

COMPOUNDING AND REPACKAGING PHARMACY AGREEMENT

COMMUNITY PHARMACIES

Approved by the Council of the Alberta College of Pharmacy

December 12, 2024

COMPOUNDING AND REPACKAGING PHARMACY AGREEMENT

COMMUNITY PHARMACIES

THIS AGREEMENT made effective as of _____

BETWEEN:

_____,¹

Licensee Of _____² # _____

On Behalf Of

_____³

(the "Compounding and Repackaging Pharmacy")

- and -

_____,⁴

Licensee Of _____⁵ # _____

On Behalf Of

_____⁶

(the "Community Pharmacy")

1 Insert the name of the licensee of the Compounding and Repackaging Pharmacy here.

2 Insert the name of the Compounding and Repackaging Pharmacy and its licence number here.

3 Insert the legal name of the owner of the Compounding and Repackaging Pharmacy here.

4 Insert the name of licensee of the Community Pharmacy here.

5 Insert the name of the Community Pharmacy and its licence number here.

6 Insert the legal name of the owner of the Community Pharmacy here.

WHEREAS:

- The licensee of the Community Pharmacy holds a community pharmacy licence;
- Licensees of community pharmacies must ensure that the pharmacy is willing and able to provide compounding services normally available in pharmacy practice in accordance with the Standards for the Operation of Licensed Pharmacies;
- The licensee of the Compounding and Repackaging Pharmacy holds a compounding and repackaging pharmacy licence;
- Pharmacists and pharmacy technicians employed by the Community Pharmacy dispense drugs to patients of the Community Pharmacy and require the services of the Compounding and Repackaging Pharmacy to compound or repack drugs, or both, so that the pharmacists and pharmacy technicians at the Community Pharmacy can dispense those drugs to patients of the Community Pharmacy;
- The Compounding and Repackaging Pharmacy is willing to compound or repack drugs, or both, for the Community Pharmacy;
- The Community Pharmacy and the Compounding and Repackaging Pharmacy wish to enter into an agreement for the provision of compounding or repackaging services, or both, by the Compounding and Repackaging Pharmacy as contemplated by the Standards for the Operation of Licensed Pharmacies;
- The Community Pharmacy and the Compounding and Repackaging Pharmacy recognize that under the terms of the Pharmacy and Drug Regulation, the licensee of the Compounding and Repackaging Pharmacy must ensure that the Compounding and Repackaging Pharmacy only provides pharmacy services to the Community Pharmacy under the terms of a written contract that includes the terms required by the Council of the College and is in the form required by the Registrar of the College;

THEREFORE, the Community Pharmacy and the Compounding and Repackaging Pharmacy mutually covenant and agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement:

"Agreement" includes the Schedules to the Agreement and any amendment made to this Agreement or the Schedules;

"College" means the Alberta College of Pharmacy;

"community pharmacy licence" means a community pharmacy licence issued under section 5(1)(a) of the *Pharmacy and Drug Act*;

"compounding and repackaging pharmacy licence" means a compounding and repackaging pharmacy licence issued under section 5(1)(b) of the *Pharmacy and Drug Act*;

"controlled substance" has the same meaning as a controlled substance in the *Controlled Drugs and Substances Act*, SC 1996, c 19 and includes any substance that is prohibited, regulated, controlled or targeted under a regulation made or continued under that Act;

"dispense" means to provide a drug to or for a person or an animal pursuant to a prescription;

"drug" means a substance or combination of substances referred to in section 31, 32 or 33 of the *Pharmacy and Drug Act* or defined as an emergency release drug or a special access drug under the *Pharmacy and Drug Act* and any combination of such substance or substances with any other substance;

"*Health Information Act*" means the *Health Information Act*, RSA 2000, c H-5;

"*Health Professions Act*" means the *Health Professions Act*, RSA 2000, c H-7;

“pharmacist” means a regulated member of the College registered on the clinical pharmacist register or the courtesy pharmacist register who holds a practice permit issued under the *Health Professions Act*;

“Pharmacists and Pharmacy Technicians Profession Regulation” means the Pharmacists and Pharmacy Technicians Profession Regulation, AR 129/2006;

“*Pharmacy and Drug Act*” means the *Pharmacy and Drug Act*, RSA 2000, c P-13;

“Pharmacy and Drug Regulation” means the Pharmacy and Drug Regulation, AR 240/2006;

“pharmacy technician” means a regulated member of the College registered on the pharmacy technician register or the courtesy pharmacy technician register who holds a practice permit issued under the *Health Professions Act*;

“prescription” means a direction by a person who is authorized by an Act of the Legislature of Alberta or an Act of the Parliament of Canada to prescribe drugs, directing that a drug be dispensed to or for the patient named in the direction;

“Privacy Officer” means the responsible affiliate designated by the Community Pharmacy as responsible for ensuring the Community Pharmacy complies with the *Health Information Act* and the policies and procedures that Act requires the pharmacy to establish or adopt;

“Registrar” means the Registrar of the College;

“Repackaging” means subdividing or breaking up a manufacturer’s original package of a drug for the purpose of dividing and assembling the drug in larger or smaller quantities for redistribution or sale;

“Services” means the services as set out in Schedule “A”.

1.2 Any reference to a statute, regulation, bylaw, standard or other legislative instrument is a reference to that statute, regulation, bylaw, standard or other legislative instrument as amended or replaced from time to time.

1.3 The singular includes the plural and vice versa.

1.4 The following Schedules form part of this Agreement:

Schedule “A” – Description of the Services Under This Agreement; and

Schedule “B” – Guarantees of Quality of the Ingredients and of the Products of Compounding and Repackaging.

1.5 If there is a conflict between a Schedule and a provision in the body of this Agreement, the provision in the body of this Agreement prevails.

2. SERVICES

2.1 The Compounding and Repackaging Pharmacy shall provide the Services in accordance with this Agreement.

2.2 The Services shall be provided under the direction of the licensee of the Compounding and Repackaging Pharmacy.

2.3 Where the Services involve compounding a drug, the Services shall be provided by:

- (a) a pharmacist at the Compounding and Repackaging Pharmacy;
- (b) under the direction or supervision of a pharmacist at the Compounding and Repackaging Pharmacy as authorized by the Pharmacists and Pharmacy Technicians Profession Regulation.

- 2.4 Nothing in this Agreement allows the Compounding and Repackaging Pharmacy to compound or repackage a drug for or on behalf of the Community Pharmacy unless the Community Pharmacy:
- (a) holds a valid prescription for a patient for the drug to be compounded or repackaged; or
 - (b) has a reasonable expectation of receiving a valid prescription for a patient for the drug in the immediate future.
- 2.5 Subject to article 2.6, nothing in this Agreement allows the Compounding and Repackaging Pharmacy to sell or provide a controlled substance except on a written order specifying that an amount of the controlled substance is required for emergency purposes.
- 2.6 If the Compounding and Repackaging Pharmacy is a licensed dealer under the Narcotic Control Regulations, CRC 1040 (Canada), the Compounding and Repackaging Pharmacy may, subject to the terms and conditions of its licence under the Narcotics Control Regulations, sell or provide those narcotics specified in its licence to the Community Pharmacy.

3. TERM AND RENEWAL

- 3.1 The term of this Agreement is from _____ to _____ (the "Term").⁷
- 3.2 This Agreement may be renewed for a term mutually agreed to by the parties in writing (the "Renewal Term").

4. TERMINATION

- 4.1 This Agreement is automatically terminated if:
- (a) the community pharmacy licence held by the licensee of the Community Pharmacy expires, is suspended, is cancelled or is otherwise terminated;
 - (b) the compounding and repackaging pharmacy licence held by the licensee of the Compounding and Repackaging Pharmacy expires, is suspended, is cancelled or is otherwise terminated; or
 - (c) an order is made by a hearing tribunal constituted under the *Health Professions Act* or the *Pharmacy and Drug Act*, or both, that prevents the Services being provided by the Compounding and Repackaging Pharmacy or being received by the Community Pharmacy.
- 4.2 Despite article 4.1(a), this Agreement is not automatically terminated if:
- (a) a community pharmacy licence has been issued by the College to a new licensee for the Community Pharmacy and the new licensee has affirmed this Agreement in writing; or
 - (b) the Community Pharmacy is, with the permission of the Registrar, being operated under the personal management, control and supervision of another pharmacist under section 14(2) of the *Pharmacy and Drug Act* and that pharmacist has affirmed this Agreement in writing.
- 4.3 Despite article 4.1(b), this Agreement is not automatically terminated if:
- (a) a compounding and repackaging licence has been issued by the College to a new licensee for the Compounding and Repackaging Pharmacy and the new licensee has affirmed this Agreement in writing; or
 - (b) the Compounding and Repackaging Pharmacy is, with the permission of the Registrar, being operated under the personal management, control and direction of another pharmacist under section 14(2) of the *Pharmacy and Drug Act* and that pharmacist has affirmed this Agreement in writing.

⁷ Insert the beginning and end dates of the term of the Agreement.

- 4.4 Except as otherwise provided in this Agreement, if either party fails to perform or observe any covenant contained in this Agreement, that party may give written notice to the other party describing in general terms the nature of the default and requiring the other party to remedy the default within _____ days.⁸
- 4.5 If a party, who has received a notice under article 4.4, fails to remedy the default within the time specified in article 4.4, the other party may by further written notice terminate this Agreement.
- 4.6 The parties may terminate this Agreement by mutual agreement in writing.
- 4.7 To ensure that this Agreement remains consistent with any new directions of the Council of the College made under section 19(a)(i) of the Pharmacy and Drug Regulation, after the effective date of this Agreement, the parties agree to renegotiate the terms of this Agreement to comply with those new directions and to make the necessary amendments to this Agreement in accordance with articles 5.4 and 19.3 within 30 working days of the issuance of any new directions.
- 4.8 If the parties are unable to reach an agreement and make the necessary amendments to this Agreement under article 4.7, this Agreement terminates on the 31st working day after those directions are issued.
- 4.9 For the purposes of articles 4.7 and 4.8, a direction by the Council of the College is issued when it is passed by the Council and is posted on the website of the College.

5. LICENCES

- 5.1 Throughout the Term and any Renewal Term, the Compounding and Repackaging Pharmacy shall ensure that its operations are managed, controlled and supervised by a licensee who:
- (a) maintains a compounding and repackaging licence for the Compounding and Repackaging Pharmacy;
 - (b) maintains the Compounding and Repackaging Pharmacy in accordance with all applicable legislation and any standards and the Code of Ethics adopted by the College; and
 - (c) complies with the requirements of and any conditions imposed on the compounding and repackaging pharmacy licence.
- 5.2 Throughout the Term and any Renewal Term, the Community Pharmacy shall ensure that its operations are managed, controlled and supervised by a licensee who:
- (a) maintains a community pharmacy licence for the Community Pharmacy;
 - (b) ensures the Community Pharmacy operates in accordance with all applicable legislation and any standards and the Code of Ethics adopted by the College; and
 - (c) complies with the requirements of and any conditions imposed on the community pharmacy licence.
- 5.3 Each party shall disclose to the other party the conditions, if any, imposed on the pharmacy licence.
- 5.4 Each party shall ensure that if there is any proposed amendment to this Agreement, the licensee is advised of it and approves it in writing before it becomes effective.

⁸ Insert the number of days the parties agree upon.

6. COMPLIANCE WITH LEGISLATIVE REQUIREMENTS

6.1 Each party warrants that it, its licensee, its proprietor, its employees and agents will comply with all legislative requirements applicable to the provision of the Services under this Agreement or legislative restrictions on the provision of the Services under this Agreement or in any way relating to this Agreement, including but not limited to legislative requirements or legislative restrictions imposed under the following:

- (a) the *Controlled Drugs and Substances Act*, SC 1996, c 19 and all regulations made or continued under it;
- (b) the *Food and Drugs Act*, RSC 1985, c F-27 and all regulations made or continued under it;
- (c) the *Health Professions Act* and all regulations made or continued under it;
- (d) the Standards of Practice for Pharmacists and Pharmacy Technicians adopted by the College;
- (e) the Code of Ethics adopted by the College;
- (f) the *Government Organization Act*, RSA 2000, c G-10, Schedule 7.1 and all regulations made or continued under it;
- (g) the *Pharmacy and Drug Act* and all regulations made or continued under it;
- (h) the Standards for the Operation of Licensed Pharmacies adopted by the College;
- (i) the *Health Information Act* and all regulations made or continued under it.

6.2 In addition, and for greater clarity, the Compounding and Repackaging Pharmacy warrants that it, its licensee, its proprietor, its employees and agents will comply with

- (a) the Standards for Pharmacy Compounding of Non-Sterile Preparations; and
- (b) the Model Standards for Compounding Sterile Non-Hazardous and the Model Standards for Compounding Sterile Hazardous Preparations created by the National Association of Pharmacy Regulatory Authorities, and approved by the Council of the College of Pharmacy

as applicable, in respect of the services provided under this Agreement.

6.3 Neither party will do anything under this Agreement to frustrate or limit access to documents or information which the College may lawfully require be produced by the parties, their licensees, their proprietors, pharmacists, pharmacy technicians or individuals employed or otherwise engaged by the parties in relation to the provision of the Services.

7. HEALTH INFORMATION ACT

7.1 The Compounding and Repackaging Pharmacy recognizes that in relation to the Services it is an affiliate of the Community Pharmacy for the purposes of the *Health Information Act*.

7.2 The Compounding and Repackaging Pharmacy shall provide the Services under this Agreement in a manner that complies with:

- (a) the Compounding and Repackaging Pharmacy's responsibilities under the *Health Information Act* as an affiliate of the Community Pharmacy; and
- (b) the reasonable written policies of the Community Pharmacy respecting compliance with the *Health Information Act* that have been provided to the Compounding and Repackaging Pharmacy in relation to health information as defined in the *Health Information Act*.

7.3 The Compounding and Repackaging Pharmacy shall have a system in place for ensuring compliance with the *Health Information Act* that is satisfactory to the Community Pharmacy, acting reasonably.

- 7.4 The Compounding and Repackaging Pharmacy shall provide a description of the system referred to in article 7.3 to the Community Pharmacy, respond to reasonable questions about the system from the Community Pharmacy and allow the Community Pharmacy to audit compliance with the system, acting reasonably.
- 7.5 Where a breach of the *Health Information Act* occurs in the provision of the Services or otherwise in relation to this Agreement as result of an action or omission by the Compounding and Repackaging Pharmacy, its licensee, proprietor, agents or employees, the Compounding and Repackaging Pharmacy shall:
- (a) promptly take the steps necessary to minimize the impact of the breach and to prevent a re-occurrence;
 - (b) immediately advise the Privacy Officer of the occurrence and the nature of the occurrence;
 - (c) cooperate with and assist the Community Pharmacy with any efforts it is required to take to mitigate the impact of the breach on the individuals affected by the breach;
 - (d) investigate the cause of the breach and document the findings;
 - (e) report the findings of the investigation to the Privacy Officer;
 - (f) develop a remedial plan, if required, and provide a copy to the Privacy Officer;
 - (g) review the findings of the investigation and the remedial plan, if any, with the Privacy Officer and answer questions or receive comments from the Privacy Officer about either of them;
 - (h) implement the remedial plan, if any; and
 - (i) allow the Community Pharmacy, acting reasonably, to verify and audit the implementation of the remedial plan.
- 7.6 In accessing the Services under this Agreement and in undertaking any other act under this Agreement, the Community Pharmacy shall ensure that it, its licensee, proprietor, employees and agents comply with the *Health Information Act*.

8. RECORDS TO BE KEPT SEPARATE

- 8.1 If the Compounding and Repackaging Pharmacy also operates as a community pharmacy under a community pharmacy licence, the Compounding and Repackaging Pharmacy shall keep the records relating to its operations as a community pharmacy separate and distinct from the records relating to the Services it provides under this Agreement.

9. ACCESS TO RECORDS

- 9.1 The Compounding and Repackaging Pharmacy shall, on reasonable notice in writing from the Community Pharmacy:
- (a) provide the Community Pharmacy with access to any records relating to the provision of the Services under this Agreement; and
 - (b) provide the Community Pharmacy with a true copy of any records relating to the provision of the Services under this Agreement.
- 9.2 The Compounding and Repackaging Pharmacy may charge a reasonable fee for copying records required to be provided under article 9.1(b).
- 9.3 In addition to any requirements under section 27(1) of the Pharmacy and Drug Regulation, if the Compounding and Repackaging Pharmacy's licence is suspended, cancelled or otherwise terminated, the Compounding and Repackaging Pharmacy must make arrangements to enable the Community Pharmacy

to continue to access any records relating to the provision of the Services under this Agreement in accordance with the record keeping requirements of the College.

9.4 This section survives termination of this Agreement.

10. ACCESS TO INFORMATION ABOUT INGREDIENTS

10.1 The Compounding and Repackaging Pharmacy shall provide the Community Pharmacy with the following information about each drug that is compounded or repackaged under this Agreement:

- (a) a list of the ingredients;
- (b) the strength of each ingredient; and
- (c) the quantity of each ingredient.

11. EMERGENCY CONTACT

11.1 Each party shall ensure that an appropriate individual employed by the party is readily available at all times to deal with any emergency in relation to the Services or arising out of the Services that places life or health at risk.

11.2 For the purposes of article 11.1, the Compounding and Repackaging Pharmacy shall have a system in place to ensure that for 24 hours a day, seven days a week, there is a pharmacist available and readily accessible, who has access to the necessary information about any drugs compounded or repackaged as part of the Services.

12. TRANSPORTATION AND STORAGE

12.1 In providing the Services, the Compounding and Repackaging Pharmacy shall use appropriate methods of storing, packaging and transporting drugs to ensure the security and integrity of the drugs.

12.2 The Compounding and Repackaging Pharmacy shall take appropriate steps required to ensure the security and confidentiality of any personal or health information accompanying drugs during storage and transport.

13. DISPENSING

13.1 The Compounding and Repackaging Pharmacy agrees and acknowledges that its pharmacists or pharmacy technicians shall not dispense any drug compounded or repackaged as part of the Services to any patient of the Community Pharmacy.

13.2 The Compounding and Repackaging Pharmacy shall send any drug compounded or repackaged as part of the Services to the Community Pharmacy for dispensing to the patients of the Community Pharmacy by pharmacists or pharmacy technicians at the Community Pharmacy.

13.3 Pharmacists or pharmacy technicians at the Community Pharmacy are responsible for dispensing any drugs provided to the Community Pharmacy under this Agreement to the patients of the Community Pharmacy.

14. INSPECTION OF PHARMACY

14.1 Upon reasonable notice being provided by the Community Pharmacy, the Compounding and Repackaging Pharmacy shall allow the licensee of the Community Pharmacy to inspect the Compounding and Repackaging Pharmacy's facilities used in relation to the provision of the Services.

14.2 Subject to articles 9.1 and 10.1, the Compounding and Repackaging Pharmacy may impose reasonable confidentiality requirements in relation to observations made and information received during an inspection under article 14.1.

15. QUALITY OF WORK AND PRODUCT

- 15.1 The Compounding and Repackaging Pharmacy shall use appropriate and accepted processes in carrying out the compounding and repackaging activities included within the Services.
- 15.2 The Compounding and Repackaging Pharmacy guarantees the quality of products used in the compounding or repackaging of any drug under this Agreement in accordance with Schedule “B”.
- 15.3 The Compounding and Repackaging Pharmacy guarantees the quality of all drugs compounded or repackaged, or both, under this Agreement in accordance with Schedule “B”.

16. COMMUNITY PHARMACY’S OBLIGATION

- 16.1 In any request for Services under this Agreement, the Community Pharmacy, through its licensee, shall ensure that its pharmacists do not refer a prescription to the Compounding and Repackaging Pharmacy for the purposes of obtaining the Services unless its pharmacists have taken reasonable steps to ensure that the prescription is:
 - (a) valid; and
 - (b) current, accurate, complete and appropriate.
- 16.2 The Community Pharmacy shall, through its licensee, ensure that its pharmacists and pharmacy technicians dispense any drugs that are compounded or repackaged by the Compounding and Repackaging Pharmacy under this Agreement to the Community Pharmacy’s patients in accordance with the Standards of Practice for Pharmacists and Pharmacy Technicians.
- 16.3 Without limiting the generality of article 16.2, the Community Pharmacy shall, through its licensee, ensure that its pharmacists will be responsible for all patient interaction and are responsible to ensure the appropriateness of the drug therapy.
- 16.4 Nothing in this Agreement removes the requirement for a pharmacist or pharmacy technician dispensing a drug at the Community Pharmacy to perform a final check in accordance with Standard 7.14 of the Standards of Practice for Pharmacists and Pharmacy Technicians.

17. TERRITORIAL RESTRICTION ON SERVICES PROVIDED UNDER THIS AGREEMENT

- 17.1 The parties acknowledge that under this Agreement, as specified in the [Policy Direction for Compounding and Repackaging⁹](#) adopted by the Council of the College to be effective on April 1, 2025,
 - (a) the Compounding and Repackaging Pharmacy must not compound or repackage drugs for a community or institutional pharmacy that is not located in Alberta, and
 - (b) the Community Pharmacy must not obtain compounding and repackaging services from a pharmacy that is not located in Alberta.

18. PROVISION OF CONTRACT TO REGISTRAR

- 18.1 The parties each acknowledge that the Registrar of the College is entitled to request a copy of this Agreement from either of them and that upon receipt of such a request that party is required to provide a copy to the Registrar.

⁹ The Policy direction for compounding and repackaging (the Policy”) contemplates that there may be exceptional cases of need where compounding and repackaging services may be provided to or acquired from outside Alberta. If that circumstance applies and all the criteria of the Policy are met, a different form of contract must be used that is tailored to that circumstance and the requirements of the Policy. An example of the applicable form may be obtained by contacting The Registrar at compoundingandrepackaging@abpharmacy.ca at the College.

19. GENERAL

- 19.1 Subject to article 19.2 this Agreement contains the entire understanding between the parties relating to the subject matter contained in it and supersedes all prior oral and written understandings, arrangements and agreements relating to the subject matter contained in it.
- 19.2 This Agreement is designed to address the regulatory requirements under section 19(a) of the Pharmacy and Drug Regulation and is not designed to address the commercial relationship between the parties, which may be governed by a commercial agreement that is
- (a) not inconsistent with this Agreement; and
 - (b) available to the Registrar to ensure compliance with clause (a).
- 19.3 Any amendment to this Agreement must be in writing and signed by both parties.
- 19.4 Any variation, alteration or waiver of any of the rights or obligations of the parties under this Agreement must be in writing and signed by the parties.
- 19.5 Each of the provisions contained in this Agreement is distinct and severable and no waiver of any provision of this Agreement shall constitute a waiver of any other provision nor shall any waiver of any provision of this Agreement constitute a continuing waiver unless otherwise expressly provided.
- 19.6 Neither party may assign this Agreement or any portion of it.
- 19.7 This Agreement shall be interpreted in accordance with and is governed by the laws of the Province of Alberta.
- 19.8 The following provisions survive termination of this Agreement: articles 6, 7, 8, 9, 10, 11, and 15.
- 19.9 Each party warrants that the licensee of its pharmacy is authorized to sign this Agreement on its behalf.
- 19.10 This Agreement shall enure to be the benefit of and be binding upon the parties hereto and their respective personal representatives, executors, administrators, successors and permitted assigns.
- 19.11 This Agreement applies only to the provision of Services in the Province of Alberta.

20. REVIEW OF AGREEMENT ON OR BEFORE THE THIRD ANNIVERSARY

- 20.1 In the event that the Term of this Agreement under article 3 is greater than 3 years, the parties agree that they shall meet to review this Agreement on or before the third anniversary of the date the Agreement is made effective to ensure that the terms of the Agreement are current and relevant.
- 20.2 The parties shall:
- (a) keep minutes of the meeting referred to in article 20.1;
 - (b) ensure that the minutes are signed by the licensee of each party;
 - (c) provide a copy of the minutes to the Registrar on request.

WHEREFORE THE PARTIES to this Agreement have duly executed this Agreement to be effective as of the date written above.

<COMPOUNDING AND REPACKAGING PHARMACY>

Per: _____

<NAME of licensee>

<SIGNATURE of licensee>

<COMMUNITY PHARMACY>

Per: _____

<NAME of licensee>

<SIGNATURE of licensee>

SCHEDULE "A"

DESCRIPTION OF THE SERVICES UNDER THIS AGREEMENT

The Compounding and Repackaging Pharmacy shall provide the Services to the Community Pharmacy, which shall include, but are not limited to, the following:

SCHEDULE "B"

GUARANTEES OF QUALITY OF THE INGREDIENTS AND OF THE PRODUCTS OF COMPOUNDING AND REPACKAGING