MONTANA BOARD OF PHARMACY (301 S PARK, 4TH FLOOR, HELENA, MT 59601 - Delivery) P. O. Box 200513 Helena, Montana 59620-0513 PHONE (406) 444-6880 FAX (406) 841-2305 E-MAIL: dlibsdpha@mt.gov WEBSITE: pharmacy.mt.gov

ILLEGIBLE AND INCOMPLETE APPLICATIONS WILL BE RETURNED. (Please allow 30 days for processing from the date that the Board has a complete routine application)

A BUSINESS CANNOT OPERATE IN MONTANA IN ANY MANNER WITHOUT AN ACTIVE MONTANA LICENSE

LICENSE REQUIREMENTS 24.174.830 LIMITED SERVICE PHARMACY:

- A limited service pharmacy is defined as a family planning clinic:
- (a) operating under contract with the Department of Public Health and Human Services (DPHHS); or

(b) providing pharmaceutical care under the review of a consulting pharmacist and dispensing legend drugs, but which is not under contract with DPHHS.

- Each limited service pharmacy must apply for a license from the board and submit the required fee.
- The Board shall grant a license to operate a limited service pharmacy to qualified applicants. A licensed family planning clinic may operate satellite locations under the same license if identified on the application.
- A limited service pharmacy is not required to employ a licensed pharmacist.
- A limited service pharmacy dispensing legend drugs other than factory, prepackaged contraceptives must disclose the name, address, telephone number, and title of the designated person in charge of the limited service pharmacy. The person in charge is responsible for the limited service pharmacy's compliance with all applicable state and federal statutes and rules. A person in charge may be responsible for multiple sites.
- Nothing in this rule is meant to limit or restrict the authority of a registered nurse employed by a family planning clinic, operating under contract with DPHHS, from dispensing factory, prepackaged contraceptives as authorized by <u>37-2-104</u>, <u>37-7-103</u>, or <u>50-31-307</u>, MCA.
- Schematic Drawing (floor plan) of the pharmacy drug storage area including security information
- Person-in-Charge form

FEE:

\$45 (Non-Refundable) – Pharmacy Application Fee

Make check or money order payable to the Montana Board of Pharmacy

- **DOCUMENTS:** The following documents must be submitted to the Board office in order to complete the license application. Please make 8 ½" x 11" copies of the following and submit with the application:
 - Schematic Drawing (floor plan) of the pharmacy drug storage area including security information
 - Person-in-Charge Agreement

APPLICATION PROCEDURES:

- When the application file is complete, it will be processed and considered by Board staff for permanent licensure. The applicant may be notified if additional information is required or if required to appear before the Board for an interview.
- If the application is considered a non-routine application, there may be a delay in processing of the application. You may be requested to provide additional information, or make a personal appearance before the Board during a regularly scheduled Board meeting and/or the application may require Board consideration. Non-routine applications may take up to 120 days to process.

PROCESSING PROCEDURES:

- Once a routine application is complete, the application takes up to 30 days to process from the time it is received in the Board office.
- The applicant will be notified in writing of any deficient or missing items from the application file.
- Once a routine application is processed and approved a permanent license will be issued. The pharmacy license must be posted in a conspicuous place in the pharmacy.

ADDITIONAL RULE INFORMATION:

- A limited service pharmacy must display its license in a conspicuous place at the facility.
- The board may annually inspect limited service pharmacies, including any satellite locations. The board may inspect more often for cause. Such inspections must include assurance that the limited service pharmacy provides adequate:

(a) drug labeling;

(b) counseling materials to all patients, including the name of the limited service pharmacy's consulting pharmacist, where required;

(c) contact information of a knowledgeable individual at the clinic in the event of an adverse reaction;

- (d) records maintenance and retention; and
- (e) drug storage and security.
- A registered nurse or provider with prescriptive authority, employed by a family planning clinic operating under contract with DPHHS, may dispense oral antibiotics used to treat Chlamydia to a patient diagnosed with Chlamydia and to a sexual contact or partner of a patient diagnosed with Chlamydia. All appropriate records shall be maintained on-site. The antibiotics dispensed must:

 (a) be prepackaged and preparity labeled in accordance with state law;
 (b) be prepackaged and preparity labeled in accordance with state law;

(a) be prepackaged and properly labeled in accordance with state law;

(b) include appropriate counseling materials informing the patient of the potential risks involved in taking the drug; and

(c) contain contact information for the healthcare provider or a consulting pharmacist to provide advice or answer questions.

 Change in Location – whenever a limited service pharmacy changes physical location, including within the existing business location, it shall submit a new schematic or floor plan, for Board approval.

Whenever a limited service pharmacy changes its physical location outside of its then existing business location, its original license becomes void and must be surrendered. The limited service pharmacy shall submit a new license application, including a new schematic and floor plan of the new location, for the Board's approval at least 30 days before such change occurs.

- Change of Person-in-Charge when the person-in-charge leaves the employment of such limited service pharmacy, the person will be held responsible for the proper notification to the Board of such termination of services. Within 72 hours of termination of services of the person-in-charge, a new person-in-charge must be designated and an affidavit filed with the Board.
- **Pharmacy Closure** Upon closure of a limited service pharmacy, the original license becomes void and must be surrendered to the Board within ten days.
- Pharmacy Compliance All new limited service pharmacies shall be in compliance with ARM 24.174.830 at the time the limited service pharmacy is opened for business.

For information with regard to the processing of this application or other concerns please contact the Board of Pharmacy staff at the website pharmacy.mt.gov or email at dlibsdpha@mt.gov

PLEASE BE SURE TO REVIEW THE MONTANA LAWS AND RULES FOR THE OPERATION OF A LIMITED SERVICE PHARMACY ON THE WEBSITE

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Application for Licensure as Limited Service Pharmacy:

1.	FAMILY PLANNING CLINIC NAME:
	(OPERATING UNDER CONTRACT WITH THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES (DPHHS)
	OR
	FAMILY PLANNING CLINIC NAME: (PROVIDING PHARMACEUTICAL CARE UNDER THE REVIEW OF A CONSULTING PHARMACIST AND DISPENSING LEGEND DRUGS, BUT WHICH IS NOT UNDER CONTRACT WITH DPHHS)
2.	MAILING ADDRESS:
3.	PHYSICAL ADDRESS:
	EMAIL ADDRESS:
4.	TELEPHONE: FAX
5.	TAX ID NUMBER:
6.	PLEASE LIST THE NAME, ADDRESS, EMAIL ADDRESS, TELEPHONE OF SATELLITE LOCATIONS:
7.	PERSON-IN-CHARGE:
	NAME
	ADDRESS
	CITY STATE ZIP CODE
	TELEPHONE NUMBER FAX

PERSONAL HISTORY QUESTIONS IMPORTANT INSTRUCTIONS AND NOTICE

- 1. Please read the following questions carefully. Giving an incomplete or false answer is unprofessional conduct and may result in denial of your application or revocation of your license. *See*, 37-1-105, MCA.
- 2. You have a continuing duty to update the information you provide in your application and supplemental responses, including while your application is pending and after you are granted a license.
- 3. Upon submittal of your application form, for every "yes" answer provided, you will receive a request for specific information or documents associated with the question. Your application is not complete until staff receive all information requested.
- 4. [Business Entities only] "You" in these instructions and questions refers to individuals authorized to answer questions on behalf of the facility, organization, or entity applying for licensure and not personally to the individuals.
- 5. [Business Entities with Persons in Charge] "You" in these instructions and questions refers to associates or agents of the facility, organization, or entity applying for licensure who must answer these questions personally as individuals.

PERSONAL HISTORY QUESTIONS

	Have you ever had any license, certificate, registration, or other privilege to serve as a volunteer or practice a profession denied, revoked, suspended, or restricted by a public or private local, state, federal, tribal, religious, or foreign authority?	Yes	No
2.	Have you ever surrendered a credential like those listed in number 1, in connection with or to avoid action by a public or private local, state, federal, tribal, religious, or foreign authority?	Yes	No
3.	Have you ever resigned to avoid discipline, been suspended, or been terminated from a volunteer or employment position?	Yes	No
4.	Have you ever been required to participate in a behavioral modification or assistance program in lieu of suspension or termination from a volunteer or employment position?	Yes	No
5.	Have you ever withdrawn an application for any professional license?	Yes	No
6.	As of the date of this application, are you aware of any pending complaint, investigation, or disciplinary action related to any professional license you hold?	Yes	No
7.	Are you under a current order that remains unsatisfied (e.g., fines unpaid, probation not concluded, conditions unmet?)	Yes	No
co Pro	te on Questions 8 and 9: Applicants who disclose medical, physiological, mental, or psychological nditions or chemical substance use in Question 8 or 9 may qualify for participation in the Montana ofessional Assistance Program. Please visit the board website for more information about this program. hemical substances" include alcohol, drugs, or medications, whether taken legally or illegally.		
8.	Do you have any medical, physiological, mental, or psychological condition which in any way currently (within the last 6 months) impairs or limits your ability to practice your profession or occupation with reasonable skill and safety?	Yes	No
9.	Do you currently (within the last 6 months) use one or more chemical substances in any way which impairs or limits your ability to practice your profession or occupation with reasonable skill and safety?	Yes	No
Tł	e following information is provided for Question 10 below:		
	criminal conviction may not automatically bar you from receiving a license. For more information about w a criminal conviction may impact your application, consult the board or program website.		
10	. Have you ever been convicted, entered a plea of guilty, no contest, or a similar plea, or had prosecution or sentence deferred or suspended as an adult or "juvenile convicted as an adult" in any state, federal, tribal, or foreign jurisdiction?	Yes	No
11	. Are you now subject to criminal prosecution or pending criminal charges?	Yes	No
12	. Have you ever been disciplined, censured, expelled, denied membership or asked to resign from a professional society or organization?	Yes	No
13	. Have you ever had a civil judgment entered against you in a lawsuit for incompetence, negligence, or malpractice in practicing any profession?	Yes	No

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- 14. Have you ever been disqualified from working with children, elderly persons, mentally ill persons, or Yes No other vulnerable persons?
- 15. Have you ever been placed on probation, restricted, reprimanded, suspended, revoked, resigned in Yes No lieu of action against you, or had other action taken against you by any hospital, clinic, health care facility, group medical practice, health maintenance organization, or third-party insurance provider, including Medicare and Medicaid?
- 16. Are you currently on an exclusion list by the Office of Inspector General (OIG) for the U.S. Yes No Department of Health and Human Services prohibiting you from working in a facility receiving federal funding?
- 17. Has your authority to prescribe, dispense, or administer drugs, including controlled substances, ever Yes No been denied, restricted, suspended, or revoked?
- 18. Have you ever voluntarily surrendered or had your U.S. Drug Enforcement Administration registration Yes No placed on probation, restricted, suspended, or revoked?

I authorize the release of information concerning education, training, record, character, license history and competence to practice, by anyone who might possess such information, to the Montana Board of Pharmacy. I hereby declare that the information included in this application to be true and complete to the best of my knowledge. In signing this application, I am aware that a false statement or evasive answer to any question may lead to denial of my application or subsequent revocation of licensure on ethical grounds.

I have read and will abide by the current licensure statutes and rules of the State of Montana governing the profession. I will abide by the current laws and rules that govern my practice.

Signature of Applicant

Date

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PERSON-IN-CHARGE FORM

LICENSE REQUIREMENTS 24.174.830(6) ARM LIMITED SERVICE PHARMACY:

- Complete the Limited Service Pharmacy application
- Submit the Person-in-Charge form
- A limited service pharmacy is not required to employ a licensed pharmacist.
- A limited service pharmacy dispensing legend drugs other than factory, prepackaged contraceptives must disclose the name, address, telephone number, and title of the designated person in charge of the limited service pharmacy. The person in charge is responsible for the limited service pharmacy's compliance with all applicable state and federal statutes and rules. A person in charge may be responsible for multiple sites.
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STATEMENT OF PERSON-IN-CHARGE

Name of Family Planning Clinic	License #
Address of Family Planning Clinic	

Owner of Family Planning Clinic _____

That he/she is the Person-in-Charge of the above named Family Planning Clinic and will be the Person-in-Charge until the present license expires; that if the undersigned ceases to be Person-in-Charge prior to the expiration of the license, the undersigned will notify the Board of Pharmacy of such fact and failure to do so may be cause for disciplinary action; that the undersigned agrees fully and promptly to comply with the applicable federal laws, laws of the State of Montana, and the rules and regulations of the Board of Pharmacy governing this application, applicants business, and the dispensing of permitted medications.

Signature _____

Please retain a copy of this form in the family planning clinic and send the original to the Board office