

Integrated Community Pharmacy Services Agreement

BETWEEN

Te Whatu Ora
Health New Zealand

NZBN: 9429050678402

AND

«PROVIDER_NAME»

NZBN:

«CONTRACT_STARTDATE»

By each party's respective authorised signatories signing below, each party agrees to comply with and be bound by the terms of this Agreement

Te Whatu Ora – Health New Zealand by:

Signature

Name

Position

Date

Witnessed by:

Signature

Name

Occupation

Residence

Date

«PROVIDER_NAME» by:

Signature

Signature

Name

Name

Position

Position

Date

Date

Witnessed by:

Witnessed by:

Signature

Signature

Name

Name

Occupation

Occupation

Residence

Residence

Date

Date

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Part A Background

A.1 Context of this Agreement

- (1) Te Whatu Ora – Health New Zealand (**Te Whatu Ora**), PHARMAC, pharmacy service providers, and a wide range of stakeholders in the primary care sector want to ensure that community pharmacy services are provided in an integrated manner and in a way that is fit for all New Zealanders. They agree that community pharmacy services, as an integrated component of a people-powered, collaborative model of care, need to be delivered in innovative ways, across a broad range of settings, so that all New Zealanders have equitable access to medicines and health care services. They also agree that the unique and complementary skill set of pharmacists as healthcare providers, and in particular as medicines management experts, needs to be fully utilised so as to enhance patient safety.
- (2) Te Whatu Ora also wish to implement the Pharmacy Action Plan 2016, and ensure that community pharmacy services are delivered in accordance with the New Zealand Health Strategy and other policy and strategy initiatives related to the delivery of health care services. The New Zealand Health Strategy has five themes that guide the direction of health in New Zealand, which are:
 - (a) people powered;
 - (b) closer to home;
 - (c) value and high performance;
 - (d) one team; and
 - (e) smart system.
- (3) Te Whatu Ora:
 - (a) has obligations and functions relating to the design, arrangement, and delivery of services under the Pae Ora (Healthy Futures) Act 2022 in accordance with the health sector principles, including monitoring the delivery and performance of such services;
 - (b) must comply with Crown Directions, including the direction to comply with the Government Rules of Sourcing given by the Ministers of State Services and Finance on 19 June 2014.
- (4) Te Whatu Ora also wants to ensure that this Agreement, and the way in which community pharmacy services are delivered, is flexible enough to enable it to commission Population Services to meet the needs of people living in the Geographical Area.

A.2 Purposes of this Agreement

- (1) Te Whatu Ora and the Provider have entered into this Agreement to:
- (a) implement the objectives set out above relating to the delivery of community pharmacy services, including the objectives reflected in the five themes of the New Zealand Health Strategy;
 - (b) set out the roles and responsibilities that Te Whatu Ora and the Provider have to ensure that Services are funded and provided;
 - (c) provide a framework for Te Whatu Ora and the Provider to work collaboratively and in good faith, in an environment of trust, openness, and transparency;
 - (d) describe the Services to be provided by the Provider;
 - (e) set out the terms on which the Provider will provide, and Te Whatu Ora will pay for, those Services; and
 - (f) provide that Te Whatu Ora will monitor the provision of Services by the Provider.

A.3 Structure of this Agreement and priority of Parts

- (1) This Agreement consists of:
- (a) a head agreement, which is made up of the following parts:
 - (i) Part A, which sets out the background to this Agreement;
 - (ii) Part B, which sets out service and quality requirements that apply in respect of all Services provided under this Agreement;
 - (iii) Part C, which sets out the general terms that apply in respect of all Services provided under this Agreement;
 - (iv) Part D, which sets out payment and claiming terms that apply in respect of claims made by the Provider for Services provided under this Agreement, and funding paid by Te Whatu Ora to the Provider for those Services under this Agreement; and
 - (v) Part E, which sets out definitions of words and phrases used in this Agreement; and
 - (b) one or more Service Schedules, each of which sets out the Services that the Provider will provide, and the payment that Te Whatu Ora will pay to the Provider.

- (2) The Services Schedules that may be included in this Agreement are:
- (a) the following Nationally-consistent Service Schedules that will be offered to all providers that are able to provide the Services in accordance with the relevant Service Schedule;
 - (i) Schedule 1 (Dispensing Services and Professional Advisory Services), which includes NPPA Services A, NPPA Services B, Class B Pharmaceutical Services, and Extemporaneously Compounded Preparations Services;
 - (ii) Schedule 2 (Additional Professional Advisory Services);
 - (b) the following Nationally-consistent Services Schedules that may be offered to all or some providers:
 - (i) Schedule 3A.1 (Opioid Substitution Treatment Services);
 - (ii) Schedule 3A.2 (Aseptic Services);
 - (iii) Schedule 3A.3 (Sterile Manufacturing Services);
 - (iv) Schedule 3A.4 (Clozapine Services);
 - (v) Schedule 3A.5 (Immunisation Services);
 - (c) the following Service Schedules that may be offered under this Agreement, and can be changed following the local commissioning process described in clause B.27 (Locally Commissioned Services);
 - (i) Schedule 3B.1 (Long Term Conditions Pharmacy Services);
 - (ii) Schedule 3B.2 (Community Residential Care Pharmacy Services);
 - (iii) Schedule 3B.3 (Age-Related Residential Care Pharmacy Services);
 - (iv) Schedule 3B.4 (Special Foods Services);
 - (v) Schedule 3B.5 (Community Pharmacy Anti-Coagulation Management Services);
 - (vi) Schedule 3B.6 (Smoking Cessation Services); and
 - (d) any other Service Schedules with Provider-specific terms that either amend, or are additional to, the terms of this Agreement (including terms relating to Services provided by the Provider and funded by Te Whatu Ora under this Agreement), which are included in Schedule 3C.

- (3) If there is any conflict between a provision in a Service Schedule and a provision in Parts A to E of this Agreement, the provision in Parts A to E takes precedence except that, in the case of conflict between a provision in a Service Schedule in Schedule 3C and any other provision of this Agreement, the provision in Schedule 3C takes precedence.

A.4 Term of this Agreement

- (1) This Agreement starts on «CONTRACT_STARTDATE» (the "Start Date") and continues until it is terminated in accordance with its termination provisions or at law (the "End Date").
- (2) Each Service Schedule starts on the Start Date and continues until the earlier of:
- (a) the End Date; or
 - (b) any termination or end date specified in the Service Schedule.
- (3) The effective date of this version of the Agreement, which consolidates all previous versions of the Agreement, is the date specified on the cover page of this Agreement.

A.5 How the Provider and Te Whatu Ora will work together

- (1) Te Whatu Ora and the Provider agree that they will each be guided by the relationship principles set out in subclause (2).
- (2) The Provider and Te Whatu Ora will:
- (a) work together to develop a more integrated and cohesive system that works in the best interests of New Zealanders;
 - (b) improve, promote, and protect the health of Eligible Persons, and promote the inclusion and participation in society of Eligible Persons with disabilities;
 - (c) ensure that Services are provided in accordance with legal and regulatory requirements, and relevant professional standards and codes of practice;
 - (d) act in accordance with the Crown's principles for action on the Treaty of Waitangi, and incorporate Whānau Ora approaches as appropriate;
 - (e) conduct themselves with honesty and integrity, and develop a high degree of trust;
 - (f) promote an environment of high quality, performance, and accountability, and low bureaucracy;
 - (g) work together to resolve any issues, disputes, and disagreements in a co-operative and collaborative manner; and
 - (h) seek to make the best use of finite resources in the planning and delivery of health services to achieve optimal health outcomes for people living in the Geographical

Area, and recognise that the ability of community pharmacy to advance national health objectives is dependent on its sustainability.

Part B Service and Quality Requirements

B.1 Services provided

- (1) The Provider must provide Services to Eligible Persons in accordance with this Agreement.

Pharmaceutical Schedule and other documents

B.2 Pharmaceutical Schedule and other documents

- (1) Te Whatu Ora will fund, and the Provider must provide, the Services in accordance with the following documents, which are listed in order of priority in case of any conflict:
- (a) the Pharmaceutical Schedule;
 - (b) the Data Specification;
 - (c) this Agreement; and
 - (d) the Procedures Manual.
- (2) Te Whatu Ora and the Provider agree that other documents that set out requirements that apply in relation to this Agreement may be referred to elsewhere in this Agreement, including the Service Schedules.

B.3 Changes to Pharmaceutical Schedule

- (1) The Provider acknowledges that the Pharmaceutical Schedule may be changed by PHARMAC.
- (2) If the Provider is concerned about a change to the Pharmaceutical Schedule made by PHARMAC, it may notify Te Whatu Ora in writing of its concern, and Te Whatu Ora will use reasonable endeavours to address it with PHARMAC.
- (3) If Te Whatu Ora intends to propose a change to the Pharmaceutical Schedule to PHARMAC, Te Whatu Ora will engage with provider representative groups in relation to the proposed change.

General Service requirements

B.4 Services requirements

- (1) The Provider must ensure that:
- (a) the Services are provided in a timely, equitable, and efficient manner to meet Service Users' assessed needs;
 - (b) the Services are provided in accordance with all relevant legislation;

- (c) Service delivery reflects current good practice and is provided by sufficient numbers of suitably skilled and qualified Staff, and that a professional approach is taken to all stages of Service delivery for Service Users;
 - (d) Service User records and other information about the Services and related administrative processes meet legislative and accepted professional and sector standards;
 - (e) it maintains formal and documented processes to plan and implement safe and timely treatments, referrals, and transfers; and
 - (f) it co-operates and maintains linkages with other providers and community agencies to promote effective service delivery.
- (2) The Provider must support any public health campaigns that are being run by Te Whatu Ora , the Ministry of Health, or the Public Health Agency and that are relevant to the Services provided by the Provider, as reasonably required by Te Whatu Ora.

Regulatory and professional obligations

B.5 Professional obligations

- (1) The Provider must comply with the following when providing the Services:
- (a) the Pharmacy Services Standards;
 - (b) the Code of Ethics; and
 - (c) any professional requirements or regulatory standards that may be specified by the Pharmacy Council, the Ministry of Health, Te Whatu Ora, or a regulatory body, from time to time.

B.6 Code of Consumers' Rights

- (1) The Provider must provide the Services in accordance with the requirements of the Code of Consumers' Rights.
- (2) The Provider must enable Service Users, their families/whānau, and other relevant people to make complaints, and have a procedure for identifying and managing complaints that complies with the Code of Consumers' Rights.

B.7 Respect for privacy, dignity, religion, and culture

- (1) The Provider must ensure that there is respect for the personal privacy and dignity of Service Users during Service delivery, and that the Services are provided in a manner that shows respect for Service Users' religious and cultural beliefs and practices.

- (2) The Provider must establish and maintain processes to ensure the confidentiality of Service User information in compliance with the Privacy Act 2020 and the Health Information Privacy Code 2020.

B.8 Abuse and neglect

- (1) The Provider must develop, implement, and document policies and processes that:
 - (a) enable Staff to identify abuse or neglect of Service Users if possible;
 - (b) clearly outline appropriate action that may be taken by Staff who suspect the occurrence of abuse or neglect; and
 - (c) attempt to resolve any incidents of abuse or neglect in an appropriate and timely manner.

B.9 Children's Act 2014

- (1) If the Provider provides children's services, as that term is defined in section 15 of the Children's Act 2014, the Provider must comply with its obligations under the Act, including that the Provider must:
 - (a) adopt a child protection policy that complies with section 19 of the Act as soon as practicable after the Start Date; and
 - (b) review the policy within three years from the date of its adoption or most recent review, and at least every three years after that.
- (2) The Provider must conduct, or cooperate with Te Whatu Ora in relation to, worker safety checks as required by the Children's Act 2014.
- (3) Nothing in this clause limits or reduces the Provider's obligations under clause B.8.

B.10 Service User advocates

- (1) The Provider must:
 - (a) inform Service Users, in a manner appropriate to their communication needs, of their right to have an advocate, including to support the resolution of any complaint;
 - (b) support Service Users' access to an advocate, as needed; and
 - (c) co-operate with advocacy agencies when they are carrying out their advocacy role.

B.11 Ethics approvals

- (1) If the Provider takes part in research involving Service Users or members of the public, the Provider must comply with the Code of Ethics and seek, obtain, and comply with any ethics approvals required.

*Eligibility for Services***B.12 Eligibility of Service Users**

- (1) Te Whatu Ora and the Provider agree that the eligibility of a Service User to receive the Services, or any benefit or subsidy in respect of Services or Pharmaceuticals, must be determined in accordance with the following (as relevant):
- (a) the Eligibility Direction;
 - (b) the eligibility criteria set out in the Health Entitlement Cards Regulations 1993;
 - (c) the rules and requirements set out in the Pharmaceutical Schedule; and
 - (d) the terms set out in this Agreement, including any eligibility requirements set out in a Service Schedule.
- (2) Subject to subclause (3), the Provider can determine whether a person is an Eligible Person by:
- (a) the Service User Subsidy Category code on the Prescription Form;
 - (b) checking the person's eligibility with the Prescriber; or
 - (c) verifying eligibility with the Service User in accordance with guidelines published by Te Whatu Ora (if any).
- (3) The Provider may rely on the Prescriber's information about a Service User's eligibility, except that if the Provider thinks that the information may not be correct, the Provider must use its best endeavours to check the correctness of the information with the Prescriber.
- (4) The Provider must comply with clause B.17(2), which relates to refusing Services, if the Provider refuses to provide a Service to a person because:
- (a) the person is not an Eligible Person; or
 - (b) in relation to a Population Service, the person does not meet eligibility requirements for the Service.

B.13 Disputes about eligibility

- (1) Any dispute relating to whether or not a person is an Eligible Person will be determined by the Minister or their delegate.

B.14 Provider may provide services not funded by Te Whatu Ora

- (1) Subject to subclause (2) and clause C.2, nothing in this Agreement prevents the Provider from providing services to the following people, provided that the Provider does not claim for providing those services under this Agreement:
- (a) people who are not Eligible Persons; and
 - (b) people who do not meet eligibility or other requirements for a Service funded by Te Whatu Ora under this Agreement.
- (2) If the Provider provides Services to a person who is not an Eligible Person, clause D.4 applies.

B.15 Eligibility for Population Services

- (1) The Provider may only provide a Service User with a Population Service if:
- (a) the Service User meets any eligibility requirements for the Population Service set out in the relevant Service Schedule; and
 - (b) the provision of the Service by the Provider to the Service User complies with the requirements set out in the relevant Service Schedule.

Access to Services

B.16 Service information

- (1) The Provider must have available for Eligible Persons and other interested parties information that describes:
- (a) the Services the Provider offers;
 - (b) the location of those Services;
 - (c) the hours of access;
 - (d) how to access the Services (eg, whether a referral is required);
 - (e) Service Users' rights and responsibilities; and
 - (f) any other information necessary to enable Eligible Persons to access the Services.

B.17 Refusing Services

- (1) The Provider may refuse to provide Services:
 - (a) to or for a Service User if personal, moral, or religious beliefs prevent the pharmacist from providing the Service, as permitted by the Code of Ethics; and
 - (b) to or for a person if the person is not eligible for the Service in accordance with clause B.12(4).
- (2) The Provider must develop and implement processes to ensure the immediate safety of persons who are refused Services, which must provide for:
 - (a) sufficient preliminary assessment to determine whether the person is eligible for the Services, does not require the Services, or should be refused the Services;
 - (b) advice to the person or their family/whānau of alternative services that are available (if any) and, if necessary, formal referral of the person to an alternative service;
 - (c) documenting the reasons for refusing Services and informing Te Whatu Ora, if required; and
 - (d) otherwise managing the refusal of Services.
- (3) The Provider must follow the processes developed and implemented as outlined in subclause (2) whenever the Provider refuses to provide Services to a person.

B.18 Barriers to access

- (1) The Provider must minimise any barriers to Service Users accessing the Services to the extent that such matters are within the Provider's reasonable control.

Location of Services

B.19 Service provision from within Geographical Area

- (1) Provider must provide Services only within the Geographical Area, unless Te Whatu Ora agrees otherwise in writing (which agreement may be subject to conditions).
- (2) To avoid doubt, the provision of Services to or for a Service User who resides in an area outside of the Geographical Area and who presents a Prescription Form to the Provider on an individual basis because the Service User is out of that geographical area is not providing Services outside of the Geographical Area.

B.20 Location

- (1) The Provider may not change the location of its Premises:
- (a) unless it has notified Te Whatu Ora in writing of the proposed change at least 20 Business Days before the change; and
 - (b) subject to clause B.20(1C), if Te Whatu Ora has a policy relating to population access to community pharmacy services, without Te Whatu Ora's prior written consent (which will not be unreasonably withheld).
- (1A) When making a decision under subclause (1)(b), Te Whatu Ora will have regard to (but is not limited by) the following:
- (a) the proximity of other community pharmacies to the proposed location;
 - (b) the needs of the Provider's current Service Users; and
 - (c) the likely needs of the population that may be served at the proposed location.
- (1B) The Provider must give Te Whatu Ora information about the proposed change of location, including the proposed new address of its Premises, and any further details that Te Whatu Ora may reasonably request.
- (1C) If Te Whatu Ora has not notified the Provider in writing of its decision under subclause (1)(b) within 20 Business Days from receipt of the notice given under subclause (1)(a), Te Whatu Ora's consent is deemed to be given.
- (2) The Provider may not provide Services from more than one Premises unless:
- (a) the Provider is permitted to do so by the relevant Service Schedule; or
 - (b) Te Whatu Ora agrees in writing (which agreement may be subject to conditions).
- (3) If the Provider provides Services from more than one Premises, the Provider must meet the following requirements:
- (a) the Provider must submit all Claims for Services provided from all Premises in a single Claim, and as a single batch;
 - (b) the Provider's database must identify the Premises to which each Claim Item relates; and
 - (c) the Provider may only Dispense a Repeat Item that is a Class B Pharmaceutical from the Premises from which the Initial Item was Dispensed.
- (4) If Te Whatu Ora agreed that the Provider could provide Services from more than one Premises under a previous agreement between the Provider and Te Whatu Ora, that

agreement is deemed to have been given under subclause (2)(b), and will continue in accordance with any conditions specified by Te Whatu Ora.

Expert advisory group

B.21 Expert advisory group

- (1) The Provider and Te Whatu Ora acknowledge that a national expert advisory group has been established to advise on pharmacy and pharmacist services generally, whose functions include:
 - (a) providing expert advice in relation to community pharmacy services, including advice on service design and service models;
 - (b) considering changes that could be made to this Agreement for consideration as part of a National Annual Agreement Review in accordance with clause B.23; and
 - (c) receiving and considering matters referred to it as part of the National Annual Agreement Review.
- (2) The Provider and Te Whatu Ora acknowledge and agree that, as set out in clause B.22(2), the expert advisory group will include two provider representatives appointed on the basis of their expertise, one of whom must be a Pharmacist.
- (3) The Provider and Te Whatu Ora acknowledge that the expert advisory group will have a terms of reference.

Provider representatives

B.22 Provider representatives

- (1) The Provider may, from time to time, appoint a person or organisation to represent it in relation to this Agreement, including:
 - (a) as the Provider's representative in the National Annual Agreement Review;
 - (b) as the Provider's representative in relation to local commissioning proposals by Te Whatu Ora as described in clause B.29;
 - (c) to provide advice or assistance to the Provider in relation to a Dispute as set out in clauses C.19 to C.24.
- (2) The Provider and Te Whatu Ora acknowledge that the expert advisory group referred to in clause B.21 will include two provider representatives, one of whom must be a Pharmacist, as set out in clause B.21(2).

- (3) The Provider and Te Whatu Ora agree that any representative appointed by the Provider in relation to the National Annual Agreement Review will also represent the Provider in relation to:
- (a) the Pack Fee Recalculation; and
 - (b) any changes to the Permitted Pharmacy Charges Rules made in accordance with clause D.7(6).
- (4) To avoid doubt:
- (a) the Provider may appoint different representatives for each of the different purposes set out in subclause (1); and
 - (b) the appointment of a Provider representative does not prevent the Provider and Te Whatu Ora from communicating with each other about, or discussing, matters relating to their relationship (including any Disputes), this Agreement, and the provision of Services, from time to time.

National Annual Agreement Review

B.23 National Annual Agreement Review

- (1) The Provider and Te Whatu Ora agree that, before 1 July each year, there will be a national review of the Nationally-consistent Parts and Service Schedules of this Agreement (and the same agreement between other providers and Te Whatu Ora – Health New Zealand).
- (2) Service Schedules in Schedule 3B may also be considered as part of the National Annual Agreement Review.
- (3) The Provider and Te Whatu Ora agree that:
- (a) Te Whatu Ora will participate in the National Annual Agreement Review either directly or through a representative; and
 - (b) the Provider may participate in the review either directly or by appointing a person or organisation to participate in the review on its behalf in accordance with clause B.22.
- (4) The Provider and Te Whatu Ora acknowledge that each National Annual Agreement Review will consider:
- (a) reasonable cost pressure adjustments; and
 - (b) any matters that may affect providers on a national basis identified by:
 - (i) Te Whatu Ora representatives;

- (ii) providers or provider representatives appointed in accordance with clause B.22; or
 - (iii) the expert advisory group described in clause B.21; and
- (c) any amendments to this Agreement proposed by any of the persons or groups described in paragraph (b), which could include:
 - (i) proposals for new Services to be provided under this Agreement and funded by Te Whatu Ora through the inclusion of new Service Schedules in Schedule 3A;
 - (ii) significant amendments to this Agreement; and
 - (iii) minor or technical amendments to this Agreement.
- (5) The Provider and Te Whatu Ora acknowledge that each National Annual Agreement Review will be guided by a terms of reference.

B.24 Changes following National Annual Agreement Review

- (1) The Provider and Te Whatu Ora agree that any changes to this Agreement made following a National Annual Agreement Review will be effective only if agreed by Te Whatu Ora and the Provider as a Voluntary Variation in accordance with clause C.27.

B.25 Further reviews

- (1) The Provider and Te Whatu Ora agree that they and their representatives may carry out additional reviews of the Nationally-consistent Parts and Service Schedules of this Agreement if it is desirable to do so in advance of the next National Annual Agreement Review.

B.26 Special provisions relating to Schedule 1

- (1) Te Whatu Ora and the Provider agree that:
 - (a) Te Whatu Ora will undertake, with the expert advisory group described in clause B.21, a review of the Services described in Schedule 1, to determine whether, and if so how, the Dispensing Services and Professional Advisory Services described in Schedule 1 could be provided by different entities; and
 - (b) the review will consider, amongst other things:
 - (i) Service User access, needs, and safety;
 - (ii) service design, including the description of Dispensing Services and Professional Advisory Services in Schedule 1;
 - (iii) funding implications, including how pricing for Dispensing Services and Professional Advisory Services should be determined;

- (iv) any necessary IT changes; and
 - (v) any resulting changes that might need to be made to this Agreement.
- (2) Te Whatu Ora agrees that any changes to Schedule 1 following the review must be proposed by Te Whatu Ora as part of a National Annual Agreement Review to which clause B.23 applies.
- (3) Te Whatu Ora agrees that it will not propose any changes to Schedule 1 that would allow the Dispensing Services and Professional Advisory Services described in Schedule 1 to be provided by different entities:
 - (a) if the Pharmacy Council advises that the changes would be inconsistent with Pharmacists' professional obligations under their scope of practice or the Code of Ethics; or
 - (b) that would come into effect before 1 October 2019.

Changes relating to Schedule 3B (Locally Commissioned Services)

B.27 Changes to Service Schedules in Schedule 3B

- (1) This clause applies if Te Whatu Ora wants to make a change to:
 - (a) a Service described in a Service Schedule in Schedule 3B, which could include adding a new Service Schedule to Schedule 3B; or
 - (b) the providers that provide the Services described in a Service Schedule in Schedule 3B.
- (2) If Te Whatu Ora wants to change a Service Schedule in Schedule 3B, including by adding a new Service Schedule to Schedule 3B, and the changed or new Service Schedule will not be offered to all providers, the Service Schedule must be for a fixed term.
- (3) Te Whatu Ora will, as soon as reasonably practicable, advise the Provider, other providers that may be affected by the proposed change, and any provider representatives appointed for this purpose under clause B.22, of the proposed change, including by providing the following details:
 - (a) a summary of the proposed change;
 - (b) a proposed implementation plan, including any impacts on Service Users and how they will be managed; and
 - (c) how Te Whatu Ora intends to procure the Services and indicative timeframes for the procurement process.

- (4) Te Whatu Ora will give the persons and organisations that it advises of a proposed change under subclause (3) a reasonable opportunity to respond to the proposed change.
- (5) The Provider acknowledges that Te Whatu Ora may also engage with other interested parties including other health care providers, community representatives, and consumers in relation to a proposed change.
- (6) Any change made to a Service Schedule, or the addition of a new Service Schedule, following a proposal by Te Whatu Ora will be effective only if agreed by Te Whatu Ora and the Provider as a Voluntary Variation in accordance with clause C.27.

B.28 Special provisions relating to Schedule 3B.1 (LTC Services)

- (1) This clause applies if Te Whatu Ora proposes a variation to Schedule 3B.1 (Long Term Conditions Pharmacy Services) of its agreements with the Provider or any community pharmacy providers, which could include amending that Service Schedule or replacing it with a new Service Schedule.
- (2) If the Provider provides services under Schedule 3B.1, Te Whatu Ora will offer to continue to contract with the Provider for the Services described in any new or amended Service Schedule ("New Services"), provided that the Provider is able to provide the New Services to Services Users eligible for the New Services in accordance with the requirements of the new or amended Service Schedule.
- (3) The Provider must comply with any transitional requirements in the new or amended Service Schedule in respect of any LTC Service User registered with the Provider immediately before the new or amended Service Schedule comes into effect, including any requirements relating to transition planning for LTC Service Users who are eligible for the New Services.
- (4) This clause expires on 30 September 2020.

B.29 Special provisions relating to additional funding for Schedule 3B Services

- (1) Te Whatu Ora agrees that, each year of this Agreement commencing on 1 July, it will make available to the Provider and other community pharmacy providers in the Geographical Area, an amount equal to the portion of the \$4.1 million per annum for that Geographical Area made available by Te Whatu Ora to fund Locally Commissioned Services ("Local Commissioning Funding").
- (2) Te Whatu Ora will make the Local Commissioning Funding available for the following purposes:
 - (a) to continue to fund the following Services on the same basis as they were funded as at 30 September 2018:
 - (i) LTC Services;

- (ii) workforce development; and
 - (iii) Smoking Cessation Services;
 - (b) for locally commissioning a new Service that was not covered under any Service Schedule in Schedule 3B as at 30 September 2018;
 - (c) for increasing investment in an existing Service described in a Service Schedule in Schedule 3B, above the amount that was made available for that Service in the 12 months ending on 30 September 2018; or
 - (d) any combination of the above.
- (3) To avoid doubt, Te Whatu Ora's commitment that is set out in this clause:
- (a) does not require Te Whatu Ora to pay for Services that are not provided;
 - (b) does not prevent Te Whatu Ora from changing the Services funded using the Local Commissioning Funding (provided Te Whatu Ora complies with subclause (2)); and
 - (c) is not a commitment that the Provider will be entitled to any portion of the funding.

Changes to Services in Schedule 3C

B.30 Changes to Services in Schedule 3C

- (1) Te Whatu Ora and the Provider may agree to change to a Service Schedule in Schedule 3C, which could include adding a new Service Schedule to Schedule 3C, by agreeing to a Voluntary Variation in accordance with clause C.27.

Staff and Premises

B.31 Staff requirements

- (1) The Provider must ensure that each Staff member that is involved in the provision of Services:
- (a) has the qualifications and professional registrations necessary to provide the Services; and
 - (b) complies with any legal and professional requirements.

B.32 Staff management

- (1) The Provider must establish and implement staff management processes that are consistent with good human resource practice and that include, without limitation:
- (a) clearly defined and documented responsibilities and accountabilities for all Staff providing Services;
 - (b) systems for ensuring the sighting and recording of qualifications and all professional practice certificates and requirements annually, including in respect of new Staff appointments and new Staff qualifications;
 - (c) access to adequate supervision and training to ensure that Staff are competent to meet the requirements of their positions, and are able to contribute to the ongoing development of service quality;
 - (d) appropriate supervision of trainees, volunteers, and other relevant support Staff; and
 - (e) Staff providing the Services are clearly identifiable to Service Users and others.

B.33 Premises

- (1) The Provider must:
- (a) ensure that the Premises from which the Provider provides Services is, to the extent required by law, licensed by the relevant regulatory authority;
 - (b) comply with any requirements or conditions of its licence; and
 - (c) comply with the requirements specified in the Pharmacy Services Standards and any other legal or professional requirements.
- (2) The Provider must ensure that:
- (a) all buildings, plant, and equipment used in Service delivery are fit for their purpose and are maintained adequately and in safe working order;
 - (b) all equipment and supplies required to provide the Services are available, including necessary provisions for management of emergencies; and
 - (c) safety and emergency equipment and related information is clearly displayed and accessible.

Māori health and other population groups

B.34 Māori health

- (1) The Provider must, with reference to He Korowai Oranga – Māori Health Strategy and Whakatātaka Tuarua – Māori Health Action Plan, contribute to improvements in Whānau Ora and to the reduction in Māori health inequalities by:
 - (a) recognising the cultural values and beliefs that influence the effectiveness of services for Māori; and
 - (b) consulting and including Māori in service design and delivery.

B.35 Māori health in Quality Improvement Plan

- (1) If reasonable, given the demographic characteristics of the Provider's Service Users, the Provider must include in its Quality Improvement Plan a Māori health section that:
 - (a) contains policies and practices that recognise Māori health priorities and delivers Services to benefit Māori while recognising their diverse needs;
 - (b) is of a depth and scope appropriate to the Provider's circumstances; and
 - (c) takes into account the needs of Māori Service Users and the strategic or policy direction of the Crown on Māori health as advised by Te Whatu Ora from time to time.

B.36 Māori needs and Service initiatives

- (1) The Provider must meet the needs of Māori in relation to the delivery of the Services by:
 - (a) reducing barriers to accessing the Services by Māori Service Users;
 - (b) facilitating the involvement of whānau and others, if appropriate;
 - (c) developing relationships with Māori health providers; and
 - (d) educating and training Staff as appropriate.
- (2) The Provider must:
 - (a) participate in Māori health programmes initiated by Te Whatu Ora, PHOs, or Māori health providers as is reasonable;
 - (b) work towards adopting a culturally appropriate labelling and advice protocol for Māori Service Users who identify themselves as requiring this additional service; and

- (c) work towards using culturally appropriate destruction services for needles and other skin piercing devices that have come into contact with bodily fluids, for Māori Service Users who identify themselves as requiring this additional service.

B.37 Māori principles

- (1) To support its Māori Service Users and Staff, the Provider must support the introduction of appropriate Māori principles/tikanga within its organisation in such a way as to promote the holistic approach of Māori to health care.
- (2) An explanation of the approach is described below:

Wairua	Spirit or spirituality	A recognition that the Māori view of spirituality is inextricably related to the wellbeing of the Māori Service User.
Aroha	Compassionate love	The unconditional acceptance that is the heart of care and support.
Tūrangawaewae	A place to stand	The place the person calls home, where their origins are. Must be identified for all Māori Service Users who wish it to be.
Whānaungatanga	The extended family	The family or group which takes responsibility for its members and must be informed of where each member is.
Tapu/Noa	Sacred/profane	The recognition of the cultural means of social control envisaged in tapu and noa, including its implications for providers working with Māori Service Users.
Mana	Authority, standing	Services must recognise the mana of Māori Service Users.
Tangata whenua	Hapu or iwi that holds mana whenua over an area	In relation to a particular area, means the hapu or iwi that holds mana whenua or customary authority over that area.
Manaaki	To care for and show respect to	Services show respect for Māori values, traditions, and aspirations.
Kawa	Protocol of the marae, land, iwi	Determines how things are done in various circumstances. Respect for kawa is very important. If the kawa is not known, the tangata whenua should be consulted.

B.38 Promotion of equitable health outcomes

- (1) Te Whatu Ora and the Provider recognise that there are differences in health outcomes in some population groups, and that different approaches and resources are required to achieve equitable health outcomes for different people with different levels of advantage.
- (2) The Provider must provide the Services to different population groups in a manner that promotes equitable health outcomes.
- (3) To promote equitable health outcomes (including those for Maori Service Users), Te Whatu Ora may develop an equity plan for the district.
- (4) If Te Whatu Ora develops an equity plan, the Provider agrees that it will:
 - (a) if requested, assist Te Whatu Ora to develop the equity plan;
 - (b) take all reasonable steps to implement the equity plan; and
 - (c) report, if requested, on its implementation of the equity plan.

B.39 Te Whatu Ora's assistance

- (1) Te Whatu Ora will assist the Provider to meet its obligations in relation to equity plans, Māori Service Users and other population groups.

Governance, management, and quality improvement

B.40 Governance and management

- (1) The Provider must develop and implement governance and management systems to ensure:
 - (a) efficiency, effectiveness, and continuity in the provision of the Services to Service Users; and
 - (b) compliance with all legal, regulatory, and contractual obligations relating to Service delivery.

B.41 Quality Improvement Plan

- (1) The Provider must develop and implement policies and procedures to comply with its obligations under this Agreement for the ongoing development and improvement of Service delivery quality.
- (2) The Provider must have a written Quality Improvement Plan, and review and update its plan as appropriate, on an annual basis.

- (3) The Provider's Quality Improvement Plan must:
- (a) include a statement of the Provider's organisational philosophy and Service quality objectives;
 - (b) assign responsibilities and accountabilities for quality activities;
 - (c) describe systems and processes for maintaining and developing the quality of ongoing Service delivery and for defining priorities and new initiatives for quality development; and
 - (d) include monitoring systems, measuring systems, and processes to evaluate the effectiveness of quality activities and progress against the Quality Improvement Plan, including systems and processes for dealing with issues arising from Service User complaints or identified from Service User satisfaction surveys.
- (4) The Provider must implement its Quality Improvement Plan from the Start Date, unless the Provider did not receive funding for community pharmacy services before 1 April 2018, in which case the Provider must implement its Quality Improvement Plan no later than six months after it first received funding.

B.42 Quality systems and process

- (1) The Provider must ensure that the quality systems and processes developed under clause B.41(3)(c):
- (a) require that the Provider comply with appropriate professional and other standards relevant to the Services;
 - (b) provide for Staff and Service User input into quality development activities;
 - (c) provide for the development of documented policies and procedures, if necessary to support effective and safe Service delivery, including processes for regular review and updating of such documents and for ensuring that they are readily accessible, known to, and implemented by Staff; and
 - (d) provide for the Provider and its Staff who are Pharmacists to attend and participate in Pharmacist education seminars and programmes.

B.43 Quality requirements for Māori

- (1) The Provider must develop and implement processes to bring the perspective of Māori to its provision of Services that are suited to the scope and location of Services provided and their impact on Māori and, if appropriate, include using linkages developed with Māori to ensure that appropriate processes are in place to:
- (a) monitor and evaluate whether the Provider's Services are meeting the needs of Māori;

- (b) identify and, if possible, attempt to remove barriers to accessing the Provider's services by Māori Service Users;
- (c) if appropriate, facilitate the involvement of whānau in the care and treatment of Māori Service Users; and
- (d) ensure that the Provider's services are responsive to Māori cultural practices that are relevant to Māori Service Users.

B.44 Cultural training and support for Staff

- (1) The Provider must develop and implement, with the support of its linkages with Māori, appropriate processes to:
 - (a) provide cross-cultural training for Staff; and
 - (b) provide culturally appropriate support to Māori Staff.

B.45 Facilitating support

- (1) If the Provider provides Services to a Māori Service User, the Provider must, if the Māori Service User wishes, facilitate support from whānau/hapu/iwi, kuia/kaumātua, rongoā practitioners, spiritual advisors, Māori Staff, and others, as appropriate.

Risk management

B.46 Health and Safety policies and procedures

- (1) The Provider must identify, evaluate, and manage key risks to Service Users, Staff, and visitors to the Provider's facilities, and in particular must:
 - (a) comply with the requirements of the Health and Safety at Work Act 2015; and
 - (b) have documented policies and procedures to guide the Provider and its Staff in meeting health and safety requirements including, without limitation:
 - (i) policies and procedures to protect Service Users, Staff, and visitors from infections that could occur as a result of Service delivery that are consistent with nationally accepted guidelines and the requirements set out in the Health and Disability Services (Infection Prevention and Control) Standards (NZS8134.3:2008); and
 - (ii) documented systems to manage security appropriate to the degree and range of risks relevant to the Services provided, including the security of Pharmaceuticals, chemical supplies, equipment, and the facilities.

B.47 Incident reporting

- (1) The Provider must develop and implement processes for defining, recording, and resolving incidents and adverse events that include an internal documented reporting process that enables the early identification of any incidents and adverse event trends and the appropriate corrective and preventive strategies available.

B.48 Civil defence

- (1) The Provider must co-operate with any civil defence emergency activity as appropriate in the Geographical Area, and have a civil defence plan for its organisation that details how the Provider intends to manage continued delivery of the Services in the event of a major incident.

B.49 Health emergency planning

- (1) The Provider must participate in the development of the district or regional Health Emergency Plan coordinated by Te Whatu Ora to ensure the needs of the Provider's Service Users and Staff are met during a health emergency.
- (2) The Provider and Te Whatu Ora agree that the Health Emergency Plan will:
 - (a) outline the human, financial, and other roles and resources that each participant, including Te Whatu Ora, primary care providers, and pharmacy providers, will contribute in responding to an emergency, including substitution of services to meet the health emergency; and
 - (b) identify the Provider's response to an emergency event, which should be conducted with an "all hazards" approach to emergency planning.
- (3) The Provider must work with Te Whatu Ora and relevant participants to ensure the Health Emergency Plan is reviewed periodically to maintain currency and, if requested by Te Whatu Ora, be involved in processes to ensure that emergency responses are integrated, coordinated, and exercised.
- (4) Te Whatu Ora agrees that the level of participation required of the Provider will be reasonable and reflective of the nature of the services and the expected roles and services the Provider would provide in an emergency situation.
- (5) Te Whatu Ora will negotiate with the Provider to contribute to the Provider's costs if extraordinary funding is available to manage an emergency.

Record keeping

B.50 Service User Records

- (1) The Provider must maintain Service Users' Records and other related information, including in relation to Pharmaceuticals Dispensed to Service Users, in accordance with its legal and professional obligations.
- (2) The Provider must transfer information about Service Users to a clinical information system repository maintained by or on behalf of Te Whatu Ora, as required by Te Whatu Ora, provided that Te Whatu Ora provides access to the repository at no cost to the Provider, and the transfer of information complies with the Provider's and Te Whatu Ora's obligations under the Health Information Privacy Code 2020.

B.51 Financial and business Records

- (1) The Provider must operate in accordance with sound financial and business management principles, procedures, and practices.
- (2) The Provider must maintain full and proper financial and business Records in accordance with generally accepted accounting principles, procedures, and practices, and best business practice generally, and any legal obligations applicable to the Provider.
- (3) The Provider must be able to account for any Services it provides in a way that ensures financial separation between those Services and any other activities it is engaged in.

B.52 Security and preservation of Records

- (1) The Provider must preserve and protect the safety, security, and confidentiality of the Records in accordance with best practice and its legal obligations, including that:
 - (a) the Provider must have in place appropriate back-up and disaster recovery procedures to protect against loss of information; and
 - (b) if the Provider ceases to provide some or all Services, it must ensure that all Records are properly preserved and transferred to any replacement provider as required by law or otherwise as appropriate.

B.53 Accuracy of information

- (1) If the Provider is required to submit or give Te Whatu Ora any information under this Agreement, the Provider must ensure that the information is accurate and complete to the best of its knowledge and belief, and it must identify any material inaccuracies or uncertainties at the time the information is given or submitted or at the time the Provider discovers the inaccuracy or uncertainty.

Reporting

B.54 Reports

- (1) The Provider must give Te Whatu Ora any reports required by a Service Schedule, the Procedures Manual, or the Data Specification.

B.55 Ad-hoc reports

- (1) Te Whatu Ora may require the Provider to give Te Whatu Ora additional reasonable information about the Services from time to time, including to enable Te Whatu Ora to report to any Minister of the Crown on the use of public funds under this Agreement.
- (2) If Te Whatu Ora requires additional information:
 - (a) Te Whatu Ora will notify the Provider of Te Whatu Ora's reasonable information requirements, the reasons for those requirements, and the purposes for which the information will be used;
 - (b) Te Whatu Ora will advise the Provider of the timeframe for providing the information, which must be reasonable; and
 - (c) the Provider must give Te Whatu Ora every reasonable assistance to obtain the required information.

B.56 Cost of reporting

- (1) The costs to the Provider of giving Te Whatu Ora reports and information under this Agreement must be met by the Provider and are deemed to have been included in the prices for the Services.

B.57 Financial reporting by Te Whatu Ora

- (1) Te Whatu Ora agrees that:
 - (a) it will provide information held by their Payment Agent about the total amount of expenditure by Te Whatu Ora in each Quarter on all Services (except for Services described in a Service Schedule in Schedule 3C); and
 - (b) it will, on a six monthly basis, provide the following information about any Locally Commissioned Services for which Te Whatu Ora's Payment Agent does not hold payment information:
 - (i) information about the Services for which Te Whatu Ora has contracted; and
 - (ii) the amount that Te Whatu Ora has made available for those Services.

Part C General Terms

No exclusivity

C.1 Rights not exclusive

- (1) Te Whatu Ora and the Provider agree that this Agreement gives the Provider the right to provide Services, but does not give the Provider the right to provide Services to the exclusion of other providers.
- (2) Te Whatu Ora has the right to contract with other providers, including those in the Provider's area of expertise or vicinity, for the provision of Services.

Third party relationships, including subcontracting

C.2 Rights not to impinge

- (1) The Provider must not enter into any contract, arrangement, or understanding with any other person that would prejudice its ability to meet its obligations under this Agreement.

C.3 Prohibition on incentives and inducements

- (1) The Provider must comply with the requirements in the Code of Ethics relating to incentives, gifts, hospitality, and referrals.

C.4 Subcontracting

- (1) Subject to the requirements of clauses C.2 to C.6, the Provider may subcontract any aspect of the Services if Te Whatu Ora has given its prior written approval, which will not be unreasonably withheld.
- (2) The Provider may subcontract some or all of the Services if:
 - (a) the subcontractor has the qualifications or accreditations, experience, competency, and availability to enable it to perform all of the obligations that the Provider is subcontracting in accordance with this Agreement;
 - (b) the subcontract includes provision for the delegated Services to be performed in accordance with this Agreement, including provisions that:
 - (i) require the subcontractor to give the Provider any information Te Whatu Ora requires in relation to this Agreement (which the Provider must give to Te Whatu Ora);

- (ii) provide that Te Whatu Ora has direct access to the subcontractor's premises and Records and can Audit the subcontractor as if the Audit provisions in this Agreement referred to the subcontractor;
- (iii) prohibit the subcontractor from transferring, assigning or subcontracting its rights and obligations under the subcontract without Te Whatu Ora's prior written consent;
- (iv) require the subcontractor to have insurance cover in terms identical or substantially similar to those set out in clause C.51; and
- (v) provide that Te Whatu Ora may exercise its rights under this Agreement in relation to the performance of the obligations of the subcontractor under the subcontract, and enforce those rights in accordance with the Contract and Commercial Law Act 2017.

C.5 Information about subcontracts

- (1) The Provider must, if requested by Te Whatu Ora, give an Auditor a copy of any subcontract entered into by the Provider under this Agreement.
- (2) Te Whatu Ora and the Provider agree that the Auditor will not disclose to Te Whatu Ora the details of the financial arrangement between the Provider and its subcontractor, but that the Auditor may advise Te Whatu Ora if the Auditor considers that the financial arrangements may prejudice the Provider's ability to perform its obligations under this Agreement.
- (3) Te Whatu Ora may specify at any time:
 - (a) Services in respect of which Te Whatu Ora may require the Provider to give further information about any subcontracts the Provider has entered into in order to provide the Services; and
 - (b) the nature of any information Te Whatu Ora reasonably requires about those subcontracts, excluding any information relating to the financial benefits arising from the subcontract in respect of the Services.

C.6 Responsibility and liability for others

- (1) Te Whatu Ora and the Provider are each responsible and liable in all respects for the acts and omissions of their employees, subcontractors, contractors, agents, or other personnel in complying (or failing to comply) with their obligations under this Agreement.

Confidentiality and publicity

C.7 Confidentiality

- (1) Except as provided under this Agreement, neither Te Whatu Ora nor the Provider will disclose the other's Confidential Information to any person.
- (2) Te Whatu Ora or the Provider may publish this Agreement, except for any Confidential Information contained within it, in any media, including publication on the internet.
- (3) Te Whatu Ora and the Provider may only disclose Confidential Information:
 - (a) to those involved in the provision of Services under this Agreement, if necessary;
 - (b) to Te Whatu Ora or the Provider's professional advisors, agents, and representatives;
 - (c) if disclosure is permitted under this Agreement;
 - (d) required to be disclosed to the Crown under a Crown Direction;
 - (e) that is already in the public domain without being in breach of this clause;
 - (f) to the extent required by law, including if it is necessary for Te Whatu Ora to disclose Confidential Information under the Official Information Act 1982, to Ministers, Te Whatu Ora, or other public sector agencies, or otherwise in accordance with Te Whatu Ora's public law obligations;
 - (g) if the other party has consented in writing to such disclosure.
- (4) Te Whatu Ora and the Provider will each ensure that they collect, use, store, and disclose Confidential Information in accordance with any legal requirements, and disclose Health Information only if permitted by the Privacy Act 2020 and the Health Information Privacy Code 2020.
- (5) Te Whatu Ora and the Provider will ensure that Confidential Information is subject to user authorisation procedures.

C.8 Public statements

- (1) Neither party nor its representatives may, during or after the term of this Agreement, either directly or indirectly criticise the other publicly, without first discussing the matters of concern with the other in good faith and in a co-operative and constructive manner.
- (2) Subclause (1) does not prevent either party from discussing any matters of concern with its Staff, advisors, or representatives.

C.9 Use of name, logo, or fact of relationship

- (1) Neither party may use the other's logo, name, or the fact that there is a business relationship between them, in any advertising or for any other promotional purpose without the prior written consent of the other.

Audits

C.10 Purpose of Audit

- (1) Te Whatu Ora carries out audits to help ensure that public money is effectively used in the health sector so as to improve the quality of Services and the provision of Pharmaceuticals and related advice and information, and to provide optimum health benefits to Eligible Persons.
- (2) The purpose of an Audit is to enable Te Whatu Ora to inspect, monitor, audit, investigate, review, and evaluate whether the Provider:
 - (a) is delivering the Services in accordance with this Agreement;
 - (b) is claiming payments in accordance with this Agreement; and
 - (c) is complying with its obligations under this Agreement, the Pharmaceutical Schedule, the Data Specification, and the Procedures Manual.

C.11 Te Whatu Ora's Audit obligations

- (1) In conducting an Audit, Te Whatu Ora and its Auditors:
 - (a) must comply with the Health Act 1956, the Privacy Act 2020, the Health Information Privacy Code 2020, and any other relevant law;
 - (b) may access Health Information about any Service User;
 - (c) may observe the provision of the Services;
 - (d) may survey or interview Service Users, their families, or their associates, in relation to the provision of Services in respect of the particular Service User, or any Staff;
 - (e) may, to the extent permitted by law, make copies of any part of the Records or information;
 - (f) must ensure that all Audit activities meet professional, legal, and contractual requirements;
 - (g) must prepare Audit reports in a timely manner and detail the facts found during the Audit; and

- (h) must, subject to any legal obligations, provide information and prompt responses to all relevant queries from the Provider and its Staff and Service Users about an Audit; and
- (i) must establish follow-up processes appropriate to the Audit.

C.12 The Provider's Audit obligations

- (1) The Provider must:
 - (a) comply with the Health Act 1956, the Privacy Act 2020, the Health Information Privacy Code 2020, and any other relevant law;
 - (b) if the Auditor requests information before, or instead of, an on-site visit, give the Auditor the information within the time specified (which must be reasonable);
 - (c) actively, and in a timely manner, participate in any Audit programmes and Audits;
 - (d) complete the Audit recommendations in the required timeframe;
 - (da) if Te Whatu Ora specifies actions under clause C.16(1)(d), the Provider must complete all of those actions in the timeframe required by Te Whatu Ora; and
 - (e) co-operate and give Te Whatu Ora and its Auditor all reasonable assistance to ensure that any Audit is fully and properly completed to Te Whatu Ora and its Auditor's satisfaction.
- (2) The Provider's obligation under subclause (1) is a material obligation for the purposes of this Agreement.

C.13 Appointment of Auditor(s)

- (1) Te Whatu Ora will:
 - (a) appoint one or more suitably experienced or qualified and competent member(s) of its staff, or a third party, as Auditors;
 - (b) ensure all Auditors carry out Audits in a professional and competent manner; and
 - (c) advise the Provider of the person(s) who Te Whatu Ora has appointed as Auditor(s) and their qualifications, and provide a declaration from each Auditor of any conflicts of interest they may have in a notice of an on-site Audit given in accordance with clause C.14(4) or at the time of any request for information from the Provider (whichever happens first).

C.14 Notice of on-site Audit

- (1) Subject to subclause (2), Te Whatu Ora or its Auditor(s) will give the Provider at least ten Business Days' notice that it will carry out an on-site Audit at the Provider's Premises.
- (2) Te Whatu Ora or its Auditor(s) may give less than ten Business Days' notice (including 24 hours' notice or no notice) as is reasonable in the circumstances if Te Whatu Ora has reasonable grounds to believe that:
 - (a) there has been a material breach of the Agreement; or
 - (b) a delay of ten Business Days would unreasonably prejudice the integrity of the Audit or the interests of any Eligible Person.
- (3) If Te Whatu Ora reasonably suspects that fraudulent claiming has occurred, Te Whatu Ora may conduct an on-site Audit at any time without prior notice.
- (4) The notice of on-site Audit will include:
 - (a) the date of the on-site Audit;
 - (b) the identity of the person or persons appointed as Auditor(s), their qualifications and a declaration as described in clause C.13(1)(c); and
 - (c) general advice and information about the Audit process.
- (5) Te Whatu Ora or its Auditor(s) may contact the Provider to agree on an Audit date, before giving notice.

C.15 Carrying out on-site Audits

- (1) The Provider must co-operate with Te Whatu Ora to allow its Auditor(s) to access the following as part of an on-site Audit during ordinary business hours (or any other time agreed):
 - (a) the Provider's Premises;
 - (b) the Provider's Records and any other information, in whatever form, that relates to this Agreement, the Service Users and their families and associates; and
 - (c) the Provider's Staff.
- (2) The Provider must ensure that Te Whatu Ora and its Auditor(s) have equivalent access as described in subclause (1) in relation to any Services provided through a subcontractor, contractor, agent, or other personnel.

- (3) Te Whatu Ora will ensure that an on-site Audit:
- (a) does not unreasonably disrupt the Provider's ability to provide, or the provision of, the Services;
 - (b) is conducted in a way that takes into account relevant health and safety considerations; and
 - (c) is conducted in a way that appropriately acknowledges the privacy and dignity of Service Users.
- (4) The Provider may have a person present during an on-site Audit.
- (5) Te Whatu Ora will ensure that the Auditor(s) carry out a debriefing meeting or discussion after the on site Audit to discuss the general Audit findings with the Provider and give the Provider advice on the Audit report process.

C.16 Audit reports for on-site Audits

- (1) Te Whatu Ora and the Provider acknowledge and agree that usual reporting timeframes for Audit reports for on-site Audits are as follows:
- (a) the Auditor(s) give the Provider a draft Audit report within the timeframe specified by the Auditor, which is usually 15 Business Days after the on-site Audit;
 - (b) the Provider may comment on the draft Audit report within the timeframe specified by the Auditor(s), which is usually 15 Business Days after the Auditor(s) provide the draft Audit report to the Provider;
 - (c) the Auditor(s) complete the final Audit report in a timely manner, which is usually 15 Business Days after the date on which the Provider's comments had to be provided; and
 - (d) Te Whatu Ora will consider the final Audit report and may advise the Provider no later than 20 Business Days after the Audit report is finalised of any actions (including timeframes) required by Te Whatu Ora in relation to the findings in the Audit report, which may vary from the recommendations in the Audit report.

C.17 Audits after Agreement terminated

- (1) Te Whatu Ora may carry out an Audit of this Provider after this Agreement has terminated, but only to the extent that it is relevant to the period during which this Agreement was in force.

C.18 Solvency and Financial Audits

- (1) If Te Whatu Ora has reasonable grounds to be concerned about the solvency of the Provider, or that the Provider's financial position might negatively impact on the quality and continuity of Services provided by the Provider under this Agreement, Te Whatu Ora may:
 - (a) by giving notice to the Provider, require the Provider to give Te Whatu Ora a certificate from a suitably qualified person certifying the Provider's solvency within 30 days of the notice; or
 - (b) appoint, at Te Whatu Ora's cost, a suitably independent financial analyst as an Auditor to determine whether the Provider's financial position may prejudice its ability to continue to perform its obligations under this Agreement, in accordance with this Agreement.
- (2) To avoid doubt, an Auditor appointed by Te Whatu Ora under subclause (1)(b) must not disclose the Provider's financial information to Te Whatu Ora.

*Dispute resolution***C.19 Application of Dispute resolution provisions**

- (1) Clauses C.20 to C.24 apply to disputes regarding this Agreement (a "Dispute"), but do not apply to any dispute or disagreement relating to:
 - (a) whether or not any person is an Eligible Person, which is a matter to be determined by the Minister of Health in accordance with clause B.13;
 - (b) any matter that has been referred to and is being considered by a Responsible Authority; or
 - (c) any variation proposed to this Agreement, including one of the following:
 - (i) a National Annual Agreement Review;
 - (ii) a proposal by Te Whatu Ora to make a change described in clause B.27(1), which relates to Locally Commissioned Services; or
 - (iii) a proposal by Te Whatu Ora to make a change to a Service Schedule in Schedule 3C.

C.20 Resolution by agreement

- (1) If a Dispute arises under this Agreement:
 - (a) the party claiming that a Dispute exists must give notice to the other party of the nature of the Dispute; and

- (b) Te Whatu Ora and the Provider will each act in good faith and use its best endeavours to resolve the Dispute by agreement.
- (2) Te Whatu Ora and the Provider agree to use effective and efficient processes to resolve any Dispute, to the extent that Te Whatu Ora and the Provider consider that it is reasonably practicable to do so to avoid undesirable duplication given limited funding resources, which may include, if Te Whatu Ora and the Provider agree, involving a number of providers or representative bodies in a single dispute process.
- (3) The Provider may appoint a Provider representative to represent it in a Dispute, in accordance with clause B.22.

C.21 Mediation

- (1) If the Dispute is not settled by agreement 30 Business Days after receipt of the notice of the Dispute (or ten Business Days after the conclusion of the process in clause C.19(1)(b), whichever is the later) then, unless Te Whatu Ora and the Provider agree otherwise in writing, either party may refer the Dispute to mediation by giving notice to the other party and the following provisions will apply:
 - (a) the mediation will be conducted under the Resolution Institute's standard mediation agreements;
 - (b) if Te Whatu Ora and the Provider do not agree on a mediator within five Business Days after receipt of the notice of mediation, the mediator will be appointed by the Chair of the Resolution Institute (or his or her nominee) at the request of either party; and
 - (c) Te Whatu Ora and the Provider will share the mediator's fees equally.

C.22 Arbitration

- (1) If the dispute is not settled by agreement within 40 Business Days after the appointment of a mediator, unless Te Whatu Ora and the Provider agree otherwise in writing, either party may refer the Dispute to arbitration by giving notice to the other party and the following provisions will apply:
 - (a) the arbitration will be conducted by a single arbitrator under the Arbitration Act 1996; and
 - (b) if Te Whatu Ora and the Provider both do not agree on an arbitrator within five Business Days after receipt of the notice of arbitration, the arbitrator will be appointed by the President of the New Zealand Law Society (or his or her nominee) at the request of either party.

C.23 No litigation

- (1) Neither party may initiate proceedings in any court or other tribunal while the dispute resolution process referred to in clauses C.21 and C.22 is under way, unless such proceeding is necessary to preserve that party's rights.
- (2) Subclause (1) does not prevent the commencement or continuation of criminal proceedings or the referral of any matter to a Responsible Authority or other relevant professional or regulatory body, including Medsafe.

C.24 Obligations continue

- (1) Te Whatu Ora and the Provider acknowledge and agree that each party continues to be bound to comply with its obligations under this Agreement while the dispute is being resolved, except that:
 - (a) Te Whatu Ora may withhold payments from the Provider to the extent that they are the subject of the dispute; and
 - (b) the Provider is not obliged to provide Services for which it receives no payment from Te Whatu Ora.
- (2) If Te Whatu Ora withholds an amount under subclause (1), and it is determined through the dispute resolution process that Te Whatu Ora was not entitled to withhold the amount, Te Whatu Ora will repay the Provider the amount withheld plus Default Interest (applicable for the period of the withholding).

Variations to this Agreement

C.25 Variations

- (1) This Agreement may be varied:
 - (a) in order to give effect to a Crown Direction or law change in accordance with clause C.26 (a "Compulsory Variation"); or
 - (b) by mutual agreement in accordance with clause C.27 (a "Voluntary Variation").

C.26 Procedure for Compulsory Variations

- (1) If Te Whatu Ora considers that it is likely that a Compulsory Variation will be required, Te Whatu Ora will give the Provider reasonable notice of the variation if Te Whatu Ora can do so, which will include the details of the variation and a proposed draft of the variation.
- (2) Te Whatu Ora's proposed draft of the variation will be written to give effect to the relevant Crown Direction or law change in a way that endeavours to minimise any adverse impact on the Provider, financial or otherwise.

- (3) Te Whatu Ora will specify a period of time that is reasonable in the circumstances, being at least ten Business Days unless Te Whatu Ora is precluded from giving such notice, within which the Provider may reply to the notice of variation.
- (4) After the expiry of the reply period specified by Te Whatu Ora, or earlier if the parties both agree, the parties must both try to reach agreement on the terms of the variation.
- (5) Te Whatu Ora will take into account the Provider's response to the notice (if any) in implementing the variation.
- (6) If the terms of the variation are agreed such agreement must be recorded in writing and signed by both parties, and will commence on the day that the relevant Crown Direction or law change comes into effect or any earlier time that the parties agree.
- (7) If Te Whatu Ora and the Provider do not agree on the terms of the variation before the relevant Crown Direction or law change comes into effect, the Agreement will be deemed to be varied on the terms set out in Te Whatu Ora's proposed draft of the variation, subject to any changes that the parties have agreed, on the day that the Crown Direction or law change comes into effect.
- (8) If this Agreement is varied in accordance with subclause (7), and it is no longer viable, financially or otherwise, for the Provider to continue providing the Services that have been affected by the variation, the Provider may terminate the obligation to provide the relevant Services by giving at least six months' written notice to Te Whatu Ora or any shorter period of notice as is reasonable in the circumstances.

C.27 Procedure for Voluntary Variations

- (1) Any Voluntary Variation to this Agreement that Te Whatu Ora and the Provider agree, including as a result of a National Annual Agreement Review, or following a change made in accordance with clause B.27 (which relates to the local commissioning of Services described in a Service Schedule in Schedule 3B), will be effective only if agreed in writing and signed by both parties.
- (2) To avoid doubt, this Agreement continues without amendment if a Voluntary Variation proposed under subclause (1) is not agreed in writing and signed by both parties.

C.28 Nothing precludes termination

- (1) Nothing in clauses C.25 to C.27 precludes either party from terminating this Agreement (all or in part) in accordance with clauses C.29 to C.44.

Failure to perform

C.29 The Provider has failed to perform

- (1) Subject to clause C.38 (Uncontrollable Events), if the Provider fails to perform any material obligation under this Agreement, including, without limitation, its obligations under clauses D.7, D.23, and C.12, and any requirements in this Agreement relating to the reporting or provision of information, Te Whatu Ora may do one or more of the following:
- (a) seek specific performance of the Agreement;
 - (b) seek Default Interest from the Provider in accordance with clauses D.44 to D.48;
 - (c) suspend or terminate this Agreement in accordance with clauses C.31 to C.34;
 - (d) make alternative arrangements for the provision of the Services in accordance with clauses C.35 to C.37;
 - (e) withhold payments if permitted by a provision of this Agreement; or
 - (f) seek damages.

C.30 Te Whatu Ora has failed to perform

- (1) Subject to clause C.38 (Uncontrollable Events), if Te Whatu Ora fails to meet any material obligation under this Agreement, and has not remedied the failure within 30 days (or a different time period agreed by the parties) of receiving written notice of the failure from the Provider, the Provider may, in addition to any other rights it has under this Agreement or otherwise, do one or more (or none) of the following:
- (a) seek specific performance of the Agreement;
 - (b) seek Default Interest from Te Whatu Ora in accordance with clauses D.44 to D.48;
 - (c) seek damages from Te Whatu Ora;
 - (d) terminate the Agreement immediately on written notice; or
 - (e) terminate the part of the Agreement that relates to the Services in respect of which Te Whatu Ora's failure applies.

Suspension or termination for material failure to perform

C.31 Notice of failure

- (1) If Te Whatu Ora has reasonable grounds to believe that the Provider has not met any material obligation under this Agreement, Te Whatu Ora will give the Provider written notice setting out the details of the obligation that Te Whatu Ora –believes has not been met; and
 - (a) if the failure can be remedied, give the Provider 30 days to meet the obligation and to demonstrate to Te Whatu Ora's reasonable satisfaction that the obligation has been met; or
 - (b) if the failure cannot be remedied, terminate this Agreement on the expiry of a period of 30 days, or a shorter period as Te Whatu Ora considers reasonable in the interests of the health and safety of Service Users.
- (2) Despite anything else in this Agreement, if Te Whatu Ora –has reasonable grounds to believe that the health or safety of any Service User is at risk, Te Whatu Ora may suspend the Provider's right and obligation to provide the relevant Services while Te Whatu Ora investigates the issue.
- (3) Te Whatu Ora will notify the Provider of such suspension in the notice given under subclause (1).
- (4) If Te Whatu Ora is satisfied on reasonable grounds that the Provider is willing and able to perform the material obligations referred to in subclause (1) and that the health or safety of any Service User is no longer at risk, Te Whatu Ora will give the Provider written notice that the Provider must resume performance of such obligations.

C.32 Termination on seven days' notice

- (1) If, after the 30 day period referred to in clause C.31(1)(a), the Provider has not demonstrated to Te Whatu Ora's reasonable satisfaction that the Provider has met the obligation, Te Whatu Ora may terminate this Agreement on seven days' written notice, or such shorter period as Te Whatu Ora –considers reasonable in the interests of the health and safety of Service Users.

C.33 Dispute

- (1) If the Provider receives a notice under clause C.31(1), but disagrees that the obligation Te Whatu Ora believes the Provider has not met is a material obligation, the Provider:
 - (a) may refer the matter to mediation and, if necessary, arbitration in accordance with clauses C.19 to C.24; and

- (b) may appoint a representative to provide it with advice or assistance in relation to the Dispute in accordance with clause B.22.
- (2) Despite anything in clauses C.19 to C.24, if a Dispute is referred to mediation or arbitration under this clause, Te Whatu Ora and the Provider agree:
 - (a) to each use all reasonable endeavours to complete the mediation or arbitration within the 30 day period referred to in clause C.31(1);
 - (b) if it is agreed or determined that the relevant obligation is a material obligation, the Provider will have a further 30 days in addition to the original 30 days in which to meet the obligation;
 - (c) if it is agreed or determined that the relevant obligation is not a material obligation, the notice given under clause C.31(1) will have no further effect; and
 - (d) if there is no agreement or determination as to whether or not the relevant obligation is a material obligation, Te Whatu Ora may terminate this Agreement in accordance with clause C.34.
- (3) Despite clause C.33(1), the Provider agrees that the obligations set out in clauses D.23, C.12, and D.7 are material obligations.

C.34 Immediate termination

- (1) If, after the further 30 day period referred to in clause C.31(1), the Provider has not demonstrated to Te Whatu Ora's reasonable satisfaction that the Provider has met the obligation, Te Whatu Ora may terminate this Agreement on seven days' written notice, or such shorter period as Te Whatu Ora considers reasonable in the interests of the health and safety of Service Users.

C.35 Uncontrollable Events

- (1) Clauses C.31 to C.34 do not apply if the Provider's failure to perform is caused by an Uncontrollable Event.

C.36 Alternative arrangements on non-performance

- (1) If the Provider fails to perform any material obligation under this Agreement, Te Whatu Ora may make such alternative arrangements as are reasonably necessary for the provision of those Services during the period of the Provider's non-performance, at the Provider's expense.

C.37 Payment of Te Whatu Ora costs

- (1) On Te Whatu Ora's demand, the Provider must pay or reimburse Te Whatu Ora for all reasonable costs it incurs acting under clause C.36 for the period until the end of the Provider's non performance or until the End Date, whichever is the earlier.
- (2) If the Provider fails to pay or reimburse Te Whatu Ora following a demand by Te Whatu Ora, Te Whatu Ora may set off the amount owed against any amount that Te Whatu Ora owes to the Provider in accordance with clause D.43.
- (3) This clause does not apply if the Provider's failure to perform is caused by an Uncontrollable Event.

*Uncontrollable Events***C.38 Uncontrollable Events**

- (1) If either party is prevented from or delayed in performing its obligations under this Agreement by an Uncontrollable Event, the party directly affected by that Uncontrollable Event will not be in breach of the Agreement.
- (2) The party whose performance is directly affected by an Uncontrollable Event must give written notice to the other specifying:
 - (a) the nature of the circumstances giving rise to the Uncontrollable Event;
 - (b) the extent of that party's inability to perform; and
 - (c) the likely duration of that non-performance.
- (3) The party whose performance is directly affected by an Uncontrollable Event must take all reasonable steps to avoid or reduce the impact of the Uncontrollable Event on the due performance of the Agreement.
- (4) The Provider must have in place a reasonable risk management plan and sufficient funds to implement the plan (except if Te Whatu Ora has failed to make due payment).
- (5) This clause does not require a party to settle any strike, lock-out, or other industrial disturbance.
- (6) The party whose performance is directly affected by an Uncontrollable Event must resume due performance of its obligations under this Agreement as soon as is reasonably practicable after the Uncontrollable Event ends or its impact is sufficiently reduced to allow due performance.
- (7) Despite anything else in this Agreement, if the Provider is unable to provide the Services because of an Uncontrollable Event, Te Whatu Ora may make alternative arrangements for

the provision of Services during the period of the Provider's non-performance (and for such reasonable time afterwards as may be necessary to secure an alternative provider or providers at the time the alternative arrangement is entered into) as Te Whatu Ora sees fit but after consultation with the Provider.

C.39 Continued non-performance

- (1) If either party is unable to perform an obligation under this Agreement for 30 days or more because of an Uncontrollable Event, Te Whatu Ora and the Provider must try to agree to what extent, if any, the affected Services can be varied and/or continued by the Provider.
- (2) If Te Whatu Ora and the Provider cannot reach agreement within five Business Days after the end of the 30-day period, either party may terminate the relevant Services by giving at least 30 days' written notice.

Termination

C.40 Mutual agreement to terminate

- (1) Te Whatu Ora and the Provider may terminate all or part of this Agreement (including any Service Schedule) by agreement in writing, which must be signed by both parties.

C.41 Te Whatu Ora's right to terminate

- (1) Te Whatu Ora may terminate any part or all of this Agreement, including any Service Schedule:
 - (a) if the Provider has failed to meet a material obligation under this Agreement, in accordance with clauses C.31 to C.34;
 - (b) if Te Whatu Ora –has good reason to believe that the Provider is unable to carry out all of its obligations under this Agreement, immediately on written notice, subject to Te Whatu Ora consulting with the Provider first about the possibility of termination;
 - (c) if the Provider has disposed of or entered into any arrangement that will result in the disposal of a substantial part of the Provider's business, property, or assets that are required in order for the Provider to be able to carry out its obligations under this Agreement, or the same are lawfully seized or appropriated, without Te Whatu Ora's prior written consent, immediately on written notice;
 - (d) if the Provider is insolvent, unable to pay its indebtedness as it falls due, stops payment to creditors generally, or has entered into any composition or other arrangement with creditors, or if a receiver has been appointed over the Provider's assets or is put into liquidation or adjudged bankrupt, immediately on written notice;

- (e) if the Provider commits any fraudulent or unlawful action that Te Whatu Ora considers on reasonable grounds will seriously affect the Provider's ability to perform its obligations under this Agreement, immediately on written notice;
- (f) by giving the Provider six months' written notice, provided that:
 - (i) Te Whatu Ora will have regard to the relationship principles set out in clause A.5 in determining whether to give such notice;
 - (ii) each party will continue to be bound to comply with its obligations under this Agreement (including obligations under clauses C.19 to C.24) during this six-month notice period; and
 - (iii) Te Whatu Ora's right to terminate on notice applies despite any other provision in this Agreement, including if the parties are engaged in a process of Dispute resolution or variation of this Agreement;
- (g) if an Uncontrollable Event occurs, in accordance with clause C.38; or
- (h) if Te Whatu Ora gives the Provider three months' written notice that it is going to issue a Section 94 Notice in respect of community pharmacy services. This right to terminate will apply despite any other provision in this Agreement, including if the parties are engaged in a process of Dispute resolution or variation of this Agreement.

C.42 The Provider's right to terminate

- (1) The Provider may terminate this Agreement, including any Service Schedule or any part of the Agreement that relates to the Services in respect of which Te Whatu Ora's failure applies:
 - (a) in relation to material failure in accordance with clause C.30;
 - (b) in relation to a Compulsory Variation in accordance with clause C.26;
 - (c) by giving six months' written notice, provided that:
 - (i) the Provider has regard to the relationship principles set out in clause A.5;
 - (ii) each party will continue to be bound to comply with its obligations under this Agreement (including under clauses C.19 to C.24) during the six-month notice period;
 - (iii) the Provider's right to terminate on notice applies despite any other provision in this Agreement, including if the parties are engaged in a process of dispute resolution or variation of this Agreement; and
 - (d) if an Uncontrollable Event occurs, in accordance with clause C.38.

C.43 Alternatives to termination of entire Agreement

- (1) As an alternative to terminating the entire Agreement, either party may, by giving the other six months' notice, terminate the provision of any particular Services in issue (including a Service Schedule), and Te Whatu Ora may cease paying for the Services from the date of termination.
- (2) The right to terminate on notice under this clause applies despite any other provision in this Agreement, including if the parties are engaged in a process of dispute resolution or variation of this Agreement, having regard to the relationship principles set out in clause A.5.

C.44 Consequences of termination

- (1) If all Service Schedules are terminated in accordance with this Agreement, the entire Agreement will be terminated from the date on which all Service Schedules are terminated.
- (2) Termination of this Agreement will not prejudice:
 - (a) any other rights or remedies that either party may have against the other arising out of any breach of this Agreement that occurred before termination; or
 - (b) the operation of any clauses of this Agreement that are expressed or implied to have effect after termination.

Assignment and transfer

C.45 No assignment or transfer without consent

- (1) The Provider may not assign or transfer any or all of its rights or obligations under this Agreement without Te Whatu Ora's prior written consent (which will not be unreasonably withheld). The term "transfer" includes any sale, transfer, or other disposal of any majority interest in the ownership or control of the Provider (if the Provider is a limited liability company) or its business (if it is not a limited liability company).
- (2) The Provider must give Te Whatu Ora information about the proposed transferee's ability to perform its obligations under this Agreement, and any further details that Te Whatu Ora may reasonably request.
- (3) Te Whatu Ora may require reasonable conditions to be met before it consents to a transfer. In particular, Te Whatu Ora may require that the proposed transferee enter into an agreement with Te Whatu Ora on substantially similar terms and conditions set out in this Agreement.

C.46 Exception for assignment to obtain finance

- (1) The Provider may assign its right to receive payment from Te Whatu Ora under this Agreement if:
 - (a) the assignee provides or will provide finance to the Provider; and
 - (b) the assignment is for the sole purpose of ensuring the continuation or obtaining of such finance.

C.47 Assignment or transfer by Te Whatu Ora

- (1) Te Whatu Ora may assign or transfer any or all of its rights and obligations under this Agreement without the Provider's prior consent.

C.48 Consequences of transfer or assignment

- (1) This Agreement is binding on, and exists for the benefit of, both Te Whatu Ora and the Provider and their respective successors and permitted assignees or transferees, each of whom has the rights and obligations as if it were a named party to this Agreement.
- (2) The transfer or assignment of the Provider's rights or obligations under this Agreement will not prejudice:
 - (a) any other rights or remedies that either party may have against the other arising out of any breach of this Agreement that occurred before the transfer or assignment; or
 - (b) the operation of any provisions in this Agreement that are expressed or implied to have effect after such transfer or assignment has occurred.

Other terms

C.49 Notices

- (1) Te Whatu Ora –and the Provider will each respond to enquiries from the other as soon as is practicable but in no case later than ten Business Days after receiving the enquiry.
- (2) Each notice or other communication that is required to be in writing under this Agreement must include the Agreement Reference Number, and must be made by personal delivery, post, courier, email, or fax to the address or fax number, and marked for the attention of the person or office holder, advised by the addressee to the addressor to receive notices.
- (3) Any change to a party's contact details must be notified to the other party at least ten Business Days before the change comes into effect.

- (4) A notice is deemed to be received (if the addresser is not aware of any failure in the delivery) in the case of:
- (a) fax, on the Business Day on which it is sent or, if sent after 5:00pm in the place of receipt or on a non-Business Day, on the next Business Day;
 - (b) personal delivery, when it is delivered;
 - (c) post, on the third Business Day after posting;
 - (d) courier, when it is delivered; or
 - (e) email, on the Business Day on which it is sent or, if sent after 5:00pm in the place of receipt or on a non-Business Day, on the next Business Day.

C.50 Independent contractor

- (1) The Provider is engaged to provide Services as an independent contractor to Te Whatu Ora, and not as an employee or agent, that under no circumstances will Te Whatu Ora be liable to pay any sums due to the Provider's Staff under law (such as holiday pay or sick pay), and that the Provider has no authority to act on Te Whatu Ora's behalf.

C.51 Insurance

- (1) The Provider must:
- (a) have insurance to an appropriate and reasonable extent, to cover its business and assets against risks associated with the performance of and compliance with its obligations under this Agreement; and
 - (b) maintain such insurance throughout the duration of this Agreement and for as long afterwards as is prudent to provide for circumstances that may arise in relation to this Agreement after the End Date.
- (2) Te Whatu Ora may request, and the Provider must promptly give Te Whatu Ora, any information concerning the Provider's insurance.

C.52 Indemnity

- (1) The Provider will indemnify Te Whatu Ora and keep Te Whatu Ora indemnified (and will indemnify and keep indemnified the Payment Agent) against all claims, losses, damages, penalties, and reasonable costs and expenses (including all legal or other costs or expenses associated with the enforcement of this Agreement) but excluding any indirect or consequential loss, made or incurred by Te Whatu Ora that has been caused, either directly or indirectly, by the Provider's failure to comply with any provision of this Agreement, or the failure of anyone for whom the Provider is responsible under this Agreement.

- (2) Despite clause C.58, subclause (1) confers, and is to be construed to confer, a benefit enforceable by the Payment Agent, which may enforce the rights under subclause (1) as if it were named in this Agreement as a party.
- (3) If Te Whatu Ora, as the party incurring the loss under subclause (1), has contributed in some material way to the circumstances giving rise to that loss, the level of indemnity due to Te Whatu Ora will be reduced to the extent of such contribution.
- (4) Despite anything else in this Agreement, this clause will not apply if compensation for failure to comply with the relevant provision has been provided for elsewhere in this Agreement.

C.53 Warranties

- (1) Each party warrants to the other that, to the best of its knowledge and reasonable belief:
 - (a) all material information provided to the other is correct and not misleading in any material respect; and
 - (b) there is nothing impairing or preventing it from carrying out its obligations under this Agreement.
- (2) Each of the warranties in subclause (1) are deemed to be repeated continuously throughout the term of this Agreement.
- (3) If any of the warranties are not true or become no longer true, the relevant party will inform the other of the change as soon as is practicable.

C.54 Compliance with law

- (1) Each party will comply with all statutory, regulatory, and other legal requirements that are applicable to the performance of its obligations under this Agreement.

C.55 Waiver

- (1) Either party may, by notice in writing to the other party, waive a right conferred under this Agreement.
- (2) Delay or failure to exercise a right does not constitute a waiver of that right.

C.56 Entire agreement

- (1) This Agreement, including any variations made or agreed by the parties as set out in clause C.25, constitutes the entire agreement and understanding between us, and supersedes and replaces all prior agreements and understandings between us in relation to the provision of community pharmacy services.

C.57 Enforceability

- (1) If any provision of this Agreement is found or held to be illegal, invalid, or unenforceable, such determination will not affect the remainder of the Agreement, which will remain in force.
- (2) If any provision of this Agreement is found or held to be illegal, invalid, or unenforceable, each party must, if possible, take the steps necessary to make reasonable modifications to any such provisions to ensure that they are legal, valid, or enforceable and, otherwise, such provisions are deemed to be modified to the extent necessary to ensure that they are legal, valid, or enforceable.

C.58 Contract and Commercial Law Act 2017

- (1) Unless otherwise provided in this Agreement, a person who is not a party to this Agreement may not enforce any of the provisions of this Agreement, and nothing in this Agreement confers any benefit on any Eligible Person or other party for the purposes of the Contract and Commercial Law Act 2017 or otherwise.

C.59 Executing this Agreement

- (1) This Agreement may be executed in any number of counterparts, each of which is to be deemed an original, but all of which together are to constitute a single instrument. A party may enter into this Agreement by executing any counterpart.
- (2) This Agreement may be executed on the basis of an exchange of faxed or emailed copies of this Agreement.

C.60 Governing law and jurisdiction

- (1) This Agreement is governed by the law of New Zealand, and the parties submit to the non-exclusive jurisdiction of the courts of New Zealand.

Part D Payment and Claiming Terms

D.1 Claiming and payment for Services

- (1) The Provider must claim for any Services that it provides in accordance with the terms set out in this Part D and the relevant Service Schedule.
- (2) The Provider must claim for any Pharmaceuticals that it Dispenses by submitting a Claim Item as part of a claim.
- (3) The Provider must claim for every Subsidised Pharmaceutical that it Dispenses in accordance with subclause (2).

D.2 Goods and Services Tax

- (1) Unless this Agreement expressly provides otherwise:
 - (a) amounts listed in this Agreement are exclusive of GST; and
 - (b) all payments made under this Agreement will be made inclusive of GST.
- (2) All claims made and invoices provided by the Provider must comply with the Goods and Services Tax Act 1985.

Charging Eligible Persons and Non-Eligible Persons

D.3 Eligible Persons

- (1) The Provider may only charge Eligible Persons for Services in accordance with clauses D.3 to D.10.

D.4 Persons who are not Eligible Persons

- (1) The Provider may not claim payment from Te Whatu Ora in relation to the provision of services to persons who are not Eligible Persons.
- (2) Nothing in this Agreement prevents the Provider from charging persons who are not Eligible Persons for providing services to those persons.
- (3) If the Provider has claimed for services provided to a person who is not an Eligible Person, Te Whatu Ora will withhold or recover payment for those services if it is apparent from the Prescription Form or otherwise known to the Provider that the person was not an Eligible Person.
- (4) Subclauses (1) to (3) also apply to the Provider in respect of people who do not meet eligibility or other requirements for a Service funded by Te Whatu Ora under this Agreement.

Co-payments, Pharmacy Charges, and Product Premiums

D.5 Co-payments

- (1) The Provider must not charge a Service User any Co-payment for Dispensing a Subsidised Pharmaceutical to the Service User that has been prescribed by:
 - (a) a Prescriber employed by Te Whatu Ora;
 - (b) a provider or Prescriber with an access or service agreement with Te Whatu Ora, or a PHO;
 - (c) an after-hours provider with an access or service agreement with Te Whatu Ora or a PHO; or
 - (d) a provider providing a fully publicly funded service under a Section 94 Notice.
- (2) The Provider may charge a Service User a Co-payment for Dispensing a Subsidised Pharmaceutical to a Service User if:
 - (a) the Subsidised Pharmaceutical has been prescribed by a Prescriber or provider that is not specified in subclause (1);
 - (b) an exemption as set out in the Procedures Manual does not apply; and
 - (c) the amount charged does not exceed the relevant maximum Co-payment amount specified in the Procedures Manual or Pharmaceutical Schedule.
- (3) If the Provider is permitted to charge a Co-payment in accordance with clause D.5(2), Te Whatu Ora will calculate the relevant payment to the Provider under Schedules 1 or 3 on the basis that the Provider collected the Co-payment from the Service User, whether or not the Provider collected some or all of the Co-payment amount.

D.6 Product Premiums

- (1) If the price of a Pharmaceutical charged by its manufacturer is more than the subsidy set out in the Pharmaceutical Schedule for the Pharmaceutical, the Provider may charge a Service User the difference between the manufacturer's price and the subsidy, plus any mark-up ("Product Premium"), in addition to any Co-payments charged, in accordance with clause D.5.
- (2) If a Service User is prescribed a Pharmaceutical that incurs a Product Premium, the Provider must inform the Service User if there is a fully subsidised Pharmaceutical on the Pharmaceutical Schedule that is an alternative to the Pharmaceutical that the Service User has been prescribed.

D.7 Pharmacy Charges

- (1) Subject to clause D.5(2) (Co-payments), clause D.6 (Product Premiums), and subclause (2), the Provider may not charge a Service User any amount (whether characterised as voluntary or not) in connection with the provision of Services, except in accordance with the Permitted Pharmacy Charges Rules ("Pharmacy Charges").
- (2) The Provider may not charge a Service User:
 - (a) any charge that is intended to, or has the effect of, spreading the costs of circumstances described in the Permitted Pharmacy Charges Rules across Service Users more generally; or
 - (b) any other amount not expressly permitted by the Permitted Pharmacy Charges Rules.
- (3) The Provider acknowledges and agrees that its obligations under this clause constitute a material obligation for the purposes of this Agreement.
- (4) If the Provider is entitled to charge a Pharmacy Charge, it must inform the Service User of the amount of, and reason for, the Pharmacy Charge, and explain how they may avoid or reduce the Pharmacy Charge, before the Services or Pharmaceuticals are provided.
- (5) Despite anything else in this clause D.7, the Provider agrees that:
 - (a) any Pharmacy Charge it charges will be fair and reasonable;
 - (b) it will give Service Users an explanation of the reasons for, and the amount of, any Pharmacy Charge that the Provider is proposing to charge or has charged, including providing reasonable supporting evidence if the Service User requests it; and
 - (c) if requested (including as part of any Audit), it will give Te Whatu Ora an explanation of the reasons for, and amounts of, any Pharmacy Charges that the Provider is proposing to charge or has been charging Service Users, including providing reasonable supporting evidence if requested.
- (6) The Provider and Te Whatu Ora acknowledge that:
 - (a) at least annually, or more frequently if required, Te Whatu Ora will review the Permitted Pharmacy Charges Rules, and may, if required following that review, amend those rules after engaging with provider representatives appointed as described in clause B.22(3)(b) ; and
 - (b) to avoid doubt, amendments to the Permitted Pharmacy Charges Rules do not need to be made as a Compulsory Variation, or agreed as a Voluntary Variation.

D.8 Providing information to Eligible Persons

- (1) The Provider must make information regarding any Co-payments, Pharmacy Charges, and Product Premiums accessible and publicly known by displaying the information, or how to obtain the information so it can be easily sighted by a Service User before the Provider Dispenses a Pharmaceutical or provides Services.

D.9 Prescription subsidy scheme

- (1) The Provider must promote, and provide information about, the prescription subsidy scheme, and ensure that Service Users can participate in the scheme, including by recording the information of Service Users.

D.10 Receipts for Subsidised Pharmaceuticals

- (1) The Provider must give a Service User a receipt for any prescribed Subsidised Pharmaceutical provided to the Service User that includes the name of the Pharmaceutical and the cost to the Service User for the provision of the Pharmaceutical.
- (2) The Provider does not need to give a Service User a receipt:
 - (a) for a Subsidised Pharmaceutical for which the Service User is not charged, unless requested by the Service User; or
 - (b) to avoid doubt, for any prescribed Pharmaceutical that is not a Subsidised Pharmaceutical.

*Pack Fee***D.11 Pack Fee Recalculation**

[Deleted]

*Claiming procedures***D.12 Basis of claims**

- (1) The Provider may claim a payment from Te Whatu Ora if the Provider has provided the Services and Dispensed the Pharmaceuticals in accordance with:
 - (a) the Pharmaceutical Schedule;
 - (b) the Data Specification;
 - (c) the Procedures Manual;
 - (d) this Part D; and

- (e) any other requirements set out in each Service Schedule.

D.13 Electronic claiming

- (1) The Provider must submit each claim electronically, in accordance with the Data Specification and any other guidelines issued by Te Whatu Ora or its Payment Agent.
- (2) Te Whatu Ora may change the electronic address to which claims must be submitted by giving at least ten Business Days' notice to the Provider of the change.

D.14 Claim certification

- (1) The Provider must certify (in the form approved by Te Whatu Ora or the Payment Agent) the truth and accuracy of each claim and that the Provider has complied with this Agreement.
- (2) Te Whatu Ora will not accept a claim for payment that has not been certified.
- (3) The Provider must certify each claim by using the electronic signature and key assigned to each Pharmacist providing Services (and which each Pharmacist is responsible for keeping confidential).

D.15 Due Date for claims

- (1) For the purposes of this Agreement there are four Claim Periods in each calendar month, being:
 - (a) the first day to the end of the seventh day of the calendar month (First Claim Period);
 - (b) the eighth day to the end of the 15th day of the calendar month (Second Claim Period);
 - (c) the 16th day to the end of the 23rd day of the calendar month (Third Claim Period); and
 - (d) the 24th day to the end of the last day of the calendar month (Fourth Claim Period).
- (2) The Provider must submit each claim by the fourth Business Day after the last day of the Claim Period to which the claim relates ("Due Date").

D.16 Format and information for claims

- (1) The Provider must submit each claim in accordance with the requirements set out in the Data Specification and the Procedures Manual, and any requirements set out in a Service Schedule.

D.17 Prescriber information on claims

- (1) For each Claim Item the Provider submits, the Provider must include the Prescriber's health professional code and registration number (if known or included on the Prescription Form).
- (2) If a claim has less than 90% of the health professional codes and registration numbers on Claim Items (excluding Bulk Supply Orders and Practitioner's Supply Orders), Te Whatu Ora will reject the claim in accordance with clause D.25.
- (3) The Payment Agent will notify the Provider of the percentage of health professional codes and registration numbers in respect of the Claim Items in the Provider's last claim no later than one month after it received the claim.

D.18 Service User's information on claims

- (1) The Provider must use all reasonable endeavours to include the relevant Service User's NHI Number on each Claim Item submitted.
- (2) If a Service User's NHI Number on a Prescription Form is different from the NHI Number the Provider has for that Service User, the Provider must use the NHI Number on the Prescription Form unless it knows that the NHI Number is incorrect, in which case it must use the correct NHI Number.

D.19 Reliance on information from Prescribers

- (1) When submitting a claim, the Provider may rely on information it receives from a Prescriber unless the Provider has reason to believe the information is incorrect.

Claiming requirements and restrictions

D.20 Services must be provided in New Zealand

- (1) The Provider may not claim, and Te Whatu Ora will not pay the Provider, for Services or Pharmaceuticals that the Provider has provided to an Eligible Person who was not in New Zealand at the time the Services or Pharmaceuticals were provided to them.

D.21 Prescription Forms from ineligible Prescribers

- (1) If the Provider has claimed for Services provided or Pharmaceuticals Dispensed in accordance with a Prescription Form from a Prescriber who is not eligible to provide the Services or prescribe the Pharmaceuticals, Te Whatu Ora will withhold or recover payment for those Services or Pharmaceuticals if it is apparent from the Prescription Form, or otherwise known to the Provider, that the Prescriber was not eligible to provide the Services or prescribe the Pharmaceuticals.

D.22 No cost or volume shifting

- (1) The Provider must not knowingly be a party to any arrangement that results in Te Whatu Ora effectively having to pay more than once for the provision of Services in respect of the Dispensing of a Pharmaceutical to or for a Service User.
- (2) In respect of Services not involving the Dispensing of a Pharmaceutical, the Provider must not knowingly be a party to any arrangement that results in Te Whatu Ora effectively having to pay more than once for the provision of the same Services to the same Service User on the same occasion.
- (3) Unless otherwise agreed, neither party will operate in a way that shifts costs or volumes between Services that would result in additional costs to either party, other than for reasons of good clinical practice.
- (4) Without limiting subclauses (1) to (3), the Provider must not:
 - (a) claim payment from Te Whatu Ora for providing a Service to or for a Service User if another provider has or intends to claim payment for providing that Service to the Service User;
 - (b) refer to any provider any service that the Provider has been contracted to provide to Te Whatu Ora under this Agreement or any other agreement the Provider has with Te Whatu Ora, unless otherwise expressly permitted under this Agreement, or the Provider needs to make an onward referral in an emergency situation if it is unable to provide urgently needed medication; or
 - (c) act in a way that enables the Provider to claim or recover payment more than once under this Agreement, or any other agreement the Provider has with Te Whatu Ora, for providing the same service.

D.23 No unnecessary Dispensing

- (1) The Provider must not act in any way that increases its revenue from Te Whatu Ora artificially, including by Dispensing Pharmaceuticals more frequently than is necessary.
- (2) The Provider's obligation under this clause is a material obligation for the purposes of this Agreement.

D.24 Compliance advice

- (1) If the Provider is uncertain whether an activity it is engaging in, or proposing to engage in, is prohibited by clauses D.20 to D.23, it may seek clarification from Te Whatu Ora or its Payment Agent, and Te Whatu Ora will provide advice on the matter.

Rejecting claims

D.25 Rejecting claims

- (1) Te Whatu Ora may reject all or part of a claim if it believes on reasonable grounds that the Provider has submitted incomplete or inaccurate information, or has not complied with claiming restrictions or requirements.
- (2) If the claim was submitted by the Due Date, Te Whatu Ora will notify the Provider that its claim or a part of its claim has been rejected and the reason for the rejection before the next Claim Period.
- (3) The Provider may correct and resubmit a claim or part of a claim.
- (4) If a resubmission results in the Provider owing money to Te Whatu Ora, Te Whatu Ora may recover that money in accordance with clause D.43.
- (5) If the Provider corrects and resubmits a claim:
 - (a) before the Final Due Date, it will be paid in accordance with clause D.39;
 - (b) after the Final Due Date, the claim will be treated as a late claim under clauses D.26 to D.28 and, if applicable, will be paid in accordance with clause D.40.
- (6) An adjustment amount may be paid under this Agreement from time to time, being an amount agreed between the Provider and the Payment Agent or determined by Te Whatu Ora, that is to be recovered in respect of an overpayment or reimbursed in respect of an underpayment.

D.26 Time limit for receiving Claim Items

- (1) Subject to clauses D.27 and D.28 and any requirements in a Service Schedule, the Provider must provide all Claim Items to Te Whatu Ora no later than three months after the date on which the Pharmaceutical is Dispensed or the Service is provided.

D.27 Submission out of time

- (1) If the Provider does not submit or resubmit a Claim Item of more than \$20 by the applicable Final Due Date, the Provider may submit it out of time together with a written explanation of the reason for the delay.
- (2) If, in Te Whatu Ora's opinion, the Provider has established reasonable grounds for the late submission, Te Whatu Ora will pay the Claim Item.

D.28 No submission after six months

- (1) Te Whatu Ora will not, in any circumstances, be required to pay a Claim Item submitted or resubmitted more than six months after the date of the Service.

D.29 Verification of Claim Item

- (1) Te Whatu Ora may require the Provider to verify a Claim Item by giving 15 Business Days' notice to the Provider of that requirement.

Submitting Prescription Forms

D.30 Submitting Prescription Forms

- (1) The Provider must submit Prescription Forms to Te Whatu Ora in accordance with the requirements set out in the Data Specification and the Procedures Manual.
- (2) The Provider must submit all original Prescription Forms associated with a claim in batches to the Payment Agent.
- (3) Each batch must:
 - (a) fully substantiate the claim and each Claim Item;
 - (b) be filed in order of the date of Dispensing within the batch; and
 - (c) be accompanied by a batch record sheet (in the form approved by the Payment Agent) completed, dated, and signed by a person with authority to sign on the Provider's behalf.
- (4) The Provider must ensure any variances between the original Prescription Form and the computer record or supply are clearly annotated on the Prescription Form for clarification.

D.31 Date for submission of Prescription Forms

- (1) The Provider may retain Prescription Form batches for up to five months after the date of Dispensing.
- (2) If a batch is not received by the Payment Agent six months after the date of Dispensing, Te Whatu Ora or the Payment Agent may give notice to the Provider requesting that the batch be submitted.
- (3) If the batch is not received by the Payment Agent within 30 days after the date of the notice given under subclause (2), Te Whatu Ora may withhold from the Provider an amount equivalent to the total amount claimed in the batch the Payment Agent has not received, until the batch is received by the Payment Agent.

Paying claims

D.32 Te Whatu Ora's obligation to pay

- (1) Subject to clause D.33, Te Whatu Ora will pay the Provider for Pharmaceuticals Dispensed and Services provided in accordance with clauses D.3 to D.31 and clauses D.32 to D.43.
- (2) The payment by Te Whatu Ora will be deemed to have been made on behalf of the Service User in respect of whom the payment was made.

D.33 Withholding payments

- (1) Te Whatu Ora may withhold an amount payable for Services provided under Schedule 1 or Schedule 3B.1 of this Agreement for each of the following defaulting actions that the Provider commits:
 - (a) if the Provider breaches clause D.7 of this Agreement, Te Whatu Ora may withhold up to 5% of all amounts payable under clauses 18 and 19 of Schedule 1 and clauses 14 and 15 of Schedule 3B.1 that are or become due to the Provider subsequent to Te Whatu Ora becoming aware of the breach;
 - (b) if the Provider fails to report and give information in accordance with this Agreement, Te Whatu Ora may withhold up to 5% of all amounts payable under clauses 15 and 16 of Schedule 1, and clauses 14 and 15 of Schedule 3B.1 that are or become due to the Provider after Te Whatu Ora becoming aware of the Provider's failure.
- (2) If Te Whatu Ora intends to withhold an amount in accordance with subclause (1), Te Whatu Ora:
 - (a) will give 30 days' notice of its intention to withhold payment in accordance with subclause (1); and
 - (b) will discuss with the Provider, within that 30-day period, any issues relating to the Provider's failure to comply with clause D.7 or the reporting and information requirements (as applicable).
- (3) If the Provider does not cease breaching clause D.7, or does not remedy its failure to comply with the reporting and provision of information requirements (as applicable) within the 30 day period, Te Whatu Ora may withhold such payments until the Provider complies.
- (4) A payment withheld under subclause (1) will be paid to the Provider if it is found to have complied with clause D.7 or the reporting and provision of information requirements (as applicable) as an outcome of the dispute resolution process in C.19 to C.24.
- (5) Despite clause C.24(1)(b), the Provider must continue to provide Services if Te Whatu Ora withholds payments in accordance with this clause D.33.

- (6) The withholding rights specified in this clause D.33 are Te Whatu Ora's non-exclusive remedies in the event of a breach of clause D.7 or the reporting and information requirements (as applicable), and do not limit Te Whatu Ora's other rights and remedies available under this Agreement or existing at law, in equity, or otherwise, now or after the termination of this Agreement.

D.34 Access to Records

- (1) The Provider, its agent, or (with the Provider's consent) its representative may access a copy of any relevant records regarding it that are kept by Te Whatu Ora (including any records of the volume of Dispensed Pharmaceuticals claimed by the Provider) to review the payments Te Whatu Ora has made to the Provider under this Agreement, provided that:
- (a) the Provider must give written notice if it wants to access such records;
 - (b) Te Whatu Ora will determine (acting reasonably):
 - (i) the information to be provided under this clause so as not to cause an unreasonable burden for Te Whatu Ora; and
 - (ii) the time frame for providing such information;
 - (c) if a request causes a direct cost or an unreasonable burden to Te Whatu Ora, then it may charge a cost for providing the information.

D.35 Dispute over payment

- (1) If a dispute arises under this Agreement in respect of whether Te Whatu Ora has paid the Provider the correct amount for Services provided or Pharmaceuticals Dispensed, this dispute will be determined in accordance with the procedures set out in C.19 to C.24.

Payment time frames

D.36 Payment Date

- (1) Subject to subclause (2) and any requirements specified in a Service Schedule, the Payment Date for claims is:
- (a) the First Claim Period, the 28th day of that calendar month;
 - (b) the Second Claim Period, the fifth day of the following calendar month;
 - (c) the Third Claim Period, the 12th day of the following calendar month; and
 - (d) the Fourth Claim Period, the 20th day of the following calendar month,

- (2) If a Payment Date falls on a day that is not a Business Day, the Payment Date is the first Business Day following the Payment Date.

D.37 Rounding

- (1) Te Whatu Ora will, when calculating payments owed to the Provider, round the amount that it pays to the Provider for a Pharmaceutical, or for a claim made under this Agreement, up to the nearest cent.

D.38 Form of payment

- (1) Te Whatu Ora will pay amounts it owes into the bank account advised by the Provider.
- (2) The Provider may change the bank account into which payments are made by giving ten Business Days' written notice to Te Whatu Ora.

D.39 Payment of claim after Due Date

- (1) If a Claim Item is not submitted or resubmitted by the Due Date for that Claim Item, but is submitted or resubmitted before the Final Due Date, Te Whatu Ora will pay the Provider for the Claim Item no later than the Payment Date for the next Due Date that arises.

D.40 Payment of a late Claim Item

- (1) If a Claim Item is not submitted or resubmitted by the Final Due Date but is accepted in accordance with clause D.26 to D.28, Te Whatu Ora will pay the Provider for the Claim Item no later than the next Payment Date specified in clause D.36.

D.41 Payment variations

- (1) If Te Whatu Ora believes, on reasonable grounds, that a claim is partially valid and partially invalid, Te Whatu Ora will pay the valid portion only, and reject the invalid portion.

D.42 Overpayment

- (1) If the Provider fails to provide all or part of the Services for which Te Whatu Ora has paid under this Agreement, or if, for any reason excluding those set out in subclauses (2) and (3), Te Whatu Ora has overpaid the Provider for Pharmaceuticals or Services, Te Whatu Ora:
- (a) will determine the actual amount of the overpayment; and
 - (b) will notify the Provider of the overpayment and provide, to the extent reasonably possible, information about the overpayment, and the amount that Te Whatu Ora intends to recover if that amount is less than the actual amount of the overpayment; and
 - (c) may recover the amount from the Provider by way of set-off under clause D.43.

- (2) If the Provider owes Te Whatu Ora an amount as a result of the Provider's error in relation to a claim:
- (a) Te Whatu Ora will notify the Provider of the overpayment and provide, to the extent reasonably possible, information about the overpayment; and
 - (b) the due date for the repayment will be the next Payment Date after Te Whatu Ora's notice to the Provider; and
 - (c) Te Whatu Ora may recover the amount from the Provider by way of set-off under clause D.43.
- (3) If the Provider owes Te Whatu Ora an amount as a result of an error by Te Whatu Ora – Health New Zealand, its Payment Agent, or PHARMAC in relation to a payment:
- (a) Te Whatu Ora will notify the Provider of the overpayment and provide, to the extent reasonably possible, information about the reason for the overpayment; and
 - (b) Te Whatu Ora may, subject to subclause (5), recover the amount from the Provider by way of set-off under clause D.43, as set out in subclause (4).
- (4) Te Whatu Ora may recover the overpayment from the Provider by setting-off the amount owed from one or more payments made to the Provider in accordance with clause D.43, provided that:
- (a) the maximum amount that Te Whatu Ora may set-off from the total amount paid to the Provider in any calendar month is the greater of:
 - (i) an amount equal to 5% of the average of the total net monthly amounts paid to the Provider in each calendar month in the Quarter immediately preceding the month(s) in which the overpayment will be recovered; or
 - (ii) \$500; and
 - (b) to avoid doubt, Te Whatu Ora may recover the overpayment by set-off from more than one payment, until the overpayment is recovered in full.
- (5) Te Whatu Ora may not recover an amount owed by the Provider due to an error by Te Whatu Ora, its Payment Agent, or PHARMAC that was made more than one year before the date on which Te Whatu Ora notifies the Provider of the fact of the overpayment.
- (6) Nothing in this clause prevents Te Whatu Ora and the Provider from agreeing to alternative arrangements for repayment of an amount that has been overpaid.

D.43 Power of set-off

- (1) If the Provider owes Te Whatu Ora an amount under this Agreement, or any previous agreement, including in the case of overpayment under clause D.42 or if the Provider is obliged to indemnify Te Whatu Ora under clause C.52, Te Whatu Ora may set that amount off against any amount that it owes to the Provider at any time, after Te Whatu Ora has given the Provider written notice of its intention to do so.
- (2) If Te Whatu Ora exercises the power of set-off, the Provider will be deemed to have made payment to Te Whatu Ora to the extent of the set-off.

Default Interest

D.44 Te Whatu Ora may charge Default Interest

- (1) Subject to subclause (2) and clauses D.46 and D.48, if the Provider does not pay an amount due to Te Whatu Ora under this Agreement, Te Whatu Ora or its Payment Agent may charge the Provider interest from the date payment was due until the amount due is paid (Default Interest).
- (2) Te Whatu Ora may not charge Default Interest if the Provider owes Te Whatu Ora an amount as a result of Te Whatu Ora 's, its Payment Agent's, or PHARMAC's error in relation to a payment.

D.45 Provider may charge Default Interest

- (1) Subject to clauses D.46 and D.48, if Te Whatu Ora does not pay an amount due to the Provider under this Agreement, the Provider may charge Te Whatu Ora Default Interest from the date payment was due until the amount due is paid.
- (2) If Te Whatu Ora owes the Provider an amount as a result of Te Whatu Ora's or its Payment Agent's or PHARMAC's error in relation to a payment, Default Interest will be calculated from the Payment Date on which the amount was due.
- (3) If Te Whatu Ora owes the Provider an amount as a result of the Provider's error in relation to a claim, the due date for payment will be one month after the Provider's notice to Te Whatu Ora.

D.46 Charging Default Interest on \$50 or less

- (1) Subject to clause D.48, if either party owes the other \$50 or less under this Agreement, no Default Interest is payable unless that amount is still due three months after the Payment Date, in which case the party owed may charge the other Default Interest from the date payment is due until the amount due is paid.

D.47 Default Interest rate

- (1) The Default Interest rate is two percentage points per annum above the average New Zealand dollar 90-day bank bill rate (rounded up to the nearest second decimal place as appearing at 11.00am or as soon as practicable after that time on the relevant day on page BKBM of the Reuters screen (or its successor or equivalent page)), and will be calculated on a daily basis.

D.48 Notice of intention to charge Default Interest

- (1) In order for the due party to claim, and the defaulting party to be liable to pay, the Default Interest, the due party must give written notice to the defaulting party and the Payment Agent of its intention to claim Default Interest no later than 30 days after the date payment was due.
- (2) If the Provider or its agent gives notice, Te Whatu Ora will not be liable to pay Default Interest unless the notice includes:
- (a) the Provider's name (as shown on the cover of this Agreement);
 - (b) the Agreement Reference Number;
 - (c) the Provider's payee number;
 - (d) Te Whatu Ora's name; and
 - (e) the details of the payment to which the Default Interest relates.

Part E Definitions

E.1 Definitions

- (1) In this Agreement, unless the context requires otherwise, the following words and phrases have the following meaning:

Agreement means this agreement for the funding and provision of the Services

Agreement Reference Number means the unique identification number printed on the cover of this Agreement

ARRC Pharmacy Services means age-related residential care pharmacy services, which are described in Schedule 3B.3 (if applicable)

Aseptic Services means aseptic services, which includes syringe driver services, and which are described in Schedule 3A.2 (if applicable)

Audit includes inspection, monitoring, audit, investigation, review, and evaluation of the Provider's performance and compliance with the terms of this Agreement on the terms set out in clauses C.10 to C.18

Auditor means an auditor appointed by Te Whatu Ora to carry out an Audit under clause C.13 or as otherwise provided under this Agreement

Brand-switch Fee means the amount paid in relation to brand switch advice as set out in the Pharmaceutical Schedule

Bulk Supply Order has the same meaning given to it in the Pharmaceutical Schedule

Business Day means a day other than a Saturday, a Sunday, a public holiday under the Holidays Act 2003, or any day from 25 December to 2 January of any year

Claim Item means the transaction relating to the Dispensing of a Pharmaceutical

Claim Period means one of the four claim periods in a calendar month as described in clause D.15

Class B Pharmaceuticals Services means the Dispensing of a Class B Pharmaceutical, as described in Schedule 1

Class B Pharmaceutical means a Pharmaceutical that is a class B controlled drug under the Misuse of Drugs Act 1975 and, for the purpose of this Agreement, includes buprenorphine+naloxone

Clozapine Services means clozapine services, which are provided in accordance with Schedule 3A.4 (if applicable)

Code of Ethics means the publication issued by the Pharmacy Council under section 118(i) of the HPCA Act

Code of Consumers' Rights means the code set out in the Schedule to the under the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996

Commercial Information:

- (a) means any information disclosed by either party to the other, either before or during the term of the Agreement, or arising out of the operation of the Agreement, that Te Whatu Ora and the Provider agree is confidential or that may reasonably be considered to be confidential, taking into account all circumstances, including the manner of disclosure, and the circumstances in which disclosure occurred; but
- (b) excludes the terms of this Agreement unless both parties agree otherwise

Compulsory Variation means a variation to this Agreement described in clause C.25(1)(a)

Confidential Information includes Commercial Information and Health Information

Co-payment means a patient contribution that a Service User may be charged for Dispensing a Pharmaceutical that is determined in accordance with clause D.5(2)

CPAM Services means community pharmacy anti-coagulation management services, which are provided in accordance with Schedule 3B.5 (if applicable)

CRC Pharmacy Services means community residential care pharmacy services, which are provided in accordance with Schedule 3B.2 (if applicable)

Crown Direction means a direction given by the Crown or a Minister under section 103 of the Crown Entities Act 2004 or otherwise to Te Whatu Ora

CSC means a community services card as defined in the Health Entitlement Card Regulations 1993

Data Specification means the Pharmaceutical Transaction Data Specification available at www.tas.health.co.nz (or any other website advised by Te Whatu Ora from time to time), as amended by Te Whatu Ora from time to time following engagement with provider representatives

Default Interest means the interest to be paid on late payments in accordance with clauses D.44 to D.48

Dentist means a person registered as a dentist with the Dental Council under the HPCA Act who holds a current annual practising certificate

Dispensing means the process of a Pharmacist providing a Pharmaceutical to or for a Service User in accordance with Schedule 1

Dispensing Services means services provided in relation to the Dispensing of Pharmaceuticals, which are provided in accordance with Schedule 1

Due Date means the fourth Business Day following the Claim Period to which the claim relates

Eligible Person means a person who is eligible to receive publicly funded health services as specified in the Eligibility Direction

Eligibility Direction means a direction issued by the Minister that is continued under clause 30 of Schedule 1 of the Pae Ora (Healthy Futures) Act 2022, or specified in regulations made under section 102 of the Pae Ora (Healthy Futures) Act 2022

End Date means the date on which this Agreement ends, as set out in clause A.4

Extemporaneously Compounded Preparation means an extemporaneously compounded preparation that is not available as a proprietary product and is therefore required to be compounded by the Provider as described in the Pharmaceutical Schedule, and which contains two or more Subsidised Pharmaceuticals, and does not include the reconstitution of antibiotic liquids

Extemporaneously Compounded Preparations Services are services relating to provision of an Extemporaneously Compounded Preparation, which are described in Schedule 1

Final Due Date means the date specified in clause D.26 by when a claim must be received by Te Whatu Ora – Health New Zealand

First Claim Period means the period described in clause D.15(1)(a)

Fourth Claim Period means the period described in clause D.15(1)(d)

Geographical Area means the geographical area for which the former District Health Board that was originally a party to this Agreement was responsible, as set out in Schedule 1 of the NZPHD Act

GST means the tax imposed under the Goods and Services Tax Act 1985

Handling Fee means the handling fee that serves as a marker of Dispensing activity set out in the relevant Service Schedule

Handling Fee Multiplier means the handling fee multiplier for a Pharmaceutical set out in the relevant Service Schedule

Health and Disability Commissioner means the Commissioner appointed under the Health and Disability Commissioner Act 1994

Health Information has the meaning set out in the Health Information Privacy Code

Health Information Privacy Code means the code relating to privacy of Health Information issued under section 46 of the Privacy Act 2020

He Korowai Oranga means the Māori Health Strategy published by Te Whatu Ora as amended or replaced from time to time

HPCA Act means the Health Practitioners Competence Assurance Act 2003

HPI Number means health practitioner index number

HUHC means a high use health card, as defined in the Health Entitlement Card Regulations 1993

Immunisation Services means influenza immunisation services that are provided in accordance with Schedule 3A.5 (if applicable)

Initial Item means a Pharmaceutical that is an item with a prescription ID suffix /0 (without repeats) or the first item in an intended sequence of items with a prescription ID suffix /1 (repeats available)

Item means an Initial Item or a Repeat Item

Locally Commissioned Services has the meaning set out in clause A.3(2)(c)

LTC Services means long term condition pharmacy services, which are provided in accordance with Schedule 3B.1 (if applicable)

Medical Practitioner means a person registered as a medical practitioner with the Medical Council of New Zealand under the HPCA Act who holds a current annual practising certificate

Medicines Act means the Medicines Act 1981

Medicines Regulations means the Medicines Regulations 1984

Medsafe means the New Zealand Medicines and Medical Devices Safety Authority or its successor

Midwife means a person registered as a midwife with the Midwifery Council under the HPCA Act who holds a current annual practising certificate

Minister means the Minister of Health

Monitored Therapy Medicine means a Pharmaceutical on the list of monitored therapy medicine Pharmaceuticals maintained by or on behalf of Te Whatu Ora – Health New Zealand

National Annual Agreement Review means the review described in clause B.23

Nationally-consistent means all provisions in Parts A to E, Schedule 1, Schedule 2, and all Service Schedules in Schedule 3A of this Agreement

Negative A3 or J3 Transaction means a sequence of individual transactions, being the Dispensing of an Initial Item plus Repeat Items (if any) (a "Transaction Sequence") if:

- (a) the Provider is permitted to charge a Co-payment in accordance with clause D.5(2); and
- (b) the value of the Transaction Sequence would be nil or a negative amount if the Handling Fee multiplied by the Handling Fee Multiplier for each individual transaction in the Transaction Sequence was at least \$5.44

NHI Number means a National Health Index number

NPPA or named patient pharmaceutical assessment has the same meaning as set out in the Pharmaceutical Schedule

NPPA Policy has the same meaning as set out in the Pharmaceutical Schedule

NPPA Services A is the Dispensing of a Pharmaceutical that is listed on the Pharmaceutical Schedule to or for a Service User whose application is approved under the NPPA Policy

NPPA Services B is the Dispensing of a Pharmaceutical that is not listed on the Pharmaceutical Schedule to or for a Service User whose application is approved under the NPPA Policy

NZPHD Act means the New Zealand Public Health and Disability Act 2000

Opioid Substitution Treatment Services means services for opioid dependence, which are provided in accordance with Schedule 3A.1 (if applicable)

Owed Pharmaceutical means part of a Pharmaceutical that the Provider Dispenses to or for a Service User in a second (or subsequent) transaction, because the Provider was unable to Dispense the full quantity of the Pharmaceutical, as prescribed, in the initial transaction

Payment Agent means the agent engaged by Te Whatu Ora to pay providers on Te Whatu Ora's behalf, and unless otherwise advised by Te Whatu Ora is Sector Operations, a business unit of Te Whatu Ora

Payment Date means any one of the four payment dates in a calendar month as described in clause D.15

Permitted Pharmacy Charges Rules means the publication entitled Permitted Pharmacy Charges Rules as amended by Te Whatu Ora from time to time

Per Pack Fee means an amount paid by Te Whatu Ora as an additional margin payment towards the procurement and stockholding costs for a subsidised pack of a Pharmaceutical as listed in the Pharmaceutical Schedule, being:

- (a) \$0.27; except that
- (b) if less than a full pack of the relevant Pharmaceutical as listed in the Pharmaceutical Schedule is Dispensed, the Per Pack Fee will be paid on a pro-rated basis

PHARMAC means the Pharmaceutical Management Agency

Pharmaceutical means a medicine, therapeutic medical device, or related product or thing

Pharmaceutical Schedule means the pharmaceutical schedule published by PHARMAC, and available on PHARMAC's website at <https://www.pharmac.govt.nz/Schedule> (or any other website advised by PHARMAC or Te Whatu Ora from time to time)

Pharmaceutical Schedule Pack Subsidy means the subsidy specified in the Pharmaceutical Schedule at which a pack of the relevant Pharmaceutical is subsidised (excluding GST)

Pharmacist means a person registered as a pharmacist with the Pharmacy Council who holds a current annual practising certificate under the HPCA Act

Pharmacy Charges has the meaning given to it in clause D.7

Pharmacy Council means the Pharmacy Council established as a Responsible Authority

Pharmacy Services Standards means Health and Disability Services Standards – Pharmacy Services Standard NZS 8134.7:2010, as amended or replaced from time to time

PHO means a primary health organisation

Population Service means any Service described in Schedule 3 (if applicable)

Practitioner means a Medical Practitioner, a Dentist, a Midwife, or a designated Prescriber (as that term is defined in the Medicines Act), who holds a current annual practising certificate, or any other health professional who is legally permitted to prescribe Pharmaceuticals to Eligible People

Practitioner's Supply Order has the same meaning given to it in the Pharmaceutical Schedule

Premises means the location from where the Provider provides the Services or where anything relating to the Services occurs or is kept, including the location of the Records

Prescription Form means a prescription form, medicines order (including a Bulk Supply Order or Practitioner's Supply Order), Quitcard, or other request, which is prepared by a Practitioner in accordance with all applicable legislation

Prescriber means a Practitioner who is authorised under all applicable legislation to prescribe Pharmaceuticals to Eligible People

Procedures Manual means the publication entitled Pharmacy Procedures Manual available at www.tas.health.nz (or any other website advised by Te Whatu Ora from time to time), as amended by Te Whatu Ora from time to time following engagement with provider representatives

Product Premium has the meaning given to it in clause D.6

Professional Advisory Services means advisory services provided in relation to the Dispensing of Pharmaceuticals, which are provided in accordance with Schedule 1

Provider means you, being a person or a company licensed to operate a pharmacy under the Medicines Act

Provider Reference Number means the Provider's unique identification number printed on the cover of this Agreement

PSC means a pharmaceutical subsidy card as defined in the Health Entitlement Card Regulations 1993

Quality Improvement Plan means the plan developed in accordance with clause B.41

Quarter means the quarter in a year beginning on 1 October, 1 January, 1 April, or 1 July

Records means all records and information held by the Provider or its Staff, or on the Provider's behalf, in whatever form, including written and electronic forms, which are relevant to the provision of the Services, including Service User records and financial accounts

Repeat Item means a Pharmaceutical that is the second or subsequent item Dispensed in an intended sequence of Pharmaceuticals to be Dispensed, which has a prescription ID suffix that is /2 or greater

Responsible Authority means a body appointed as an authority under section 114 of the HPCA Act, and includes the Pharmacy Council and the Health and Disability Commissioner

Schedule 3 means Schedule 3A, Schedule 3B, and Schedule 3C

Second Claim Period means the period described in clause D.15(1)(b)

Section 94 Notice means a notice that was made, or deemed to have been made, under section 94 of the Pae Ora (Healthy Futures) Act 2022

Service User means an Eligible Person who uses any Services under this Agreement and includes, if applicable, the Service User's caregiver or representative

Service Schedule means a schedule to this Agreement

Services means the services provided by the Provider under this Agreement, and includes the Dispensing of Pharmaceuticals and the provision of Professional Advisory Services

Smoking Cessation Services means smoking cessation services, which are provided in accordance with Schedule 3B.6 (if applicable)

Special Food means a special food listed in the Pharmaceutical Schedule

Special Foods Services means special foods services, which are provided in accordance with Schedule 3B.4 (if applicable)

Specialist has the same meaning given to it in of the Pharmaceutical Schedule

Specific Brand means a Pharmaceutical that is identified by reference to the manufacturer's brand name for the Pharmaceutical and not by reference to the Pharmaceutical's generic active ingredient or ingredients

Staff includes the Provider's employees, sub-contractors, contractors, agents, and other personnel connected with the provision of Services

Start Date means the date the Agreement commences, as set out in clause A.4

Sterile Manufacturing Services means the sterile manufacturing services, which are provided in accordance with Schedule 3A.3 (if applicable)

Subsidised Pharmaceutical means a Pharmaceutical that is listed on the Pharmaceutical Schedule and a NPPA B Pharmaceutical

Te Whatu Ora –means Te Whatu Ora, Health New Zealand, a Crown entity established by the Pae Ora (Healthy Futures) Act 2022

Transaction Sequence has the meaning set out in the definition of "Negative A3 or J3 Transaction"

Third Claim Period means the period described in clause D.15(1)(c)

Uncontrollable Event means an event that is beyond the reasonable control of the party immediately affected by the event (including if Te Whatu Ora has failed to make a payment due because of an event beyond Te Whatu Ora's reasonable control), but does not include any risk or event that the party claiming could have prevented or overcome by taking reasonable care

Unregistered Medicine means a Pharmaceutical that is listed on the Pharmaceutical Schedule and Dispensed in accordance with section 26 or section 29 of the Medicines Act

Voluntary Variation means a variation to this Agreement described in clause C.25(1)(b)

Whānau Ora means that families, including Māori and Pacific families, are supported to achieve their maximum health and well-being.

E.2 Construction

- (1) **Headings:** Headings have been included in this Agreement for convenience only and are to be ignored when interpreting this Agreement.
- (2) **Part, clause, schedule, appendix:** A reference to a Part, a schedule or Service Schedule, or an appendix is a reference to a Part, a schedule or Service Schedule, or appendix to this Agreement.
- (3) **Variations:** A reference to this Agreement or another document includes any variation, novation, or replacement of it.
- (4) **Statutes:** A reference to a statute or other law includes regulations and other rules made under it, and consolidations, amendments, re-enactments, or replacements of any of them (whether before or after the date of this Agreement).
- (5) **Financial references:** References to, and expressions used in connection with, financial calculations, valuations, accounting, or financial reporting functions or their description in this Agreement have the meanings ascribed to like expressions or expressions of similar intent under generally accepted accounting practice.
- (6) **Singular includes plural:** The singular includes the plural and vice versa.
- (7) **Person includes groups:** The word person includes an individual, a body corporate, an association of persons (whether corporate or not), a trust, a state, and an agency of state, in each case, whether or not having a separate legal personality.
- (8) **Person includes successors:** A reference to a person includes a reference to the person's executors, administrators, successors, substitutes (including, but not limited to, persons taking by novation) and permitted assigns.
- (9) **Joint and several:** An agreement, representation, or warranty in favour of two or more persons is for the benefit of them jointly and severally, and an obligation of two or more persons binds them jointly and severally.
- (10) **Currency:** A reference to \$ or dollars is a reference to New Zealand dollars and all amounts payable under this Agreement are to be paid in that currency.
- (11) **Notice:** All periods of time for notice exclude the days on which they are given and include the days on which they expire.

- (12) **Business Day:** Anything required by this Agreement to be done on a particular day that is not a Business Day may be done on the next Business Day.
- (13) **Including without limitation:** Any reference to "including", "include", "includes", or "in particular" does not limit the generality of the relevant statement.

SCHEDULE 1

DISPENSING AND PROFESSIONAL ADVISORY SERVICES

The Services

1. Background and Service objectives

1.1 Te Whatu Ora wants to fund:

- (a) Dispensing Services to enable Eligible Persons to have appropriate access to Pharmaceuticals in a way that is responsive to the health needs and priorities of Service Users and communities: and
- (b) Professional Advisory Services to enable Eligible Persons to whom Pharmaceuticals are Dispensed to have appropriate access to clinical checks, professional advice, and counselling services that are responsive to the health needs and priorities of Service Users and communities.

1.2 This Schedule sets out the terms and conditions on which Te Whatu Ora will fund, and the Provider must provide, the Dispensing and Professional Advisory Services.

2. Dispensing Services

2.1 The Provider must, on receiving a Prescription Form in respect of a Service User, Dispense each Pharmaceutical in the form in accordance with this Schedule.

3. Dispensing Services requirements

3.1 When Dispensing a Pharmaceutical, the Provider must (either following or at the same time as carrying out the services described in clause 4.1(a) of this Schedule):

- (a) perform all checks necessary to ensure, in accordance with legal and professional requirements, that the Provider can prepare the Pharmaceutical in accordance with paragraph (b);
- (b) prepare the Pharmaceutical consistent with the Prescription Form, including (as relevant) by counting, pouring, packaging, and labelling the Pharmaceutical;
- (c) check and ensure that the prepared Pharmaceutical is consistent with the Prescription Form;
- (d) deliver the Pharmaceutical to the Service User or their representative; and
- (e) record the Dispensing in a manner that enables Te Whatu Ora to access Dispensing information using the Service User's NHI Number.

3.2 The Provider must comply with any rules about the Dispensing and substitution of Specific Brands, as set out in the Pharmaceutical Schedule, the Medicines Act, and any other relevant legislation or regulations.

3.3 When Dispensing a Pharmaceutical that is not registered in New Zealand, the Provider must comply with the requirements set out in sections 26 and 29 of the Medicines Act.

4. Professional Advisory Services requirements

4.1 The Provider must provide the following Professional Advisory Services:

- (a) in relation to any Pharmaceutical it Dispenses to or for a Service User in accordance with clause 3 of this Schedule, undertake a check in accordance with legal and professional requirements, including to ensure that:
 - (i) the Pharmaceutical specified in the Prescription Form is clinically appropriate for use by the Service User; and
 - (ii) the Prescription Form:
 - (1) meets all legal and professional requirements; and
 - (2) meets the criteria for payment set out in the Pharmaceutical Schedule; and
- (b) provide, in accordance with professional standards and any relevant guidelines, professional advice and counselling to the Service User, as and when is clinically appropriate, to ensure that the Service User has sufficient knowledge to enable optimal therapy.

5. Service User medication profile

5.1 The Provider must maintain, in relation to each Service User for whom a Pharmaceutical is Dispensed, a Service User medication profile that includes, to the best of the Provider's knowledge:

- (a) the Pharmaceuticals that the Service User is currently receiving; and
- (b) other relevant information, such as previous Pharmaceuticals taken, reactions to any Pharmaceuticals and other medicines that the Provider is aware the Service User is currently taking and which may influence the Service User's Pharmaceutical management at that time.

6. Reporting to Prescriber

6.1 The Provider must report any significant issues with the Prescription to the Prescriber, including any problems with the Prescription Form, or if the Provider has reasonable grounds

to suspect that a Service User may be abusing the prescribed Pharmaceutical or that it could be detrimental to the Service User's health.

7. Brand substitution

- 7.1 If a Service User is prescribed a Specific Brand, but the Provider determines that the Service User should be Dispensed a different brand of the Pharmaceutical, the Provider must inform the Service User of the brand substitution.

8. Needle exchange and disposal scheme

- 8.1 The Provider must make available to any person, on request or otherwise if it is appropriate for the Provider to do so, written information about:
- (a) the needle syringe exchange scheme, whether or not the Provider participates in this scheme, and a list of providers of the needle syringe exchange scheme in the Provider's local area; and
 - (b) the safe disposal of used syringes, needles, and other skin piercing devices, including a list of places where a person may take used syringes, needles, and other skin piercing devices for safe disposal.

9. Opioid Substitution Treatment Services on an ad hoc or intermittent basis

- 9.1 The Provider may choose to provide Opioid Substitution Treatment Services on an ad hoc or intermittent basis in response to a request from a Service User for such Services.
- 9.2 In providing those Services, the Provider must comply with the New Zealand Practice Guidelines for Opioid Substitution Treatment issued by Te Whatu Ora in relation to community pharmacy dispensing of methadone and buprenorphine+naloxone.
- 9.3 The Provider must not provide the Services to more than two Service Users in a Claim Period unless agreed in writing by Te Whatu Ora.
- 9.4 The Provider must notify Te Whatu Ora in writing if the Provider decides to stop providing Opioid Substitution Treatment Services on an ad hoc or intermittent basis as soon as practicable after making that decision.

10. Practitioner's Supply Orders and Bulk Supply Orders

- 10.1 The Provider must:
- (a) Dispense Pharmaceuticals, in accordance with a Practitioner's Supply Order, in a suitable manner for use by Prescribers; and
 - (b) Dispense Pharmaceuticals, in accordance with a Bulk Supply Order, in a suitable manner for use by private hospitals or approved institutions.

11. Opening hours

- 11.1 The Provider must provide Dispensing and Professional Advisory Services for a minimum of five days a week unless such period is affected by a public holiday.
- 11.2 The Provider must use its best endeavours to ensure a level of access to Dispensing and Professional Advisory Services that meets the reasonable needs of Service Users.
- 11.3 Te Whatu Ora may require the Provider to provide Dispensing and Professional Advisory Services outside of the ordinary business hours of 8:00am to 6:00pm on Monday to Friday (excluding public holidays in the Geographical Area), or for more than five days a week if necessary to ensure a level of access that meets the reasonable needs of Service Users.
- 11.4 If Te Whatu Ora requires the Provider to provide Dispensing and Professional Advisory Services outside of the ordinary business hours specified in clause 11.3, or for more than five days a week, Te Whatu Ora will agree to specific terms and conditions with the Provider relating to the provision of such Services.
- 11.5 The Provider will not be in breach of its obligations under this Agreement if its Premises are closed for short periods of a few hours in special circumstances on isolated occasions.
- 11.6 When a Provider's Premises are closed, the Provider must ensure that a notice is prominently displayed on the outer door or window of its Premises that specifies:
- (a) the period when its Premises are closed; and
 - (b) how Eligible People can obtain essential Pharmaceuticals during the period when its Premises are closed.
- 11.7 The Provider must notify Te Whatu Ora if the closure of its Premises will unreasonably inconvenience Service Users in the Provider's area.

12. Waiting times for Services

- 12.1 Except as specified in clause 12.2, after a Prescription Form has been presented by or on behalf of a Service User, the Provider must ensure that:
- (a) 90% of Service Users receive the relevant Pharmaceuticals within one hour if the Prescription Form is presented during a Business Day;
 - (b) 99% of Service Users receive the relevant Pharmaceuticals before the end of the next Business Day, if the Prescription Form is presented during a Business Day; and
 - (c) 100% of Service Users receive the relevant Pharmaceuticals within two Business Days, if the Prescription Form is presented during a Business Day.

- 12.2 If the Provider provides Opioid Substitution Treatment Services in accordance with clause 9, the Provider must comply with the following waiting times:
- (a) 95% of existing approved Service Users must be provided with the methadone or buprenorphine+naloxone dose within 15 minutes of arriving at the Provider's Premises, and 100% of existing approved Service Users must be provided with the dose within 30 minutes of arriving at the Provider's Premises; and
 - (b) 95% of newly approved Service Users must be provided with the methadone or buprenorphine+naloxone dose within 30 minutes of arriving at the Provider's Premises, and 100% of newly approved Service Users must be provided with the dose within two hours of arriving at the Provider's Premises, provided that all relevant documentation for the Service User is satisfactory.
- 12.3 The Provider must maintain, or be able to obtain, adequate stocks of all Pharmaceuticals necessary to meet the above waiting time requirements, and the Provider's failure to do so will not be an Uncontrollable Event.
- 12.4 Waiting times outside the requirements in clause 12.1 may be acceptable to Te Whatu Ora if the Provider and the Service User agree otherwise.
- 12.5 The waiting times requirements do not apply if a Pharmaceutical is not readily available in New Zealand at the time the Provider is asked to Dispense the Pharmaceutical.

13. Service linkages

- 13.1 The Provider must, if appropriate, have effective links with relevant services, including:
- (a) primary medical and nursing services, including local organisations;
 - (b) Māori primary and community care providers;
 - (c) Pacific primary and community care providers;
 - (d) child health services;
 - (e) mental health services;
 - (f) maternity services;
 - (g) dental services;
 - (h) private specialists;
 - (i) public health services; and
 - (j) Service User advocacy services, including Māori and Pacific Islands advocacy services.

Fees, payments, and claiming rules

14. Dispensing Services and Professional Advisory Services Fees

- 14.1 Subject to clauses 35 and 36, Te Whatu Ora will pay the Provider for providing Dispensing and Professional Advisory Services in accordance with clauses 3 to 6 of this Schedule.
- 14.2 This payment is made up of:
- (a) a Dispensing Transaction Fee calculated in accordance with clause 16, which includes the Handling Fee paid in respect of the Pharmaceutical; and
 - (b) a Case Mix Service Fee calculated in accordance with clauses 17 to 27.

Dispensing Transaction Fee

15. Additional claiming and payment rule for Dispensing Transaction Fee

- 15.1 The Provider must not Dispense, under this Schedule, Pharmaceuticals as part of the following Services:
- (a) Opioid Substitution Treatment, except in accordance with clause 9;
 - (b) Aseptic Services;
 - (c) Sterile Manufacturing Services;
 - (d) CPAMS Services;
 - (e) Clozapine Services;
 - (f) Smoking Cessation Services; or
 - (g) Influenza Immunisation Services.
- 15.2 Clause 15.1 does not prevent the Provider from Dispensing a Pharmaceutical as part of a Service described in clause 15.1 if that Service is included in a Service Schedule in Schedule 3.
- 15.3 The Provider must not claim, and Te Whatu Ora will not pay, for the Dispensing of a Pharmaceutical in accordance with this Schedule if the Provider is entitled to claim for the Dispensing of the Pharmaceutical in accordance with a Schedule 3 Service Schedule.

16. Dispensing Transaction Fee

- 16.1 Te Whatu Ora will pay the Provider a Dispensing Transaction Fee for each Pharmaceutical that the Provider Dispenses to or for a Service User in accordance with this Agreement.

16.2 The Dispensing Transaction Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the total fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:

(a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and

(b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

PF = the Per Pack Fee

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 1.00

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any)

Case Mix Service Fee

17. Case Mix Service Fee

17.1 Subject to clause 17.2, Te Whatu Ora will pay the Provider a Case Mix Service Fee in relation to:

(a) each Initial Item Dispensed to or for a Service User in a month, in accordance with clause 18; and

(b) each Repeat Item Dispensed to or for a Service User in a month, in accordance with clause 19.

17.2 Te Whatu Ora is not required to pay a Case Mix Service Fee in relation to the Dispensing of a Pharmaceutical:

(a) in accordance with a Practitioner's Supply Order or Bulk Supply Order;

- (b) as part of the provision of Class B Pharmaceutical Services, Extemporaneously Compounded Preparations Services, NPPA Services A, NPPA Services B, or any Population Service;
- (c) for Owed Pharmaceuticals; and
- (d) if the Pharmaceutical is not a Subsidised Pharmaceutical.

18. Case Mix Service Fee for Initial Items

18.1 The Case Mix Service Fee for each Initial Item Dispensed to or for a Service User in a month is calculated as follows:

$$R = \sum (((II \times C) \times IRVU) \times ISF) \times GST$$

where:

- R = the total fee (inclusive of GST) that Te Whatu Ora will pay the Provider in relation to each Initial Item Dispensed to or for a Service User in the month
- \sum = the sum of each combination of the number of Initial Items Dispensed to or for a Service User on a single day (II in this formula) in the month
- II = the number of Initial Items Dispensed to or for a Service User by the Provider on a single day in the month
- C = the number of times that the Provider Dispenses the number of Initial Items as set out above to or for an individual Service User on a single day in the month
- IRVU = the relative value unit that corresponds with the number of Initial Items Dispensed to or for the Service User on that day (excluding any Initial Items described in clause 17.2) as follows:
 - (a) 1.00 if one, two, or three Initial Items are Dispensed
 - (b) 1.02 if four Initial Items are Dispensed
 - (c) 1.03 if five Initial Items are Dispensed
 - (d) 1.04 if six or more Initial Items are Dispensed
- ISF = the initial base service fee, which is \$5.03 (GST exclusive)
- GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing).

- 18.2 If the Provider does not include the NHI Number in an Initial Item Claim Item, the IRVU for the purpose of the calculation in clause 18.1 will be 1.00.

19. Case Mix Service Fee for Repeat Items

- 19.1 The Case Mix Service Fee for each Repeat Item Dispensed to or for a Service User in a month is calculated as follows:

$$R = \sum((N \times RRVU) \times RSF) \times GST$$

where:

R = the total fee (inclusive of GST) that Te Whatu Ora will pay to the Provider in relation to each Repeat Item Dispensed to or for a Service User in the month

\sum = the sum of each combination of the number of Repeat Items with a different prescription ID suffix Dispensed to or for a Service User in the month

N = the number of times Repeat Items with the same prescription ID suffix are Dispensed by the Provider in the month

RRVU = the relative value unit that corresponds with the prescription ID suffix for the Repeat Item Dispensed to or for the Service User as follows:

(a) 1.00 if the Prescription ID suffix is 2 or 3

(b) 0.60 if the Prescription ID suffix is 4 to 12

(c) 0.40 if the Prescription ID suffix is 13 to 28

(d) 0.35 if the Prescription ID suffix is 29 or any higher number

RSF = the repeat base service fee, which is \$3.27 (GST exclusive)

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing).

20. Calculation and payment of Case Mix Service Fees

- 20.1 Te Whatu Ora will calculate and pay the Provider Case Mix Service Fees for Initial Items and Repeat Items Dispensed in a month in three stages as set out in clauses 21 to 23, being:

- (a) stage one, which is the calculation of the Advanced Case Mix Service Fee payable;
- (b) stage two, which is the calculation of the Interim Case Mix Service Fee payable; and
- (c) stage three, which is the calculation of the Final Case Mix Service Fee payable.

21. Stage one: Advanced Case Mix Service Fees

- 21.1 Subject to clause 26.3, on the first Business Day of each month Te Whatu Ora will pay the Provider an Advanced Case Mix Service Fee Payment for Items that the Provider is expected to Dispense in the month.
- 21.2 The Advanced Case Mix Service Fee will be calculated using the formula set out in clauses 18 and 19, on the basis of the number of Initial Items and Repeat Items that Te Whatu Ora estimates will be Dispensed to or for Service Users in the month.

22. Stage two: Interim Case Mix Service Fees

- 22.1 On the first Business Day of the third month after Te Whatu Ora paid the Provider an Advanced Case Mix Service Fee, Te Whatu Ora will recalculate the Case Mix Service Fee payable to the Provider for the month for which an Advanced Case Mix Service Fee was paid (the "Interim Case Mix Service Fee").
- 22.2 The Interim Case Mix Service Fee will be calculated using the formula set out in clauses 18 and 19, on the basis of the actual number of Initial Items and Repeat Items that were Dispensed to or for Service Users during the relevant month.
- 22.3 If the difference between the Interim Case Mix Service Fee and the Advanced Case Mix Service Fee for the month is:
- (a) a positive number, Te Whatu Ora will pay the difference to the Provider on the first Business Day of the month; or
 - (b) a negative number, Te Whatu Ora will deduct the difference from the payment made to the Provider on the first Business Day of the month.

23. Stage three: Final Case Mix Service Fees

- 23.1 After the end of each year ending 30 June, Te Whatu Ora will recalculate the Case Mix Service Fee payable to the Provider for each month of the year ending 30 September ("Final Case Mix Service Fee").
- 23.2 The Final Case Mix Service Fee will be calculated using the formula set out in clauses 18 and 19, on the basis of the actual number of Initial Items and Repeat Items that were Dispensed to or for Services Users during each month.
- 23.3 If the difference between the Final Case Mix Service Fee and the Interim Case Mix Service Fee is:
- (a) a positive number, Te Whatu Ora will pay that amount to the Provider as soon as reasonably practicable and by no later than the end of the year after the year to which the amount relates; or

- (b) a negative number, Te Whatu Ora will advise the Provider that the Provider owes that amount to Te Whatu Ora as soon as reasonably practicable and by no later than the end of the year after the year to which the amount relates, and will deduct the amount from the next payment paid to the Provider after advising the Provider of the amount owed.

24. Additional Case Mix Service Fee claim rule

- 24.1 If the Provider submits a Claim Item for Pharmaceuticals Dispensed in a month outside the time required by Te Whatu Ora to calculate the Provider's Interim Case Mix Service Fee Payment for the month, Te Whatu Ora will pay a Case Mix Service Fee for the Claim Item as part of the Final Case Mix Service Fee calculated in accordance with clause 23.
- 24.2 To avoid doubt, if the Provider does not submit a Claim Item for Dispensing within the time required by Te Whatu Ora to calculate the Provider's Actual Case Mix Service Fee Payment for the relevant Service Month, Te Whatu Ora will pay Case Mix Service Fees in accordance with clause 19.

25. Calculation and payment of Case Mix Service Fee if Agreement terminated

- 25.1 Te Whatu Ora and the Provider agree that the recalculations described in clauses 22 and 23 will occur, and those clauses will apply, even after this Agreement is terminated, except that if the amount recalculated is a negative number, that amount will be an overpayment for the purpose of clause D.42.

26. Data used for calculation of Case Mix Service Fee

- 26.1 Subject to clauses 26.2 and 26.3, Te Whatu Ora will, when estimating Initial Items and Repeat Items in accordance with clause 21.2, use data from the third calendar month before the relevant month, as adjusted using a Seasonal Adjuster.
- 26.2 If ownership of the Provider changes between the two months described in clause 26.1, Te Whatu Ora will use data relating to the previous owner.
- 26.3 If Te Whatu Ora does not have data from the months described in clause 26.1 because the Provider is a new Provider, Te Whatu Ora is not required to calculate or pay any Advanced Case Mix Service Fee Payments until it has that data.

27. Case Mix Service Fee and Negative A3 and J3 Transactions (including quarterly reviews)

- 27.1 For the purpose of this Schedule, and despite anything else in this Agreement, a Pharmaceutical that is Dispensed as part of a Negative A3 or J3 Transaction is not an Initial Item for which the Provider may claim or be paid a Case Mix Service Fee.
- 27.2 Te Whatu Ora will calculate Advanced Case Mix Service Fee payments, Interim Case Mix Service Fee payments, and Final Case Mix Service Fee payments owed to the Provider on the

assumption that the Dispensing of a Pharmaceutical is not part of a Negative A3 or J3 Transaction if:

- (a) the prescription ID suffix of the Pharmaceutical is /0 and the Dispensing Services Fee payable for the Dispensing of the Pharmaceutical is greater than zero; or
- (b) the prescription ID suffix of the Pharmaceutical is /1 or any higher number (indicating that the Pharmaceutical being Dispensed has Repeat Items available or is a Repeat Item).

27.3 Te Whatu Ora will, each Quarter, review the Case Mix Service Fees paid to the Provider in respect of each Pharmaceutical to determine whether any Pharmaceuticals that Te Whatu Ora assumed were Dispensed as part of a Negative A3 or J3 Transaction were in fact not Dispensed as part of a Negative A3 or J3 Transaction.

27.4 If Te Whatu Ora determines that a Pharmaceutical was assumed to have been Dispensed as part of a Negative A3 or J3 Transaction, but was not in fact Dispensed as part of a Negative A3 or J3 Transaction, Te Whatu Ora will pay the Provider a Case Mix Service Fee for the Dispensing of the Pharmaceutical on the first Business Day after the review is complete.

27.5 The Case Mix Service Fee for the Pharmaceutical referred to in clause 27.4 is calculated as follows:

$$R = (IRVU \times ISF) \times GST - RITV$$

where:

R = the Case Mix Service Fee in respect of each such Pharmaceutical (inclusive of GST) that Te Whatu Ora will pay the Provider

IRVU = the relative value unit assigned to the Dispensing, which is 1.01

ISF = the initial base service fee, which is \$5.03 (GST exclusive)

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

RITV = the GST inclusive amount of the Transaction Sequence, excluding the Case Mix Service Fee (which is treated as a positive amount)

27.6 To avoid doubt, the review will not affect any other payments that Te Whatu Ora has paid to the Provider, nor will it mean that the IRVU for Initial Items that were Dispensed at the same time as the Pharmaceuticals that were the subject of the review will be changed.

27.7 To avoid doubt, this clause (and any provisions required to give effect to this clause) will continue to apply after the End Date.

Other fees, payments, and claiming rules

28. Fee for Class B Pharmaceutical Services

28.1 Subject to clauses 35 and 36, Te Whatu Ora will pay the Provider a fee for each Class B Pharmaceutical that the Provider Dispenses to or for a Service User (including for the provision of Opioid Substitution Treatment Services in accordance with clause 9), and for which the Provider makes a claim, in accordance with this Agreement.

28.2 The fee is calculated in accordance with clause 16.2, except that:

HFM = the Handling Fee Multiplier for the Pharmaceutical is 6.89

28.3 The Provider may not claim, and Te Whatu Ora will not pay, for the Dispensing of a Pharmaceutical as part of the provision of Opioid Substitution Treatment Services under this clause, except if those services are provided in accordance with clause 9.

29. Fee for Practitioner's Supply Orders and Bulk Supply Orders

29.1 Te Whatu Ora will pay the Provider a fee for each Pharmaceutical that the Provider Dispenses for a Service User in accordance with a Practitioner's Supply Order or Bulk Supply Order, and for which the Provider makes a claim in accordance with this Agreement.

29.2 The fee is calculated in accordance with clause 16.2, except that:

HFM = the Handling Fee Multiplier for the Pharmaceutical is 5.30

30. Fee for NPPA Services A

30.1 Subject to clauses 35 and 36, Te Whatu Ora will pay the Provider a fee for each Pharmaceutical that is listed on the Pharmaceutical Schedule that the Provider Dispenses to or for a Service User whose application is approved under the NPPA Policy ("NPPA Services A").

30.2 The fee for NPPA Services A is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the total fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

- M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:
- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and
 - (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more, or if the Pharmaceutical is a Special Food
- PF = the Per Pack Fee
- HF = the Handling Fee for the Pharmaceutical, which is \$1.13
- HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 5.30 unless:
- (a) the Pharmaceutical is a Class B Pharmaceutical, in which case the Handling Fee Multiplier is 6.89
 - (b) the Provider was required to extemporaneously compound a mixture containing the Pharmaceutical, in which case the Handling Fee Multiplier is 7.95
- GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)
- CoP = the Co-payment that the Provider may charge the Service User (if any)

31. Fee for NPPA Services B

- 31.1 Subject to clauses 35 and 36, Te Whatu Ora will pay the Provider a fee for each Pharmaceutical that the Provider Dispenses to or for a Service User that is not listed on the Pharmaceutical Schedule and for which the Provider makes a claim in accordance with this Agreement, ("NPPA Services B") if:
- (a) the payment is permitted by the funding policy for NPPA Services that applied at the date of Dispensing; and
 - (b) the Pharmaceutical is Dispensed in accordance with a NPPA authority.

31.2 The fee is calculated as follows:

$$R = ((NPPAc + (HF \times HFM)) \times GST) - CoP$$

where:

R = the total fee that Te Whatu Ora will pay the Provider (if R is a positive number)

NPPAc = the GST exclusive price paid by the Provider for the minimum purchase order of the Pharmaceutical required to supply the Pharmaceutical on the date of Dispensing

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 7.95

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any)

31.3 Te Whatu Ora and the Provider may agree on an alternative claiming and payment arrangement for NPPA Services B.

32. Fee for Extemporaneously Compounded Preparations Services

32.1 Subject to clauses 35 and 36, Te Whatu Ora will pay the Provider a fee for each Extemporaneously Compounded Pharmaceutical that the Provider Dispenses to or for a Service User, and for which the Provider makes a claim, in accordance with this Agreement.

32.2 The fee is calculated as follows:

$$R = ((\Sigma Sc + (\Sigma (Sc \times M)) + \Sigma PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the total fee that Te Whatu Ora will pay the Provider (if R is a positive number)

ΣSc = the sum of the GST exclusive subsidies of each component Pharmaceutical listed on the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for each component Pharmaceutical, which is:

- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the component Pharmaceutical is less than \$150.00; and
- (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the component Pharmaceutical is \$150.00 or more

ΣPF = the sum of the Per Pack Fees for the Pharmaceuticals

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 7.95 unless:

- (a) the Provider was required to Dispense the Pharmaceutical as part of the provision of NPPA Services, in which case the Handling Fee Multiplier is 5.30
- (b) the Provider was required to extemporaneously compound a mixture containing a Class B Pharmaceutical, in which case the Handling Fee Multiplier is 6.89
- (c) the Provider was required to extemporaneously compound a mixture to provide Aseptic Services, in which case the Handling Fee Multiplier is 26.50

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any)

33. Additional payment for Dispensing Unregistered Medicines

33.1 Te Whatu Ora will pay the Provider an additional fee for each Unregistered Medicine that is a Subsidised Pharmaceutical that the Provider Dispenses to a Service User and for which the Provider makes a claim, in accordance with this Agreement, in addition to any other amount that Te Whatu Ora may be required to pay for the Dispensing of the Pharmaceutical under any Service Schedule.

33.2 Subject to clause 33.3, the additional payment is calculated as follows:

$$R = ((Sc \times M2) + AF + CF) \times GST$$

where:

R = the additional payment that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M2 = a top-up margin payment towards the procurement and stockholding costs for the Pharmaceutical, which is:

(a) 0.07 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and

(b) 0.06 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

AF = an additional margin payment of \$3.00 towards the additional administration costs of Dispensing an Unregistered Medicine

CF = an additional payment of \$5.30 towards the additional counselling costs of Dispensing an Unregistered Medicine

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing).

33.3 Te Whatu Ora and the Provider agree that:

- (a) the Provider will be paid only one additional margin payment (referred to as "AF" in clause 33.2), and one additional counselling payment (referred to as "CF" in clause 33.2) per Service User per Pharmaceutical per calendar month in which the Pharmaceutical is Dispensed to or for a Service User; and
- (b) if more than one Unregistered Medicine is extemporaneously compounded, Te Whatu Ora will pay the Provider in accordance with clause 33.2 in respect of each Unregistered Medicine.

33.4 Te Whatu Ora will:

- (a) calculate the additional fee that is payable to the Provider under this clause for each Unregistered Medicine it Dispenses in a Quarter; and
- (b) pay the Provider the fee no later than two months after the last day of the Quarter.

34. Brand-switch Fee

34.1 Te Whatu Ora will pay the Provider a Brand-switch Fee for the provision of brand switch advice in respect of a Pharmaceutical if:

- (a) the Pharmaceutical Schedule provides for the payment of a Brand-switch Fee in respect of the Pharmaceutical; and
- (b) the Provider claims the Brand-switch Fee in accordance with this Agreement.

35. Payments for Owed Pharmaceuticals

35.1 If the Provider claims for Dispensing an Owed Pharmaceutical in accordance with this Schedule, Te Whatu Ora will pay the Provider the applicable payment except that:

HF = the Handling Fee for the Owed Pharmaceutical is 0

36. Recovery of amounts by Te Whatu Ora (except for Negative A3 or J3 Transactions)

36.1 Subject to clause 36.2, if, in any of the formula set out in this Schedule, "R" is a negative number:

- (a) that number will be treated as a positive amount; and
- (b) Te Whatu Ora will be entitled to recover that amount from the Provider (including by way of set-off).

36.2 Te Whatu Ora will not recover (nor be entitled to recover) the amount "R" if the Dispensing of the Pharmaceutical is a Negative A3 or J3 Transaction.

Definitions

37. Definitions that apply to this Schedule

37.1 In this Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

Advanced Case Mix Service Fee Payment means a payment made to the Provider at the beginning of each month in accordance with clause 21

Interim Case Mix Service Fee Payment means a payment that may be paid to the Provider in accordance with clause 22

Seasonal Adjuster means an adjuster to the base month data to reflect expected national Dispensing activity changes in a certain period of time due to seasonal factors, the number of Business Days in the relevant month, or the time of the year.

SCHEDULE 2

ADDITIONAL PROFESSIONAL ADVISORY SERVICES

1. Background

- 1.1 Te Whatu Ora wants to implement the Pharmacy Action Plan to enable the community pharmacy workforce to deliver maximum value to the health system and contribute to the objectives of the New Zealand Health Strategy reflected in the Strategy's five themes.
- 1.2 Te Whatu Ora acknowledges that, in addition to the Professional Advisory Services that the Provider provides in relation to the Dispensing of a Pharmaceutical under Schedule 1, the Provider also provides other professional advisory services to Service Users. That reflects that Pharmacists are accessible to many Service Users and are medicines experts, and so are able to provide health promotion and prevention services for individuals and their populations that (among other things):
- (a) improve Service Users' understanding of medicines to help ensure that medicines are used safely and effectively;
 - (b) help achieve the best medicines outcomes for Service Users; and
 - (c) contribute to public health programmes.
- 1.3 Accordingly, Te Whatu Ora wants to provide additional funding to the Provider to recognise the provision of all professional advisory services that are provided to Service Users.

2. Payment of Additional Professional Advisory Services Payment

- 2.1 Subject to clauses 3 and 4, Te Whatu Ora will pay the Provider an Additional Professional Advisory Services Payment each Quarter, in three equal monthly instalments.
- 2.2 Te Whatu Ora will pay each instalment on the 14th day of each month.

3. Calculation of Additional Professional Advisory Services Payment

- 3.1 Before the first monthly instalment for a Quarter is due to be paid, Te Whatu Ora will calculate the Additional Professional Advisory Services Payment to be paid to the Provider for the Quarter in accordance with clause 3.2.

- 3.2 Subject to clause 3.3, the Additional Professional Advisory Services Payment that Te Whatu Ora will pay to the Provider for a Quarter will be calculated as follows:

AP =

$$\left(\frac{PI \times W1}{\sum (PI \times W1)} \times 0.70 \times PP \right) + \left(\frac{PUV \times W2}{\sum (PUV \times W2)} \times 0.30 \times PP \right)$$

where:

AP = the Additional Professional Advisory services Payment paid to the Provider for a Quarter

PI = the total number of Items Dispensed to or for all Service Users by the Provider in the Reference Quarter, for which there was an Accepted Claim

W1 = a weighting applied to the PI being:

- (a) in relation to a Service User whose NHI number is recorded on an Accepted Claim made by the Provider for the Dispensing, the total number of Items Dispensed to or for the Service User recorded on those claims, multiplied by the following:
 - (i) 1.8 for Māori or Pacific Island Service Users with a CSC or HUHC;
 - (ii) 1.4 for Māori or Pacific Island Service Users without a CSC or HUHC;
 - (iii) 1.4 for non-Māori or Pacific Island Service Users with a CSC or HUHC;
 - (iv) 1.0 for all other Service Users
- (b) in relation to a Service User for whom no NHI number is recorded on an Accepted Claim made by the Provider for the Dispensing, the total number of Items Dispensed to or for the Service User recorded on those claims is multiplied by 1.0

$\sum (PI \times W1)$ = the total weighted number of Items Dispensed to or for a Service User by all providers in the Reference Quarter, for which there was an Accepted Claim

PUV = the total number of Unique Visits of all Services Users who presented to the Provider, for which there was an Accepted Claim

- W2 = a weighting applied to the PUV, being the Unique Visits of each Service User whose NHI number is recorded on a claim made by the Provider, multiplied by the following:
- (a) 1.8 for Māori or Pacific Island Service Users with a CSC or HUHC;
 - (b) 1.4 for Māori or Pacific Island Service Users without a CSC or HUHC;
 - (c) 1.4 for non- Māori or Pacific Island Service Users with a CSC or HUHC;
 - (d) 1.0 for all other Service Users
- $\Sigma(\text{PUV} \times \text{W2})$ = the total weighted number of Unique Visits of all Service Users who presented to all providers, for which there was an Accepted Claim
- PP = the Payment Pool for the Quarter, which is \$12,150,000

- 3.3 If this Agreement terminates on or before the payment date in a month, or the Provider stops providing Services on or before that payment date, Te Whatu Ora will not pay an Additional Professional Advisory Services Payment to the Provider for that (or any subsequent) month.

4. Commencement

- 4.1 Te Whatu Ora and the Provider agree that this Schedule will apply from 1 July 2023.

5. Not Used

6. Definitions that apply to this Schedule

- 6.1 In this Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

Accepted Claim means a claim that is submitted, and not rejected, before the Claim Date

Claim Date means, in relation to a Quarter, the day that is 30 days after the end of the Reference Quarter

Reference Quarter means, in relation to a Quarter for which an Additional Professional Advisory Services Payment is paid, the Quarter before the immediately preceding Quarter

Unique Visits means, in relation to a Service User whose NHI number is recorded on a claim made by a provider, the number of months in the Quarter (being either 1, 2, or 3 months) in which the Service User presented to the provider

SCHEDULE 3A.1

OPIOID SUBSTITUTION TREATMENT SERVICES

The Services

1. Background and service objectives

- 1.1 Te Whatu Ora wishes to fund Opioid Substitution Treatment Services that provide appropriate access to comprehensive, integrated, and continuing alcohol and drug services guided by harm reduction philosophies.
- 1.2 This Schedule applies only to services associated with methadone or buprenorphine+naloxone prescribed for the treatment of opioid dependence, and does not cover services associated with the use of methadone or buprenorphine+naloxone for other indications, such as pain.
- 1.3 The philosophy guiding Opioid Substitution Treatment Services recognises that abstinence may be a long-term goal for most Service Users, but that it is legitimate for providers to work with Service Users who wish, without an abstinence goal, to make an established pattern of injecting, or other drug use, safer.

2. Eligible Service Users

- 2.1 Eligible Service Users are Service Users who are referred to the Provider:
 - (a) by an opioid substitution treatment service; or
 - (b) by Prescribers authorised under the Misuse of Drugs Act 1975 to offer methadone or buprenorphine+naloxone for the treatment of opioid dependence.

3. Access

- 3.1 The Provider must provide Opioid Substitution Treatment Services for a minimum of five days a week, unless such period is affected by a public holiday.
- 3.2 The Provider must have written policies in place to demonstrate how Opioid Substitution Treatment Services will be provided to Service Users that require "consume on premises" doses when the Provider's Premises is closed.
- 3.3 The Provider must ensure that Service Users have access to Opioid Substitution Treatment Services over weekends and public holidays if clinically required.

4. Service components

- 4.1 The Provider must provide Opioid Substitution Treatment Services in accordance with the following requirements:
- (a) the relevant clauses in Schedule 1, in particular clause 9 of Schedule 1;
 - (b) the protocol issued by Te Whatu Ora concerning community dispensing of methadone or buprenorphine+naloxone; and
 - (c) any written agreements the Provider may develop with Service Users receiving Opioid Substitution Treatment Services from the Provider in accordance with the Opioid Substitution Treatment New Zealand Practice Guidelines.
- 4.2 The services the Provider must provide, as part of providing Opioid Substitution Treatment Services, include:
- (a) providing methadone or buprenorphine+naloxone pursuant to Prescription Forms issued by an opioid substitution treatment service, or by authorised Prescribers;
 - (b) supervising the daily consumption of "consume on premises" methadone or buprenorphine+naloxone doses when the Provider's Premises is open;
 - (c) arranging for the collection of "takeaway doses" for the days when the Provider's Premises is closed, if these have been specifically requested by the Prescriber;
 - (d) ensuring that all methadone or buprenorphine+naloxone Dispensed by the Provider as "takeaway doses" is Dispensed in secure containers and packaging and in accordance with the Provider's written policy;
 - (e) advising and assisting Service Users and Prescribers to enhance compliance with all concurrent prescribed medicines; and
 - (f) developing and implementing a written protocol that sets out how the Provider will liaise with an opioid substitution treatment service and prescribing general practitioners on a regular basis, in a manner appropriate to the needs of the Provider's Service Users, including statements about communications regarding verification of doses, side-effects, complaints about Service Users, and any difficulties arising as a result.

5. Number of Service Users for Opioid Substitution Treatment Services

- 5.1 Subject to clause 5.2, the Provider may provide Opioid Substitution Treatment Services to any number of Service Users on a regular basis, provided that it is able to comply with the processes and safety requirements set out in clause 4, and the other requirements set out in this Agreement in respect of all Service Users.

- 5.2 Te Whatu Ora and the Provider may agree on a maximum number of Service Users who may regularly access Opioid Substitution Treatment Services from the Provider.

6. Withdrawing from Opioid Substitution Treatment Services

- 6.1 If the Provider terminates this Schedule in accordance with clauses C.31 to C.37, Te Whatu Ora may agree to waive the notice period and allow the Provider to immediately stop providing Opioid Substitution Treatment Services, if Te Whatu Ora is satisfied that the Provider has made reasonable endeavours to arrange an alternative provider of Opioid Substitution Treatment Services in the Provider's area, to maintain continuous Opioid Substitution Treatment Services.
- 6.2 The Provider must notify the Opioid Substitution Treatment Service, and Prescribers authorised under the Misuse of Drugs Act 1975 to offer methadone or buprenorphine+naloxone for the treatment of dependence in the Provider's area, of:
- (a) the Provider's intention to stop providing the Service;
 - (b) the date from which the Provider will no longer be providing the Service; and
 - (c) the alternative arrangements that the Provider has made for the continued provision of the Service.

7. Waiting times for Opioid Substitution Treatment Services

- 7.1 Waiting times for Opioid Substitution Treatment Services must not exceed the following waiting times:
- (a) 95% of existing approved Service Users must be provided with the methadone or buprenorphine+naloxone dose within 15 minutes of arriving at the Provider's Premises, and 100% of existing approved Service Users must be provided with the dose within 30 minutes of arriving at the Provider's Premises; and
 - (b) 95% of newly approved Service Users must be provided with the methadone or buprenorphine+naloxone dose within 30 minutes of arriving at the Provider's Premises, and 100% of newly approved Service Users must be provided with the dose within two hours of arriving at the Provider's Premises, provided that all relevant documents are satisfactory.

8. Facilities and settings

- 8.1 The Provider must provide Opioid Substitution Treatment Services in a private and confidential manner, and in a way that minimises the concerns of other Service Users.

9. Service linkages

9.1 The Provider must have effective links with:

- (a) the service providers and organisations specified in clause 13 of Schedule 1; and
- (b) local alcohol and drug treatment service providers.

Co-dispensing

10. Pharmaceuticals co-dispensed when providing Opioid Substitution Treatment Services

10.1 Te Whatu Ora – Health New Zealand:

- (a) recognises that sometimes a Prescriber may consider it to be clinically necessary for a Service User receiving Opioid Substitution Treatment Services to be Dispensed one or more Co-dispensed Pharmaceuticals; and
- (b) wishes to provide additional funding to the Provider to provide an additional level of service to those Service Users that is not reflected in the Service Fees for providing Services to that Service User when Dispensing Co-dispensed Pharmaceuticals.

10.2 If the Provider provides Opioid Substitution Treatment Services to or for a Service User that receives a Co-dispensed Pharmaceutical, the Provider may register that Service User as being eligible to receive Co-dispensed Opioid Services by providing the following information to the Payment Agent:

- (a) confirmation that the Service User is eligible to receive Co-dispensed Opioid Services and is entitled to be included on the national register (for convenience, the process for registering a Service User to receive Co-dispensed Opioid Services will be similar to the process used when registering a Service User to receive CRC Pharmacy Services); and
- (b) the name of the Service User, the start date from when the Service User started receiving Co-dispensed Opioid Services, and the NHI Number of the Service User.

10.3 The Provider may only claim for providing Co-dispensed Opioid Services to or for a Service User who has been registered as being eligible to receive Co-dispensed Opioid Services as required under clause 10.2, and who has not been subsequently removed from the national register.

10.4 The Provider must inform the Payment Agent as soon as the Provider becomes aware that the Service User is no longer receiving any Co-dispensed Pharmaceuticals and so should be removed from the national register.

- 10.5 Te Whatu Ora may also require, at its absolute discretion, that a Service User be removed from the national register, and the Provider may not claim for providing Co-dispensed Opioid Services to the Service User, if Te Whatu Ora considers that the Service User does not receive or is not Prescribed Co-dispensed Pharmaceuticals, or if the Provider has acted contrary to clause D.22 in respect of any claim that relates, in any way, to Co-dispensed Opioid Services.
- 10.6 The Provider must not:
- (a) register a Service User to receive LTC Services if the Provider has registered the Service User as being eligible to receive Co-dispensed Opioid Services; or
 - (b) register a Service User to receive Co-dispensed Opioid Services if that Service User is also registered with the Provider to receive LTC Services.

Fees, payments, and claiming rules

11. Additional claiming and payment rules for Opioid Substitution Treatment Services

- 11.1 If the Provider provides Co-dispensed Opioid Services to or for a Service User, the Provider must claim, and will be paid, in respect of each Co-dispensed Pharmaceutical Dispensed to or for the Service User as follows:
- (a) for Class B Pharmaceuticals, NPPA Services A, NPPA Services B, and Extemporaneously Compounded Preparation Services, in accordance with the relevant provisions in Schedule 1;
 - (b) for Aseptic Services, in accordance with Schedule 3A.2 (if applicable);
 - (c) for Clozapine Services, in accordance with Schedule 3A.4 (if applicable); and
 - (d) for Special Foods Services, in accordance with Schedule 3B.4 (if applicable).
- 11.2 Subject to clause 11.1, if the Provider makes a claim under this Schedule in relation to the Dispensing of a Pharmaceutical to or for a Service User, the Provider must not claim, and Te Whatu Ora will not pay:
- (a) a Dispensing Transaction Fee or Case Mix Service Fee under Schedule 1; or
 - (b) for the provision of any other Population Service under a Service Schedule in Schedule 3.
- 11.3 Despite anything else in this Agreement, any Pharmaceutical Dispensed as part of the provision of a Population Service will not be a Co-dispensed Pharmaceutical and the Provider must claim for the Dispensing of the Pharmaceutical under the relevant Service Schedule. If a Pharmaceutical Dispensed when providing Opioid Substitution Treatment Services is an

Extemporaneously Compounded Preparation, the Provider must claim for the Dispensing of the Pharmaceutical under this Schedule (rather than Schedule 1).

- 11.4 If the Provider Dispenses an Unregistered Medicine in accordance with this Schedule, Te Whatu Ora will pay the Provider an additional payment for Dispensing the Unregistered Medicine in accordance with clause 33 of Schedule 1.

12. Opioid Substitution Treatment Service Fee

- 12.1 Te Whatu Ora will pay the Provider an Opioid Substitution Treatment Service Fee for each Pharmaceutical that the Provider Dispenses to or for a Service User in accordance with this Agreement.

- 12.2 The Opioid Substitution Treatment Service Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the Opioid Substitution Treatment Service Fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:

- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and
- (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

PF = the Per Pack Fee

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 6.89

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any)

- 12.3 Subject to clause 12.4, if "R" is a negative number:

- (a) that number will be treated as a positive amount; and

- (b) Te Whatu Ora will be entitled to recover that amount from the Provider (including by way of set-off).

12.4 Te Whatu Ora will not recover (nor be entitled to recover) the amount "R" if the Dispensing of the Pharmaceutical is a Negative A3 or J3 Transaction.

13. Opioid Substitution Treatment Service Fee for Co-dispensed Opioid Services

13.1 If the Provider provides Co-dispensed Opioid Services, the Opioid Substitution Treatment Service Fee that Te Whatu Ora will pay to the Provider is calculated in accordance with clause 12, except that:

HFM = the Handling Fee Multiplier for the Pharmaceutical is 5.30

Definitions

14. Definitions that apply to this Schedule

14.1 In this Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

Co-dispensed Opioid Services means the supervision and monitoring services provided in addition to any services that would be provided to or for a Service User who is receiving Dispensing Services and Professional Advisory Services, when the Provider is Dispensing a Co-dispensed Pharmaceutical to or for a Service User

Co-dispensed Pharmaceutical means:

- (a) a Pharmaceutical not connected with the treatment of opioid dependence that a Prescriber (other than a Prescriber contracted by the Provider) clinically requires the Provider to Dispense to or for a Service User who is receiving Opioid Substitution Treatment Services (if either methadone or buprenorphine+naloxone is being Dispensed), on the same frequency as a Pharmaceutical that is being Dispensed in connection with the treatment of opioid dependence (provided that the Pharmaceutical is Dispensed at least weekly), and is Dispensed to a Service User at the same time as that Service User receives Opioid Substitution Treatment Services in order to ensure overall adherence to a medication regime (as evidenced by a relevant Prescription Form); and
- (b) if the Provider is Dispensing at least one Pharmaceutical described in paragraph (a) to a Service User, any other Pharmaceutical that the Provider Dispenses to the Service User.

SCHEDULE 3A.2

ASEPTIC SERVICES

The Services

1. Background and service objectives

- 1.1 Te Whatu Ora wishes to fund Aseptic Services to as part of an integrated community health service to:
- (a) enable Service Users to have appropriate access to services for which the preparation of an aseptic preparation, including a syringe driver for approved pumps, is required;
 - (b) enhance palliative care provided to terminally ill and other Eligible Service Users;
 - (c) provide Service Users with the best quality and most cost-effective services, within available funding, based on established professional and quality management standards and codes of practice;
 - (d) provide specialist advice as required to ensure optimal Service User management; and
 - (e) ensure Service User and Staff safety.

2. Eligible Service Users

- 2.1 Eligible Service Users are Service Users who:
- (a) choose to access Aseptic Services from the Provider; and
 - (b) are prescribed one or more Pharmaceuticals requiring aseptic manufacture, including syringes for use in a syringe driver if the syringe driver is for use in the Service User's home, a private hospital, or an institution.

3. Access

- 3.1 The Provider must provide Aseptic Services for a minimum of five days a week during usual business hours unless such period is affected by a public holiday.
- 3.2 The Provider must use its best endeavours to ensure a level of access to Aseptic Services that meets the reasonable needs of the Provider's Eligible Service Users, which may include 24-hour access to Syringe Driver Services.

4. Service components

- 4.1 Any preparation that is required to be manufactured under aseptic conditions must be prepared in accordance with this Schedule.
- 4.2 The services the Provider must provide as part of providing Aseptic Services include:
- (a) Dispensing Pharmaceuticals and providing Professional Advisory Services in accordance with clauses 3 to 6 of Schedule 1; and
 - (b) preparing aseptic preparations in accordance with the Pharmacy Services Standards, including by compounding such preparations in accordance with established and validated procedures and methods of preparation.

5. Facilities and settings

- 5.1 The Provider must prepare syringes and preparations requiring aseptic manufacturing conditions in accordance with the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods or any other standards or guidelines specified by Medsafe, as amended from time to time.

6. Waiting times for Services

- 6.1 The Provider must Dispense:
- (a) 99% of Pharmaceuticals (including syringe drivers) within 24 hours, if the relevant Prescription Form is presented during a Business Day; and
 - (b) 100% of Pharmaceuticals (including syringe drivers) within two Business Days, if the relevant Prescription Form is presented during a Business Day.
- 6.2 The Provider must maintain adequate stocks of all Pharmaceuticals to meet the waiting times in clause 6.1.
- 6.3 Waiting times outside these requirements may be acceptable to Te Whatu Ora if there is mutual agreement reached between the Provider and the Service User.
- 6.4 The waiting times in clause 6.1 do not apply if the Pharmaceutical is not available in New Zealand at the time that the Provider is presented with the Prescription Form.

7. Service linkages

- 7.1 The Provider must have effective links with:
- (a) the service providers and organisations specified in clause 13 of Schedule 1;
 - (b) palliative care providers;

- (c) pain management services; and
- (d) other services requiring the manufacture of aseptic preparations.

Fees, payments, and claiming rules

8. Additional claiming and payment rules for Aseptic Services

8.1 If the Provider provides any of the following Services in respect of a Pharmaceutical requiring aseptic manufacture, the Provider must claim, and will be paid, in accordance with this Schedule (and not any other Schedule of this Agreement):

- (a) Class B Pharmaceutical Services;
- (b) NPPA Services A;
- (c) NPPA Services B;
- (d) Extemporaneously Compounded Preparations Services;
- (e) Clozapine Services; or
- (f) Special Foods Services.

8.2 Subject to clause 8.3, if the Provider makes a claim under this Schedule in relation to the Dispensing of a Pharmaceutical requiring aseptic manufacture, the Provider must not claim, and Te Whatu Ora will not pay for:

- (a) Dispensing of the Pharmaceutical and providing Professional Advisory Services in relation to the Dispensing of the Pharmaceutical in accordance with clauses 3 to 6 of Schedule 1; or
- (b) the provision of any other Population Service under a Service Schedule in Schedule 3.

8.3 If the Provider Dispenses an Unregistered Medicine in accordance with this Schedule, Te Whatu Ora will pay the Provider an additional payment for Dispensing the Unregistered Medicine in accordance with clause 33 of Schedule 1.

9. Aseptic Services Fee

9.1 Te Whatu Ora will pay the Provider an Aseptic Services Fee for each Pharmaceutical that the Provider Dispenses to or for a Service User in accordance with this Agreement.

9.2 The Aseptic Services Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the Aseptic Services Fee that Te Whatu Ora will pay the Provider (if R is a positive number) number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:

(a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and

(b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

PF = the Per Pack Fee

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 26.50

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any)

SCHEDULE 3A.3

STERILE MANUFACTURING SERVICES

The Services

1. Background and service objective

1.1 Te Whatu Ora wishes to fund Sterile Manufacturing Services as part of an integrated community health service to:

- (a) enable Service Users to have appropriate access to sterile manufacturing services;
- (b) provide Service Users with the best quality and most cost-effective services, within available funding, based on established professional and quality management standards and codes of practice;
- (c) provide specialist advice as required to ensure optimal Service User management; and
- (d) ensure Service User and Staff safety.

1.2 This Schedule is specific to the preparation of eye drops and other products requiring sterile manufacturing, and does not apply in respect of Pharmaceuticals that require aseptic preparation.

2. Eligible Service Users

2.1 Eligible Service Users are Service Users who:

- (a) choose to access Sterile Manufacturing Services from the Provider; and
- (b) are prescribed Pharmaceuticals requiring sterile manufacture and:
 - (i) a commercially available preparation is not available; and
 - (ii) the Pharmaceutical is for use in the Service User's own home, a private hospital, or an institution.

3. Access

3.1 The Provider must provide Sterile Manufacturing Services for a minimum of five days a week during usual business hours unless such period is affected by a public holiday.

3.2 The Provider must use its best endeavours to ensure a level of access to Sterile Manufacturing Services that meets the reasonable needs of the Provider's Eligible Service Users, which may include 24-hour access to Sterile Manufacturing Services.

4. Service components

4.1 The services the Provider must provide as part of providing Sterile Manufacturing Services include:

- (a) Dispensing Pharmaceuticals and providing Professional Advisory Services in accordance with clauses 3 to 6 of Schedule 1; and
- (b) preparing sterile preparations that comply with the requirements of the Pharmacy Services Standards (specified as necessary by Medsafe), including compounding those preparations in accordance with established and validated procedures and methods of preparation.

5. Facilities and settings

5.1 The Provider must prepare sterile preparations, at a minimum in a laminar flow cabinet or an isolator, and the room in which the preparation is prepared must meet the Pharmacy Services Standards specified as necessary by Medsafe, which means:

- (a) the room air environment meets the Grade B requirements; and
- (b) the laminar flow and isolator air environments are Grade A, as defined in the standards or any other standards or guidelines specified by Medsafe, as amended from time to time.

6. Waiting times for Services

6.1 The Provider must Dispense:

- (a) 99% of Pharmaceuticals within 24 hours, if the relevant Prescription Form is presented during a Business Day; and
- (b) 100% of Pharmaceuticals within two Business Days, if the relevant Prescription Form is presented during a Business Day.

6.2 The Provider must maintain adequate stocks of all Pharmaceuticals to meet the waiting times in clause 6.1.

6.3 Waiting times outside these requirements may be acceptable to Te Whatu Ora if there is mutual agreement reached between the Provider and the Service User.

6.4 The waiting times in clause 6.1 will not apply if the Pharmaceutical is not available in New Zealand at the time that the Provider is presented with the Prescription Form.

7. Service linkages

7.1 The Provider must have effective links with:

- (a) the service providers and organisations specified in clause 13 of Schedule 1;
- (b) any organisation providing sterile manufacturing services; and
- (c) hospital pharmacies providing sterile services.

*Fees, payments, and claiming rules***8. Additional claiming and payment rules for Sterile Manufacturing Services**

- 8.1 If the Provider provides Class B Pharmaceutical Services, NPPA Services A, NPPA Services B, or Extemporaneously Compounded Preparations Services to or for a Service User in accordance with this Schedule, the Provider must claim for each Pharmaceuticals Dispensed to the Service User in accordance with the relevant provisions in Schedule 1.
- 8.2 If the Provider Dispenses an Unregistered Medicine in accordance with this Schedule, Te Whatu Ora will pay the Provider an additional payment for Dispensing the Unregistered Medicine in accordance with clause 33 of Schedule 1.

9. Sterile Manufacturing Services Fee

- 9.1 Te Whatu Ora will pay the Provider a Sterile Manufacturing Services Fee for each Pharmaceutical that the Provider Dispenses in accordance with this Agreement.
- 9.2 The Sterile Manufacturing Services Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

- R = the Sterile Manufacturing Services Fee that Te Whatu Ora will pay the Provider (if R is a positive number)
- Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

- M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:
- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and
 - (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more
- PF = the Per Pack Fee
- HF = the Handling Fee for the Pharmaceutical, which is \$1.13
- HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 26.50
- GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)
- CoP = the Co-payment that the Provider may charge the Service User (if any).

SCHEDULE 3A.4

CLOZAPINE SERVICES (MONITORED THERAPY MEDICINE SERVICES)

The Services

1. Background and service objectives

- 1.1 This Service Schedule relates to the provision of clozapine, blood test monitoring, and recording of Dispensing of clozapine.
- 1.2 Prescribers and providers will play appropriate roles in the safe provision of clozapine.
- 1.3 The purpose of Clozapine Services is to ensure that providers are able to support Service Users taking clozapine appropriately, in a way that reflects best practice for the management of this Pharmaceutical.

2. Eligible Service Users

- 2.1 Eligible Service Users are Service Users who are prescribed clozapine.

3. Access

- 3.1 Clozapine Services must be available to Service Users at all times when the Provider's Premises is open for normal business, in accordance with clause 11 of Schedule 1.

4. Service components

- 4.1 The Provider must provide Clozapine Services in accordance with the following requirements:
 - (a) clauses 3 to 6 of Schedule 1; and
 - (b) the Clozapine Protocol.
- 4.2 The Provider must, before Dispensing clozapine:
 - (a) obtain and monitor full blood count test results for each Service User;
 - (b) liaise, in respect of each Service User, with the pharmaceutical company that supplies the relevant brand of clozapine, which is listed in the Pharmaceutical Schedule and is being Dispensed to the Service User, to update and maintain complete individual patient records; and
 - (c) liaise with Prescribers, as appropriate, in the monitoring and interpretation of blood results.

- 4.3 Primary responsibility for interpretation of the blood results and authorisation of treatment with clozapine will remain with the Prescriber.
- 4.4 Not used
- 4.5 The Provider must be familiar with, and comply with, the requirements set out in:
- (a) any guidelines issued by Te Whatu Ora concerning the use of atypical anti-psychotic drugs; and
 - (b) relevant sections of Te Whatu Ora hospital provider protocols for the use of clozapine.
- 4.6 The Provider must be familiar with the adverse reactions, side effects, and interactions that can occur with clozapine.
- 4.7 The services the Provider must provide, as part of providing Clozapine Services, include:
- (a) receiving and monitoring relevant blood test results;
 - (b) liaising with, and referring to, Prescribers and/or liaison persons agreed with the Prescriber;
 - (c) discussing significant matters with the Service User in accordance with clause 4 of Schedule 1, including:
 - (i) emphasising the importance of adherence with their medication;
 - (ii) setting out the requirement to consult Prescribers immediately at the first signs of a cold, influenza, sore throat, or any other infection;
 - (iii) re-emphasising the importance of having blood tests on the day that they are due; and
 - (iv) explaining the importance of safe storage for clozapine; and
 - (d) maintaining additional Records associated with Clozapine Services, including updating the clozapine supplier website with the date of any Dispensing carried out.

5. Referral processes

- 5.1 The Provider must consult with the Prescriber if there is evidence that:
- (a) blood monitoring requirements are not being complied with;
 - (b) blood results are abnormal; or

- (c) a Service User is not registered with a blood monitoring programme run by the relevant clozapine supplier.

5.2 If clause 5.1 applies, the Provider must carry out the instructions of the Prescriber in relation to the provision of Clozapine Services, which may include withholding previously prescribed Pharmaceuticals.

6. Service linkages

6.1 The Provider must have effective links with:

- (a) the service providers and organisations specified in clause 13 of Schedule 1;
- (b) secondary mental health services;
- (c) community mental health services; and
- (d) the relevant pharmaceutical supplier's (or other pharmaceutical industry's) clozapine co-ordinator.

7. Exclusions

7.1 The provision of extra compliance packaging, being a quantity that exceeds the packaging provided with clozapine by the clozapine supplier, will not be reimbursed by Te Whatu Ora – Health New Zealand.

Quality requirements

8. Quality requirements

8.1 Clozapine must only be provided once a satisfactory blood result has been received.

8.2 Prescription Forms for clozapine must be written by a qualified Prescriber.

8.3 The Provider acknowledges and agrees that the prescribing and Dispensing of clozapine is subject to restrictions issued by Te Whatu Ora – Health New Zealand, including the requirement for blood monitoring.

8.4 In order to be qualified to provide Clozapine Services, the Provider must:

- (a) have read, and be able to comply with, this Service Schedule and the Clozapine Protocol;
- (b) ensure that relevant Staff have completed the questionnaire on the Dispensing of clozapine and submitted it to the relevant pharmaceutical supplier; and

- (c) ensure that relevant Staff have attended regular training on the Dispensing of clozapine at least annually, and record that this has occurred. The training package and records must be available for audit purposes.
- 8.5 The ability to comply with the requirements in clauses 8.4(b) and 8.4(c) above is dependent on the questionnaire and training session being developed and made available to providers by Te Whatu Ora – Health New Zealand.
- 8.6 Clozapine Services must only be provided by a Pharmacist that complies with the requirements specified in clause 8.4(a) and has completed the questionnaire, training and annual validation sessions and recording, detailed in clauses 8.4(b) and 8.4(c), when these are available to providers.
- 8.7 The Provider is responsible for the management of Clozapine Services at all times.
- 8.8 The Provider must comply with any quality requirements set out in the Clozapine Protocol.

Fees, payments, and claiming rules

9. Additional claiming and payment rules for Clozapine Services

- 9.1 Subject to clause 9.2, if the Provider is required to provide Extemporaneously Compounded Preparations Services for clozapine Dispensed to or for a Service User under this Schedule, the Provider must claim, and will be paid, in accordance with Schedule 1 (and not under this Schedule).
- 9.2 If the Provider makes a claim under this Schedule in relation to the Dispensing of clozapine, the Provider must not claim, and Te Whatu Ora will not pay, for the Dispensing under any other Service Schedule.
- 9.3 If the Provider Dispenses an Unregistered Medicine in accordance with this Schedule, Te Whatu Ora will pay the Provider an additional payment for Dispensing the Unregistered Medicine in accordance with clause 33 of Schedule 1.

10. Clozapine Services Fee

- 10.1 Te Whatu Ora will pay the Provider a Clozapine Services Fee for each Pharmaceutical that the Provider Dispenses to or for a Service User and claims in accordance with this Agreement.

10.2 The Clozapine Services Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the Clozapine Services Fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:

(a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and

(b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

PF = the Per Pack Fee

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 10.60

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any).

10.3 Subject to clause 10.4, if "R" is a negative number:

(a) that number will be treated as a positive amount; and

(b) Te Whatu Ora will be entitled to recover that amount from the Provider (including by way of set-off).

10.4 Te Whatu Ora will not recover (nor be entitled to recover) the amount "R" if the Dispensing of the Pharmaceutical is a Negative A3 or J3 Transaction.

Definitions

11. Definitions that apply to this Service Schedule

- 11.1 In this Service Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

Clozapine Protocol means the document titled *Protocol for the Dispensing of Clozapine by Community Pharmacies*, published by Te Whatu Ora, as amended by Te Whatu Ora from time to time following engagement with provider representatives.

SCHEDULE 3A.5

IMMUNISATION SERVICES

The Services

1. Background and service objectives

1.1 Pharmacist Vaccinators and Authorised Vaccinators employed by pharmacies are well equipped to offer and administer Vaccines to Eligible Service Users. Therefore, Te Whatu Ora wishes to fund the delivery of Immunisation Services by community pharmacy providers who opt to deliver these Immunisation Services to Eligible Service Users, in order to achieve the following service objectives:

- (a) Eligible Service Users have increased access to Immunisation Services;
- (b) the burden of general practice consultations, hospitalisations, and deaths associated with illnesses for which there is a Vaccine in the Eligible Service User population is reduced;
- (c) a quality service is delivered, as prescribed by the Immunisation Standards, and to meet National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017; and
- (d) all Vaccines given by Pharmacist Vaccinators and Authorised Vaccinators are recorded on the Immunisation Portal.

2. Eligible Service Users

2.1 Eligible Service Users are Service Users:

- (a) who are eligible to receive a publicly funded Vaccine; and
- (b) to whom Pharmacist Vaccinators or Authorised Vaccinators are permitted to administer the Vaccines under the Medicines Regulations 1984.

2.2 The Provider must not provide, or claim for providing, a Vaccine to:

- (a) people who are not Eligible Service Users;
- (b) people who have experienced previous serious adverse reactions or anaphylaxis to any Vaccine or one of its components; or
- (c) people who have already been vaccinated with the relevant dose of the Vaccine.

2.3 If in doubt as to any of the matters listed in clause 2.2, the Provider will look up information on the Immunisation Portal, and, if necessary, contact the person's general practice to confirm the person's immunisation status.

- 2.4 If a person is acutely unwell with a fever or other systemic illness, the Provider should defer immunisation and the person should be directed to their general practitioner for medical treatment if required.

3. Service components

3.1 The Provider must:

- (a) ensure that Immunisation Services are provided by:
 - (i) a Pharmacist Vaccinator; or
 - (ii) an Authorised Vaccinator;
- (b) provide Immunisation Services in accordance with the:
 - (i) Pharmaceutical Schedule;
 - (ii) Immunisation Standards;
 - (iii) Immunisation Handbook;
 - (iv) National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017, including achievement of "Cold Chain Accreditation"; and
 - (v) the National Immunisation Schedule;
- (c) record the Vaccines given by a Pharmacist Vaccinator or Authorised Vaccinator on the Immunisation Portal, and include all of the required information in the Immunisation Portal, including the Eligible Service User's National Health Index number.

4. Equipment, resources, and support

- 4.1 The Provider must maintain all equipment required to provide a quality, safe, effective, and efficient service that meets the requirements of the Immunisation Standards and National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.
- 4.2 The Provider must purchase the Vaccines from the supplier notified to it by Pharmac.
- 4.3 The cost of the Vaccines will be advised by Pharmac from time to time, and Te Whatu Ora will advise the Provider of any change to the cost as soon as practicable after the change.
- 4.4 The Pharmacist Vaccinator or Authorised Vaccinator must be supported by another individual trained in First Aid and CPR.

5. Service linkages

5.1 The Provider must establish and maintain linkages with:

- (a) local PHOs and general practices;
- (b) all providers that provide Immunisation Services;
- (c) the Provider's local Medical Officer of Health;
- (d) the Provider's local Immunisation Coordinator;
- (e) the district Immunisation nurse leader; and

(f) the Immunisation Advisory Centre.

6. Performance Measures

- 6.1 The effectiveness of Immunisation Services delivered by the Provider and other community pharmacy providers will be measured by whether, for each Vaccine, the percentage of Eligible Service Users who receive the Vaccine, is increased from the previous year's percentage.

Fees, payments, and claiming rules

7. Payment for Immunisation Services

- 7.1 Subject to clause 8, the Provider may claim, and Te Whatu Ora will pay, an Immunisation Services Fee for administering a Vaccine to an Eligible Service User in accordance with this Schedule.
- 7.2 The Immunisation Services Fee is the purchase cost (if any) (inclusive of GST) of the Vaccine administered to an Eligible Service User, and one of the following:
- (a) \$36.05 (GST exclusive) for administering a Vaccine to an Eligible Service User, unless a Vaccine has already been administered to that Eligible Service User on the same day; or
 - (b) if the zoster (shingles) vaccine and the influenza vaccine are administered to an Eligible Service User on the same day:
 - (i) \$36.05 (GST exclusive) for administering the first Vaccine (the zoster (shingles) vaccine or the influenza vaccine) to that Eligible Service User; or
 - (ii) \$20.52 (GST exclusive) for administering the second Vaccine (a zoster (shingles) vaccine or an influenza vaccine) to that Eligible Service User.
- 7.3 The payment for provision of Immunisation Services under this Schedule is a stand-alone payment, independent of any other payments under this Agreement.

8. Conditions of payment

- 8.1 Te Whatu Ora will pay the Provider an Immunisation Services Fee only if:
- (a) the Vaccine dose has not already been given, or a reasonable effort has been made to check that it has not already been given, to the relevant Eligible Service User; and
 - (b) the claim relates to a Vaccine administered by a Pharmacist Vaccinator or Authorised Vaccinator;
 - (c) the claim is made in accordance with any requirements specified in this Agreement or specified in writing by Te Whatu Ora.
- 8.2 Unless clause 7.2(b) applies, the Provider is not entitled to receive more than one Immunisation Services Fee if more than one Vaccine is administered to an Eligible Service User on the same day.

9. No payment to be sought from Eligible Service Users

- 9.1 The Provider must not in any circumstances demand or accept any Product Premium, Pharmacy Charge, Co-payment, or any other fee from any Eligible Service User to whom the Provider provides Immunisation Services.
- 9.2 To avoid doubt, clauses D.5 to D.10 do not apply to the Provider's provision of Immunisation Services unless the Provider provides Immunisation Services to a person other than an Eligible Service User, in which case clause D.4 applies.

*Definitions***10. Definitions that apply to this Service Schedule**

- 10.1 In this Service Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

Authorised Vaccinator means any person who is authorised by the Director-General of Health or a Medical Officer of Health to administer vaccines in accordance with section 44A of the Medicines Regulations 1984, and who has completed the vaccinator requirements set out in Appendix 4 of the Immunisation Handbook

Eligible Service Users means the persons described in clause 2

Immunisation Handbook means the "Immunisation Handbook 2020" as published by the Ministry and updated from time to time, including any handbook prepared by the Ministry to replace that Handbook

Immunisation Portal means the national computerised information system that holds immunisation details of New Zealand patients at the time of an immunisation. The Immunisation Portal will be the Aotearoa Immunisation Register when it is developed.

Immunisation Standards means the Immunisation standards for vaccinators and Guidelines for organisations offering immunisation services published by the Ministry and set out in Appendix 3 of the Immunisation Handbook, and includes any successor guidelines or protocols prepared by the Ministry for the same or similar purposes

Immunisation Services means the immunisation services described in this Schedule

Medical Officer of Health has the meaning given to that term in the Health Act 1956

National Standard for Vaccine Storage and Transportation for Immunisation Providers 2017 means the National Standard for Vaccine Storage and Transportation for Immunisation Providers 2017 - 2nd edition, October 2019 for cold chain management of the same name published by the Ministry, and includes any successor guidelines or protocols prepared by the Ministry for the same or similar purposes

Pharmacist Vaccinator means:

- (a) a Pharmacist who has completed the vaccinator requirements, as outlined in Appendix 4 of the Immunisation Handbook; and
- (b) in relation to influenza vaccines, includes a registered intern Pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health.

Vaccine means:

- (a) any vaccine that can be administered by a Pharmacist Vaccinator or an Authorised Vaccinator and is listed on the Pharmaceutical Schedule as being funded for provision through pharmacy when provided to Eligible Service Users in accordance with this Schedule; but
- (b) excludes any COVID-19 vaccine.

SCHEDULE 3B.1

LONG-TERM CONDITIONS PHARMACY SERVICES

The Services

1. Background and Service objectives

- 1.1 Te Whatu Ora wishes to fund the provision of LTC Services to Service Users with a diagnosed Long Term Condition in the Geographical Area, who have poor medicine adherence, and who are assessed as having the capacity and willingness to receive additional support.
- 1.2 Te Whatu Ora wishes to fund LTC Services as part of an integrated community health service that:
- (a) improves the Service User's health outcomes, including their understanding of all the medicines prescribed for them, and any other medicines they are taking;
 - (b) assists the Service User to adhere to, and persevere with, their medicines regime, and to manage any prescribed changes to that regime;
 - (c) ensures that community Pharmacists participate in, and provide meaningful input into, the multidisciplinary team, and provide continuity of care to the Service User in conjunction with their primary, community, secondary, and residential care teams;
 - (d) contributes to professional relationships between Prescribers and Pharmacists that support improved prescribing practices and appropriateness of medicines;
 - (e) ideally results in one shared care plan, co-ordinated by the Service User's primary care provider, that is available to all providers involved with the Service User's care, and the Service User;
 - (f) minimises acute admissions to hospital and delays entry to residential care; and
 - (g) obtains the best value by targeting the Service Users who meet the LTC Criteria, and providing them with LTC Services most suited to their needs.

2. Eligible Service Users

- 2.1 Te Whatu Ora will fund the Provider to provide LTC Services to Service Users who:
- (a) meet the LTC Access Criteria; and
 - (b) have been approved as being eligible to receive LTC Services in accordance with this Service Schedule and the LTC Services Protocol.

3. Approval to provide LTC Services to Service Users

- 3.1 If the Provider identifies a Service User as being likely to meet the LTC Access Criteria, or a Service User or their health care provider asks the Provider to consider if they are eligible to receive LTC Services, the Provider will:
- (a) discuss the LTC Access Criteria and LTC Services programme with the Service User; and
 - (b) assess the eligibility of the Service User against the LTC Access Criteria in accordance with the LTC Services Protocol.
- 3.2 If the Provider determines that the Service User is eligible to receive LTC Services, the Provider must:
- (a) determine the level of LTC Services that the Service User requires;
 - (b) select the Essential LTC Services that the Service User will receive, according to the priority of that Service User's needs across the Provider's patient population;
 - (c) obtain the written agreement of the Service User to enter the LTC Services programme and to use the Provider as the Service User's ongoing regular provider of pharmacy services while they are receiving the LTC Services; and
 - (d) complete the approvals process set out in the LTC Services Protocol so that the Provider will be eligible to receive funding for the LTC Services it provides to that Service User.

4. Service User changing Providers

- 4.1 If a Service User that is approved to receive LTC Services wishes to receive LTC Services from:
- (a) the Provider instead of a different provider, then, if the Provider agrees to provide LTC Services to that Service User (such agreement not to be unreasonably withheld), the Provider must obtain that Service User's agreement to receive LTC Services from the Provider, and must notify the Service User's former provider, Te Whatu Ora – Health New Zealand, its Payment Agent, and all relevant members of that Service User's multidisciplinary care team of the change; or
 - (b) a provider other than the Provider, then, on receipt of notification of the change from the Service User or the other provider, the Provider must adjust its records accordingly, not restrict the ability of the Service User to change providers, and make no claims in respect of that Service User under this Schedule.
- 4.2 The Provider must comply with the process set out in the LTC Services Protocol when carrying out its obligations under clause 4.1.

5. Exiting Service Users from the LTC Services programme

- 5.1 The Provider must, as required by the LTC Services Protocol, assess each LTC Service User against the LTC Exit Criteria to determine whether that Service User meets any of the LTC Exit Criteria.
- 5.2 If a Service User meets the LTC Exit Criteria, the Provider must immediately exit the Service User in accordance with the process specified in the LTC Services Protocol.
- 5.3 Te Whatu Ora may, on the basis of the Records available to it and following discussion with the Provider and any applicable members of the multidisciplinary care team, require the Provider to exit a Service User from the LTC Services programme by notifying the Provider accordingly, in which case:
- (a) the Provider must exit the Service User in accordance with the LTC Services Protocol; and
 - (b) Te Whatu Ora will stop paying the Provider to provide LTC Services to the Service User from the day the Service User exits the programme.
- 5.4 If the LTC Services Protocol is amended during the term of this Agreement:
- (a) the Provider must review the status of each LTC Service User against the LTC Access Criteria and LTC Exit Criteria to determine whether each LTC Service User is still eligible to receive LTC Services; and
 - (b) if a LTC Service User meets the LTC Exit Criteria, the Provider must exit the Service User in accordance with the LTC Services Protocol the next time the Provider contacts the Service User.

6. Annual cap on number of Service Users in the LTC Services

- 6.1 Te Whatu Ora will notify the Provider, on or before 1 July of each year, of the cap on the number of Service Users in the Geographical Area who may receive LTC Services during the year commencing on 1 July (the LTC Annual Cap).
- 6.2 Te Whatu Ora agrees that, while this Service Schedule is in force, the LTC Annual Cap for the Geographical Area will be no less than the LTC Annual Cap as at 30 September 2018.
- 6.3 Te Whatu Ora will monitor and report publicly each month on the number of Service Users in the Geographical Area that are receiving LTC Services in accordance with the LTC Services Protocol.
- 6.4 Te Whatu Ora will notify the Provider in writing when the number of Service Users in the Geographical Area receiving LTC Services has reached 97% of the LTC Annual Cap.

- 6.5 If the number of Service Users in the Geographical Area receiving LTC Services reaches 100% of the LTC Annual Cap:
- (a) Te Whatu Ora will notify the Provider in writing that the LTC Annual Cap has been reached;
 - (b) Te Whatu Ora will suspend approvals for all applications for new Service Users in the Geographical Area to receive LTC Services; and
 - (c) the Provider must not assess Service Users under clause 3.1(b) unless and until the suspension has been lifted in accordance with clause 6.7.
- 6.6 Te Whatu Ora will continue to monitor and report publicly each month on the number of Service Users in the Geographical Area receiving LTC Services during the suspension.
- 6.7 If the number of Service Users receiving LTC Services in the Geographical Area drops to below 99% of the LTC Annual Cap, Te Whatu Ora will lift the suspension.
- 6.8 To avoid doubt, nothing in this clause affects those Service Users already receiving LTC Services or the Provider's entitlement to payment for providing LTC Services to those existing Service Users.

7. Service components

- 7.1 The Provider must, as appropriate, provide the following Essential LTC Services to each Service User:
- (a) Dispensing Pharmaceuticals and providing Professional Advisory Services in accordance with clauses 3 to 6 of Schedule 1;
 - (b) medicines reconciliation services, being that the Provider collects and compares information from Prescribers on the Service User's medicines in order to identify the most accurate list of medicines the Service User is taking;
 - (c) synchronisation services, being that the Provider coordinates the quantities of all the Service User's medications Dispensed to the earliest common date so that the next prescription periods can be aligned;
 - (d) reminder services, whereby the Provider provides each Service User with a reminder, in a form agreed with them, about when their next supply of Pharmaceuticals is to be collected;
 - (e) regular screening of a Service User's compliance with, and adherence to, their medicines regime and the provision of medicines alignment services, as further specified (if applicable) in the LTC Services Protocol;

- (f) Dispensing services, with Dispensing frequency tailored to the needs of the Service User and compliant with the requirements of the Pharmaceutical Schedule Rules; and
 - (g) regular engagement, as deemed appropriate or agreed, with members of the Service User's multidisciplinary care team, and in particular, engagement with their key medical practitioner(s), in order to provide the Service User's multidisciplinary care team with information about the Service User's progress in improving the Service User's management of their medications and compliance and adherence with their medicines regime.
- 7.2 The Provider must regularly and proactively make contact with the Service User, with clear agreement about mutual expectations and the LTC Services available.
- 7.3 The LTC Services the Provider provides to each Service User must be supported by appropriate documentation, which the Provider must make available for Te Whatu Ora's inspection and Audit.
- 7.4 Te Whatu Ora and the Provider acknowledge that it may not be appropriate to provide all of the Essential LTC Services to a LTC Service User from the date that Services User is approved to receive LTC Services.
- 7.5 The Provider must follow the process set out in the LTC Services Protocol for transitioning a Service User on to the appropriate Essential LTC Services.
- 7.6 Without limiting clause D.22, the Provider must not refer a LTC Service User to another provider for that provider to provide Dispensing Services to the LTC Service User, unless otherwise expressly permitted under this Agreement or if the Provider needs to make an onward referral in an emergency situation in which the Provider is unable to provide urgently needed medication.
- 8. Record keeping**
- 8.1 The Provider must maintain up-to-date Records for each LTC Service User, documenting in detail the Services the Provider provides to the LTC Service User, including the frequency with which the Provider provides LTC Services to that Service User, as well as supporting the initiation, continuation, and cessation of LTC Services in relation to the Service User.
- 9. Reporting**
- 9.1 The Provider must comply with any reporting requirements set out in the LTC Services Protocol.

Fees, payment, and claiming rules

10. Additional claiming and payment rules for LTC Services

- 10.1 The Provider must provide the NHI Number and date of birth of each LTC Service User for which the Provider submits a claim.
- 10.2 If the Provider provides any of the following Services to a LTC Service User, the Provider must claim, and will be paid, in respect of each Pharmaceutical Dispensed to or for the LTC Service User as follows:
- (a) for Class B Pharmaceutical Services, NPPA Services A, NPPA Services B, and Extemporaneously Compounded Preparations Services, in accordance with the relevant provisions in Schedule 1;
 - (b) for Aseptic Services, in accordance with Schedule 3A.2 (if applicable);
 - (c) for Clozapine Services, in accordance with Schedule 3A.4 (if applicable); and
 - (d) for Special Foods Services, in accordance with Schedule 3B.4 (if applicable).
- 10.3 Subject to clause 10.2, if the Provider makes a claim under this Schedule in relation to the Dispensing of a Pharmaceutical to or for a LTC Service User, the Provider must not claim, and Te Whatu Ora will not pay:
- (a) for Dispensing Services or for providing Professional Advisory Services under clauses 3 to 6 of Schedule 1;
 - (b) for the Dispensing of a Co-dispensed Pharmaceutical under Schedule 3A.1; or
 - (c) for the provision of any other Population Service under a Service Schedule in Schedule 3.

Fees and payments for LTC Services

11. Payment for LTC Services

- 11.1 Te Whatu Ora will pay the Provider the following fees for LTC Services provided to LTC Service Users in accordance with this Schedule and the LTC Services Protocol:
- (a) a LTC Dispensing Transaction Fee, in accordance with clause 12;
 - (b) a LTC Monthly Services Fee, in accordance with clause 13; and
 - (c) a LTC Case Mix Service Fee, in relation to the Dispensing of an Initial Item to or for a Service User, in accordance with clause 15;

- (d) a LTC Case Mix Service Fee in relation to the Dispensing of a Repeat Item to or for a Service User, in accordance with clause 16; and
- (e) a Brand-switch fee, in accordance with clause 26.

LTC Dispensing Transaction Fee

12. LTC Dispensing Transaction Fee

12.1 Subject to clauses 12.3 and 12.4, Te Whatu Ora will pay the Provider a LTC Dispensing Transaction Fee for each Pharmaceutical that the Provider Dispenses to or for a LTC Service User, and claims in accordance with this Agreement and the LTC Services Protocol.

12.2 The LTC Dispensing Transaction Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the LTC Dispensing Services Fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:

- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; or
- (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

PF = the Per Pack Fee

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 1.00

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any).

12.3 Subject to clause 12.4, if "R" is a negative number:

- (a) that number will be treated as a positive amount; and

- (b) Te Whatu Ora will be entitled to recover that amount from the Provider (including by way of set-off).
- 12.4 Te Whatu Ora will not recover (nor be entitled to recover) the amount "R" if the Dispensing of the Pharmaceutical is a Negative A3 or J3 Transaction.

LTC Monthly Services Fee

13. LTC Monthly Services Fee

- 13.1 Subject to clauses 13.4 and 13.5, Te Whatu Ora will pay the Provider a LTC Monthly Services Fee of \$21.00 (GST exclusive) for each LTC Service User who is registered as receiving LTC Services from the Provider:
- (a) in the month to which the claim relates as at the cut-off date; and
 - (b) in the previous month, if the LTC Service User was first registered with the Provider after the cut-off date in the previous month (in which case the LTC Monthly Services Fee for the LTC Service User will be paid on a pro-rata basis).
- 13.2 Te Whatu Ora will pay the LTC Monthly Services Fees on the basis of the information submitted by the Provider to the national LTC Service User register.
- 13.3 Te Whatu Ora will pay the LTC Monthly Services Fee on the seventh Business Day of each month.
- 13.4 Te Whatu Ora will not pay the Provider a LTC Monthly Services Fee for a LTC Service User if the Provider has not Dispensed a Pharmaceutical to the LTC Service User within the 120-day period before the first day of the month to which the payment relates.
- 13.5 If a person ceases to be registered with the Provider as a LTC Service User, but Te Whatu Ora has paid the Provider a LTC Monthly Services Fee for the LTC Service User, Te Whatu Ora may recover (on a pro-rata basis) the Monthly Service Fee amount from the date the Service User ceased to be registered as receiving LTC Services.

LTC Case Mix Service Fee

14. LTC Case Mix Service Fee

- 14.1 Subject to clause 14.2, Te Whatu Ora will pay the Provider a LTC Case Mix Service Fee in relation to:
- (a) each Initial Item Dispensed to or for a LTC Service User in a month, in accordance with clause 15; and

- (b) each Repeat Item Dispensed to or for a LTC Service User in a month, in accordance with clause 16.

14.2 Te Whatu Ora is not required to pay a LTC Case Mix Service Fee for Items Dispensed by the Provider:

- (a) in accordance with a Practitioner Dispensing Order or Bulk Dispensing Order;
- (b) as part of the provision of Class B Pharmaceutical Services, Extemporaneously Compounded Preparations Services, NPPA Services A, NPPA Services B, or any Population Service;
- (c) for Owed Pharmaceuticals; or
- (d) if the Pharmaceutical is not a Subsidised Pharmaceutical.

15. LTC Case Mix Service Fee for Initial Items

15.1 The Case Mix Service Fee for each Initial Item Dispensed to or for a LTC Service User in a month is calculated as follows:

$$R = \sum (((II \times C) \times IRVU) \times ISF) \times GST$$

where:

- R = the total fee (inclusive of GST) that Te Whatu Ora will pay the Provider in relation to each Initial Item Dispensed to or for a LTC Service User in the month
- \sum = the sum of each combination of the number of Initial Items Dispensed to or for a LTC Services User on a single day (II in this formula) in the month
- II = the number of Initial Items Dispensed to or for a LTC Service User by the Provider on a single day in the month
- C = the number of times that the Provider Dispenses the number of Initial Items as set out above are Dispensed to or for an individual Service User on a single day in the month
- IRVU = the relative value unit that corresponds with the number of Initial Items Dispensed to or for the Service User on that day (excluding any Initial Items described in clause 14.2) as follows:
 - (a) 1.00 if one, two, or three Initial Items are Dispensed
 - (b) 1.02 if four Initial Items are Dispensed

(c) 1.03 if five Initial Items are Dispensed

(d) 1.04 if six or more Initial Items are Dispensed

ISF = the initial base service fee, which is \$5.03 (GST exclusive)

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing).

16. LTC Case Mix Service Fee for Repeat Items

16.1 The LTC Case Mix Service Fee for each Repeat Item Dispensed to or for a LTC Service User in a month is calculated as follows:

$$R = \sum(((N \times RRVU) \times RSF) \times GST)$$

where:

R = the total fee (inclusive of GST) that Te Whatu Ora will pay to the Provider in relation to each Repeat Item Dispensed to or for a LTC Service User in the month

\sum = the sum of each combination of the number of Repeat Items with a different prescription ID suffix Dispensed to or for a Service User in the month

N = the number of times Repeat Items with the same prescription ID suffix are Dispensed by the Provider in the month

RRVU = the relative value unit that corresponds with the prescription ID suffix for the Repeat Item Dispensed to or for the Service User as follows:

(a) 1.00 if the Prescription ID suffix is 2 or 3

(b) 0.60 if the Prescription ID suffix is 4 to 12

(c) 0.40 if the Prescription ID suffix is 13 to 28

(d) 0.35 if the Prescription ID suffix is 29 or any higher number

RSF = the repeat base service fee, which is \$3.27 (GST exclusive)

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing).

17. Calculation and payment of LTC Case Mix Service Fees

- 17.1 Te Whatu Ora will calculate and pay the Provider LTC Case Mix Service Fees for Initial Items and Repeat Items Dispensed in a month in three stages as set out in clauses 18 to 20, being:
- (a) stage one, which is the calculation of the Advanced LTC Case Mix Service Fee payable;
 - (b) stage two, which is the calculation of the Interim LTC Case Mix Service Fee payable;
and
 - (c) stage three, which is the calculation of the Final LTC Case Mix Service Fee payable.

18. Stage one: Advanced LTC Case Mix Service Fees

- 18.1 Subject to clause 23.3, on the first Business Day of each month Te Whatu Ora will pay the Provider an Advanced LTC Case Mix Service Fee Payment for Items that the Provider is expected to Dispense in the month.
- 18.2 The Advanced LTC Case Mix Service Fee will be calculated using the formula in clauses 15 and 16, on the basis of the number of Initial Items and Repeat Items that Te Whatu Ora estimates will be Dispensed to Service Users in the month.

19. Stage two: Interim LTC Case Mix Service Fees

- 19.1 On the first Business Day of the third month after Te Whatu Ora paid the Provider an Advanced LTC Case Mix Service Fee, Te Whatu Ora will recalculate the LTC Case Mix Service Fee payable to the Provider for the month for which an Advanced Case Mix Service Fee was paid (the "Interim LTC Case Mix Service Fee").
- 19.2 The Interim LTC Case Mix Service Fee will be calculated using the formula in clauses 15 and 16, on the basis of the actual number of Initial Items and Repeat Items Dispensed to or for Services Users in the month.
- 19.3 If the difference between the Interim LTC Case Mix Service Fee and the Advanced LTC Case Mix Service Fee for the month is:
- (a) a positive number, Te Whatu Ora will pay the difference to the Provider on the first Business Day of the month; or
 - (b) a negative number, Te Whatu Ora will deduct the difference from the next LTC Case Mix Service Fee paid to the Provider.

20. Stage three: Final LTC Case Mix Service Fees

- 20.1 After the end of each year ending 30 September, Te Whatu Ora will recalculate the LTC Case Mix Service Fee payable to the Provider for each month of the year ending 30 June ("Final LTC Case Mix Service Fee").

- 20.2 The Final LTC Case Mix Service Fee will be calculated using the formula in clauses 15 and 16, on the basis of the actual number of Initial Items and Repeat Items Dispensed to or for Services Users during each month.
- 20.3 If the difference between the Final LTC Case Mix Service Fee and the Interim LTC Case Mix Service Fee is:
- (a) a positive number, Te Whatu Ora will pay that amount to the Provider as soon as reasonably practicable and by no later than the end of the year after the year to which the amount relates; or
 - (b) a negative number, Te Whatu Ora will advise the Provider that the Provider owes that amount to Te Whatu Ora as soon as reasonably practicable and by no later than the end of the year after the year to which the payment relates, and will deduct the amount from the next payment paid to the Provider after advising the Provider of the amount owed.

21. Calculation and payment of LTC Case Mix Service Fee if Agreement is terminated

- 21.1 Te Whatu Ora and the Provider agree that the recalculations described in clauses 19 and 20 will occur, and those clauses will apply, even after this Agreement is terminated, except that if the amount recalculated is a negative number, that amount will be an overpayment for the purpose of clause D.42.

22. Additional LTC Case Mix Service Fees claim rules

- 22.1 If the Provider submits a Claim Item for Pharmaceuticals Dispensed in a month outside the time required by Te Whatu Ora to calculate the Provider's Interim LTC Case Mix Service Fee Payment for the month, Te Whatu Ora will pay a LTC Case Mix Service Fee for the Claim Item as part of the Final Case Mix Service Fee calculated in accordance with clause 20.
- 22.2 To avoid doubt, if the Provider does not submit a Claim Item for Dispensing within the time required by Te Whatu Ora to calculate the Provider's Actual LTC Case Mix Service Fee Payment for the relevant Service Month, Te Whatu Ora will pay LTC Case Mix Service Fees in accordance with clause 20.

23. Data used for calculation of LTC Case Mix Service Fee

- 23.1 Subject to clauses 23.2 and 23.3, Te Whatu Ora will, when estimating Initial Items and Repeat Items in accordance with clause 18, use data from the third calendar month before the relevant month, as adjusted using a Seasonal Adjuster.
- 23.2 If ownership of the Provider changes between the two months described in clause 23.1, Te Whatu Ora will use data relating to the previous owner.

23.3 If Te Whatu Ora does not have data from the months described in clause 23.1 because the Provider is a new Provider, Te Whatu Ora is not required to calculate or pay any Advanced LTC Case Mix Service Fee Payments until it has that data.

23.4 Subject to clause 23.5, the additional payment is calculated as follows:

$$R = ((Sc \times M2) + AF + CF) \times GST$$

where:

R = the additional payment that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M2 = a top-up margin payment towards the procurement and stockholding costs for the Pharmaceutical, which is:

(a) 0.07 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and

(b) 0.06 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

AF = an additional margin payment of \$3.00 towards the additional administration costs of Dispensing an Unregistered Medicine

CF = an additional payment of \$5.30 towards the additional counselling costs of Dispensing an Unregistered Medicine

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing).

23.5 Te Whatu Ora and the Provider agree that:

(a) the Provider will be paid only one additional margin payment (referred to as "AF" in clause 23.4) and one counselling fee payment (referred to as "CF" in clause 23.4) per LTC Service User per Pharmaceutical per calendar month in which the Pharmaceutical is Dispensed to or for a Service User; and

(b) if more than one Unregistered Medicine is extemporaneously compounded, Te Whatu Ora will pay the Provider, in accordance with clause 23.4, an additional payment for each Unregistered Medicine.

24. LTC Case Mix Service Fee and Negative A3 and J3 Transactions (including quarterly reviews)

- 24.1 For the purpose of this Schedule, and despite anything else in this Agreement, a Pharmaceutical that is Dispensed as part of a Negative A3 or J3 Transaction is not an Initial Item for which the Provider may claim or be paid a LTC Case Mix Service Fee.
- 24.2 Te Whatu Ora will calculate Advanced LTC Case Mix Service Fee payments, Interim LTC Case Mix Service Fee payments, and Final LTC Case Mix Service Fee payments owed to the Provider on the assumption that the Dispensing of a Pharmaceutical is not part of a Negative A3 or J3 Transaction if:
- (a) the prescription ID suffix of the Pharmaceutical is /0 and the LTC Dispensing Services Fee payable for the Dispensing of the Pharmaceutical is greater than zero; or
 - (b) the prescription ID suffix of the Pharmaceutical is /1 or any higher number (indicating that the Pharmaceutical being Dispensed has Repeat Items available or is a Repeat Item).
- 24.3 Te Whatu Ora will, each Quarter, review the LTC Case Mix Service Fees paid to the Provider in respect of each Pharmaceutical to determine whether any Pharmaceuticals that Te Whatu Ora assumed were Dispensed as part of a Negative A3 or J3 Transaction were in fact not Dispensed as part of a Negative A3 or J3 Transaction.
- 24.4 If Te Whatu Ora determines that a Pharmaceutical was assumed to have been Dispensed as part of a Negative A3 or J3 Transaction, but was not in fact Dispensed as part of a Negative A3 or J3 Transaction, Te Whatu Ora will pay the Provider a LTC Case Mix Service Fee for the Dispensing of the Pharmaceutical on the first Business Day after the review is complete.
- 24.5 If clause 24.4 applies, the LTC Case Mix Service Fee for the Pharmaceutical is calculated as follows:

$$R = (IRVU \times ISF) \times GST - RITV$$

where:

R = the LTC Case Mix Service Fee in respect of each such pharmaceutical (inclusive of GST) that Te Whatu Ora will pay the Provider

IRVU = the relative value unit assigned to the Dispensing, which is 1.01

ISF = the initial base service fee, which is \$5.03 (GST exclusive)

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

RITV = the GST inclusive amount of the Transaction Sequence, excluding the Case Mix Service Fee (which is treated as a positive amount).

- 24.6 To avoid doubt, the review will not affect any other payments that Te Whatu Ora has paid to the Provider, nor will it mean that the IRVU for Initial Items that were Dispensed at the same time as the Pharmaceuticals that were the subject of the review will be changed.
- 24.7 To avoid doubt, this clause (and any provisions required to give effect to this clause) will continue to apply after the End Date.

25. Additional payment for Dispensing Unregistered Medicines

- 25.1 Te Whatu Ora will pay the Provider an additional fee for each Unregistered Medicine that is a Subsidised Pharmaceutical that the Provider Dispenses to or for a LTC Service User and for which the Provider makes a claim in accordance with this Schedule, in addition to any other amount that Te Whatu Ora may be required to pay for the Dispensing of the Pharmaceutical under this Schedule.

Brand-switch Fee

26. Brand-switch Fee

- 26.1 Te Whatu Ora will pay the Provider a Brand-switch Fee for the provision of brand switch advice in respect of a Pharmaceutical if:
- (a) the Pharmaceutical Schedule provides for the payment of a Brand-switch Fee in respect of the Pharmaceutical; and
 - (b) the Provider claims the Brand-switch Fee in accordance with this Agreement.

Definitions

27. Definitions that apply to this Service Schedule

- 27.1 In this Service Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

Essential LTC Services means the services described in clause 7

Long Term Condition means a medical condition specified as a long term condition in the LTC Services Protocol

LTC Access Criteria means the access criteria for LTC Services for the Geographical Area, as set out in the LTC Services Protocol

LTC Annual Cap has the meaning set out in clause 6.1

LTC Dispensing Transaction Fee means the fee paid in accordance with clause 12

LTC Exit Criteria means the exit criteria for LTC Services for the Geographical Area, as set out in the LTC Services Protocol

LTC Monthly Services Fee means the fee paid in accordance with clause 13

LTC Services Protocol means the publication titled "LTC Services Protocol", which is available at www.tas.health.nz (or any other website advised by Te Whatu Ora – Health New Zealand), as amended by Te Whatu Ora from time to time following engagement with provider representative groups

LTC Case Mix Service Fee means the fee paid in respect of the Dispensing of Initial Items in accordance with clause 15, and the fee paid in respect of the Dispensing of Repeat Items in accordance with clause 16

LTC Service Patient Eligibility Assessment Form means the form used by providers to assess Service Users for eligibility to receive LTC Services, which includes documenting the Service User's medication needs in a medication management plan

LTC Service User means a Service User registered to receive LTC Services from the Provider in accordance with this Schedule.

SCHEDULE 3B.2

COMMUNITY RESIDENTIAL CARE PHARMACY SERVICES

The Services

1. Background and service objectives

- 1.1 Te Whatu Ora wishes to fund Community Residential Care (CRC) Pharmacy Services for Service Users living in community residential care.
- 1.2 CRC Pharmacy Services are community health services that:
- (a) provide CRC Service Users with the best quality and most cost-effective community pharmacy services, within available funding, based on established professional and quality management standards and codes of practice;
 - (b) provide pharmacy advice as required to ensure optimal medicines management for Service Users; and
 - (c) contribute to Service User and Staff safety.

2. Eligible Service Users

- 2.1 Eligible Service Users are Service Users who are:
- (a) people living in a CRC Service who require community residential support services because they have one or more of the following conditions:
 - (i) a physical or sensory disability;
 - (ii) an intellectual disability;
 - (iii) a psychiatric disability (including drug and alcohol or addiction rehabilitation); and
 - (iv) a disabling chronic health condition (eg, a neurological condition or a stroke); and
 - (b) children or young people who live in an Oranga Tamariki Care and Protection or Youth Justice Residence under section 364 of the Oranga Tamariki Act 1989.

3. Access

- 3.1 The Provider must:
- (a) provide CRC Pharmacy Services for a minimum of five days a week during usual business hours unless such period is affected by a public holiday;

- (b) use its best endeavours to ensure a level of access to CRC Pharmacy Services that meets the reasonable needs of the Provider's Eligible Service Users; and
- (c) provide CRC Pharmacy Services during normal business hours to minimise the need for after-hours pharmacy services, as agreed between the Provider and the CRC Service Provider.

4. Service components

4.1 The services the Provider must provide as part of providing CRC Pharmacy Services include:

- (a) Dispensing Pharmaceuticals and providing Professional Advisory Services in accordance with clauses 3 to 6 of Schedule 1;
- (b) maintaining an accurate dispensing record and medication profile for every CRC Service User, and making it available, if requested, to:
 - (i) the CRC Service User, and members of the CRC Service User's multidisciplinary team; and
 - (ii) any other another provider or CRC Service Provider to which the CRC Service User transfers; and
- (c) synchronisation and reconciliation services, as appropriate, for each CRC Service User.

5. Delivery times

5.1 Unless Te Whatu Ora agrees otherwise in writing, in order to minimise unnecessary Dispensing and waste of Pharmaceuticals, the Provider must not deliver Pharmaceuticals to a CRC Service Provider earlier than five Business Days before the expected first administration of the Pharmaceutical to the relevant CRC Service User, unless:

- (a) the Pharmaceutical is not available in New Zealand at the time that the Provider is presented with the Prescription Form; or
- (b) the Provider and the CRC Service User agree arrangements for the Dispensing of medication if the Service User is away from the CRC Service or their home for a period of time and medication is taken away.

6. Notification of provision of Services

6.1 No later than one month after the date on which the Provider first provides CRC Pharmacy Services to a CRC Service User, until such time as this information can be provided electronically to the national register, the Provider must inform the Payment Agent in writing of the following:

- (a) the CRC Service User's name, NHI Number, and date of birth;

- (b) the start date of CRC Pharmacy Services;
- (c) the end date of CRC Pharmacy Services, if applicable;
- (d) the name of the CRC Service Provider (in which the CRC Service User to whom the Provider is providing CRC Pharmacy Services resides); and
- (e) the Provider's name and provider number.

7. Service linkages

7.1 The Provider must have effective links with:

- (a) the service providers and organisations specified in clause 13 of Schedule 1; and
- (b) the CRC Service Providers providing services to the Provider's CRC Service Users.

Fees, payments, and claiming rules

8. Additional claiming and payment rules for CRC Pharmacy Services

8.1 The Provider must not provide, or claim for providing, CRC Services to:

- (a) Service Users that receive:
 - (i) ARRC Pharmacy Services;
 - (ii) LTC Services;
- (b) Service Users living in their own homes or in rented accommodation, living with family, or in a boarding arrangement, whether or not they are receiving regular medication oversight or support services from a disability provider;
- (c) Service Users living in community support houses; or
- (d) Service Users receiving respite care in a CRC Service.

8.2 If the Provider provides any of the following Services to a CRC Service User, the Provider must claim, and will be paid, in respect of each Pharmaceutical Dispensed to or for a CRC Service User as follows:

- (a) for Class B Pharmaceutical Services, NPPA Services A, NPPA Services B, and Extemporaneously Compounded Preparations Services, in accordance with the relevant provisions in Schedule 1;
- (b) for Aseptic Services, in accordance with Schedule 3A.2 (if applicable);
- (c) for Clozapine Services, in accordance with Schedule 3A.4 (if applicable); and

(d) for Special Foods Services, in accordance with Schedule 3B.4 (if applicable).

8.3 Subject to clause 8.2, if the Provider makes a claim under this Schedule in relation to the Dispensing of a Pharmaceutical to or for a CRC Service User, the Provider must not claim, and Te Whatu Ora will not pay:

(a) for the Dispensing of the Pharmaceutical or for Professional Advisory Services relating to the Dispensing of the Pharmaceutical in accordance with clauses 3 to 6 of Schedule 1;

(b) for the provision of any other Population Service under a Service Schedule in Schedule 3.

8.4 If the Provider Dispenses an Unregistered Medicine in accordance with this Schedule, Te Whatu Ora will pay the Provider an additional payment for Dispensing the Unregistered Medicine in accordance with clause 33 of Schedule 1.

8.5 The Provider must provide the date of birth of each CRC Service User for which the Provider submits a claim.

9. Payment for CRC Pharmacy Services

9.1 Te Whatu Ora will pay the Provider a CRC Pharmacy Services Fee for each Pharmaceutical that the Provider Dispenses to or for a Service User and claims in accordance with this Agreement.

9.2 The CRC Pharmacy Services Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the CRC Pharmacy Services Fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:

- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; and
- (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more

PF	=	the Per Pack Fee
HF	=	the Handling Fee for the Pharmaceutical, which is \$1.13
HFM	=	the Handling Fee Multiplier for the Pharmaceutical, which is 5.30
GST	=	1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)
CoP	=	the Co-payment that the Provider may charge the Service User (if any)

9.3 Subject to clause 9.4, if "R" is a negative number:

- (a) that number will be treated as a positive amount; and
- (b) Te Whatu Ora will be entitled to recover that amount from the Provider (including by way of set-off).

9.4 Te Whatu Ora will not recover (nor be entitled to recover) the amount "R" if the Dispensing of the Pharmaceutical is a Negative A3 or J3 Transaction.

Definitions

10. Definitions that apply to this Service Schedule

10.1 In this Service Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

CRC Service means a community residential care service run by a CRC Service Provider that provides CRC Service Users with accommodation (either in a large facility or in individual units/group housing) and rehabilitative support

CRC Service Provider means an organisation funded by a Government agency to provide CRC services to CRC Service Users, and non-subsidised Service Users

CRC Service User means a Service User described in clause 2.

SCHEDULE 3B.3

AGE-RELATED RESIDENTIAL CARE PHARMACY SERVICES

The Services

1. Background and Service objectives

1.1 Te Whatu Ora wishes to fund pharmacy services for ARRC Service Users in ARRC Facilities:

- (a) to ensure appropriate pharmacy services and advice are provided to ARRC Service Users and to those Service Users' ARRC Providers; and
- (b) as part of an integrated community health service that:
 - (i) provides ARRC Service Users with the best quality and most cost-effective Services, within available funding, based on established professional and quality management standards and codes of practice;
 - (ii) provides specialist advice as required to ensure optimal medicines management for ARRC Service Users;
 - (iii) works with prescribers, administering staff, and providers of medicines to ensure that systems are in place that minimise the unnecessary Dispensing and waste of Pharmaceuticals; and
 - (iv) ensures ARRC Service User and Staff safety.

2. Eligible Service Users

2.1 Te Whatu Ora will fund the Provider to provide ARRC Pharmacy Services to ARRC Service Users.

2.2 To avoid doubt, a person who resides in a rest home or long-stay care hospital (including an ARRC Facility) who has not been needs assessed as requiring long-term residential care in a hospital or rest home indefinitely, is not an ARRC Service User.

3. Access

3.1 The Provider must:

- (a) provide ARRC Pharmacy Services for a minimum of five days a week during usual business hours unless such period is affected by a public holiday;
- (b) use its best endeavours to ensure a level of access to ARRC Pharmacy Services that meets the reasonable needs of ARRC Service Users; and

- (c) provide ARRC Pharmacy Services during normal business hours to minimise the need for after-hours pharmacy services, as agreed between the Provider and each ARRC Provider.

4. Service components

4.1 The services the Provider must provide as part of providing ARRC Pharmacy Services include:

- (a) Dispensing Pharmaceuticals and providing Professional Advisory Services in accordance with clauses 3 to 6 of Schedule 1;
- (b) implementing systems for the distribution and administration of Pharmaceuticals to ARRC Service Users' ARRC Providers that support the guidelines issued by Te Whatu Ora about medicines care for residential aged care;
- (c) maintaining an accurate medication profile for every ARRC Service User and making it available, if requested, to:
 - (i) the ARRC Service User and members of the ARRC Service User's multidisciplinary team; and
 - (ii) any other provider, ARRC Provider, or secondary care Practitioner that the ARRC Service User transfers to;
- (d) synchronisation, reconciliation, and review services, as appropriate for each ARRC Service User;
- (e) encouraging compliance by, and drug efficacy for, each ARRC Service User by providing information, support, advice, and education to the ARRC Facility staff who are competent in medicines management, involving the ARRC Service User if and when appropriate;
- (f) making a Pharmacist available to ARRC Service Users and the ARRC Providers of relevant ARRC Facilities on a regular basis to provide support, information, and advice to the ARRC Service Users and, as appropriate, ARRC Providers and ARRC Facility staff members; and
- (g) providing a delivery service to ARRC Service Users in ARRC Facilities.

5. Delivery times

5.1 Unless Te Whatu Ora agrees otherwise in writing, in order to minimise unnecessary Dispensing and waste of Pharmaceuticals, the Provider must not deliver a Pharmaceutical to an ARRC Service User in an ARRC Facility earlier than five Business Days before the expected first administration of the Pharmaceutical to the relevant ARRC Service User.

- 5.2 The delivery times in clause 5.1 do not apply if a Pharmaceutical is not available in New Zealand at the time that the Provider is presented with the Prescription Form.

6. Notification of provision of Services

- 6.1 The Provider must inform Te Whatu Ora in writing (or electronically using the HPI Number) of the names of the ARRC Facilities in which ARRC Service Users to whom the Provider provides ARRC Pharmacy Services reside, within one month:

- (a) of the Commencement Date; or
- (b) in the case of a new ARRC Facility that the Provider has not previously informed Te Whatu Ora about, within one month of the date on which the Provider first provides ARRC Pharmacy Services to an ARRC Service User in that ARRC Facility.

7. Service linkages

- 7.1 The Provider must have effective links with:

- (a) the service providers and organisations specified in clause 13 of Schedule 1;
- (b) palliative care providers;
- (c) pain management service providers; and
- (d) the ARRC Providers of the relevant ARRC Facilities.

Fees, payments, and claiming rules

8. Additional claiming and payment rules for ARRC Pharmacy Services

- 8.1 If the Provider provides any of the following Services to an ARRC Service User, the Provider must claim, and will be paid, in respect of each Pharmaceutical Dispensed to or for an ARRC Service User as follows:

- (a) for Class B Pharmaceutical Services, NPPA Services A, NPPA Services B, and Extemporaneously Compounded Preparations Services, in accordance with the relevant provisions in Schedule 1;
- (b) for Aseptic Services, in accordance with Schedule 3A.2 (if applicable);
- (c) for Clozapine Services, in accordance with Schedule 3A.4 (if applicable); and
- (d) for Special Foods Services, in accordance with Schedule 3B.4 (if applicable).

- 8.2 Subject to clause 8.1, if the Provider makes a claim under this Schedule in relation to the Dispensing of a Pharmaceutical to or for an ARRC Service User, the Provider must not claim, and Te Whatu Ora will not pay:
- (a) for the Dispensing of the Pharmaceutical and providing Professional Advisory Services in relation to the Dispensing of the Pharmaceutical in accordance with clauses 3 to 6 of Schedule 1; or
 - (b) for the provision of any other Population Service under a Service Schedule in Schedule 3.
- 8.3 If the Provider Dispenses an Unregistered Medicine in accordance with this Schedule, Te Whatu Ora will pay the Provider an additional payment for Dispensing the Unregistered Medicine in accordance with clause 33 of Schedule 1.
- 8.4 The Provider must provide the date of birth of each ARRC Service User for which the Provider submits a claim.

9. ARRC Pharmacy Services Fee

- 9.1 Te Whatu Ora will pay the Provider an ARRC Pharmacy Services Fee for each Pharmaceutical that the Provider Dispenses in accordance with this Agreement.
- 9.2 The ARRC Pharmacy Services Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the ARRC Pharmacy Services Fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is:

- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceuticals is less than \$150.00; and
- (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceuticals is \$150.00 or more

PF = the Per Pack Fee

HF = the Handling Fee for the Pharmaceutical, which is \$1.13

HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 5.30

GST = 1.15 (or such other amount as correctly reflects the current GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any)

9.3 Subject to clause 9.4, if "R" is a negative number:

(a) that number will be treated as a positive amount; and

(b) Te Whatu Ora will be entitled to recover that amount from the Provider (including by way of set-off).

9.4 Te Whatu Ora will not recover (nor be entitled to recover) the amount "R" if the Dispensing of the Pharmaceutical is a Negative A3 or J3 Transaction.

Definitions

10. Definitions that apply to this Service Schedule

10.1 In this Service Schedule, unless the context requires otherwise, the following words and phrases have the following meaning:

ARRC Facility means a hospital or rest home, which may contain dementia or psycho-geriatric beds, for which an ARRC Provider provides ARRC Pharmacy Services to ARRC Service Users

ARRC Provider means a provider who has an agreement with Te Whatu Ora to provide ARRC Pharmacy Services

ARRC Service User means a Service User who has been positively needs assessed as requiring long-term residential care in a hospital or rest home indefinitely under the Residential Care and Disability Support Services Act 2018, and is receiving ARRC Pharmacy Services from an ARRC Provider in an ARRC Facility.

SCHEDULE 3B.4

SPECIAL FOODS SERVICES

The Services

1. Background and service objectives

- 1.1 Te Whatu Ora wishes to fund Special Foods Services to enable Service Users to have appropriate access to Special Foods in a community setting.

2. Eligible Service Users

- 2.1 Eligible Service Users are Eligible Persons who are prescribed Special Foods.

3. Access

- 3.1 The Provider must provide Special Foods Services to Eligible Service Users at all times when the Provider's Premises is open for normal business, in accordance with clause 11 of Schedule 1.

4. Service components

- 4.1 The Provider must Dispense Special Foods in accordance with clauses 3 to 6 of Schedule 1.

5. Service linkages

- 5.1 The Provider must have effective links with:
- (a) the service providers and organisations specified in clause 13 of Schedule 1;
 - (b) Prescribers in the Provider's area who prescribe Special Foods; and
 - (c) appropriate support groups for Service Users of Special Foods Services.

Fees, payments, and claiming rules

6. Additional claiming and payment rules for Special Foods Services

- 6.1 If the Provider is permitted to charge a Co-payment in accordance with clause D.5(2), the Provider may only charge a Service User one Co-payment if the Service User receives more than one flavour of the same type of Special Food listed in the Pharmaceutical Schedule.
- 6.2 If the Provider provides NPPA Services A or NPPA Services B to or for a Service User in accordance with this Schedule, the Provider must claim for each Pharmaceutical Dispensed to the Service User in accordance with the relevant provisions in Schedule 1.

7. Special Foods Services Fee

7.1 Te Whatu Ora will pay the Provider a Special Foods Services Fee for each Special Food that the Provider Dispenses to or for a Service User in accordance with this Agreement.

7.2 The Special Foods Services Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP$$

where:

R = the Special Foods Services Fee that Te Whatu Ora will pay the Provider (if R is a positive number)

Sc = the GST exclusive subsidy specified for the Special Food in the Pharmaceutical Schedule on the date of Dispensing

M = a margin towards the procurement and stockholding costs for the Special Food, which is 0.04

PF = the Per Pack Fee

HF = the Handling Fee for the Special Food, which is \$1.13

HFM = the Handling Fee Multiplier for the Special Food, which is 5.30

GST = 1.15 (or such other amount as correctly reflects the GST rate on the date of Dispensing)

CoP = the Co-payment that the Provider may charge the Service User (if any)

7.3 Subject to clause 7.4, if "R" is a negative number:

(a) that number will be treated as a positive amount; and

(b) Te Whatu Ora will be entitled to recover that amount from the Provider (including by way of set-off).

7.4 Te Whatu Ora will not recover (nor be entitled to recover) the amount "R" if the Dispensing of the Pharmaceutical is a Negative A3 or J3 Transaction.

SCHEDULE 3B.5

COMMUNITY PHARMACY ANTI-COAGULATION MANAGEMENT SERVICES

The Services

1. Background and service objectives

- 1.1 This Service Schedule relates to the anti-coagulation management of Service Users on warfarin by accredited providers.
- 1.2 The objective of the Community Pharmacy Anti-coagulation Management (CPAM) Service is the provision of International Normalised Ratio (INR) point-of-care testing by providers, and the adjustment of warfarin doses within a defined range with the aid of an approved decision-support system.
- 1.3 The CPAM Service aims to:
- (a) support Service Users and their families/whānau to better understand and manage their warfarin medication;
 - (b) reduce warfarin-related adverse medication events;
 - (c) improve accessibility and convenience for Service Users;
 - (d) improve multidisciplinary management of Service Users prescribed warfarin by a community pharmacy service;
 - (e) reduce the burden on Medical Practitioners; and
 - (f) prioritise services to the following patient groups, if possible:
 - (i) people with venous access issues;
 - (ii) people with poor attendance at their GP practice, or people that GP practices have difficulty contacting with the results of the INR test;
 - (iii) people with reduced compliance and/or with reduced warfarin control;
 - (iv) high needs patients/people with poor health literacy; and
 - (v) people with mobility issues.

2. Eligible Service Users

- 2.1 Eligible Service Users are Service Users who:
- (a) have a Medical Practitioner;

- (b) are referred to the Provider by the Medical Practitioner, and who delegates point-of-care warfarin testing, dose adjustment and associated patient counselling to the Provider;
- (c) are taking warfarin medication and either:
 - (i) require warfarin loading and initial stabilisation; or
 - (ii) have overlapping warfarin medication with low molecular weight heparin (LMWH);
- (d) are mobile and able to access CPAM Services;
- (e) consent to registration in the CPAM Service;
- (f) do not:
 - (i) reside in an Aged Residential Care Facility (unless otherwise agreed by Te Whatu Ora that CPAM Services may be provided in this setting); or
 - (ii) have anti-phospholipid syndrome, anti-cardiolipid syndrome, lupus anti-coagulant syndrome; and/or
- (g) are not receiving active anti-neoplastic treatment.

3. Exit criteria

3.1 The Provider must disenrol a Service User from the CPAM Service if:

- (a) the Service User chooses to exit the CPAM Service, leaves the Geographical Area, or is managed by another provider;
- (b) the Service User dies; or
- (c) the Service User is non-compliant or has not attended the CPAM Service.

3.2 If clause 3.1(b) applies, the Provider's obligation to disenrol the Service User arises when the Provider is informed that the Service User has died.

3.3 Unless otherwise agreed and advised by Te Whatu Ora – Health New Zealand, the maximum number of Service Users that the Provider may provide CPAM Services to is 50.

4. Access

4.1 The Provider must provide CPAM Services to Service Users at all times when the Provider's Premises is open for normal business, subject to the conditions set out in clause 11 of Schedule 1 and the availability of an accredited Pharmacist.

5. Service components

5.1 The Provider must provide CPAM Services in accordance with clauses 3 to 6 of Schedule 1.

5.2 The services the Provider must provide as part of providing CPAM Services include:

- (a) obtaining the consent of the Service User to be registered with the Provider for the CPAM Service;
- (b) documenting Medical Practitioner consent to be involved in the CPAM Service and acceptance of the CPAM Service standing order;
- (c) undertaking Service User assessment each time the INR test is undertaken in order to establish the Service User's history and any symptoms, and if any Service User factors may influence the results (eg, a missed dose of warfarin);
- (d) performing the INR test using a drop of blood on the test strip of an approved testing device using an approved decision support tool;
- (e) dose adjustment made by the supervising Pharmacist supported by an approved decision support tool with a validated dosing algorithm supported by published data;
- (f) giving the Service User the results of the INR test and providing advice on the dose of warfarin to take each day until the next INR test as a hard copy dosing calendar;
- (g) giving the Service User counselling and education about warfarin medication, and when required, using an approved Warfarin Education Programme;
- (h) electronically providing the Medical Practitioner with information on the results of the monitoring and changes to the warfarin regime;
- (i) requesting medical review by the Service User's Medical Practitioner if any INR test result is less than 1.5 or more than 4.0;
- (j) contacting the Service User's Medical Practitioner directly if the Pharmacist is concerned about the Service User's symptoms, results, or the dose recommendation;
- (k) keeping a full record of the Service User's care management plan as provided by the approved online decision support tool;
- (l) undertaking quality assurance activities (in accordance with clause 7);
- (m) auditing anti-coagulant management by regularly monitoring anti-coagulant control of Service Users and cumulative results using approved decision support software;
- (n) auditing compliance for timeliness of testing in order to identify Service Users with compliance issues using the approved decision support software;

- (o) recording the incidence of adverse events (in particular the incidence of bleeding) including hospital admissions using the approved decision support software; and
- (p) sending the results to a laboratory test repository, if available, via Healthlink.

6. Service linkages

- 6.1 A strong professional relationship must be in place between the Medical Practitioner and the Provider.
- 6.2 The Provider will work within the framework of local anti-coagulation policies, procedures and referral processes.
- 6.3 The Provider will ensure that the Premises has an appropriate secure IT connection to allow electronic linkage with general practice.
- 6.4 The Provider will ensure that the Premises is involved in an organised system of external quality assurance in accordance with clause 7.

7. Quality requirements

- 7.1 The following quality requirements also apply to CPAM Services:
 - (a) the Provider must undertake the following internal quality control activities:
 - (i) deliver the Service as per the standing order, and undertake annual reviews to ensure Pharmacists accredited to undertake the Service are operating according to the standing order;
 - (ii) perform testing in line with the standard operating procedure;
 - (iii) report on adverse events, anti-coagulant control and patient compliance in each quarterly monitoring report; and
 - (iv) ensure internal quality control testing on the INR Monitoring device is performed in line with the recommended procedure (a code chip is supplied by the manufacturer to regularly calibrate the machine);
 - (b) be involved with an organised system of external quality assurance (eg, National External Quality Assessment Service (United Kingdom), or The Royal College of Pathologists of Australasia (Australia) RCPA) or other external quality assurance programme, for example with the local laboratory, and may, as an additional quality check, compare test results on selected Service Users;
 - (c) ensure access to a private area within the Premises for testing and counselling; and

- (d) undertake a quarterly CPAM Service evaluation to determine quality outcomes and measures as measured against goals determined by Te Whatu Ora or the Pharmaceutical Society.

8. Qualified Provider

8.1 In order to provide CPAM Services:

- (a) the Pharmacists providing the CPAM Service must have a current Annual Practicing Certificate with no restrictions; and
- (b) at least two Pharmacists for each Premises must have attended an accredited CPAM Services training course and be accredited to provide CPAM Services, and are re-accredited every two years.

- 8.2 If there is a reason that the requirements in clause 8.1(b) cannot be met (eg, the Pharmacist is a sole operator) Te Whatu Ora must be satisfied that the Provider can guarantee safety and quality of the CPAM Services in the event of unexpected absence or leave.

9. Safety

- 9.1 The Medical Practitioner retains overall responsibility for management of Service Users, but delegates that care to the Pharmacist through a standing order.
- 9.2 The Provider will work within the framework of local anti-coagulation policies, procedures, and referral processes.
- 9.3 The Pharmacist is responsible for the quality assurance programme that ensures the test device, used to carry out the tests described in clause 7, is providing reliable results.

Reporting requirements

10. Reporting requirements

- 10.1 The Provider must record each Service User's NHI Number and, if requested by Te Whatu Ora – Health New Zealand, will provide NHI number information to Te Whatu Ora for more detailed analysis.
- 10.2 The Provider will be advised of any additional reporting requirements.
- 10.3 The Provider must report quarterly to Te Whatu Ora as follows, using an agreed reporting template:

Reporting Period	Report Due
1 July – 30 September	20 October

Reporting Period	Report Due
1 October – 31 December	20 January
1 January – 31 March	20 April
1 April – 30 June	20 July

Quarterly Report	
Quarterly Summary	Number of Service Users registered by NHI Number with the CPAM Service in the quarter (ie, active Service Users plus new Service Users minus Service Users who have exited the CPAM Service)
	Average number of INR tests per quarter
	Documentation of key performance indicators <ul style="list-style-type: none"> • Compliance (Tests on time, 1-3 days, 4-7 days, 7+ days) • Control (Tests in range, tests above, tests below) • Adverse events (Total recorded bleeds, Total recorded hospital admissions)
	A brief narrative report outlining progress implementing the service in this quarter, and any issues experienced.

10.4 The Provider must send the quarterly reports to performance_reporting@health.govt.nz or

Performance Reporting, Sector Operations,
Te Whatu Ora – Health New Zealand
Private Bag 1942
Dunedin 9054

or such other email address or address as advised by the Payment Agent.

Fees, payments, and claiming rules

11. CPAM Services Fee

11.1 Te Whatu Ora will pay the Provider a Dispensing Services Fee for each Pharmaceutical that the Provider Dispenses to or for a Service User and claims in accordance with this Agreement, in accordance with Schedule 1.

11.2 Te Whatu Ora will pay the Provider a CPAM Services Fee as follows:

- (a) if the Provider has not previously provided CPAM Services, a one-off payment of \$1,600 for establishment costs; and

- (b) \$47.25 per month for each CPAM Service User to whom the Provider provided CPAM Services in the month.
- 11.3 Te Whatu Ora will pay the CPAM Services Fee on receipt of a valid GST tax invoice that meets all legal requirements and contains the following information:
- (a) unique invoice number;
 - (b) invoice date (date invoice produced);
 - (c) GST number;
 - (d) provider name;
 - (e) claimant number;
 - (f) agreement number;
 - (g) address;
 - (h) contact details (phone, fax and email);
 - (i) District name;
 - (j) Service provided;
 - (k) volume (if required);
 - (l) period claiming for;
 - (m) amount excluding GST;
 - (n) GST amount;
 - (o) total amount including GST; and
 - (p) purchase unit number.
- 11.4 The Provider must send its invoice to provider_invoices@health.govt.nz or such other email address as advised by the Payment Agent.

Volumes of Service Users

12 Maximum numbers of Service users

- 12.1 The standard number of Service Users stated in clause 3.3 is 50. This figure is revised to a maximum of **XX** Service users. **(delete if the number of service users is 50)**

SCHEDULE 3B.6

SMOKING CESSATION SERVICES

The Services

1. Background and service objectives

1.1 Te Whatu Ora wishes to fund the provision of Smoking Cessation Services to Service Users who want to quit smoking by:

- (a) helping people to stop smoking completely, as soon as possible; and
- (b) providing an accessible and effective service to all people who smoke.

1.2 The evidence-based interventions that are the focus of the Smoking Cessation Services include providing:

- (a) information about access and use of approved cessation pharmacotherapies; and
- (b) behavioural support, which may be delivered in many ways including telephone, online, and face to face (individually or group based).

1.3 The Provider is encouraged to target high priority populations for the Smoking Cessation Service, meaning:

- (a) people with a mental health diagnosis;
- (b) pregnant women (of any ethnicity) because of the serious impacts of smoking during pregnancy;
- (c) smoking partners of, and family living with, pregnant women; and
- (d) Māori and Pacific people.

2. Eligible Service Users

2.1 Eligible Service Users are Service Users who:

- (a) present a Prescription to the Provider for a smoking cessation medicine;
- (b) present to purchase a smoking cessation product from the Provider;
- (c) ask the Provider to register them for Smoking Cessation Services; or
- (d) present and to whom the Provider provides subsidised nicotine replacement therapy without a Prescription

2.2 The Provider must not provide, or claim for providing, Smoking Cessation Services:

- (a) to people who are already receiving Smoking Cessation Services from another provider; or
- (b) to or for a Service User in excess of the Cap described in clause 3(1).

3. Cap on number of Service Users

3.1 Te Whatu Ora will notify the Provider in writing on or before 1 July of each year of the cap on the total number of Services Users the Provider may register to receive the Smoking Cessation Services ("Cap").

3.2 The Provider must:

- (a) monitor the number of Service Users registered by the Provider to receive Smoking Cessation Services; and
- (b) not register new Service Users to receive Smoking Cessation Services if the number of registered Service Users reaches the Cap.

3.3 If Te Whatu Ora receives an application from the Provider requesting an increase in the Cap, Te Whatu Ora may, in its sole discretion, increase the Cap by notice in writing to the Provider.

4. Exit criteria

4.1 The Provider may stop providing Smoking Cessation Services to or for a Service User if:

- (a) the Service User has successfully quit;
- (b) the Provider reasonably considers that no further interventions are required (four sessions are recommended as a minimum standard);
- (c) the Service User decides to discontinue receiving the Smoking Cessation Services; or
- (d) the Service User is unable to be contacted after a minimum three attempts by the Provider using at least two methods of contact (eg, telephone and letter).

5. Service components

5.1 The services the Provider must provide as part of providing the Smoking Cessation Service include:

- (a) an initial contact with the Service User that:
 - (i) provides information on what the Smoking Cessation Service offers (including information about follow-up support sessions and behavioural support approach);

- (ii) motivates and encourages the Service User to complete ongoing follow up support sessions;
- (iii) assesses the Service User's needs (including degree of tobacco dependence, smoking history, social circumstances, and suitable times to attend or be contacted);
- (iv) helps the Service User to set a Target Quit Date (TQD); and
- (v) builds a system of support that best matches the Service User's needs; and
- (b) mutually agreed and scheduled follow up support sessions with the Service User that include:
 - (i) provision of information about follow up support services;
 - (ii) provision of support that boosts and maintains motivation, addresses tobacco withdrawal symptoms, addresses issues with medication use, helps Service Users to maintain abstinence and provides basic coping strategies as needed; and
 - (iii) working with family and whānau, as appropriate, to enable them to provide the necessary support for the Service User to stop smoking.

5.2 Te Whatu Ora and the Provider acknowledge that:

- (a) providing four sessions is recommended as a minimum standard, however it is recognised that some individuals may require more, and some may succeed with fewer sessions; and
- (b) the majority of the follow-up support sessions should be conducted within the first four weeks following the Service User's TQD (because relapse is most likely during this period).

6. Settings

- 6.1 Smoking Cessation Services may be delivered in one or more settings including, but not limited to, health care settings, community settings (eg, Marae, churches, community centres), by telephone, or at the Service User's home (with the appropriate safety systems in place).

7. Key inputs

- 7.1 Smoking Cessation Services may be delivered by any Staff who have completed the appropriate smoking cessation training to the standard approved by Te Whatu Ora – Health New Zealand.

8. Service linkages

- 8.1 The Provider must liaise with other health care professionals as appropriate to ensure clinical continuity and address Service Users' other health/social needs, including by notifying each Service User's primary health care provider of the Smoking Cessation Service delivered as well as the outcome (if possible).

*Quality requirements***9. Quality requirements**

- 9.1 The Provider must comply with the Provider Quality Standards described in the Operational Policy Framework: <https://nsfl.health.govt.nz/system/files/documents/publications> including any successor standards prepared by Te Whatu Ora for the same or similar purposes.
- 9.2 The Provider must demonstrate in particular that:
- (a) there is a plan per Service User for the follow up support sessions; and
 - (b) these sessions were conducted in accordance with the terms of this Schedule, and the outcomes were recorded in accordance with the requirements set out in clauses 10 and 11.
- 9.3 The Provider is also expected to comply with guidelines issued by Te Whatu Ora concerning helping people to stop smoking.

*Reporting requirements***10. Quarterly reports**

- 10.1 The Provider must, for each Service User:
- (a) prepare and submit a quarterly report containing the information set out in the table in clause 10.4; and
 - (b) submit the report to Te Whatu Ora on the 20th of the second month following the end of each calendar quarter.
- 10.2 The report must contain information on all Service Users who registered with the Provider to receive Smoking Cessation Services and set a TQD in the preceding calendar quarter.
- 10.3 The quarterly report submitted on 20 February of each year must contain information on all Service Users who set a TQD in the second Quarter, including quit outcomes for each Service User (refer to Part C of the table in clause 10.4).

10.4 The information to be included in quarterly reports is as follows:

A. Demographic Information

Information Submitted	Definition/Explanation
Gender	<ul style="list-style-type: none"> • Male • Female – Pregnant • Female – Not Pregnant
Ethnicity	The Ethnicity Data Protocols for the Health and Disability Sector describes procedures for the standardised collection, recording, and output of ethnicity data for the New Zealand health and disability sector.
Age Group	<ul style="list-style-type: none"> • Under 19 years • 19 to 29 years • 30 to 39 years • 40 to 49 years • 50 to 59 years • 60 + years • Unknown

B. Service Information (per Service User)

Information Submitted	Definition/Explanation
Number of Treatment Sessions	<ul style="list-style-type: none"> • Less than 4 • 4 to 8 Sessions • 9 to 16 Sessions • 17+ Sessions • Number of Sessions Unknown
Time to first cigarette (from time of waking), specifically:	<ul style="list-style-type: none"> • Within 5 minutes • 6–30 minutes • 31–60 minutes • After 60 minutes <p>This provides an indication of the level of addiction and may impact on outcomes.</p>

Information Submitted	Definition/Explanation
Medication use (Yes/No):	<ul style="list-style-type: none"> • NRT (nicotine patches, gum, and lozenges) • Bupropion • Nortriptyline • Varenicline • Specify whether the Service User used any of these medicines during the first three months of receiving the Smoking Cessation Services.
Referrals	<ul style="list-style-type: none"> • Recruited by pharmacy • Self-referral • Primary care (GP) • Family/whānau • Other

C. Quit Outcomes (per Service User)

Information Submitted	Definition/Explanation
<p>For each Service User who set a TQD in Quarter Two provide each of the two outcome measures listed below (1-2):</p> <ul style="list-style-type: none"> • abstinent Yes/No (refer below for definition of "abstinent"/ "abstainer") 	<p>The 4-week abstinence rate should be greater than 35% if self-reported.</p> <p>The outcome at the 4-week point allows for estimation of long-term abstinence rates.</p> <p>Note: No Carbon Monoxide Validation is required as part of this Service.</p>

Information Submitted	Definition/Explanation
1. At four weeks after TQD	<p>The Provider must contact each Service User at four weeks after their TQD. At this follow-up, Service Users must answer the following question by choosing one of the four options (a–d).</p> <p>Over the past two weeks have you smoked at all?</p> <p>[a] No, not a single puff</p> <p>[b] Yes, just a few puffs</p> <p>[c] Yes, between 1 and 5 cigarettes</p> <p>[d] Yes, more than 5 cigarettes</p> <p>Only those who answer '[a] No, not a single puff' will qualify as abstainers.</p>
2. At longest follow up point after TQD	<p>If resources allow, longer-term follow-up (e.g. at 3 or 6 months) can provide a further check on the effectiveness of the Smoking Cessation Services, especially if the Provider is providing Smoking Cessation Services to specific populations.</p> <p>Longer-term follow-up is not compulsory, nor does it mean that the Provider is required to see clients on a regular basis for this length of time. However, if the Provider does follow-up, then the date and smoking status must be recorded.</p> <p>Smoking status should be measured by asking Service Users to answer the following question by choosing one of the four options (a–d):</p> <p>Over the past four weeks have you smoked at all?</p> <p>[a] No, not a single puff</p> <p>[b] Yes, just a few puffs</p> <p>[c] Yes, between 1 and 5 cigarettes</p> <p>[d] Yes, more than 5 cigarettes</p> <p>Only those who answer '[a] No, not a single puff' will qualify as abstainers.</p>

11. Year-end reports

- 11.1 The Provider must submit a year-end report containing the following information by 31 July each year:

Reporting Requirement	Information Submitted
Service Information	<p>A narrative that describes the approach to treatment taken, which includes information such as:</p> <ul style="list-style-type: none"> • average number of treatment sessions per Service user • method of service delivery (telephone/face-to-face, group/individual) • other relevant information.

*Fees, payments, and claiming rules***12. Smoking Cessation Services Fee**

- 12.1 The Provider may claim for providing Smoking Cessation Services to or for a Service User by submitting a valid tax invoices on a monthly basis, with each invoice to be provided on or before the 20th day of the month following the month in which the Service Users were registered, with the Provider to receive the Smoking Cessation Services and who set a Target Quit Date (TQD) in that month.
- 12.2 A tax invoice must contain the following information:
- unique invoice number;
 - invoice date (date invoice produced);
 - GST number;
 - provider name;
 - claimant number;
 - agreement number;
 - address;
 - contact details (phone, fax and email);
 - District name;
 - Service provided;

- (k) volume (if required);
 - (l) period claiming for;
 - (m) amount excluding GST;
 - (n) GST amount;
 - (o) total amount including GST; and
 - (p) purchase unit number.
- 12.3 The Provider must send its invoice to provider_invoices@health.govt.nz or such other email address as advised by the Payment Agent.
- 12.4 On receipt of a valid invoice that complies with the requirements set out in clause 12.1 and 12.2, Te Whatu Ora will pay the Provider \$100.00 (GST exclusive) for each Service User ("Smoking Cessation Services Fee"), up to the Cap, to whom the Provider provided Smoking Cessation Services in accordance with this Schedule.
- 12.5 Te Whatu Ora will pay a Smoking Cessation Services Fee on the 20th day of the month following the month in which Te Whatu Ora received the invoice.
- 12.6 Te Whatu Ora will pay the Provider a Smoking Cessation Services Fee only if the Service User has not previously registered with another provider, or the Provider has made a reasonable effort to check that the Service User has not previously registered to receive Smoking Cessation Services from another provider.
- 12.7 Nothing in this Schedule entitles the Provider to receive more than the Smoking Cessation Service Fee if it registers the same Service User to receive Smoking Cessation Services more than once.
- 13. No payment to be sought from Service Users**
- 13.1 Despite clause D.7, the Provider must not in any circumstances demand or accept any Co-payment, charge, or other fee from a Service User to whom the Provider provides Smoking Cessation Services.

SCHEDULE 3C.1

[OTHER SERVICES]