispensing medication profile shall be maintained for every patient receiving a medication that is dispensed by a DMP clinic pharmacy in accordance with Section 58-17b-309 for a period of at least one year from the date of the most recent prescription fill or refill. The medication profile shall be kept as part of the patient's medical record and include, as a minimum, the following information:

- full name of the patient, address, telephone number, date of birth or age, and gender;
- patient history where significant, including known allergies and drug reactions; and
- a list of drugs being dispensed including:
 - name of prescription drug;
 - strength of prescription drug;
 - quantity dispensed;
 - prescription drug lot number and name of manufacturer;
 - date of filling or refilling;
 - charge for the prescription drug as dispensed to the patient;
 - any additional comments relevant to the patient's drug use; and
 - documentation that patient counseling was provided

Patient counseling

Facilities shall have a counseling area to allow for confidential patient counseling, where applicable. A pharmacy facility shall orally offer to counsel but shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses or declines such counseling. The offer to

counsel shall be documented and said documentation shall be available to DOPL. These records shall be maintained for a period of five years and be available for inspection within 7-10 business days. Only a pharmacist, pharmacy intern, or DMP may orally provide counseling to a patient or patient's agent and answer questions concerning prescription drugs.

A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery, shall provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses and provide each patient with a toll-free telephone number by which the patient can contact the pharmacist or pharmacy intern at the pharmacy for counseling.

A pharmacy may only deliver a prescription drug to a patient or patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or returned to the pharmacy.

A DMP who is dispensing hormonal contraception shall include the following elements when providing patient counseling:

- the name and description of the prescription drug;
- the dosage form, dose, route of administration and duration of drug therapy;
- intended use of the drug and expected action;
- special directions and precautions for preparation, administration and use by the patient;
- common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- techniques for self-monitoring drug therapy;
- proper storage;
- prescription refill information;
- action to be taken in the event of a missed dose;
- physician comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and
- the date after which the prescription should not be taken or used, or the beyond use date.

Many commercial EMR systems have an embedded resource that can be used to generate medication guides. Please see <https://www.fda.gov/media/116651/download> for a medication guide template.

Drug Storage

The facility should be stocked with quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety, and welfare. The facility must be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within the facility.

The medication storage area must meet the following standards:

- Area is well lighted, well ventilated, clean and sanitary;
- Equipped to permit the orderly storage of prescription drugs in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the drug inventory;
- Equipped with a security system to permit detection of entry at all times when the physician's office or clinic is closed;
- At a temperature which is maintained within a range compatible with the proper storage of drugs; and
- Securely locked with only a licensed DMP or authorized pharmacy personnel having access to the pharmacy when the pharmacy is closed

If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the temperature of the refrigerator or freezer shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. A system of regularly checking for outdated legend drugs should be developed if not already in practice.

If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy.

Specific storage instructions by contraceptive method:

Oral contraceptives	
<i>Sprintec® and other oral contraceptives</i>	<ul style="list-style-type: none"> ● Store at 20° to 25°C (68° to 77°F) ● Protect from light.
<i>Ella®</i>	<ul style="list-style-type: none"> ● Store at 20° to 25°C (68 to 77°F). [See USP controlled room temperature.] ● Keep the blister in the outer carton in order to protect from light.
<i>Plan B®</i>	<ul style="list-style-type: none"> ● Store Plan B One-Step at 20° to 25°C (68 to 77° F) [see USP Controlled Room Temperature].
Contraceptive Patch	
<i>Xulane®</i>	<ul style="list-style-type: none"> ● Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

	<ul style="list-style-type: none"> ● Store patches in their protective pouches. Apply immediately upon removal from the protective pouch. ● Do not store in the refrigerator or freezer.
Contraceptive Ring	
<i>NuvaRing</i> [®]	<ul style="list-style-type: none"> ● Prior to dispensing to the user, store refrigerated 2-8°C (36-46°F). After dispensing to the user, NuvaRing can be stored for up to 4 months at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. ● Avoid storing NuvaRing in direct sunlight or at temperatures above 30°C (86°F). ● For the Dispenser: When NuvaRing is dispensed to the user, place an expiration date on the label. The date should not exceed either 4 months from the date of dispensing or the expiration date, whichever comes first.

Dispensing

A DMP pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility.

A dispensing medical practitioner shall inform the patient:

- that the drug dispensed by the practitioner may be obtained from a pharmacy unaffiliated with the practitioner.
- The directions for appropriate use of the dispensed drug.
- The potential side effects to the use of the dispensed drug.
- How to contact the dispensing medical practitioner if the patient has questions or concerns regarding the drug.

A system of stock rotation should determine which items are to be used first, on either a first-in/first-out (FIFO) or first-expiry/first-out (FEFO) basis. Regular checking of expiry dates and removal of expired stock facilitates stock rotation, as does placing stock to be used first at the front of the shelf.

It is recommended that DMP clinic pharmacies develop and enforce a formal system for refilling prescriptions.

Appendix A

58-17b-803. Qualifications for licensure as a dispensing medical practitioner -- Scope of practice.

Effective 7/1/2015

- (1) An applicant for a license as a dispensing medical practitioner shall:
 - (a) be licensed in good standing under at least one of the chapters listed in Subsection [58-17b-102\(23\)\(a\)](#); and
 - (b) submit an application for a license as a dispensing medical practitioner in a form prescribed by the division and pay a fee established by the division.
- (2) The division shall accept the licensing in good standing under Subsection [\(1\)](#) in lieu of requiring an applicant for a license under this part to comply with Sections [58-17b-303](#) and [58-17b-307](#).
- (3) A dispensing medical practitioner may dispense, in accordance with this part:
 - (a) a cosmetic drug and an injectable weight loss drug if:
 - (i) the drug was prescribed by the dispensing medical practitioner to the dispensing medical practitioner's patient; and
 - (ii) the dispensing medical practitioner complies with administrative rules adopted by the division under Section [58-17b-802](#);
 - (b) a cancer drug treatment regimen if the dispensing medical practitioner complies with Section [58-17b-805](#); and
 - (c) a pre-packaged drug to an employee or a dependent of an employee at an employer sponsored clinic if the dispensing medical practitioner:
 - (i) treats an employee, or the dependent of an employee, of one of an exclusive group of employers at an employer sponsored clinic;
 - (ii) prescribes a prepackaged drug to the employee or the employee's dependent;
 - (iii) dispenses the prepackaged drug at the employer sponsored clinic; and

- (iv) complies with administrative rules adopted by the division in consultation with the Board of Pharmacy that establish labeling, record keeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements.

(Note that the previous section has not been updated to include the legend, non-controlled drugs approved under Section R156-83-306 for prescribing by an online prescriber)

(4) A dispensing medical practitioner:

(a) shall inform the patient:

(i) that the drug dispensed by the practitioner may be obtained from a pharmacy unaffiliated with the practitioner;

(ii) of the directions for appropriate use of the dispensed drug;

(iii) of potential side effects to the use of the dispensed drug; and

(iv) how to contact the dispensing medical practitioner if the patient has questions or concerns regarding the drug;

(b) shall report to the controlled substance database in the same manner as required in Section [58-37f-203](#); and

(c) may delegate the dispensing of the drug if the individual to whom the dispensing was delegated is:

(i) employed by the dispensing medical practitioner or the outpatient clinic setting in which the dispensing medical practitioner works; and

(ii) acting under the direction of a dispensing medical practitioner who is immediately available on site for any necessary consultation.

(5) If the chapter that governs the license of a dispensing medical practitioner, as listed in Subsection [58-17b-102\(23\)](#), requires physician supervision in its scope of practice requirements, the dispensing medical practitioner shall only dispense a drug under the supervision of an individual licensed under [Chapter 67, Utah Medical Practice Act](#), or [Chapter 68, Utah Osteopathic Medical Practice Act](#).

Appendix B

R156-17b-603. Operating Standards - Pharmacist-In-Charge, Remote Dispensing Pharmacist-in-Charge, or Dispensing-Medical-Practitioner-In-Charge.

(Guidelines that not applicable to DMP dispensing of hormonal contraceptives have been excerpted)

(1) The Dispensing Medical Practitioner in Charge (DMPIC) shall have the responsibility to oversee the operation of the pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, durable medical equipment, and medical supplies. The DMPIC shall be personally in full and actual charge of the pharmacy.

(2) In accordance with Subsections 58-17b-103(1) and 58-17b-601(1), a unique email address shall be established by the DMPIC to be used for self-audits or pharmacy alerts initiated by the Division. The DMPIC shall notify the Division of the pharmacy's email address in the initial application for licensure.

(3) The relevant duties of the DMPIC shall include:

- (a) assuring that a DMP or DMP designee dispenses drugs or devices, including:
 - (i) labeling; and
 - (ii) ensuring that drugs are dispensed safely and accurately as prescribed;
- (b) assuring that pharmacy personnel deliver drugs to the patient or the patient's agent, including ensuring that drugs are delivered safely and accurately as prescribed;
- (c) assuring that a DMP communicates to the patient or the patient's agent, at their request, information concerning any prescription drugs dispensed to the patient by DMP;
- (d) assuring that a reasonable effort is made to obtain, record and maintain patient medication records;
- (e) education and training of pharmacy personnel;
- (f) establishment of policies for procurement of prescription drugs and devices and other products dispensed from the pharmacy;
- (g) disposal and distribution of drugs from the pharmacy;
- (i) storage of all materials, including drugs, chemicals and biologicals;
- (j) maintenance of records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and regulations;
- (k) establishment and maintenance of effective controls against theft or diversion of prescription drugs and records for such drugs;

(l) if records are kept on a data processing system, the maintenance of records stored in that system shall be in compliance with pharmacy requirements;

(m) legal operation of the pharmacy including meeting all inspection and other requirements of all state and federal laws, rules and regulations governing the practice of pharmacy;

(n) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;

(o) if permitted to use an automated pharmacy system for dispensing purposes:

(i) ensuring that the system is in good working order and accurately dispenses the correct strength, dosage form and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards; and

(ii) implementation of an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed for pharmaceutical care;

(q) assuring that all pharmacy personnel have the appropriate licensure;

(r) assuring that no pharmacy operates with a ratio of DMP to other pharmacy personnel in circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;

(s) assuring that the DMPIC assigned to the pharmacy is recorded with the Division and that the Division is notified of a change in DMPIC within 30 days of the change; and

(t) assuring, with regard to the unique email address used for self-audits and pharmacy alerts, that:

(i) the pharmacy uses a single email address; and

(ii) the pharmacy notifies the Division, on the form prescribed, of any change in the email address within seven calendar days of the change.

Appendix C

DMP as defined in [58-17b-102\(23\)\(a\)](#)

- (23) "Dispensing medical practitioner" means an individual who is:
- (a) currently licensed as:
 - (i) a physician and surgeon under [Chapter 67, Utah Medical Practice Act](#);
 - (ii) an osteopathic physician and surgeon under [Chapter 68, Utah Osteopathic Medical Practice Act](#);
 - (iii) a physician assistant under [Chapter 70a, Utah Physician Assistant Act](#);
 - (iv) a nurse practitioner under [Chapter 31b, Nurse Practice Act](#); or
 - (v) an optometrist under [Chapter 16a, Utah Optometry Practice Act](#), if the optometrist is acting within the scope of practice for an optometrist; and
 - (b) licensed by the division under the Pharmacy Practice Act to engage in the practice of a dispensing medical practitioner.
- (24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy located within a licensed dispensing medical practitioner's place of practice.

Appendix D

Checklist 1: DMP Application

The first step to dispensing hormonal based contraception on-site is to become licensed to do so. This checklist outlines the steps that need to be taken to apply for a DMP license. Once the application has been submitted, please refer to the “Preparing for and Passing Inspection Checklist” for the next steps.

Determine who will apply for a DMP License

The individual must be an actively practicing physician, DO, APRN, or PA. You may wish to select more than one individual, depending on availability. DMP’s can only be licensed at one site.

Create a DMP email address and use it in the application

This unique email address will be used for self-audits or pharmacy alerts from DOPL.

Fill out the “Dispensing Medical Practitioner” application and submit it to DOPL

An application will need to be submitted for each individual applying for a DMP license. The application can be accessed and submitted online at <https://dopl-egov.commerce.utah.gov/> or a completed copy may be printed and mailed or submitted in-person to DOPL. See https://dopl.utah.gov/pharm/dispensing_practitioner_application.pdf for a pdf of the application. Please contact FPE for assistance in paying application fees.

Fill out the “Dispensing Medical Practitioner Clinic” application and submit it to DOPL

Submit one application for your clinic’s DMP license. The application can be accessed and submitted online at <https://dopl-egov.commerce.utah.gov/> or a completed copy may be printed and mailed or submitted in-person to DOPL. See https://dopl.utah.gov/pharm/dispensing_practitioner_clinic_application.pdf for a pdf of the application. Please contact FPE for assistance in paying application fees.

Once the application is approved, you will receive a conditional DMP and DMP Clinic Pharmacy license

Schedule and prepare for an inspection from DOPL (see “Preparing for and Passing Inspection Checklist”)



Please note that this inspection may occur at any point after you have submitted your application.

Checklist 2: Preparing for and Passing Inspection

The second step to dispensing hormonal based contraception on-site is to pass inspection. This checklist outlines the steps that need to be taken to prepare for and pass inspection. Once the inspection has been passed, please refer to the “Dispensing Checklist” for the next steps.

Prepare for inspection

The clinic must pass an inspection by DOPL. All following checklist items are based off of DOPL’s inspection form, which can be found at

https://dopl.utah.gov/pharm/DispensingMedicalPractitionerClinicPharmacy_inv.pdf

Ensure clinic has all the following manuals readily accessible (print or electronic):

- [UCA 58-1 \(DOPL Licensing Act\)](#)
- [UAC R156-1 \(General Rules of DOPL\)](#)
- [UCA 58-17b \(Pharmacy Practice Act\)](#)
- [UAC R156-17b \(Pharmacy Practice Act Rules\)](#)
- [UCA 58-37 \(Controlled Substance Act\)](#)
- [UAC R156-37 \(Controlled Substance Act Rules\)](#)
- [UCA 5B-37f \(Controlled Substance Database Act\)](#)
- [UAC R156-37f \(Controlled Substance Database Act Rules\)](#)
- [Code of Federal Regulations](#)
- [FDA Approved Drug Product \(Orange Book\)](#)
- [General Drug References](#)

If manuals are kept electronically, they must be downloaded or bookmarked and easily accessible.

- Meet all staffing requirements (see “Staffing Requirement Checklist”)**
- Meet all drug labeling requirements (see “Drug Labeling Checklist”)**
- Meet all drug recordkeeping requirements (see “Drug Recordkeeping Checklist”)**
- Meet all patient counseling requirements (see “Patient Counseling Checklist”)**
- Meet all drug storage requirements (see “Drug Storage Checklist”)**
- Pass inspection**

Upon passing inspection, a standard DMP and DMP Clinic Pharmacy license will be issued and must be renewed every 2 years.

Checklist 3: Staffing Requirements

The third step to dispensing hormonal based contraception on-site is to prepare for inspection by meeting staffing requirements. This checklist outlines the steps that need to be taken to meet staffing requirements. Once the inspection has been passed, please refer to the “Dispensing Checklist” for the next steps.

Maintain a current list of all licensed employees who are involved in pharmacy practices at your clinic

Include names, license classifications, license numbers, and license expiration dates. This includes DMPs and DMP designees. The list can be printed or electronic, and should be easy to retrieve for inspection by DOPL.

Determine the correct ratio of DMPs to DMP designees

The DMP in charge should make sure that this ratio would not pose an unreasonable risk of harm to public health, safety, and welfare.

Determine a staffing schedule

A DMP or DMPIC can delegate another clinic employee to dispense drugs. This “DMP designee” can only dispense when the DMP is immediately available on site to consult.

Create ID tags for all DMP’s and DMP designees who interact with patients or the public

ID tags must be clearly visible, readable, and worn at all times. The ID tags should include the individual’s name and their position.

Pharmacy employees must identify their license classification when communicating by any means, written, verbal, or electronic

Maintain a record of all DMP and DMP designee initials or identification codes for at least 5 years

The record should identify each DMP and DMP designee by name, initials, and identification code (if using). Initials or identification codes must be unique so that each DMP or DMP designee can be uniquely identified. Do not use identical initials or identification codes.

The following checklist items apply if you choose to utilize DMP designees

Train DMP Designees

Training should be formal or on-the-job and should cover all topics that are relevant to the DMP practice.

Document DMP Designee training completion

Documentation should include the name of the individual trained, the individual or entity that provided the training, a list of topics covered during the training program, and the training completion date.

Checklist 4: Drug Labeling

The fourth step to dispensing hormonal based contraception on-site is to prepare for inspection by meeting drug labeling requirements. This checklist outlines the steps that need to be taken to meet drug labeling requirements. Once the inspection has been passed, please refer to the “Dispensing Checklist” for the next steps.

- Create and maintain a master list of serial numbers for all drugs**
- Label all pre-packaged hormonal contraceptives**

Labels should be securely affixed to all pre-packaged hormonal contraceptives and must contain at least the following information:

- Name of the physician prescribing and dispensing the drug
- Address and telephone number of the clinic where the drug is being prescribed and dispensed
- Serial number of the prescription as assigned by the dispensing physician
- Filling date of the prescription or its last dispensing date
- Name of the patient
- Name of the prescriber
- Directions for use and cautionary statements, if any
- Trade, generic or chemical name
- Amount dispensed, and the strength of dosage form
- Beyond use date

Check your software systems to see if there is an integrated labeling function.

- Maintain records of all prescription files, including refill information, for at least 5 years**

Records may be kept on paper or electronically, and should be immediately retrievable.

- Only process electronically signed prescriptions under the following conditions:**
 - The pharmacy uses a pharmacy application that meets all the applicable requirements
 - The prescription is otherwise in conformity with the requirements of the Code of Federal Regulations
 - Certification Authority [CA] has been obtained
 - The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form

Checklist 5: Drug Recordkeeping

The fifth step to dispensing hormonal based contraception on-site is to prepare for inspection by meeting drug recordkeeping requirements. This checklist outlines the steps that need to be taken to meet drug recordkeeping requirements. Once the inspection has been passed, please refer to the “Dispensing Checklist” for the next steps.

Keep inventory for each drug dispensed

Records can be kept in print or electronically. Records should be available to DOPL on request. General requirements include:

- The DMP is responsible for taking all required inventories, but may delegate the task to another person
- Inventory records must be maintained for at least five years and be readily available for inspection
- Inventory records must be filed separately from all other records
- Include out-of-date drugs in the inventory
- The person taking the inventory and the DMP must record the date and time the inventory was taken (may be taken either at the opening or closing of the business). The inventory must be signed by the DMP and include the date and time the inventory was taken.
- Inventory must be completed upon the initial opening of the pharmacy, annually, when there is change of ownership, and if/when the pharmacy closes permanently. The signature of the physician and the date of the inventory shall be documented within 72 hours, or three working days, on these inventories.
- The initial inventory shall be completed within three working days of the date on which the physician begins to dispense a drug under Section 58-17b-309
- The annual inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs.

Keep a prescription dispensing medication profile for each patient receiving a drug dispensed by the DMP

Records can be kept in print or electronically and should be available to DOPL on request. Profiles must be kept for at least one year from the date of the most recent prescription fill or refill. The medication profile shall be kept as part of the patient's medical record and include at least the following information:

- Full name, address, telephone number, date of birth or age, and gender of the patient
- Patient history where significant, including known allergies and drug reactions
- A list of drugs being dispensed including:
 - Name of prescription drug

- Strength of prescription drug
- Quantity dispensed
- Prescription drug lot number and name of manufacturer
- Date of filling or refilling
- Charge for the prescription drug as dispensed to the patient
- Any additional comments relevant to the patient's drug use
- Documentation that patient counseling was provided

Checklist 6: Patient Counseling

The sixth step to dispensing hormonal based contraception on-site is to prepare for inspection by meeting patient counseling requirements. This checklist outlines the steps that need to be taken to meet patient counseling requirements. Once the inspection has been passed, please refer to the “Dispensing Checklist” for the next steps.

Designate an area for confidential patient counseling

You must orally offer to counsel each patient or patient’s agent

The facility shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such counseling. Only a DMP may orally provide counseling to a patient or patient's agent and answer questions concerning prescription drugs.

Document the offer to counsel

Keep the documentation for at least 5 years. Documentation should be available at DOPL’s request within 7-10 business days.

Provide counseling (by a DMP) to a patient or patient agent when they accept the offer

Patient counseling should include at least the following information:

- Name and description of the prescription drug
- Dosage form, dose, route of administration and duration of drug therapy
- Intended use of the drug and expected action
- Special directions and precautions for preparation, administration and use by the patient
- Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur
- Techniques for self-monitoring drug therapy
- Proper storage
- Prescription refill information
- Action to be taken in the event of a missed dose
- Physician comments relevant to the individual's drug therapy, including any other information specific to the patient or drug
- Date after which the prescription should not be taken or used, or the beyond use date

A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and dispenses prescription drugs to the patient by means other than personal delivery, must still provide patient counseling to a patient regarding each prescription drug dispensed to them. The patient should be provided with a toll-free telephone number by which they can contact the pharmacy for counseling from a DMP

- ❑ **A pharmacy may only deliver a prescription drug to a patient or patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel**

Delivery by means other than in-person are acceptable only if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or returned to the pharmacy.

Checklist 7: Drug Storage

The seventh step to dispensing hormonal based contraception on-site is to prepare for inspection by meeting drug storage requirements. This checklist outlines the steps that need to be taken to meet drug storage requirements. Once the inspection has been passed, please refer to the “Dispensing Checklist” for the next steps.

Manage product stock

The facility should be stocked with quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public’s health, safety, and welfare. Initially, it will be necessary to find suppliers and order products.

The medication storage area should be:

- Maintained by a DMP who dispenses hormonal contraception
- Well lighted, well ventilated, clean and sanitary
- Equipped to permit the orderly storage of prescription drugs including clear identification, separation, and easy retrieval of products, and an environment necessary to maintain the integrity of the drugs
- Equipped with a security system to permit detection of entry at all times when the physician's office or clinic is closed
- At a temperature which is maintained within a range compatible with the proper storage of drugs (see chart below)
- Securely locked with only a licensed DMP or authorized pharmacy personnel having access to the pharmacy when the pharmacy is closed

Obtain a refrigerator or freezer, if needed to properly store drugs

- The temperature of the refrigerator or freezer shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing (see chart below)
- The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation
- The pharmacy shall retain each log entry for at least three years

All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals, and in correlation to the beyond use date imprinted on the label

If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy.

Specific storage instructions by contraceptive method:

Oral contraceptives	
<i>Sprintec® and other oral contraceptives</i>	<ul style="list-style-type: none"> ● Store at 20° to 25°C (68° to 77°F) ● Protect from light.
<i>Ella®</i>	<ul style="list-style-type: none"> ● Store at 20° to 25°C (68 to 77°F). [See USP controlled room temperature.] ● Keep the blister in the outer carton in order to protect from light.
<i>Plan B®</i>	<ul style="list-style-type: none"> ● Store Plan B One-Step at 20° to 25°C (68 to 77° F) [see USP Controlled Room Temperature].
Contraceptive Patch	
<i>Xulane®</i>	<ul style="list-style-type: none"> ● Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] ● Store patches in their protective pouches. Apply immediately upon removal from the protective pouch. ● Do not store in the refrigerator or freezer.
Contraceptive Ring	
<i>NuvaRing®</i>	<ul style="list-style-type: none"> ● Prior to dispensing to the user, store refrigerated 2-8°C (36-46°F). After dispensing to the user, NuvaRing can be stored for up to 4 months at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. ● Avoid storing NuvaRing in direct sunlight or at temperatures above 30°C (86°F). ● For the Dispenser: When NuvaRing is dispensed to the user, place an expiration date on the label. The date should not exceed either 4 months from the date of dispensing or the expiration date, whichever comes first.

Checklist 8: Dispensing

The final step to dispensing hormonal based contraception on-site is to dispense correctly. This checklist outlines the steps that need to be taken to dispense hormonal based contraception on-site correctly.. These steps should only be taken after passing inspection (see “Preparing for and Passing Inspection Checklist” and associated checklists) and receiving a standard DMP and DMP Clinic Pharmacy license.

- A pharmacy shall not dispense a prescription drug or device to a patient unless a DMP is physically present and immediately available in the facility**
- A dispensing medical practitioner shall inform the patient:**
 - that the drug dispensed by the practitioner may be obtained from a pharmacy unaffiliated with the practitioner.
 - The directions for appropriate use of the dispensed drug.
 - The potential side effects to the use of the dispensed drug.
 - How to contact the dispensing medical practitioner if the patient has questions or concerns regarding the drug.
- A system of stock rotation should determine which items are to be used first, on either a first-in/first- out (FIFO) or first-expiry/first-out (FEFO) basis**

This includes regular checking of expiration dates and removal of expired stock. It also includes placing stock to be used first at the front of the shelf.

- Determine and enforce a formal system for prescription refills**