

Integrated pharmacist services in the community agreement

BETWEEN

[District Health Board]

AND

[Provider]

1 July 2018

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

[insert name] District Health Board by:

Signature
Name
Position
Date
Witnessed by:
Signature
Name
Occupation
Residence
Date

[Provider name] by:

<div>Signature</div>	<div>Signature</div>
<div>Name</div>	<div>Name</div>
<div>Position</div>	<div>Position</div>
<div>Date</div>	<div>Date</div>
<div>Witnessed by:</div>	<div>Witnessed by:</div>
<div>Signature</div>	<div>Signature</div>
<div>Name</div>	<div>Name</div>
<div>Occupation</div>	<div>Occupation</div>
<div>Residence</div>	<div>Residence</div>
<div>Date</div>	<div>Date</div>

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Part A Background

A.1 Context of this Agreement

- (1) The Ministry of Health, District Health Boards, PHARMAC, pharmacist service providers, and a wide range of stakeholders in the primary care sector want to ensure that community pharmacist services are provided in an integrated manner and in a way that is fit for all New Zealanders. They agree that pharmacist 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) The Ministry and District Health Boards also wish to implement the Pharmacy Action Plan 2016, and ensure that pharmacist 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) The DHB also wants to ensure that this Agreement, and the way in which community pharmacist services are delivered, is flexible enough to enable it to commission Population Services to meet the needs of people living in the DHB's Geographical Area.

A.2 Purposes of this Agreement

- (1) The DHB and the Provider have entered into this Agreement to:
 - (a) implement the objectives set out above relating to the delivery of community pharmacist services, including the objectives reflected in the five themes of the New Zealand Health Strategy;
 - (b) set out the roles and responsibility that the DHB and the Provider have to ensure that Services are funded and provided;
 - (c) provide a framework for the DHB 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 the DHB will pay for, those Services; and
 - (f) provide that the DHB 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 the DHB 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 the DHB will pay to the Provider.
- (2) The Services Schedules that may be included in this Agreement are:
 - (a) Schedule 1 (Pharmaceutical Supply Services), which includes NPPA Services A, NPPA Services B, Class B Pharmaceutical Services, and Extemporaneously Compounded Preparations Services;
 - (b) Schedule 2 (Professional Advisory Services);
 - (c) Schedule 3A.1 (Opioid Substitution Treatment Services);
 - (d) Schedule 3A.2 (Aseptic Pharmacist Services);
 - (e) Schedule 3A.3 (Sterile Manufacturing Services);
 - (f) Schedule 3A.4 (Pharmacist Clozapine Services);
 - (g) Schedule 3A.5 (Pharmacist Influenza Immunisation Services);
 - (h) Schedule 3B.1 (Long Term Conditions Pharmacist Services);
 - (i) Schedule 3B.2 (Community Residential Care Pharmacist Services);
 - (j) Schedule 3B.3 (Age-Related Residential Care Pharmacist Services);
 - (k) Schedule 3B.4 (Special Foods Services);
 - (l) Schedule 3B.5 (Community Pharmacist Anti-Coagulation Management Services);
 - (m) Schedule 3B.6 (Smoking Cessation Services);
 - (n) any other Service Schedules relating to Services provided by the Provider and funded by the DHB 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.

A.4 Term of this Agreement

- (1) This Agreement starts on [1 July 2018] (the "Start Date") and continues until it is terminated in accordance with its termination provisions or at law (the "End Date").
- (2) 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 the DHB will work together

- (1) The DHB and the Provider agree that they will each be guided by the relationship principles set out in subclause (2):
- (2) The Provider and the DHB 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 People, and promote the inclusion and participation in society of Eligible People 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 ourselves 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 DHB's Geographical Area.

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 The Pharmaceutical Schedule and other documents

- (1) The DHB 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 Pharmaceutical Transactions Data Specification;
 - (c) this Agreement; and
 - (d) the Procedures Manual.
- (2) The DHB 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 the DHB in writing of its concern, and the DHB will use reasonable endeavours to address it with PHARMAC.
- (3) If the DHB intends to propose a change to the Pharmaceutical Schedule to PHARMAC, the DHB 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 has formal and documented processes are maintained to plan and implement safe and timely treatments, referrals, and transfers; and

- (f) it co-operates, and maintains a range of linkages, with other providers and community agencies to promote effective service delivery.
- (2) The Provider must participate in, or support, any public health campaigns relevant to the Services being run by the DHB or Ministry, as reasonably required by the DHB.

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, or any other regulatory body, from time to time.

B.6 Code of Consumers' Rights

- (1) The Provider must provide the Services in accordance with all 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 1993 and the Health Information Privacy Code 1994.

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 Vulnerable Children Act 2014

- (1) If the Provider provides children's services, as that term is defined in section 15 of the Vulnerable Children 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 the DHB in relation to, worker safety checks as required by the Vulnerable Children 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) The DHB 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, will 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 terms and conditions set out in the Pharmaceutical Schedule; and
 - (d) the terms set out in this Agreement.
- (2) The Provider can determine whether a person is an Eligible Person by:
 - (a) identifying eligibility by the 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 the Ministry.
- (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.

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.

B.14 Providing Services to ineligible persons

- (1) If the Provider provides Services or Pharmaceuticals to a person who is not an Eligible Person, the Provider must comply with clause D.4.

B.15 Eligibility for Population Services

- (1) Unless a Service User is eligible to receive one or more Population Services, the Provider may only provide the Service User with Product Supply Services and Professional Advisory Services.
- (2) If a Service User is eligible for one or more Population Services provided by the Provider, the Provider must provide the Service User with each Population Service.

Access to Services

B.16 Service information

- (1) The Provider must have available for Eligible People 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 People to access the Services.

B.17 Declining Services

- (1) The Provider may decline to provide Services to a Service User on the basis of conscientious objection if permitted by the Code of Ethics.
- (2) The Provider must develop and implement processes to ensure the immediate safety of persons and others who are not eligible for the Services or who are declined Services, which must provide for:
 - (a) sufficient preliminary assessment to determine whether the person is eligible for the Services, does not require Services, or should be declined the Services;
 - (b) advice to the person or their family/whānau of alternative services that are available and, if necessary, formal referral of the person to an alternative service;
 - (c) documenting the reasons for declining Services and informing the DHB, if required; and
 - (d) otherwise managing the declining of Services.

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 DHB's Geographical Area

- (1) The Provider must provide Services only within the DHB's Geographical Area, unless the DHB agrees otherwise in writing (which may be subject to conditions).
- (2) To avoid doubt, the provision of Services to a Service User who resides in the geographical area of another District Health Board 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 the DHB's Geographical Area.

B.20 Location

- (1) The Provider must advise the DHB in writing if the Provider changes the location of its Premises, no later than ten Business Days after the change, by giving the new address of its Premises.
- (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) the DHB agrees in writing (which may be subject to conditions).

Staff and Premises

B.21 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.22 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 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.23 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.24 Māori health

- (1) The Provider must, with reference to He Korowai Oranga – Māori Health Strategy and Whakataatanga – 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.25 Māori health in Quality Improvement Plan

- (1) If reasonable, given the demographic make-up 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 the DHB from time to time.

B.26 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 the DHB, 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 body fluids, for Māori Service Users who identify themselves as requiring this additional service.

B.27 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.
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.28 Other population groups

- (1) The DHB and the Provider recognise that the needs of some population groups, in addition to Māori, may be or may become a priority in relation to improving health outcomes and that they need to be prepared to seek to meet those needs as they arise and evolve over time.
- (2) The Provider must provide the Services to members of other population groups in a manner that meets their diverse needs.

B.29 DHB's assistance

- (1) The DHB will assist the Provider to meet its obligations in relation to Māori Service Users and other population groups.

Governance, management, and quality improvement

B.30 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.31 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 and 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 from the DHB for community pharmacist services before 1 January 2018, in which case the Provider must implement its Quality Improvement Plan no later than six months after it first received funding from the DHB.

B.32 Quality systems and process

- (1) The Provider must ensure that the quality systems and processes developed under clause B.31(3)(d):
 - (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) require the Provider and its Staff who are Pharmacists to attend and participate in Pharmacist education seminars and programmes in the DHB's Geographical Area.

B.33 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.34 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.35 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/kaumatua, rongoa practitioners, spiritual advisors, Māori Staff, and others, as appropriate.

Risk management

B.36 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 it 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.37 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.38 Civil defence

- (1) The Provider must co-operate with any civil defence emergency activity as appropriate in the DHB's 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.39 Health emergency planning

- (1) The Provider must participate in the development of the district or regional Health Emergency Plan coordinated by the DHB to ensure the needs of the Provider's Service Users and Staff are met during a health emergency.
- (2) The Provider and the DHB agree that the Health Emergency Plan will:
 - (a) outline the human, financial and other roles and resources that each participant, including District Health Boards, primary care providers, and pharmacist 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 the DHB and relevant participants to ensure the Health Emergency Plan is reviewed periodically to maintain currency and, if requested by the DHB, be involved in processes to ensure that emergency responses are integrated, coordinated and exercised.
- (4) The DHB 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) The DHB will negotiate with the Provider to contribute to the Provider's costs if extraordinary funding is available to manage an emergency.

Record keeping

B.40 Service User Records

- (1) The Provider must maintain Service Users' Records and other related information, including in relation to Pharmaceuticals Supplied to Service Users, in accordance with its legal and professional obligations.

B.41 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.42 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.
- (2) The Provider must have in place appropriate back-up and disaster recovery procedures to protect against loss of information.
- (3) If the Provider ceases to provide some or all Services, it must ensure that all Records are properly preserved and, if appropriate, transferred to any replacement provider.

B.43 Accuracy of information

- (1) If the Provider is required to submit or give the DHB 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.

Relationships and advisory arrangements

B.44 Relationship meetings

- (1) The Provider and the DHB agree that they may, from time to time, meet to discuss matters relating to their relationship, this Agreement, and the provision of Services.

B.45 Contract Group and Expert Advisory Group

- (1) The Provider and the DHB agree that a Contract Group and the Expert Advisory Group will each have:
 - (a) the functions specified in this Agreement; and
 - (b) any functions set out in a terms of reference for the group.
- (2) The Provider and the DHB agree that the membership and procedures for the conduct of meetings of each group will be set out in the group's terms of reference, which the group may update from time to time.

Reporting

B.46 Reports

- (1) The Provider must give the DHB any reports required by a Service Schedule, the Procedures Manual, or the Pharmacist Data Transfer Specification.

B.47 Ad-hoc reports

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

B.48 Cost of reporting

- (1) The costs to the Provider of giving the DHB 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.

Evaluation of Services

B.49 Provider Service User satisfaction surveys

- (1) At appropriate intervals, and at least annually, the Provider must carry out Service User satisfaction surveys to assess the quality of the Provider's Service delivery, in accordance with District Health Board or Ministry guidelines.
- (2) The Provider must give the DHB the results of any Service User satisfaction surveys if requested.

B.50 DHB surveys

- (1) The DHB may, from time to time, undertake surveys of Service Users, Prescribers and Pharmacists.
- (2) The Provider and the DHB acknowledge and agree that a survey is not an Audit.

Part C General terms

No exclusivity and additional services

C.1 Rights not exclusive

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

C.2 Provider may provide services not funded by the DHB

- (1) Subject to clause C.4, the Provider may provide services to people that are not Eligible People, or not eligible for a Population Service.

C.3 Additional services

- (1) The Provider agrees that, if it wants to provide and receive funding for any service that it is not providing under this Agreement:
 - (a) the DHB may have access to and review the Provider's Records (including any Audit records) and any other relevant information, to enable the DHB to assess the Provider's ability to provide the service; and
 - (b) the Provider must make the Records (including any Audit records) and other information available to the DHB and give it all reasonable assistance in relation to the review.

Third party relationships, including subcontracting

C.4 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.5 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.6 Subcontracting

- (1) Subject to the requirements of clauses C.4 to C.8, the Provider may subcontract any aspect of the Services if the DHB 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 the DHB requires in relation to this Agreement (which the Provider must give to the DHB);
- (ii) provide that the DHB 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 the DHB'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.58;
- (v) provide that the DHB 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.7 Information about subcontracts

- (1) The Provider must give the DHB a copy of any subcontract made under this clause.
- (2) The Auditor will not disclose to the DHB the details of the financial arrangement between the Provider and its subcontractor, but may advise if he or she considers that the financial arrangements may prejudice the Provider's ability to perform its obligations under this Agreement.
- (3) The DHB may specify at any time:
 - (a) Services in respect of which the DHB 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 the DHB reasonably requires about those subcontracts, excluding any information relating to the financial benefits arising from the subcontract in respect of the Services.

C.8 Responsibility and liability for others

- (1) The DHB 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.9 Confidentiality

- (1) Except as provided under this Agreement, neither the DHB nor the Provider will disclose the other's Confidential Information to any person.
- (2) The DHB or the Provider may publish this Agreement, except for any Confidential Information contained within it, in any media, including publication on the internet.
- (3) The DHB and the Provider may only disclose Confidential Information:
 - (a) to those involved in the provision of Services under this Agreement, if necessary;
 - (b) to the DHB or the Provider's professional advisors and agents;
 - (c) if disclosure is permitted under this Agreement;

- (d) required to be disclosed to the Crown under a Crown Direction or Crown Funding Agreement;
 - (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 the DHB to disclose Confidential Information under the Official Information Act 1982, to Ministers, the Ministry, or other public sector agencies, or otherwise in accordance with the DHB's public law obligations;
 - (g) if the other party has consented in writing to such disclosure.
- (4) The DHB and the Provider will ensure that they collect, use, store, and disclose Confidential Information in accordance with any legal requirements, and discloses of Health Information only if permitted by the Privacy Act 1993 and the Health Information Privacy Code 1994.
 - (5) The DHB and the Provider will ensure that Confidential Information is subject to user authorisation procedures.

C.10 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 fully 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 or advisors.

C.11 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.12 Purpose of Audit

- (1) The DHB 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 Pharmaceutical advice and information and to provide optimum health benefits to Eligible Persons.
- (2) The purpose of an Audit is to enable the DHB to inspect, monitor, audit, investigate, review, and evaluate whether the Provider:
 - (a) is delivering the Services, including the Supply and management of Pharmaceuticals, 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 Pharmaceutical Transactions Data Specification, and the Procedures Manual.

C.13 Appointment of auditors

- (1) The DHB will:
 - (a) appoint a suitably experienced or qualified and competent member of its staff, or a third party, as an Auditor; and

- (b) ensure all Auditors carry out Audits in a professional and competent manner.

C.14 Notice of Audit

- (1) Subject to subclause (2), the DHB will give the Provider at least ten Business Days' notice that it will carry out an Audit.
- (2) The DHB may give less than ten Business Days' notice (including 24 hours' notice or no notice) as is reasonable in the circumstances if the DHB 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 the DHB reasonably suspects that fraudulent claiming has occurred, the DHB may conduct an Audit at any time without prior notice.
- (4) The notice of Audit will include:
 - (a) the date of the Audit;
 - (b) the identity of the person or persons appointed as Auditors and their qualifications, if any, and a declaration from such person or persons of any conflicts of interest they may have; and
 - (c) general advice and information about the Audit process.
- (5) The DHB or its Auditor may contact the Provider to agree on an Audit date, before giving notice.

C.15 On-site Audits

- (1) This clause applies if the Audit includes an on-site visit to the Provider's Premises.
- (2) If the Auditor requests information before the on-site visit, the Provider must give the Auditor the information within the time specified (which must be reasonable).
- (3) The Provider must co-operate with the DHB to allow its Auditor to access the following 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.
- (4) The Provider must ensure that the DHB and its Auditor has equivalent access in relation to any Services provided through a subcontractor, contractor, agent, or other personnel.
- (5) The DHB will ensure that an 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.
- (6) The Provider may have a person present during the on-site visit.

- (7) The DHB will ensure that the Auditor carries out a debriefing meeting after the on-site visit to discuss the general Audit findings with the Provider and give the Provider advice on the Audit report process.

C.16 Conduct of Audits

- (1) The DHB and the Provider acknowledge and agree that any Audit will comply with the Health Act 1956, the Privacy Act 1993, the Health Information Privacy Code 1994, and any other relevant law.
- (2) In conducting an Audit, the DHB, and its Auditors:
 - (a) may access Health Information about any Service User;
 - (b) may observe the provision of the Services;
 - (c) 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;
 - (d) may, to the extent permitted by law, make copies of any part of the Records or information;
 - (e) must ensure that all Audit activities meet professional, legal, and contractual requirements;
 - (f) must prepare Audit reports in a timely manner detailing the facts found during the Audit; and
 - (g) must provide information and prompt responses to all relevant queries from the Provider and its Staff and Service Users about an Audit; and
 - (h) must establish follow-up processes appropriate to the Audit.

C.17 Audit reports for on-site Audits

- (1) The DHB and the Provider acknowledge and agree that usual reporting timeframes for Audit reports for on-site Audits are as follows:
 - (a) the Auditor gives the Provider a draft Audit report within the timeframe specified by the Auditor, which is usually 15 Business Days after the on-site visit;
 - (b) the Provider may comment on the draft Audit report within the timeframe specified by the Auditor, which is usually 15 Business Days after the Auditor provides the draft Audit report;
 - (c) the Auditor completes 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;
 - (d) the Auditor will arrange any verification with the Provider as necessary; and
 - (e) the DHB will consider and decide on actions in respect of the Audit report and give its response to the Provider no later than 20 Business Days after the Audit report.

C.18 The Provider's Audit obligations

- (1) The Provider must:
 - (a) actively, and in a timely manner, participate in any Audit programmes and Audits;
 - (b) address Audit recommendations in the required timeframe; and
 - (c) co-operate and give the DHB and its Auditor all reasonable assistance to ensure that any Audit is fully and properly completed to the DHB and its Auditor's satisfaction.

- (2) The Provider's obligation under subclause (1) is a material obligation for the purposes of clauses C.36 to C.51.

C.19 Audits after Agreement terminated

- (1) The DHB 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.20 Solvency Audits

- (1) The DHB and the Provider acknowledge and agree that the purpose of a solvency Audit is to ensure continuity of Services under this Agreement.
- (2) If the DHB is concerned about the solvency of the Provider's business, the DHB may give notice requesting, and the Provider must give to the DHB a certificate from a suitably qualified person certifying the Provider's solvency within 30 days of the request.

C.21 Financial Audits

- (1) The DHB may appoint, at its cost, a suitably independent financial analyst as an Auditor to determine:
- (a) the correctness of the financial information given to the DHB by the Provider;
 - (b) the Provider's calculations of the cost of providing the Services; and
 - (c) the Provider's overall financial position.
- (2) An Auditor appointed to carry out a financial Audit must not disclose to the DHB information described in subclause (1) but may advise the DHB if they consider that the Provider's financial position may prejudice its ability to perform its obligations under this Agreement.

Dispute resolution

C.22 Application of this Part

- (1) Clauses C.23 to C.27 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; or
 - (b) any matter that has been referred to and is being considered by:
 - (i) with the agreement of both of us, the Contract Group; or
 - (ii) a Responsible Authority.

C.23 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) the DHB and the Provider will each act in good faith and use its best endeavours to resolve the Dispute by agreement.

- (2) The DHB and the Provider agree to use effective and efficient processes to resolve any Dispute, to such extent as each of us considers that it is reasonably practicable to avoid undesirable duplication given limited funding resources, which may include, if the DHB and the Provider both agree, involving a number of providers or representative bodies in a single dispute process.

C.24 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.22(1)(b), whichever is the latter) then, unless the DHB 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 provision will apply:
 - (a) the mediation will be conducted under the Resolution Institute's standard mediation agreements;
 - (b) if we both 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) we both will share the mediator's fees equally.

C.25 Arbitration

- (1) If the dispute is not settled by agreement within 40 Business Days after the appointment of a mediator, unless the DHB 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 we 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.26 No litigation

- (1) Neither party may initiate proceedings in any court or other tribunal while the dispute resolution process referred to in clauses C.23, C.21, and C.25 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.27 Obligations continue

- (1) The DHB 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) the DHB 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 the DHB.

- (2) If the DHB withholds an amount under subclause (1), and it is determined through the dispute resolution process that the DHB was not entitled to withhold the amount, the DHB will repay the Provider the amount withheld plus Default Interest (applicable for the period of the withholding).

Reviews of, and variations to, this Agreement

C.28 Nothing precludes termination

- (1) Nothing in clauses C.29 to C.35 precludes either party from terminating this Agreement (all or in part) in accordance with clauses C.36 to C.51.

C.29 Grounds for variation

- (1) This Agreement may be varied in one of the following ways:
- (a) by mutual agreement in accordance with C.30 to C.34 (as applicable) (a "Voluntary Variation"); or
 - (b) in order to give effect to a Crown Direction or law change in accordance with clause L4 (a "Compulsory Variation").

C.30 Review of Agreement

- (1) The DHB and the Provider agree that, each year, there will be a national review of the following parts and Service Schedules of this Agreement (and the same agreement between other providers and the DHB or other District Health Boards):
- (a) Parts A to E;
 - (b) Schedule 1;
 - (c) Schedule 2;
 - (d) all Service Schedules in Schedule 3A; and
 - (e) any Service Schedule in Schedule 3B that the DHB and other District Health Boards decides to include in the review.
- (2) The DHB and the Provider agree that:
- (a) the review will be carried out in a manner that enables meaningful participation by providers and provider representative groups;
 - (b) the Provider may appoint another person or a provider representative group, to participate in the review on its behalf;
 - (c) the DHB, the Provider, other providers, and provider representative groups will have an opportunity to comment on issues relating to integrated pharmacist services in the community that affect providers on a national basis;
 - (d) the review may consider proposed amendments to the parts and Service Schedules referred to in subclause (1); and
 - (e) we will each participate in the review in good faith and use our best endeavours to reach agreement on any proposal (including proposed amendments) promptly.
- (3) The DHB and the Provider agree that each Service Schedule in Schedule 3B and Schedule 3C will be reviewed:

- (a) as specified in the relevant Service Schedule;
- (b) as otherwise agreed by both of us; or
- (c) from time to time by the DHB.

C.31 Changes to Parts A to E, Schedule 1, Schedule 2, Schedule 3A

- (1) This clause applies if the DHB and other District Health Boards want to make a change to:
 - (a) one or more clauses in Parts A to E; or
 - (b) a Service described in Schedule 1, Schedule 2, or a Service Schedule in Schedule 3A, which could include adding a new Service Schedule to Schedule 3A.
- (2) The DHB and the Provider agree that any such change:
 - (a) will be considered as part of a national review carried out in accordance with clause C.30(1) and (2); and
 - (b) may be agreed by the DHB and the Provider as a Voluntary Variation in accordance with clause C.34.

C.32 Changes to Service Schedules in Schedule 3B

- (1) This clause applies if the DHB wants to make a change to a Service described in a Service Schedule in Schedule 3B, which could include adding a new Service Schedule to Schedule 3B.
- (2) The DHB will consult with the Provider, other providers, and representative groups of providers affected by the proposed change, including by providing details of the proposed changes.
- (3) The Provider acknowledges that the DHB may also engage with other interested parties, including other health care providers and the community, in relation to a proposed change.
- (4) Any change made to a Service Schedule, or the addition of a new Service Schedule, may be agreed by the DHB and the Provider as a Voluntary Variation in accordance with clause C.34.

C.33 Changes to Services in Schedule 3C (other Service Schedules)

- (1) The DHB and the Provider may agree to change to a Service described in a Service Schedule in Schedule 3C, which could include adding a new Service Schedule to Schedule 3C, by agreeing a Voluntary Variation in accordance with clause C.34.

C.34 Procedure for Voluntary Variations

- (1) Any variation to this Agreement that the DHB and the Provider agree, including as a result of a review under clauses C.30 and C.31, or following a change made in accordance with clause C.31 to C.33, must be agreed in writing and signed by both of us.

C.35 Procedure for Compulsory Variations

- (1) If the DHB considers that it is likely that a Compulsory Variation will be required, the DHB will give the Provider reasonable notice of the variation if the DHB can do so, which will include the details of the variation and a proposed draft of the variation.
- (2) The DHB'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) The DHB will specify a period of time that is reasonable in the circumstances, being at least ten Business Days unless the DHB 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 the DHB, or earlier if the parties both agree, we must both try to reach agreement on the terms of the variation.
- (5) The DHB 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 of us, and will commence on the day that the relevant Crown Direction or law change comes into effect or any earlier time we both agree.
- (7) If the DHB 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 the DHB's proposed draft of the variation, subject to any changes that we both 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 the DHB, except that if it is not viable, financially or otherwise, for the Provider to provide the relevant Services for the duration of that notice period, the Provider may give a shorter period of notice as is reasonable in the circumstances.

Failure to perform

C.36 The Provider has failed to perform

- (1) Subject to clause C.45 (Uncontrollable Event), if the Provider fails to perform any material obligation under this Agreement, including, without limitation, its obligations under clauses D.8, D.23, and C.18, and any requirements in this Agreement relating to the reporting or provision of information, the DHB 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.41 to D.45;
 - (c) suspend or terminate this Agreement in accordance with clauses C.38 to C.41;
 - (d) make alternative arrangements for the provision of the Services in accordance with clauses C.42 to C.44;
 - (e) withhold payments if permitted by a provision of this Agreement;
 - (f) seek damages; or
 - (g) refer to the matter to the Contract Group.

C.37 The DHB has failed to perform

- (1) Subject to clause C.45 (Uncontrollable Events), if the DHB fails to meet any material obligation under this Agreement, and has not remedied the failure within 30 days (or a different time period we

agree) 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 the DHB in accordance with clauses D.41 to D.45;
- (c) seek damages from the DHB;
- (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 the DHB's failure applies.

Suspension or termination for material failure to perform

C.38 Notice of failure

- (1) If the DHB has reasonable grounds to believe that the Provider has not met any material obligation under this Agreement, the DHB will give the Provider written notice setting out the details of the obligation that the DHB 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 the DHB'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 the DHB considers reasonable in the interests of the health and safety of Service Users.
- (2) Despite anything else in this Agreement, if the DHB has reasonable grounds to believe that the health or safety of any Service User is at risk, the DHB may suspend the Provider's right and obligation to provide the relevant Services while the DHB investigates the issue.
- (3) The DHB will notify the Provider of such suspension in the notice given under subclause (1).
- (4) If the DHB 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, the DHB will give the Provider written notice that the Provider must resume performance of such obligations.

C.39 Termination on seven days' notice

- (1) If, after the 30-day period referred to in clause C.38(1), the Provider has not demonstrated to the DHB's reasonable satisfaction that the Provider has met the obligation, the DHB may terminate this Agreement on seven days' written notice, or such shorter period as the DHB considers reasonable in the interests of the health and safety of Service Users.

C.40 Dispute

- (1) If the Provider receives a notice under clause C.38(1), but disagrees that the obligation the DHB believes the provider has not met is a material obligation, the Provider may refer the matter:
 - (a) to mediation and, if necessary, arbitration in accordance with clauses C.22 to C.27; or
 - (b) with the DHB's agreement, to the Contract Group (such agreement will not be unreasonably withheld).

- (2) If the matter is referred to the Contract Group, the DHB and the Provider acknowledge and agree that the Contract Group's role is to use its best endeavours to facilitate resolution of the matter by agreement within the 30-day period referred to in clause C.38(1), including by meeting (in person or by audio or audio and visual means) and corresponding in writing as it deems necessary.
- (3) Despite anything in clauses C.22 to C.27, if a Dispute is referred to mediation arbitration, or the Contract Group under this clause, the DHB and the Provider agree:
 - (a) we will each use all reasonable endeavours to complete the mediation or arbitration within the 30-day period referred to in clause C.38(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.38(1) will have no further effect;
 - (d) if there is no agreement or determination as to whether or not the relevant obligation is a material obligation, the DHB may terminate this Agreement in accordance with clause C.41.
- (4) Despite clause C.40(1), the Provider agrees that the obligations set out in clauses D.23, C.18,, D.8(1), and D.8(2), are material obligations.

C.41 Immediate termination

- (1) If, after the further 30-day period referred to in clause C.38(1), the Provider has not demonstrated to the DHB's reasonable satisfaction that the Provider has met the obligation, the DHB may terminate this Agreement on seven days' written notice, or such shorter period as the DHB considers reasonable in the interests of the health and safety of Service Users.

C.42 Uncontrollable Events

- (1) Clauses C.38 to C.41 do not apply if the Provider's failure to perform is caused by an Uncontrollable Event.

C.43 Alternative arrangements on non-performance

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

C.44 Payment of DHB costs

- (1) On the DHB's demand, the Provider must pay or reimburse the DHB for all reasonable costs it incurs acting under clause C.43 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 the DHB following a demand by the DHB, the DHB may set off the amount owed against any amount that the DHB owes to the Provider in accordance with clause D.47.
- (3) This clause does not apply if the Provider's failure to perform is caused by an Uncontrollable Event.

Uncontrollable Events

C.45 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 process and sufficient funds (except if the DHB 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 possible 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, the DHB may make alternative arrangements for the supply 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 are entered into) as the DHB sees fit but after consultation with the Provider.

C.46 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, the DHB 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 the DHB 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.47 Mutual agreement to terminate

- (1) The DHB 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.48 The DHB's right to terminate

- (1) The DHB 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.38 to C.42;
- (b) if the DHB 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 the DHB 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 the DHB'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 the DHB 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) the DHB 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.22 to C.27) during this six-month notice period; and
 - (iii) the DHB's right to terminate on notice applies despite any other provision in this Agreement, including if we are both engaged in a process of Dispute resolution or variation of this Agreement;
- (g) if an Uncontrollable Event occurs, in accordance with clause C.45;
- (h) if the DHB gives the Provider three months' written notice that it is going to issue a Section 88 Notice in respect of pharmacist services. This right to terminate will apply despite any other provision in this Agreement, including if we are both engaged in a process of Dispute resolution or variation of this Agreement.
- (i) if the DHB offers to vary this Agreement, including following a review in accordance with clause C.30, and the Provider does not agree to the variation by 15 days after receiving the offer of variation, by giving three months' notice.

C.49 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 the DHB's failure applies:
 - (a) in relation to material failure in accordance with clause C.36(1)(g);
 - (b) in relation to a Compulsory Variation in accordance with clause C.35;

- (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) we will each continue to be bound to comply with our obligations under this Agreement (including under C.22 to C.27) 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.45.

C.50 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 the DHB 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.51 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.52 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 the DHB'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 the DHB information about the proposed transferee's ability to perform its obligations under this Agreement, and any further details that the DHB may reasonably request.
- (3) The DHB may require reasonable conditions to be met before it consents to a transfer. In particular, the DHB may require that the proposed transferee enter into an agreement with the DHB on substantially similar terms and conditions set out in this Agreement.

C.53 Exception for assignment to obtain finance

- (1) The Provider may assign its right to receive payment from the DHB 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.54 Assignment or transfer by the DHB

- (1) The DHB may assign or transfer any or all of its rights and obligations under this Agreement, including if it merges with another District Health Board, without the Provider's prior consent.

C.55 Consequences of transfer or assignment

- (1) This Agreement is binding on and exists for the benefit of both the DHB and the Provider and their respective successors and permitted assignees or transferees, each of whom has the rights and obligations as if it were named in this Agreement as a party.
- (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.56 Notices

- (1) The DHB 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 show the Agreement Reference Number and be made by facsimile, personal delivery, post, or email at the facsimile number or address, and marked for the attention of the person or office holder designated by the addressee (and advised to the addressor) to receive notices (if any).
- (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) No communication is effective until it is received by the addressee.
- (5) A communication is deemed to be received (if the addresser is not aware of any failure in the communication) in the case of:
 - (a) facsimile, on the Business Day on which it is sent or, if sent after 5pm 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 by airmail; or
 - (d) 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.57 Independent contractor

- (1) The Provider is engaged to provide Services as an independent contractor to the DHB, and not as an employee or agent, that under no circumstances will the DHB 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 the DHB's behalf.

C.58 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) The DHB may request, and the Provider must promptly give the DHB, any information concerning the Provider's insurance.

C.59 Indemnity

- (1) The Provider will indemnify the DHB and keep the DHB 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 the DHB 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.65, 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 the DHB, 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 the DHB 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.60 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.61 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.62 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.63 Entire agreement

- (1) This Agreement 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 pharmacist services.

C.64 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.65 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 that 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.66 Counterparts

- (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 facsimile copies and execution of this Agreement by such means is to be a valid and sufficient execution.

C.67 Governing law and jurisdiction

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

Part D Payment and claiming terms

D.1 Payment for Services and Pharmaceuticals

- (1) The Provider must claim for any Pharmaceuticals that are Supplied, and Services that are provided, in accordance with the terms set out in this Part D and the relevant Service Schedule.
- (2) The Provider must claim for any Services it provides and Pharmaceuticals it Supplies by submitting a Claim Item as part of a claim.

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 or Pharmaceuticals it provides in accordance with clauses D.3 to D.10.

D.4 Persons who are not Eligible

- (1) The Provider may not claim payment from the DHB in relation to the provision of Services or Pharmaceuticals to persons who are not Eligible Persons.
- (2) The Provider may charge persons who are not Eligible Persons the cost to the Provider of providing the Services and Pharmaceuticals.
- (3) If the Provider has claimed for Services or Pharmaceuticals provided to a person who is not an Eligible Person, the DHB 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 person was not an Eligible Person.

Co-payments, Pharmacist Charges, and Product Premiums

D.5 Determining and collecting Co-payments, Pharmacist Charges, and Product Premiums

- (1) The Provider must, in accordance with the requirements of the Procedures Manual, Pharmaceutical Schedule, and the Health Entitlement Cards Regulations 1993:
 - (a) determine the Co-payments, Pharmacist Charges, and Product Premiums that each Service User is required to pay for the Services provided or Pharmaceutical Supplied;
 - (b) charge and collect from the Service User, the Co-payments, Pharmacist Charges, and Product Premiums for the Services provided or the Pharmaceutical Supplied; and
 - (c) promote and provide information about the prescription subsidy scheme, and ensure they can partake in the scheme, including by recording their information to eligible Service Users.

D.6 Co-payments

- (1) The Provider may charge a Service User a Co-payment for providing Services and Supplying a Subsidised Pharmaceutical prescribed by:
 - (a) a prescriber employed by a District Health Board;
 - (b) a provider or prescriber with an access or service agreement with the Ministry, a District Health Board, or a PHO;
 - (c) an after hours provider with an access or service agreement with a DHB or PHO; or
 - (d) a provider providing a fully publicly funded service under a Section 88 Notice
- (2) The Provider must determine the amount of a Co-payment it may charge a Service User in accordance with the Procedures Manual, Pharmaceutical Schedule, and the Health Entitlement Cards Regulations 1993.
- (3) The Provider must not charge a Service User a Co-payment if an exemption as set out in the Procedures Manual applies.
- (4) Unless the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction or an exemption set out in the Procedures Manual applies, the DHB will calculate each payment payable to the Provider under Schedules 1 or 3 (if relevant) on the basis that the Provider collected the Standard Co-payment Amount from the Service User, whether or not the Provider collected some or all of the Standard Co-payment Amount.

D.7 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, in accordance with clause D.6.
- (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.8 Pharmacist Charges

- (1) Subject to clause D.6 (Co-payments), clause D.7 (Product Premiums), and subclause (1), the Provider may not charge a Service User any amount (whether characterised as voluntary or not) in connection with the provision of Services and Supply of Pharmaceuticals, except in accordance with the Permitted Pharmacist Charges Rules ("Pharmacist Charges").
- (2) The Provider may, at its discretion, charge an amount for a Pharmaceutical if it is collected by the Service User outside the ordinary business hours of 8:00am to 6:00pm on Monday to Friday (excluding public holidays in the DHB's Geographical Area), unless the Provider has contracted with the DHB to provide after hours services as part of the "zero fees for under 13s" scheme.
- (3) 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 Pharmacist Charges Rules across Service Users more generally;
 - or

- (b) any other amount not expressly permitted by the Permitted Pharmacist Charges Rules.
- (4) The Provider acknowledges and agrees that its obligations under this clause constitute a material obligation for the purposes of C.36 to C.51 of this Agreement.
- (5) If the Provider is entitled to charge a Pharmacist Charge, it must inform the Service User of the amount of, and reason for, the Pharmacist Charge, and explain how he or she may avoid or reduce the Pharmacist Charge, before the Services or Pharmaceuticals are provided.
- (6) Despite anything else in this clause D.8, the Provider agrees that:
 - (a) any Pharmacist Charge it charges will be fair and reasonable;
 - (b) it will give Service Users a rational explanation of the reasons for, and the amount of, any Pharmacist 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 the DHB a rational explanation of the reasons for, and amounts of, any Pharmacist Charges that the Provider is proposing to charge or has been charging Service Users, including providing reasonable supporting evidence if requested

D.9 Providing information to Eligible Persons

- (1) If the Provider is responsible for collecting Co-payments, Pharmacist Charges, and Product Premiums from Service Users, it must make information regarding all Co-payments, Pharmacist Charges, and Product Premiums accessible and publicly known by displaying the information, or how to obtain the information, before Supply or the provision of Services so it can be easily sighted by a Service User.

D.10 Receipts for Subsidised Pharmaceuticals

- (1) The Provider must give each Service User a receipt for any prescribed Subsidised Pharmaceutical that:
 - (a) includes the name of the Pharmaceutical and the cost to the Service User for the provision of the Pharmaceutical; and
 - (b) is given in the format set out in the Procedures Manual.
- (2) To avoid doubt, the Provider does not need to give a Service User a receipt for any prescribed Pharmaceuticals that are not Subsidised Pharmaceuticals.

Claiming procedures

D.11 Basis of claims

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

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

D.12 Electronic claiming

- (1) The Provider must submit each claim electronically, in accordance with the Pharmaceutical Transactions Data Specification and any other guidelines issued by the DHB or its Payment Agent.
- (2) The DHB 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.13 Claim certification

- (1) The Provider must certify (in the form approved by the DHB or the Payment Agent) the truth and accuracy of each claim and that the Provider has complied with this Agreement.
- (2) The DHB 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 (which each Pharmacist is responsible for keeping confidential).

D.14 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.15 Format and information for claims

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

D.16 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 Supply Orders), the DHB will reject the claim in accordance with clause H8.1.
- (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.17 Service User's information on claims

- (1) The Provider must include the 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.18 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.

D.19 Database of Specialist Prescribers

- (1) If the DHB makes available to the Provider, free of charge, a database that lists the names of all Specialists who are authorised to prescribe Pharmaceuticals, the Provider must use this database to enable it to comply with the claiming requirements set out in this Agreement, the Procedures Manual, and any relevant legislation.

Claiming requirements and restrictions

D.20 Services must be provided in New Zealand

- (1) The Provider may not claim, and the DHB 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 Supplied in accordance with a Prescription Form from a Prescriber who is not eligible to provide the Services or prescribe the Pharmaceuticals, the DHB 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 the DHB effectively having to pay more than once for the provision of Services in respect of the Supply of a Pharmaceutical to a Service User.
- (2) In respect of Services not involving the Supply of a Pharmaceutical, the Provider must not knowingly be a party to any arrangement that results in the DHB 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 clause D.22(1) to D.22(3), the Provider must not:
- (a) claim payment from the DHB for providing a service that the Provider has carried out for a provider who is contracted to provide the DHB with the service;
 - (b) refer to any provider any Service that the Provider has been contracted to provide to the DHB under this Agreement, or any other agreement the Provider has with the DHB unless otherwise expressly permitted under this Agreement (unless 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 the DHB, for providing the same service.

D.23 No unnecessary Supply

- (1) The Provider must not act in any way that increases its revenue from the DHB artificially, including by Supplying Pharmaceuticals more frequently than is necessary.
- (2) The Provider's obligation under this clause is a material obligation for the purposes of C.36 to C.51.

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 this clauses D.22 to D.24, it may seek clarification from the DHB or its Payment Agent, and the DHB will provide advice on the matter.

Rejecting claims

D.25 Rejecting claims

- (1) The DHB 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, the DHB 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 the DHB, the DHB may recover that money in accordance with clause D.47.
- (5) If the Provider corrects and resubmits a claim:
 - (a) before the Final Due Date, it will be paid in accordance with clause D.37;
 - (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.38.
- (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 the DHB, 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 the DHB not later than three months after the date on which the Pharmaceutical is Supplied or the Service 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. If, in the DHB's reasonable opinion, the Provider has established reasonable grounds for late submission, the DHB will consider that Claim Item for payment.

D.28 No submission after six months

- (1) The DHB 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) The DHB may require the Provider to verify a Claim Item by giving 15 Business Days' notice.

Submitting Prescription Forms

D.30 Submitting Prescription Forms

- (1) The Provider must submit Prescription Forms to the DHB in accordance with the requirements set out in the Pharmaceutical Transactions 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 Supply 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 Supply.
- (2) If a batch is not received by the Payment Agent six months after the date of Supply, the DHB 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), the DHB 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 The DHB's obligation to pay

- (1) Subject to paragraph (c) below, the DHB will pay the Provider for Pharmaceuticals Supplied and Services provided in accordance with clauses D.3 to D.31 and clauses D.32 to D.47.
- (2) The payment by the DHB 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) The DHB may withhold an amount payable under Schedule 2 or 3B.1 of this Agreement for each of the following defaulting actions that the Provider commits:
 - (a) if the Provider breaches clause D.8 of this Agreement, the DHB may withhold up to 5% of all amounts payable under clauses 11 and 12 of Schedule 2 and clauses 14 and 15 of Schedule 3B.1 that are or become due to the Provider subsequent to the DHB becoming aware of the breach;
 - (b) if the Provider fails to report and give information in accordance with this Agreement, the DHB may withhold up to 5% of all amounts payable under clauses 11 and 12 of schedule 2, and clauses 14 and 15 of schedule 3B.1 that are or become due to the Provider after the DHB becoming aware of the Provider's failure.
- (2) If the DHB intends to withhold an amount in accordance with subclause (1), the DHB:
 - (a) will give 30 days' notice of its intention to withhold payment in accordance with clause D.33(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.8 or the reporting and information requirements (as applicable).
- (3) If the Provider does not cease breaching clause D.8(1) to (2), or remedy its failure to comply with the reporting and provision of information requirements (as applicable) within the 30-day period, the DHB may withhold such payments until the Provider complies.
- (4) A payment withheld under clause D.33(1) will be paid to the Provider if it is found to have complied with clause D.8 or the reporting and provision of information requirements (as applicable) as an outcome of the dispute resolution process in C.22 to C.27.
- (5) Despite clause C.27(1)(b), the Provider must continue to provide Services if the DHB withholds payments in accordance with this clause D.32 to D.33.
- (6) The withholding rights specified in this clause D.32 to D.33 are the DHB's non-exclusive remedies in the event of a breach of clause D.8 or the reporting and information requirements (as applicable), and do not limit the DHB'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.

Payment time frames

D.34 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.35 Rounding

- (1) The DHB 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.36 Form of payment

- (1) The DHB 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 the DHB.

D.37 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, the DHB will pay the Provider for the Claim Item no later than the Payment Date for the next Due Date that arises.

D.38 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, the DHB will pay the Provider for the Claim Item no later than the next Payment Date specified in this clause D.34.

D.39 Payment variations

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

D.40 Overpayment

- (1) If the Provider fails to provide all or part of the Services for which the DHB has paid under this Agreement, or if, for any other reason, the DHB has overpaid the Provider for Pharmaceuticals or Services, the DHB:
 - (a) may determine the reasonable amount that the Provider must repay to the DHB;
 - (b) will notify the Provider of the overpayment; and
 - (c) may invoke its right of set-off under clause D.47 by giving notice to the Provider.
- (2) If the Provider owes the DHB an amount as a result of the DHB's, its Payment Agent's or PHARMAC's error in relation to a payment:
 - (a) the DHB will notify the Provider of the overpayment;
 - (b) the due date for the repayment will be one month after the DHB's notice to the Provider; and
 - (c) the DHB may invoke its right of set-off under clause D.47 by giving notice to the Provider.
- (3) If the Provider owes the DHB an amount as a result of the Provider's error in relation to a claim:
 - (a) the DHB will notify the Provider of the overpayment;
 - (b) the due date for the repayment will be the next Payment Date after the DHB's notice to the Provider; and

- (c) the DHB may invoke its right of set-off under clause D.47 by giving notice to the Provider.

Default Interest

D.41 DHB may charge Default Interest

- (1) Subject to clauses D.43 and D.45, if the Provider does not pay an amount due to the DHB under this Agreement, the DHB or its Payment Agent may charge the Provider interest from the date payment was due until the amount due is paid (Default Interest).

D.42 Provider may charge Default Interest

- (1) Subject to clauses D.43 and d.45, if the DHB does not pay an amount due to the Provider under this Agreement, the Provider may charge the DHB Default Interest from the date payment was due until the amount due is paid.
- (2) If the DHB owes the Provider an amount as a result of the DHB'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 the DHB 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 the DHB.

D.43 Charging Default Interest on \$50 or less

- (1) Subject to clause D.45, 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.44 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.45 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, the DHB 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) the DHB's name; and
 - (e) the details of the payment to which the Default Interest relates.

Other payment requirements

D.46 Quarterly review of Per Pack Fee

- (1) Despite anything else in this Agreement:
 - (a) the Per Pack Fee paid under this Agreement will be reviewed by District Health Boards on a quarterly basis to determine whether, in their view, the amount of the Per Pack Fee should change because of changes in the pack size of one or more Pharmaceuticals as listed on the Pharmaceutical Schedule, on the basis that the fees paid to the Provider in accordance with Schedules 1 or 3 (if relevant) for a Pharmaceutical listed on the Pharmaceutical Schedule should not materially change as a result of a change in the pack size of the Pharmaceutical;
 - (b) the District Health Boards will advise the Contract Group of the outcome of each quarterly review; and
 - (c) if the District Health Boards decide to change the Per Pack Fee, the DHB will notify the Provider of the change, which will apply from the date on which the Provider submits a claim after receiving notice of the change.

D.47 Power of set-off

- (1) If the Provider owes the DHB an amount under this Agreement, or any previous agreement, including in the case of overpayment under clause D.40 or if the Provider is obliged to indemnify the DHB under clause C.59, the DHB may set that amount off against any amount that it owes to the Provider at any time, after the DHB has given the Provider written notice of its intention to do so.
- (2) If the DHB exercises the power of set-off, the Provider will be deemed to have made payment to the DHB to the extent of the set-off.

D.48 Access to Records

- (1) The Provider or its agent may access a copy of any relevant records regarding it that are kept by the DHB (including any records of the volume of Supplied Pharmaceuticals claimed by the Provider) to review the payments the DHB 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) the DHB will determine (acting reasonably) the:
 - (i) information to be provided under this clause so as not to cause an unreasonable burden for the DHB; and
 - (ii) time frame for providing such information;
 - (c) if a request causes a direct cost or an unreasonable burden to the DHB, then it may charge a cost for providing the information.

D.49 Dispute over payment

- (1) If a dispute arises under this Agreement in respect of whether the DHB has paid the Provider the correct amount for Services provided or Pharmaceuticals Supplied, this dispute will be determined in accordance with the procedures set out in C.22 to C.27.

Part E Definitions

E.1 Definitions

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

Act means the New Zealand Public Health and Disability Act 2000

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

Aseptic Pharmacist Services means aseptic pharmacist 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 C.12 to C.21

Auditor means an auditor appointed to carry out an Audit under clause C.13

Authorising Provider means, if the Provider does not provide Professional Advisory Services to a Service User in accordance with Schedule 2, the provider who does provide such Services to the Service User

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

Business Day means a day on which the Provider's bank, the DHB's bank, and the Payment Agent's bank are open for business

Claim Item means an individual transaction relating to the provision of Services and Supply of a Pharmaceutical in accordance with this Agreement

Claim Period means one of the four claim periods in a calendar month as described in clause D.14

Class B Pharmaceuticals Services means the Supply of a Class B Pharmaceutical, which are described in Schedule 1 (if applicable)

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

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 issued under the Health and Disability Commissioner Act 1994

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 the DHB and the Provider agree is confidential or that may reasonably be considered to be confidential taking

into account all circumstances, including the manner of and circumstances in which disclosure occurred; but

(b) excludes the terms of this Agreement unless we both agree otherwise

Compulsory Variation means a variation to this Agreement described in clause C.29(1)(b)

Confidential Information includes Commercial Information and Health Information

Contract Group means the Contract Group described in clause B.45

Co-payment means a patient contribution that a Service User may be required to pay for a Pharmaceutical which is determined in accordance with clause D.6

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

CRC Pharmacist Services means community residential care pharmacist services, which are provided in accordance with Schedule 3 (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 the DHB

Crown Funding Agreement means an agreement between the DHB and the Crown under section 10 of the Act

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

Default Interest means the interest to be paid on late payments in accordance with clause D.41 to D.45

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

DHB's Geographical Area means the geographical area for which the DHB is responsible as set out in Schedule 1 of the Act

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 under section 32 of the Act

End Date means the date on which this Agreement ends

Expert Advisory Group means the Expert Advisory Group described in clause B.45

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 (if applicable)

Final Due Date means the date specified in clause D.26 by when a claim must be received by the DHB

Financial Year means the period 1 July of a year to 30 June of the following year

First Claim Period means the period described in clause D.14(1)(a)

Fourth Claim Period means the period described in clause D.14(1)(d)

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 Supply 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 1993

He Korowai Oranga means the Māori Health Strategy published by the Ministry 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

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)

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

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

Minister means the Minister of Health

Ministry means the Ministry of Health

Monitored Therapy Medicine means a Pharmaceutical on the list of monitored therapy medicine Pharmaceuticals maintained by the DHB or its agent

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

- (a) the Co-payment that the Provider may charge for the Initial Item is greater than the Standard Co-payment Amount; 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 Programme is the named patient pharmaceutical assessment programme through which Service Users can apply for funding for a Pharmaceutical not listed in the Pharmaceutical Schedule, for Unusual Clinical Circumstances, Urgent Assessment, and Hospital Pharmaceuticals in the Community (as those terms are defined in the Pharmaceutical Schedule), and whose members include Eligible Persons who were exceptional circumstances Service Users before the NPPA programme began

NPPA Services A is the Supply of a Pharmaceutical that is listed on the Pharmaceutical Schedule to a Service User approved under the NPPA Programme

NPPA Services B is the Supply of a Pharmaceutical that is not listed on the Pharmaceutical Schedule to a Service User approved under the NPPA Programme

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

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

Payment Agent means the agent engaged by the DHB to pay providers on the DHB's behalf, and unless otherwise advised by the DHB is Sector Services, a business unit of the Ministry

Payment Date means any one of the five payment dates in a calendar month as described in clause D.34

Permitted Pharmacist Charges Rules means the publication entitled Permitted Pharmacist Charges Rules as amended by District Health Boards from time to time after engaging with the Contract Group

Per Pack Fee means the amount paid by the DHB as an additional payment towards the procurement and stockholding costs for a subsidised pack of a Pharmaceutical as listed in the Pharmaceutical Schedule, as set out in the relevant Service Schedule

PHARMAC means the Pharmaceutical Management Agency

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

Pharmaceutical Schedule means the pharmaceutical schedule produced by PHARMAC, and available on PHARMAC's website at <https://www.pharmac.govt.nz/Schedule> (or any other website advised by PHARMAC or the DHB 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)

Pharmaceutical Schedule Rule on Frequency of Dispensing means the frequency of dispensing rule described in the Pharmaceutical Schedule

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

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

Pharmacist Charges has the meaning given to it in clause D.8

Pharmacy Council means the Pharmacy Council established as a Responsible Authority

Pharmacist Clozapine Services means pharmacist clozapine services, which are provided in accordance with Schedule 3 (if applicable)

Pharmacist Influenced Repeats means that the Pharmacist is not prevented by legislation, regulation, or the Pharmaceutical Rule on Dispensing Frequency from Supplying less frequently, and the repeats are clinically appropriate

Pharmacist Influenza Immunisation Services means pharmacist influenza immunisation services, which are provided in accordance with Schedule 3 (if applicable)

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

Premises means the location from where the Provider provide 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, or other request, which specifies one or more Pharmaceuticals prescribed for a named person, and is prepared by a Practitioner in accordance with the Medicines Regulations

Prescriber means a Practitioner who is authorised under the Medicines Regulations to prescribe Pharmaceuticals to Eligible People

Procedures Manual means the publication entitled Pharmacist Procedures Manual available at www.centrahtas.co.nz (or any other website advised by the DHB from time to time), as amended by the DHB from time to time following engagement with provider representatives

Product Premium has the meaning given to it in clause D.7

Product Supply Services means services provided in relation to the Supply of Pharmaceuticals, which are provided in accordance with Schedule 1 (if applicable)

Professional Advisory Services means advisory services provided in relation to the Supply of Community Pharmaceuticals, which are provided in accordance with Schedule 2 (if applicable)

Provider means the party providing Services to the DHB under this Agreement

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.31

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

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 Supplied in an intended sequence of Pharmaceuticals to be Supplied, 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 in respect of a particular profession, 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.14(1)(b)

Section 88 Notice means a notice issued under section 88 of the Act

Service User means an Eligible Person who uses any Services under this Agreement

Service Schedule means a schedule to this Agreement

Services means the services provided by the Provider under this Agreement

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

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

Specialist has the same meaning given to it in Section A 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

Standard Co-payment Amount means an amount determined by the Ministry from time to time as the pharmaceutical co-payment for each Pharmaceutical

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 3 (if applicable)

Subsidised Pharmaceutical means a Pharmaceutical that is listed on the Pharmaceutical Schedule

Supply means the process of a Pharmacist providing a Service User or their caregiver or a Prescriber with a Pharmaceutical in accordance with Schedule 1

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.14(1)(c)

Uncontrollable Event means an event that is beyond the reasonable control of the party immediately affected by the event (including if the DHB has failed to make a payment due because of an event beyond the DHB'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 Supplied in accordance with section 26 or section 29 of the Medicines Act

Voluntary Variation means a variation to this Agreement described in clauses C.29(1)(a)

Whakataataka Tuarua means the Māori Health Action Plan (2006–2011), as amended or replaced from time to time

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) **Varied document:** 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 the lawful currency of New Zealand and, unless otherwise specified, all amounts payable by a party under this Agreement are to be paid in that currency.
- (11) **Gender:** Words importing one gender include the other genders.
- (12) **Notice:** All periods of time for notice exclude the days on which they are given and include the days on which they expire.
- (13) **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.
- (14) **Including without limitation:** Any reference to "including", "include", "includes", or "in particular" does not limit the generality of the relevant statement.

SCHEDULE 1
PHARMACEUTICAL SUPPLY SERVICES

1. Background and Service objectives

- 1.1 The DHB wishes to fund Pharmaceutical Supply 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.
- 1.2 This Schedule sets out the terms and conditions on which the DHB will fund, and the Provider must provide, the Pharmaceutical Supply Services associated with the Supply of Pharmaceuticals to and for Service Users.

2. When Pharmaceutical Supply Services may be provided

- 2.1 The Provider must provide Pharmaceutical Supply Services in respect of a Service User in accordance with this Schedule:
- (a) if the Provider also provides Professional Advisory Services to the Service User in accordance with this Agreement, after the Provider has received a Prescription Form, and carried out a clinical check of the Prescription Form in accordance with clause 2(1)(a) of Schedule 2; or
 - (b) if the Provider does not provide Professional Advisory Services to the Service User in accordance with this Agreement, after the Provider has received a Prescription Form from a provider of Professional Advisory Services (Authorising Provider).

3. Pharmaceutical Supply Services requirements

- 3.1 The Provider must, when Supplying a Pharmaceutical:
- (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; 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:
 - (i) the Service User or other party, if the Provider also provides Professional Advisory Services in accordance with this Agreement; or
 - (ii) the Service User, other party, or Authorising Provider in accordance with the instructions of the Authorising Provider, if the Provider does not provide Professional Advisory Services in accordance with this Agreement; and
 - (e) record the Supply, by NHI Number, in a manner that enables the DHB to access supply information using the NHI Number.

3.2 The Provider must comply with any rules about the supply 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 Supplying 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. Service User records

4.1 If the Provider is not also providing Professional Advisory Services to a Service User in accordance with this Agreement, the Provider must:

- (a) maintain a transaction log of the Pharmaceuticals Supplied in accordance with this Schedule to the Service User, by NHI Number; and
- (b) make the log transaction available to the Authorising Provider, to enable that authorising provider to populate the Service User's medication profile.

5. Reporting to provider of Professional Advisory Services

5.1 If the Provider is not also providing Professional Advisory Services to a Service User in accordance with this Agreement, the Provider must report, as and when clinically appropriate, any significant issues that arise in the course of Supplying the Pharmaceuticals in accordance with clause 3 to the Authorising Provider, including if the Prescription Form does not comply with legal and professional requirements.

6. Restrictions on Pharmaceuticals that may be Supplied under this Schedule

6.1 The Provider must not Supply, under this Schedule, Pharmaceuticals as part of the following Services:

- (a) Opioid Substitution Treatment, except in accordance with clause 7;
- (b) Aseptic Pharmacist Services;
- (c) Sterile Manufacturing Services;
- (d) CPAMS Services;
- (e) Pharmacist Clozapine Services;
- (f) Smoking Cessation Services; or
- (g) Pharmacist Influenza Immunisation Services.

6.2 Clause 6.1 does not prevent the Provider from Supplying a Pharmaceutical as part of a Service described in clause 6.1 if that Service is included in a Service Schedule in Schedule 3.

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

7.1 The Provider may, if it is also a provider of Professional Advisory Services, 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.

7.2 In providing those Services, the Provider must comply with the protocol issued by the Ministry in relation to community pharmacist dispensing of methadone and buprenorphine+naloxone.

7.3 The Provider must not provide the Services to more than two Service Users in a Claim Period unless agreed in writing by the DHB.

7.4 The Provider must notify the DHB 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.

8. Practitioner Supply Orders and Bulk Supply Orders

8.1 The Provider must:

- (a) Supply Pharmaceuticals, in accordance with a Practitioner Supply Order, in a suitable manner for use by Prescribers; and
- (b) Supply Pharmaceuticals, in accordance with a Bulk Supply Order, in a suitable manner for use by private hospitals or approved institutions.

9. Opening hours

9.1 The Provider must provide Pharmaceutical Supply Services for a minimum of five days a week unless such period is affected by a public holiday.

9.2 The Provider must use its best endeavours to ensure a level of access to Pharmaceutical Supply Services that meets the reasonable needs of Service Users.

9.3 The DHB may require the Provider to provide Pharmaceutical Supply Services outside of the ordinary business hours of 8:00am to 6:00pm on Monday to Friday (excluding public holidays in the DHB's 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.

9.4 If the DHB requires the Provider to provide Pharmaceutical Supply Services outside of the ordinary business hours specified in clause 9.3, or for more than five days a week, the DHB may agree to specific terms and conditions with the Provider relating to the provision of such Services.

9.5 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.

9.6 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.

9.7 The Provider must notify the DHB if the closure of its Premises will unreasonably inconvenience Service Users in the Provider's area.

10. Waiting times for Services

10.1 Except as specified in clause 10.2, if the Provider does not also provide Professional Advisory Services in accordance with this Agreement, the Provider must use its best endeavours to ensure that the Authorising Provider is able to provide:

- (a) 90% of Pharmaceuticals within one hour of the Prescription Form being presented to the Authorising Provider;

- (b) 99% of Pharmaceuticals before the end of the next Business Day, if the Prescription Form is presented to the Authorising Provider during a Business Day; and
 - (c) 100% of Pharmaceuticals no later than two Business Days after the Prescription Form is presented to the Authorising Provider, if presented during a Business Day.
- 10.2 If the Provider provides Opioid Substitution Treatment Services in accordance with clause 7, 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.
- 10.3 The Provider must maintain, or be able to obtain, adequate stocks, of all Pharmaceuticals necessary to meet the above waiting time requirements; the Provider's failure to do so will not be an Uncontrollable Event.
- 10.4 Waiting times outside the requirements in clause 10.1 may be acceptable to the DHB if the Provider and the Service User agree otherwise.
- 10.5 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 Supply the Pharmaceutical.
- 11. Service linkages**
- 11.1 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.

12. Additional claiming and payment rule for Pharmaceutical Supply Services

- 12.1 The Provider must not claim, and the DHB will not pay, for the Supply of a Pharmaceutical in accordance with this Schedule if the Provider is entitled to claim for the Supply of the Pharmaceutical in accordance with a Schedule 3 schedule.

13. Pharmaceutical Supply Services Fee

- 13.1 Subject to clauses 20 and 21, the DHB will pay the Provider a Pharmaceutical Supply Services Fee for each Pharmaceutical that the Provider Supplies to or for a Service User, and for which the Provider makes a claim, in accordance with this Agreement.

- 13.2 The Pharmaceutical Supply Service Fee is calculated as follows:

$$R = ((Sc + (Sc \times M) + PF + (HF \times HFM)) \times GST) - CoP \text{ where:}$$

- R = the total fee that the DHB 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 Supply
- 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 as listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical as listed in the Pharmaceutical Schedule is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- 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 Supply)
- CoP = the Co-payment payable by the Service User (if any)

14. Pharmaceutical Supply Services Fee for Class B Pharmaceutical Services

- 14.1 Subject to clauses 20 and 21, the DHB will pay the Provider a Pharmaceutical Supply Service Fee for each Class B Pharmaceutical that the Provider Supplies to or for a Service User (including for the provision of Opioid Substitution Treatment Services in accordance with clause 7), and for which the Provider makes a claim, in accordance with this Agreement.

- 14.2 The Pharmaceutical Supply Services Fee is calculated in accordance with clause 13(2), except that:

HFM = the Handling Fee Multiplier for the Pharmaceutical is 6.89

- 14.3 The Provider may not claim, and the DHB will not pay, for the Supply 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 7.

15. Pharmaceutical Supply Services Fee for Practitioner Supply Orders and Bulk Supply Orders

- 15.1 The DHB will pay the Provider a Pharmaceutical Supply Service Fee for each Pharmaceutical that the Provider Supplies for a Service User in accordance with a Practitioner Supply Order or Bulk Supply Order, and for which the Provider makes a claim in accordance with this Agreement.

15.2 The Pharmaceutical Supply Services Fee is calculated in accordance with clause 13(2), except that:
HFM = the Handling Fee Multiplier for the Pharmaceutical is 5.30

16. Pharmaceutical Supply Services Fee for NPPA Services A

16.1 Subject to clauses 20 and 21, the DHB will pay the Provider a Pharmaceutical Supply Services Fee for each Pharmaceutical that the Provider Supplies to, or, for a Service User that is listed on the Pharmaceutical Schedule, and makes a claim in accordance with this Agreement, in accordance with any terms and conditions set out in the Pharmaceutical Schedule ("NPPA Services A").

16.2 The Pharmaceutical Supply Services Fee is calculated in accordance with clause 13(2), except that:
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 6.89

17. Pharmaceutical Supply Services Fee for NPPA Services B

17.1 Subject to clauses 20 and 21, the DHB will pay the Provider a Pharmaceutical Supply Services Fee for each Pharmaceutical that the Provider Supplies to, or for, a Service User that is not listed on the Pharmaceutical Schedule and 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 Supply; and
- (b) the Pharmaceutical is supplied in accordance with a NPPA authority.

17.2 The Pharmaceutical Supply Services Fee is calculated as follows:

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

where:

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

NPPAc= the product cost, being the GST exclusive invoice price paid by the Provider for the minimum purchase order of the Pharmaceutical required to satisfy the requirements of the Pharmaceutical on the date of Supply

HF = the Handling Fee for the Pharmaceutical, which is \$1.01

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 Supply)

CoP = the Co-payment payable by the Service User (if any)

17.3 The DHB and the Provider may agree on an alternative claiming and payment arrangement for NPPA Services B.

18. Pharmaceutical Supply Services Fee for Extemporaneously Compounded Preparations Services

18.1 Subject to clauses 20 and 21, the DHB will pay the Provider a Pharmaceutical Supply Services Fee for each Extemporaneously Compounded Pharmaceutical that the Provider Supplies to or for a Service User, and for which the Provider makes a claim, in accordance with this Agreement.

18.2 The Pharmaceutical Supply Services 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 the DHB 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 Supply
- 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 Fee as listed in the Pharmaceutical Schedule (which will be pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 7.95 unless:
- (c) the Provider was required to Supply the Pharmaceutical as part of the provision of NPPA Services, in which case the Handling Fee Multiplier is 5.30
 - (d) the Provider was required to extemporaneously compound a mixture containing a Class B Pharmaceutical, in which case the Handling Fee Multiplier is 6.89
 - (e) 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 Supply)
- CoP = the Co-payment payable by the Service User (if any)

19. Additional payment for Supplying Unregistered Medicines

19.1 The DHB will pay the Provider an additional payment for each Unregistered Medicine that is a Subsidised Pharmaceutical that the Provider Supplies and claims in accordance with this Agreement, in addition to any other amount that the DHB may be required to pay for the Supply of the Pharmaceutical under any Service Schedule.

19.2 Subject to clause 19.3, the additional payment is calculated as follows:

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

where:

- R = the additional payment that the DHB 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 Supply
- M2 = a top-up margin payment towards the procurement and stockholding costs of the Pharmaceutical, which is:
- (a) 0.07 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; or
 - (b) 0.06 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more
- AF = an additional margin fee payment of \$3.00 towards the additional administration costs of Supplying an Unregistered Medicine

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

19.3 The DHB and the Provider agree that:

- (a) the Provider will be paid only one additional margin fee payment (referred to as "AF" in clause 19.2) per Service User per Pharmaceutical per calendar month in which the Pharmaceutical is Supplied to or for a Service User; and
- (b) if more than one Unregistered Medicine is extemporaneously compounded, the DHB will pay the Provider in accordance with clause 19.2 in respect of each Unregistered Medicine.

19.4 The DHB will:

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

20. Recovery of amounts by the DHB (except for Negative A3 or J3 Transactions)

20.1 Subject to clause 20.2, 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

20.2 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

21. Payments for Owed Pharmaceuticals

21.1 If the Provider claims for Supplying an Owed Pharmaceutical in accordance with this Schedule, the DHB will pay the Provider the applicable payment except that:

HF = the Handling Fee for the Owed Pharmaceutical is 0

SCHEDULE 2
PROFESSIONAL ADVISORY SERVICES

1. Background and Service Objectives

- 1.1 The DHB wishes to fund Professional Advisory Services to enable Eligible Persons 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 the DHB will fund, and the Provider must provide, Professional Advisory Services associated with the Supply of Pharmaceuticals to Service Users.

2. Professional Advisory Services requirements

- 2.1 The Provider must, when providing Professional Advisory Services:
- (a) undertake a check in accordance with professional standards and any relevant guidelines, 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 a Service User, as and when is clinically appropriate, to ensure that the Service User has sufficient knowledge to enable optimal therapy.
- 2.2 If the Provider is not also providing Pharmaceutical Supply Services to a Service User in accordance with this Agreement, the Provider must:
- (a) give the Prescription Form to a provider of Pharmaceutical Supply Services; and
 - (b) give relevant instructions to the provider of Pharmaceutical Supply Services, including about to whom the provider must deliver the Pharmaceutical.

3. Service User medication profile

- 3.1 The Provider must maintain (including, if relevant, by incorporating information from the transaction log provided by a provider of Pharmaceutical Supply Services) a Service User medication profile, being an individual Service User profile that lists, 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.

4. Reporting to Prescriber

- 4.1 The Provider must report, taking into account any issues that a provider of Pharmaceutical Supply Services has raised with the Provider, 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.

5. Brand substitution

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

6. Needle exchange and disposal scheme

- 6.1 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.

7. Opening hours

- 7.1 The Provider must provide Professional Advisory Services for a minimum of five days a week unless such period is affected by a public holiday.
- 7.2 The Provider must use its best endeavours to ensure a level of access to Professional Advisory Services that meets the reasonable needs of Service Users.
- 7.3 The DHB may require the Provider to provide Professional Advisory Services outside of the ordinary business hours of 8.00am to 6.00pm on Monday to Friday (excluding public holidays in the DHB's 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.
- 7.4 If the DHB requires the Provider to provide Professional Advisory Services outside of the ordinary business hours specified in clause 7.3, or for more than five days a week, the DHB may agree specific terms and conditions with the Provider relating to the provision of such Services.
- 7.5 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.
- 7.6 When the 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.

- 7.7 The Provider will notify the DHB if the closure of its Premises will unreasonably inconvenience Service Users in the Provider's area.

8. Waiting times for Services

- 8.1 Unless the DHB and the Provider otherwise agree, after a Prescription Form has been presented by or on behalf of the Service User, the Provider must ensure (working with the provider Supplying the Pharmaceutical, if relevant) that:
- (a) 90% of Pharmaceuticals are Supplied within one hour of being presented;
 - (b) 99% of Pharmaceuticals are Supplied before the end of the next Business Day if presented during a Business Day; and
 - (c) 100% of Pharmaceuticals are Supplied no later than two Business Days after being presented if presented during a Business Day.
- 8.2 The Provider must be able to obtain adequate stocks of all Pharmaceuticals to meet the above waiting time requirements; and the Provider's failure to do so will not be an Uncontrollable Event.
- 8.3 Waiting times outside these requirements may be acceptable to the DHB if the Provider and the Service User agree otherwise.
- 8.4 The waiting times requirements do not apply if a Pharmaceutical is not readily available in New Zealand when the Provider is presented with the Prescription Form.

9. Service linkages

- 9.1 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.

10. Professional Advisory Services Fees

- 10.1 The DHB will pay the Provider a Professional Advisory Services Fee for Professional Advisory Services that the Provider provides in relation to the Supply of a Pharmaceutical to or for a Service User.
- 10.2 Subject to clause 10.3, the DHB will pay a Professional Advisory Services Fee for Professional Advisory Services provided in relation to:
- (a) each Initial Item Supplied to a Service User, in accordance with clause 11; and

(b) each Repeat Item Supplied to a Service User, in accordance with clause 12.

10.3 The DHB is not required to pay a Professional Advisory Services Fee for Professional Advisory Services that the Provider provides in relation to the Supply of a Pharmaceutical to or for a Service User:

- (a) if the DHB is required to pay a Brand-switch Fee under this Schedule;
- (b) in accordance with a Practitioner Supply Order or Bulk Supply Order;
- (c) as part of the provision of Class B Pharmaceutical Services, Extemporaneously Compounded Preparations Services, NPPA Services A, NPPA Services B, or any Population Service;
- (d) for Owed Pharmaceuticals; and
- (e) if the Pharmaceutical is not a Subsidised Pharmaceutical.

11. Professional Advisory Services Fee for Initial Items

11.1 Subject to clause 10.3, the DHB will pay a Professional Advisory Services Fee for Professional Advisory Services that the Provider provides in relation to each Initial Item Supplied to or for a Service User in a month.

11.2 The Professional Advisory Services Fee for the 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 the DHB will pay the Provider in respect of each Initial Item Supplied by the Provider to a Service User in a month
- \sum = the sum of each combination of the number of Initial Items Supplied to a Service User on a single day (II in this formula) in the month
- II = the number of Initial Items Supplied to a Service User by the Provider in a single day in the month
- C = the number of times that the Provider Supplies the number of Initial Items as set out above to an individual Service User on a single day in the month
- IRVU = the relative value unit that corresponds with the number of Initial Items Supplied to the Service User on that day as follows:
 - (a) 1.00 if one, two, or three Initial Items are Supplied
 - (b) 1.02 if four Initial Items are Supplied
 - (c) 1.03 if five Initial Items are Supplied
 - (d) 1.04 if six or more Initial Items are Supplied
- ISF = the initial base service fee, which \$4.43 (GST exclusive)
- GST = 1.15 (or such other amount as correctly reflects the GST rate at the time of Supply).

11.3 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 11.2 will be 1.00.

12. Professional Advisory Services Fee for Repeat Items

12.1 The DHB will pay a Professional Advisory Services Fee for Professional Advisory Services provided by the Provider in relation to the Supply of each Repeat Item Supplied to or for a Service User in a month.

12.2 The Professional Advisory Services Fee for the month is calculated as follows:

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

where:

- R = the total fee (inclusive of GST) that the DHB will pay to the Provider in respect of each Repeat Item Supplied by the Provider to a Service User in a month
- \sum = the sum of each combination of the number of Repeat Items with a different prescription ID suffix Supplied to a Service User during the month
- N = the number of times Repeat Items with the same prescription ID suffix are Supplied by the Provider during the month
- RRVU = the relative value unit that corresponds with the prescription ID suffix for the Repeat Item Supplied to 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 \$3.03 (GST exclusive)
- GST = 1.15 (or such other amount as correctly reflects the GST rate at the time of Supply).

13. Calculation and payment of Professional Advisory Services Fees

13.1 The DHB will calculate and pay the Provider Professional Advisory Services Fees for Initial Items and Repeat Items Supplied in a month in three stages as set out in clauses 14 to 16, being:

- (a) stage one, which is the calculation of the Advance Professional Advisory Services Fee payable;
- (b) stage two, which is the calculation of the Interim Professional Advisory Services Fee payable; and
- (c) stage three, which is the calculation of the Final Professional Advisory Services Fee payable.

14. Stage one: Advanced Professional Advisory Services Fees

14.1 Subject to clause 19(3), on the first Business Day of each month the DHB will pay the Provider an Advance Professional Advisory Service Fee Payment for Professional Advisory Services that the Provider is expected to provide in the month.

14.2 The Advance Professional Advisory Service Fee will be calculated using the formula set out in clauses 11 and 12, on the basis of the number of Initial Items and Repeat Items that the DHB estimates will be Supplied to Service Users in the month.

15. Stage two: Interim Professional Advisory Services Fees

15.1 On the first Business Day of the third month after the DHB paid the Provider an Advance Service Fee, the DHB will recalculate the Professional Advisory Services Fee payable to the Provider for the month for which an Advance Service Fee was paid (the "**Interim Professional Advisory Services Fee**").

15.2 The Interim Professional Advisory Services Fee will be calculated using the formula set out in clauses 11 and 12, on the basis of the actual number of Initial Items and Repeat Items that were Supplied to Service Users during the relevant month.

- 15.3 If the difference between the Interim Professional Advisory Services Fee and the Advance Professional Services Advisory Fee for the month is:
- (a) a positive number, the DHB will pay the difference to the Provider on the first Business Day of the month; or
 - (b) a negative number, the DHB will deduct the difference from the next Professional Advisory Services Fee paid to the Provider.

16. Stage three: Final Professional Advisory Services Fees

- 16.1 After the end of each Financial Year, the DHB will recalculate the Professional Advisory Services Fee payable to the Provider for each month of the Financial Year ("Final Professional Advisory Services Fee").
- 16.2 The Final Professional Advisory Services Fee will be calculated using the formula set out in clauses 11 and 12, on the basis of the actual number of Initial Items and Repeat Items that were Supplied to Services Users during each month.
- 16.3 If the difference between the Final Professional Advisory Services Fee and the Interim Professional Advisory Services Fee is:
- (a) a positive number, the DHB will pay that amount to the Provider by no later than 31 December of the year after the Financial Year to which the amount relates; or
 - (b) a negative number, the DHB will advise the Provider that the Provider owes that amount to the DHB by no later than 31 December, and will deduct the amount from the next payment paid to the Provider after advising the Provider of the amount owed.

17. Additional Professional Advisory Services Fee claim rule

- 17.1 If the Provider submits a Claim Item for Pharmaceuticals Supplied in a month outside the time required by the DHB to calculate the Provider's Interim Professional Advisory Service Fee Payment for the month, the DHB will pay a Professional Advisory Service Fee for the Claim Item as part of the Final Professional Advisory Services Fee calculated in accordance with clause 16.

18. Calculation and payment of Professional Advisory Services Fee if Agreement is terminated

- 18.1 The DHB and the Provider agree that the recalculations described in clauses 15 and 16 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.40 of this Agreement.

19. Data used for calculation of Professional Advisory Services Fee

- 19.1 Subject to clauses 19.2 and 19.3, the DHB will, when estimating Initial Items and Repeat Items in accordance with clause 14, use data from the third calendar month before the relevant month, as adjusted using a Seasonal Adjuster.
- 19.2 If ownership of the Provider changes between the two months described in clause 19.1, the DHB will use data from the previous owner.
- 19.3 If the DHB does not have data from the months described in clause 19.1 because the Provider is a new Provider, the DHB is not required to calculate or pay any Advance Service Fee Payments until it has that data.

20. Professional Advisory Services Fee for Unregistered Medicines

- 20.1 Subject to clause 20.2, the DHB will pay the Provider an additional payment of \$5.30 for providing Professional Advisory Services in respect of each Unregistered Medicine that is a Subsidised Pharmaceutical that the Provider Supplies and claims in accordance with this Agreement, in addition to any other amount that the DHB may be required to pay for the Supply of the Pharmaceutical under any Service Schedule.
- 20.2 The DHB and the Provider agree that:
- (a) the Provider may claim only one payment under clause 20.1 per Service User per Pharmaceutical per calendar month in which the Pharmaceutical is Supplied; and
 - (b) if more than one Unregistered Medicine is extemporaneously compounded, the DHB will pay that Provider an additional payment in accordance with clause 20.1 for each Unregistered Medicine.

21. Brand-switch Fee

- 21.1 The DHB will pay the Provider a Brand-switch Fee for the provision of brand substitution advice as described in clause 5 if the Provider provides, and claims for providing, that Service in accordance with this Agreement.

22. Professional Advisory Services Fees include quality incentive payments

- 22.1 The Provider acknowledges and agrees that:
- (a) 5% of the total amount paid by the DHB to the Provider under this Schedule is a quality incentive payment; and
 - (b) the DHB and the Provider may agree that the quality incentive payment will be paid in a different way.

23. Negative A3 and J3 Transactions (including quarterly reviews)

- 23.1 For the purpose of this Schedule and despite anything else in this Agreement, a Pharmaceutical that is Supplied as part of a Negative A3 or J3 Transaction is not an Initial Item for which the Provider may claim or be paid a Professional Advisory Services Fee.
- 23.2 The DHB will calculate Advance Professional Advisory Services Fee payments, Interim Professional Advisory Services Fee payments, and Final Professional Advisory Services Fee payments owed to the Provider on the assumption that the Supply 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 Pharmaceutical Supply Services Fee payable for the Supply 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 Supplied has Repeat Items available or is a Repeat Item).
- 23.3 The DHB will, each Quarter, review the Professional Advisory Service Fees paid to the Provider in respect of each Pharmaceutical to determine whether any Pharmaceuticals that the DHB assumed were Supplied as part of a Negative A3 or J3 Transaction were in fact not Supplied as part of a Negative A3 or J3 Transaction.

23.4 If the DHB determines that a Pharmaceutical was assumed to have been Supplied as part of a Negative A3 or J3 Transaction, but was not in fact Supplied as part of a Negative A3 or J3 Transaction, the DHB will pay the Provider a Professional Advisory Services Fee for the Supply of the Pharmaceutical on the first Business Day after the review is complete.

23.5 The Professional Advisory Services Fee for the Pharmaceutical referred to in clause 23.4 is calculated as follows:

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

where:

R = the Professional Advisory Services Fee in respect of each such Pharmaceutical (inclusive of GST) that the DHB will pay the Provider

IRVU = the relative value unit (IRVU), which is 1.01

ISF = the initial base service fee, which is \$4.43 (GST exclusive)

GST = 1.15 (or such other amount as correctly reflects the GST rate at the time of Supply)

RITV = the GST inclusive amount of the Transaction Sequence, excluding the Professional Advisory Services Fee (which is treated as a positive amount)

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

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

24. [Professional Advisory Services Support Payment]

24.1 [To be updated].

25. Definitions that apply to this Schedule

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

Advance Service Fee Payment means a payment made to the Provider at the beginning of each month in accordance with clause 14

Brand-switch Fee means the amount paid for Professional Advisory Services in relation to brand substitutions as set out in the Pharmaceutical Schedule

Interim Service Fee Payment means a payment that may be paid to the Provider in accordance with clause 15

Repeat Item means a Prescription Item with a prescription ID suffix that is /2 or greater

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

SCHEDULE 3A.1
OPIOID SUBSTITUTION TREATMENT SERVICES

1. Background and service objectives

- 1.1 The DHB 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 pharmacist 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 treatment service 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 Services 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 Schedules 1 and 2, in particular, clauses 2 to 5 of Schedule 1, and clauses 2 to 5 of Schedule 2;
 - (b) the protocol issued by the Ministry concerning community pharmacist 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 Supplied by the Provider as "takeaway doses" is Supplied in containers with safety caps 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.

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 The DHB 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.36 to C.44, the DHB may agree to waive the notice period and to allow the Provider to immediately stop providing Opioid Substitution Treatment Services, if the DHB 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 an 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 11 of Schedule 1; and
 - (b) local alcohol and drug treatment service providers.

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

- 10.1 The DHB recognises that sometimes a Prescriber may consider it to be clinically necessary for a Service User receiving Opioid Substitution Treatment Services to be Supplied Co-dispensed Pharmaceuticals, and wishes to provide additional funding to the Provider for providing an additional level of service to those Service Users that is not reflected in the Service Fees that the Provider would otherwise receive for providing Services to that Service User when Supplying Co-dispensed Pharmaceuticals.
- 10.2 If the Provider provides Opioid Substitution Treatment Services to 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 Pharmacist Services); and
 - (b) the name of the Service User, 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 a Service User who has been registered as being eligible to receive Co-dispensed Opioid Services as required under clause 10.2(b), 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 The DHB 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 the DHB 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 Pharmacist 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 Pharmacist Services.

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

- 11.1 If the Provider provides Co-Dispensed Pharmaceutical Services to a Service User, the Provider must claim, and will be paid, in respect of each Pharmaceutical Supplied 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;
 - (c) for Pharmacist Clozapine Services, in accordance with Schedule 3A.4; and
 - (d) for Special Foods Services, in accordance with Schedule 3B.4.
- 11.2 Subject to clause 11.1, if the Provider makes a claim under this Schedule in relation to the Supply of a Pharmaceutical to or for a Service User, the Provider must not claim, and the DHB will not pay:
- (a) for the Supply of the Pharmaceutical under Schedule 1;
 - (b) for providing Professional Advisory Services in relation to the Supply of the Pharmaceutical under Schedule 2; or
 - (c) 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 Supplied as part of the provision of a Population Service will not be a Co-dispensed Pharmaceutical and the Provider must claim for the Supply of the Pharmaceutical under the relevant Service Schedule. If a Pharmaceutical Supplied when providing Opioid Substitution Treatment Services is an Extemporaneously Compounded Preparation, the Provider must claim for the Supply of the Pharmaceutical under this Schedule (rather than Schedule 1).
- 11.4 If the Provider Supplies an Unregistered Medicine in accordance with this Schedule, the DHB will pay the Provider an additional payment for Supplying the Unregistered Medicine in accordance with clause 19 of Schedule 1, and clause 20 of Schedule 2.

12. Opioid Substitution Treatment Service Fee

12.1 The DHB will pay the Provider for each Pharmaceutical that the Provider Supplies to a Service User in accordance with this Schedule.

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 the DHB 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 Supply
- 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
 - (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more
- PF = the Per Pack Fee listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- 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 Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

12.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply 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 the DHB 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

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 a Service User who is receiving Core Pharmacy Services, when the Provider is Supplying a Co-dispensed Pharmaceutical to 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 Supply to, or for, a Service User who is receiving Opioid Substitution Treatment Services (if either

methadone or buprenorphine+naloxone is being Supplied), on the same frequency as a Pharmaceutical that is being Supplied in connection with the treatment of opioid dependence (provided that the Pharmaceutical is Supplied at least weekly), and is Supplied 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 Supplying at least one Pharmaceutical described in clause 14.1(a) to a Service User, includes any other Pharmaceutical that the Provider Supplies to the Service User.

DRAFT FOR DHB CONSULTATION

SCHEDULE 3A.2
ASEPTIC PHARMACIST SERVICES

1. Background and service objectives

- 1.1 The DHB wishes to fund Aseptic Pharmacist Services to enable Service Users to have appropriate access to these services when the preparation of any aseptic preparation, including syringe drivers for approved pumps, is required.
- 1.2 The services described in this Schedule are intended to enhance palliative care provided to terminally ill and other Eligible Persons.
- 1.3 The DHB wishes to fund Aseptic Pharmacist Services as part of an integrated community based health service that:
 - (a) provides 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;
 - (b) provides specialist advice as required to ensure optimal Service User management; and
 - (c) ensures Service User and Staff safety.

2. Eligible Service Users

- 2.1 Eligible Service Users are Eligible Persons who:
 - (a) choose to access Aseptic Pharmacist Services from the Provider; and
 - (b) are prescribed 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, in a private hospital, or an institution.

3. Access

- 3.1 The Provider must provide Aseptic Pharmacist 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 Pharmacist 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 Pharmacist Services include:
 - (a) Supplying Pharmaceuticals in accordance with clauses 2 to 5 of Schedule 1, and clauses 2 to 5 of Schedule 2; and
 - (b) preparing aseptic preparations in accordance with the Pharmacy Service 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 Supply:
- (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 the DHB 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 11 of Schedule 1;
 - (b) palliative care providers;
 - (c) pain management services; and
 - (d) other services requiring the manufacture of aseptic preparations.

8. Additional claiming and payment rules for Aseptic Pharmacist 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) Pharmacist 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 Supply of a Pharmaceutical requiring aseptic manufacture, the Provider must not claim, and the DHB will not pay:

- (a) for the Supply of the Pharmaceutical under Schedule 1;
- (b) for providing Professional Advisory Services in relation to the Supply of the Pharmaceutical under Schedule 2; or
- (c) for the provision of any other Population Service under a Service Schedule in Schedule 3.

8.3 If the Provider Supplies an Unregistered Medicine in accordance with this Schedule, the DHB will pay the Provider an additional payment for Supplying the Unregistered Medicine in accordance with clause 19 of Schedule 1, and clause 20 of Schedule 2.

9. Aseptic Pharmacist Services Fee

9.1 The DHB will pay the Provider an Aseptic Pharmacist Services Fee for each Pharmaceutical that the Provider Supplies to a Service User in accordance with this Schedule.

9.2 The Aseptic Pharmacist Services Fee is calculated as follows:

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

where:

- R = the Aseptic Pharmacist Services Fee that the DHB will pay the Provider (if R is a negative number)
- Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule as at the date of Supply
- M = a margin towards the procurement and stockholding costs for the Pharmaceutical, which is either:
 - (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 listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- 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 Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

9.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

SCHEDULE 3A.3
STERILE MANUFACTURING SERVICES

1. Background and service objective

- 1.1 The DHB wishes to fund Sterile Manufacturing Services to enable Service Users to have appropriate access to sterile manufacturing services.
- 1.2 The DHB wishes to fund Sterile Manufacturing Services as part of an integrated community based health service that:
 - (a) provides 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;
 - (b) provides specialist advice as required to ensure optimal Service User management; and
 - (c) ensures Service User and Staff safety.
- 1.3 This Schedule is specific to the preparation of eye drops and other products requiring sterile manufacturing, as distinct from aseptic manufacturing.

2. Eligible Service Users

- 2.1 Service Users are Eligible Persons who:
 - (a) choose to access Sterile Manufacturing Services from the Provider; and
 - (b) are prescribed Pharmaceuticals requiring sterile manufacture if:
 - (i) a commercially available preparation is not available; and
 - (ii) the Pharmaceutical is for use in the Service User's own home or in a private hospital or 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) Supplying Pharmaceuticals in accordance with clauses 2 to 5 of Schedule 1, and clauses 2 to 5 of Schedule 2; and
 - (b) preparing sterile preparations that comply with the requirements of the Pharmacy Service 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 Service 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 Supply:

- (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 the DHB 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 11 of Schedule 1;
- (b) any organisation providing sterile manufacturing services; and
- (c) hospital pharmacies providing sterile services.

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 a Service User in accordance with this Schedule, the Provider must claim for each Pharmaceuticals Supplied to the Service User in accordance with the relevant provisions in Schedule 1.

8.2 If the Provider Supplies an Unregistered Medicine in accordance with this Schedule, the DHB will pay the Provider an additional payment for Supplying the Unregistered Medicine in accordance with clause 19 of Schedule 1, and clause 20 of Schedule 2.

9. Sterile Manufacturing Services Fee

9.1 The DHB will pay the Provider a Sterile Manufacturing Services Fee for each Pharmaceutical that the Provider Supplies in accordance with this Schedule.

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 the DHB will pay the Provider (if R is a positive number)
- Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule as at the date of Supply
- 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 listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- HFM = the Handling Fee Multiplier for the Pharmaceutical, which is 26.50
- GST = 1.15 (such other amount as correctly reflects the GST rate on the date of Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

9.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

SCHEDULE 3A.4
CLOZAPINE SERVICES (MONITORED THERAPY MEDICINE SERVICES)

1. Background and service objectives

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

2. Eligible Service Users

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

3. Access

- 3.1 Pharmacist Clozapine Services must be available to Service Users at all times when the Provider's Premises is open for normal business, subject to the conditions set out in clause 9 of Schedule 1.

4. Service components

- 4.1 The Provider must provide Pharmacist Clozapine Services in accordance with the following requirements:
 - (a) the relevant clauses in Schedules 1 and 2, in particular, clauses 2 to 5 of Schedule 1, and clauses 2 to 5 of Schedule 2; and
 - (b) the Clozapine Protocol.
- 4.2 The Provider must, before Supplying 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 Supplied 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 continue to sit with the Prescribers.
- 4.4 The Provider must:
 - (a) maintain a record of feedback of concerns about individual Service Users;
 - (b) maintain a communication process with individual Prescribers; and
 - (c) record the Supply of clozapine on the supplier's website.
- 4.5 The Provider must be familiar with, and comply with, the requirements set out in:
 - (a) any guidelines issued by the Ministry concerning the use of atypical anti-psychotic drugs; and
 - (b) relevant sections of the DHB 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 Pharmacist 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, or their caregiver, in accordance with Schedule 2, including:
 - (i) emphasising the importance of compliance 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 Pharmacist Clozapine Services, including updating the clozapine supplier website with the date of any Supply 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 pharmaceutical supplier.
- 5.2 If clause 5.1 applies, the Provider must carry out the instructions of the Prescriber in relation to the provision of Pharmacist 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 11 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 supplier, will not be reimbursed by the DHB.

8. Additional quality requirements

- 8.1 The quality requirements set out in clauses 8.2 to 8.8 are additional to the Provider's quality obligations under this Agreement and the Clozapine Protocol.
- 8.2 Clozapine must only be provided once a satisfactory blood result has been received.
- 8.3 Prescription Forms for clozapine must be written by a qualified Prescriber.
- 8.4 The Provider acknowledges and agrees that prescribing and Supplying clozapine is subject to restrictions issued by the Ministry, including the requirement for blood monitoring.
- 8.5 In order to be qualified to provide Pharmacist 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 at least annually, and record that this has occurred. The training package and records must be available for audit purposes.
- 8.6 The ability to be able to comply with the requirement in clauses 8.5(b) and 8.5(c) above is dependent on the questionnaire and training session being developed and made available to providers by the DHB.
- 8.7 Pharmacist Clozapine Services must only be provided by a Pharmacist that complies with the requirements specified in clause 8.5(a) and has completed the questionnaire, training and annual validation sessions and recording, detailed in clauses 8.5(b) and 8.5(c), when these are available to providers.
- 8.8 The Provider is responsible for the management of Pharmacist Clozapine Services at all times.

9. Additional claiming and payment rules for Pharmacist Clozapine Services

- 9.1 Subject to clause 9.2, if the Provider is required to provide Extemporaneously Compounded Preparations Services for clozapine Supplied to, or for, a Service User under this Schedule, the Provider must claim, and will be paid, in accordance with the relevant provisions in Schedule 1 (and not under this Schedule).
- 9.2 If the Provider makes a claim under this Schedule in relation to the Supply of clozapine, the Provider must not claim, and the DHB will not pay:
 - (a) for the Supply of the Pharmaceutical under Schedule 1;
 - (b) for providing Professional Advisory Services in relation to the Supply of the Pharmaceutical under Schedule 2; or
 - (c) for the provision of any other Population Service under a Service Schedule in Schedule 3.
- 9.3 If the Provider Supplies an Unregistered Medicine in accordance with this Schedule, the DHB will pay the Provider an additional payment for Supplying the Unregistered Medicine in accordance with clause 19 of Schedule 1, and clause 20 of Schedule 2.

10. Clozapine Pharmacist Services Fee

- 10.1 The DHB will pay the Provider a Clozapine Pharmacist Services Fee for each Pharmaceutical that the Provider Supplies to a Service User and claims in accordance with this Schedule.

10.2 The Clozapine Pharmacist Services Fee is calculated as follows:

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

where:

- R = the Clozapine Pharmacist Services Fee that the DHB 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 Supply
- 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 listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- 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 Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

10.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

11. Definitions that apply to this Schedule

11.1 In this 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, which is available on TAS's website, as amended by the DHB from time to time following engagement with provider representatives.

SCHEDULE 3A.5
PHARMACIST INFLUENZA IMMUNISATION SERVICES

1. Background and service objectives

- 1.1 The DHB wishes to fund the delivery of the Influenza Vaccine and the provision of associated Influenza Immunisation Services to Eligible Service Users, in order to achieve the following service objectives:
- (a) Pharmacist Vaccinators and Authorised Vaccinators are well equipped to offer and administer Influenza Vaccines to Eligible Service Users;
 - (b) to reduce the burden of GP consultations, hospitalisations, and deaths associated with influenza in the Eligible Service User population groups;
 - (c) patients are linked to primary health care services;
 - (d) 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
 - (e) all Influenza Vaccines given by Pharmacist Vaccinators and Authorised Vaccinators are recorded on the National Immunisation Register (NIR).

2. Eligible Service Users

- 2.1 The Provider may provide Influenza Immunisation Services to Eligible Persons who are:
- (a) people aged 65 years and over; and
 - (b) pregnant women.
- 2.2 The Provider must not provide, or claim for providing, Influenza Immunisation Services, to:
- (a) people who have experienced previous serious adverse reactions or anaphylaxis to an influenza vaccine or one of its components, or a history of egg anaphylaxis (the Provider may get guidance on this from the Immunisation Handbook, or contact the individual's general practice before administering the vaccine); or
 - (b) people who have already been vaccinated with current seasonal Influenza Vaccine.
- 2.3 If in doubt the Provider will contact the person's general practice, or its DHB NIR administrator, to confirm the person's influenza 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.

3. Service components

- 3.1 The Provider must:
- (a) ensure that Influenza Immunisation Services are provided by:
 - (i) a Pharmacist who has completed the vaccinator requirements, as outlined in Appendix 4 of the Immunisation Handbook ("Pharmacist Vaccinator"); or

- (ii) an Authorised Vaccinator who has completed the vaccinator requirements, as outlined in Appendix 4 of the current online version of the Immunisation Handbook;
- (b) provide Influenza Immunisation Services in accordance with:
 - (i) the Immunisation Standards;
 - (ii) the Immunisation Handbook;
 - (iii) National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017; and
 - (iv) the Ministry's Annual Influenza Immunisation Programme.
- (c) meet the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017, including achievement of "Cold Chain Accreditation"; and
- (d) record the Influenza Vaccines given by a Pharmacist Vaccinator or Authorised Vaccinator on the NIR web portal 'ImmuniseNow,' and notify the Eligible Service User's general practice within two working days that the Service User has been immunised.

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 Influenza Vaccine from the supplier notified to it by the Ministry.
- 4.3 The cost of the Influenza Vaccine will be advised by PHARMAC from time to time, and the DHB will advise the Provider of any change to the cost as soon as practicably possible 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) PHOs and local general practices;
 - (b) all providers that provide Influenza Immunisation Services;
 - (c) the Provider's local Medical Officer of Health;
 - (d) the Provider's local Immunisation Coordinator;
 - (e) the DHB Immunisation nurse leader; and
 - (f) the Immunisation Advisory Centre.

6. Performance Measures

- 6.1 The effectiveness of Influenza Immunisation Services will be measured by whether the percentage of persons aged 65 years and over, and pregnant women receiving the Influenza Vaccination, is increased.

7. Payment for Influenza Immunisation Services

- 7.1 Subject to clause 8, the Provider may claim, and the DHB will pay, an Influenza Immunisation Services Fee for administering an Influenza Vaccine to an Eligible Service User in accordance with this Schedule.
- 7.2 The Influenza Immunisation Services Fee is:
- (a) \$19.00 (GST exclusive) for each Influenza Vaccine administered to an Eligible Service User; and
 - (b) the purchase cost (inclusive of GST) of the Influenza Vaccine administered to a Eligible Service User.
- 7.3 The payment for provision of Influenza Immunisation Services under this Schedule is a stand-alone payment, independent of any other payments under this Agreement.

8. Conditions of payment

- 8.1 The DHB will pay the Provider an Influenza Immunisation Services Fee only if:
- (a) the Influenza Vaccine 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 an Influenza Vaccine administered by a Pharmacist Vaccinator, or Authorised Vaccinator operating from the Provider's Premises.
- 8.2 Nothing in this Schedule entitles the Provider to receive more than the Influenza Immunisation Services Fee if more than one Influenza Vaccine is administered on the same occasion.

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 Influenza Immunisation Services.
- 9.2 To avoid doubt, clauses D.5 to D.10 do not apply to the Provider's provision of Influenza Immunisation Services unless the Provider provides Influenza Immunisation Services to a person other than an Eligible Service User, in which case clause D.4 applies.

10. Definitions that apply to this Schedule

- 10.1 In this 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 2014 – 3rd edition, December 2016" as published by the Ministry and updated from time to time, including any handbook prepared by the Ministry to replace that Handbook

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

Influenza Immunisation Services means the immunisation services described in this Schedule

Influenza Vaccine means an influenza vaccine that is listed on the Pharmaceutical Schedule as funded when provided to Eligible Service Users by providers in accordance with this Schedule

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

National Immunisation Register or **NIR** means the a computerised information system that holds the immunisation details of New Zealand patients

National Standard for Vaccine Storage and Transportation for Immunisation Providers 2017 means the standards 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 has the meaning set out in clause 3(1)(a)(i).

DRAFT FOR DHB CONSULTATION

SCHEDULE 3B.1
LONG-TERM CONDITIONS PHARMACIST SERVICES

1. Background and Service objectives

- 1.1 The DHB wishes to fund the provision of LTC Pharmacist Services to Service Users with a diagnosed Long Term Condition, who have poor medicine adherence, and who are assessed as having the capacity and willingness to receive additional support.
- 1.2 The DHB wishes to fund LTC Pharmacist Services as part of an integrated community based health service that:
- (a) improves the Service User's health outcomes, include 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 multi-disciplinary 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 best value by targeting the Service Users who meet the LTC Criteria, and providing them with LTC Pharmacist Services most suited to their needs.

2. Eligible Service Users

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

3. Approval to provide LTC Pharmacist 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 Pharmacist Services, the Provider will:
- (a) discuss the LTC Access Criteria and LTC Pharmacist 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 Pharmacist Services Protocol.

- 3.2 If the Provider determines that the Service User is eligible to receive LTC Pharmacist Services the Provider must:
- (a) determine the level of LTC Pharmacist Services 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 Pharmacist Services programme and to use the Provider as the Service User's ongoing regular provider of pharmacist services while they are receiving the LTC Pharmacist Services; and
 - (d) complete the approvals process set out in the LTC Pharmacist Services Protocol so that the Provider will be eligible to receive funding for the LTC Pharmacist Services it provides to that Service User.

4. Service User changing Providers

- 4.1 If a Service User that is approved to receive LTC Pharmacist Services wishes to receive LTC Pharmacist Services from:
- (a) the Provider instead of a different provider, then, if the Provider agrees to provide LTC Pharmacist Services to that Service User (such agreement not to be unreasonably withheld), the Provider must obtain that Service User's agreement to receive LTC Pharmacist Services from the Provider, and must notify the Service User's former provider, the DHB, 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 Pharmacist Services Protocol when carrying out its obligations under clause 4.1.

5. Exiting Service Users from the LTC Pharmacist Services programme

- 5.1 The Provider must, as required by the LTC Pharmacist 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 Pharmacist Services Protocol.
- 5.3 The DHB 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 Pharmacist Services programme by notifying the Provider accordingly, in which case:
- (a) the Provider must exit the Service User in accordance with the LTC Pharmacist Services Protocol; and

- (b) the DHB will stop paying the Provider to provide LTC Pharmacist Services to the Service User from the day the Service User exits the programme.

5.4 If the LTC Pharmacist 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 Pharmacist 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 Pharmacist Services Protocol the next time the Provider contacts the Service User.

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

- 6.1 The DHB will notify the Provider, on or before 1 July of each year, of the cap on the number of Service Users in the DHB's Geographical Area who may receive LTC Pharmacist Services during the Financial Year (the LTC Annual Cap).
- 6.2 The DHB will monitor and report publicly each month on the number of Service Users in the DHB's Geographical Area that are receiving LTC Pharmacist Services in accordance with the LTC Pharmacist Services Protocol.
- 6.3 The DHB will notify the Provider in writing when the number of Service Users in the DHB's Geographical Area receiving LTC Pharmacist Services has reached 97% of the LTC Annual Cap.
- 6.4 If the number of Service Users in the DHB's Geographical Area receiving LTC Pharmacist Services reaches 100% of the LTC Annual Cap:
 - (a) the DHB will notify the Provider in writing that the LTC Annual Cap has been reached;
 - (b) the DHB will suspend approvals for all applications for new Service Users in the DHB's Geographical Area to receive LTC Pharmacist 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 6.5.
- 6.5 The DHB will continue to monitor and report publicly each month on the number of Service Users in the DHB's Geographical Area receiving LTC Pharmacist Services during the suspension.
- 6.6 If the number of Service Users receiving LTC Pharmacist Services in the DHB's Geographical Area drops to below 99% of the LTC Annual Cap, the DHB will lift the suspension.
- 6.7 To avoid doubt, nothing in this clause affects those Service Users already receiving LTC Pharmacist Services or the Provider's entitlement to payment for providing LTC Pharmacist 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) the services specified in clauses 2 to 5 of Schedule 1, and clauses 2 to 5 of Schedule 2;

- (b) medicines reconciliation services, whereby 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, whereby the Provider coordinates the quantities of all the Service User's medications supplied to the earliest common date in order 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 Pharmacist Services Protocol;
- (f) dispensing services, with dispensing frequency tailored to the needs of the Service User and within 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 them with information about the Service User's progress in improving their management of their medications and compliance and adherence with their medicines regime.

7.2 The Provider must regularly and proactively make contact with the LTC Service User, with clear agreement about mutual expectations and the LTC Pharmacist Services available.

7.3 The LTC Pharmacist Services the Provider provides to each Service User must be supported by appropriate documentation, which the Provider must make available for the DHB's inspection and Audit.

7.4 The DHB 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 Pharmacist 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 an LTC Service User to another provider for that provider to provide Product Supply 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 Pharmacist Services to that Service User, as well as supporting the initiation, continuation, and cessation of LTC Pharmacist Services in relation to the Service User.

9. Reporting

9.1 The Provider must comply with any reporting requirements set out in the LTC Pharmacist Services Protocol.

10. Additional claiming and payment rules for LTC Pharmacist 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 an LTC Service User, the Provider must claim, and will be paid, in respect of each Pharmaceutical Supplied 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;
 - (c) for Pharmacist Clozapine Services, in accordance with Schedule 3A.4; and
 - (d) for Special Foods Services, in accordance with Schedule 3B.4.
- 10.3 Subject to clause 10.2(a), if the Provider makes a claim under this Schedule in relation to the Supply of a Pharmaceutical to, or for, an LTC Service User, the Provider must not claim, and the DHB will not pay:
- (a) for the Supply of the Pharmaceutical under Schedule 1;
 - (b) for providing Professional Advisory Services in relation to the Supply of the Pharmaceutical under Schedule 2; or
 - (c) for the Supply of a Co-Dispensed Pharmaceutical under Schedule 3A.1; or
 - (d) for the provision of any other Population Service under a Service Schedule in Schedule 3.

11. Payment for LTC Pharmacist Services

- 11.1 The DHB will pay the Provider the following fees for LTC Pharmacist Services provided to LTC Service Users in accordance with this Schedule and the LTC Pharmacist Services Protocol:
- (a) an LTC Product Supply Services Fee, in accordance with clause 12;
 - (b) an LTC Monthly Services Fee, in accordance with clause 13; and
 - (c) an LTC Professional Advisory Services Fee, in relation to the Supply of an Initial Item to a Service User, in accordance with clause 14; and
 - (d) an LTC Professional Advisory Services Fee in relation to the Supply of a Repeat Item to a Service User, in accordance with clause 15.
- 11.2 The DHB is not required to pay a Professional Advisory Services Fee in accordance with clause 11.1(c) or (d) for Professional Advisory Services that the Provider provides in relation to the Supply of an Initial Item or a Repeat Item to or for a Service User:
- (a) if the DHB is required to pay a Brand-switch Fee under this Schedule;
 - (b) in accordance with a Practitioner Supply Order or Bulk Supply Order;
 - (c) part of the provision of Class B Pharmaceutical Services, Extemporaneously Compounded Preparations Services, NPPA Services A, NPPA Services B, or any Population Service;
 - (d) for Owed Pharmaceuticals; and

- (e) if the Pharmaceutical is not a Subsidised Pharmaceutical.

12. LTC Product Supply Services Fee

12.1 Subject to clauses 12.3 and 12.4, the DHB will pay the Provider an LTC Product Supply Services Fee for each Pharmaceutical that the Provider Supplies to an LTC Service User, and claims in accordance with this Schedule and the LTC Pharmacist Services Protocol.

12.2 The LTC Product Supply Services Fee is calculated as follows:

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

where:

- R = the LTC Product Supply Services Fee that the DHB 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 Supply
- 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 listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- 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 Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

12.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

13. LTC Monthly Services Fee

13.1 Subject to clauses 13.4 and 13.5, the DHB 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 Pharmacist 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 The DHB 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 The DHB will pay the LTC Monthly Services Fee on the seventh Business Day of each month.

- 13.4 The DHB will not pay the Provider an LTC Monthly Services Fee for an LTC Service User if the Provider has not Supplied 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 an LTC Service User, but the DHB has paid the Provider an LTC Monthly Services Fee for the LTC Service User, the DHB 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 Pharmacist Services.

14. LTC Professional Advisory Services Fee for Initial Items

- 14.1 The DHB will pay an LTC Professional Advisory Services Fee for Professional Advisory Services that the Provider provides in relation to each Initial Item Supplied to, or for, an LTC Service User in a month.
- 14.2 The LTC Professional Advisory Services Fee for the 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 the DHB will pay the Provider for providing LTC Professional Advisory Services in the month
- \sum = the sum of each combination of the number of Initial Items Supplied to, or for, a LTC Services User on a single day (II in this formula) in the month
- II = the number of Initial Items Supplied to, or for, an LTC Service User by the Provider in a single day in the month
- C = the number of times that the number of Initial Items as set out above are Supplied 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 Supplied to, or for, the Service User on that day as follows:
- (a) 1.00 if one, two, or three Initial Items are Supplied
 - (b) 1.02 if four Initial Items are Supplied
 - (c) 1.03 if five Initial Items are Supplied
 - (d) 1.04 if six or more Initial Items are Supplied
- ISF = the initial base service fee, which is \$4.43 (GST exclusive)
- GST = 1.15 (or such other amount as correctly reflects the GST rate at the time of Supply)

15. LTC Professional Advisory Services Fee for Repeat Items

- 15.1 The DHB will pay a LTC Professional Advisory Services Fee for Professional Advisory Services that the Provider provides in relation to each Repeat Item Supplied to, or for, an LTC Service User in a month.

15.2 The LTC Professional Advisory Services Fee for the month is calculated as follows:

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

where:

- R = the total fee (inclusive of GST) that the DHB will pay to the Provider for providing LTC Professional Advisory Services in the month
- \sum = the sum of each combination of the number of Repeat Items with a different prescription ID suffix Supplied to a Service User during the month
- N = the number times Repeat Items are Supplied by the Provider during the Service Month with the particular prescription ID suffix
- RRVU = the relative value unit that corresponds with the prescription ID suffix for the Repeat Item Supplied to the Service User as follows:
- (a) 1.00 if the Prescription ID suffix is 2 or 3
 - (b) 0.6 if the Prescription ID suffix is 4 to 12
 - (c) 0.4 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 \$3.03 (GST exclusive)
- GST = 1.15 (or such other amount as correctly reflects the GST rate at the date of Supply)

16. Calculation and payment of LTC Professional Advisory Services Fees

16.1 The DHB will calculate and pay the Provider LTC Professional Advisory Services Fees for Initial Items and Repeat Items Supplied in a month in three stages as set out in clauses 17 to 19, being:

- (a) stage one, which is the calculation of the Advance LTC Professional Advisory Services Fee payable;
- (b) stage two, which is the calculation of the Interim LTC Professional Advisory Services Fee payable; and
- (c) stage three, which is the calculation of the Final LTC Professional Advisory Services Fee payable.

17. Stage one: Advance LTC Professional Advisory Services Fees

17.1 Subject to clause 22(3), on the first Business Day of each month the DHB will pay the Provider an Advance LTC Professional Advisory Service Fee Payment for LTC Professional Advisory Services that the Provider is expected to provide in the month.

17.2 The Advance LTC Professional Advisory Service Fee will be calculated using the formula in clauses 14 and 15, on the basis of the number of Initial Items and Repeat Items that the DHB estimates will be Supplied to Service Users in the month.

18. Stage two: Interim LTC Professional Advisory Services Fees

18.1 On the first Business Day of the third month after the DHB paid the Provider an Advance LTC Service Fee, the DHB will recalculate the LTC Professional Advisory Services Fee payable to the Provider for the month for which an Advance Service Fee was paid (the "Interim LTC Professional Advisory Services Fee").

18.2 The Interim LTC Professional Advisory Services Fee will be calculated using the formula in clauses 14 and 15, on the basis of the actual number of Initial Items and Repeat Items Supplied to Services Users in the month.

18.3 If the difference between the Interim LTC Professional Advisory Services Fee and the Advance LTC Professional Services Advisory Fee for the month is:

- (a) a positive number, the DHB will pay the difference to the Provider on the first Business Day of the month; or
- (b) a negative number, the DHB will deduct the difference from the next payment paid to the Provider.

19. Stage three: Final LTC Professional Advisory Services Fees

19.1 After the end of each Financial Year, the DHB will recalculate the LTC Professional Advisory Services Fee payable to the Provider for each month of the Financial Year ("Final LTC Professional Advisory Services Fee").

19.2 The Final LTC Professional Advisory Services Fee will be calculated using the formula in clauses 14 and 15, on the basis of the actual number of Initial Items and Repeat Items Supplied to Services Users during each month.

19.3 If the difference between the Final LTC Professional Advisory Services Fee and the Interim LTC Professional Advisory Services Fee is:

- (a) a positive number, the DHB will pay that amount to the Provider by no later than 31 December of the year after the Financial Year to which the amount relates; or
- (b) a negative number, the DHB will advise the Provider that the Provider owes that amount to the DHB by no later than 31 December, and will deduct the amount from the next payment paid to the Provider after advising the Provider of the amount owed.

20. Additional LTC Professional Advisory Services claim rule

20.1 If the Provider submits a Claim Item for Pharmaceuticals Supplied in a month outside the time required by the DHB to calculate the Provider's Interim LTC Professional Advisory Services Fee Payment for the month, the DHB will pay a Professional Advisory Services Fee for the Claim Item as part of the Final Professional Advisory Services Fee calculated in accordance with clause 19.

21. Calculation and payment of LTC Professional Advisory Services Fee if Agreement is terminated

21.1 The DHB and the Provider agree that the recalculations described in clauses 18 and 19 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.40.

22. Data used for calculation of LTC Professional Advisory Services Fee

22.1 Subject to clauses 22.2 and 22.3, the DHB will, when estimating Initial Items and Repeat Items in accordance with clause 17, use data from the third calendar month before the relevant month, as adjusted using a Seasonal Adjuster.

22.2 If ownership of the Provider changes between the two months described in clause 22.1, the DHB will use Supply data from the previous owner.

- 22.3 If the DHB does not have data from the months described in clause 22.1 because the Provider is a new Provider, the DHB is not required to calculate or pay any Advance LTC Professional Advisory Service Fee Payments until it has that data.

23. LTC Professional Advisory Services Fee for Supplying Unregistered Medicines

- 23.1 The DHB will pay the Provider a payment for each Unregistered Medicine that is a Subsidised Pharmaceutical that the Provider Supplies to an LTC Service User and claims in accordance with this Schedule, in addition to any other amount that the DHB may be required to pay for the Supply of the Pharmaceutical under this Schedule.

- 23.2 Subject to clause 23.3, the additional payment is calculated as follows:

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

where:

- R = the additional payment that the DHB 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 Supply
- M2 = a top-up margin payment towards the procurement and stockholding costs of the Pharmaceutical, which is:
- (c) 0.07 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is less than \$150.00; or
 - (d) 0.06 if the Pharmaceutical Schedule Pack Subsidy for the Pharmaceutical is \$150.00 or more
- AF = an additional margin fee payment of \$3.00 towards the additional administration costs of Supplying an Unregistered Medicine
- CF = a fee of \$5.30 towards the additional counselling costs involved when Dispensing an Unregistered Medicine.
- GST = 1.15 (or such other amount as correctly reflects the GST rate at the date of Supply).

- 23.3 The DHB and the Provider agree that:

- (a) the Provider will be paid only one additional margin fee payment (referred to as "AF" in clause 23.2 one counselling fee payment (referred to as "CF" in subclause (2)) per LTC Service User per Pharmaceutical per calendar month in which the Pharmaceutical is Supplied to or for a Service User; and
- (b) if more than one Unregistered Medicine is extemporaneously compounded, the DHB will pay the Provider, in accordance with clause 23.2, an additional payment for each Unregistered Medicine.

24. Brand-switch Fee

- 24.1 The DHB will pay the Provider a Brand-switch Fee for the provision of brand substitution advice as described in clause 5 of Schedule 2 if the Provider provides, and claims for providing, that Service in accordance with this Agreement.

25. LTC Professional Advisory Services Fees include quality incentive payments

- 25.1 The Provider acknowledges and agrees that:

- (a) 5% of the LTC Professional Advisory Services Fee is a quality incentive payment; and

- (b) the DHB and the Provider may agree that the quality incentive payment will be paid in a different way.

26. Additional LTC Professional Advisory Services Fee payment rules

- 26.1 To avoid doubt, if the Provider does not submit a Claim Item for Supply within the time required by the DHB to calculate the Provider's Actual Service Fee Payment for the relevant Service Month, the DHB will pay LTC Professional Advisory Services Fees in accordance with clause 19.

27. Negative A3 and J3 Transactions (including quarterly reviews)

- 27.1 We agree that, for the purpose of this Schedule and despite anything else in this Agreement, a Pharmaceutical that is Supplied as part of a Negative A3 or J3 Transaction is not an Initial Item for which the Provider may claim or be paid an LTC Professional Advisory Services Fee.
- 27.2 The DHB will calculate Advance LTC Professional Advisory Services Fee payments, Interim LTC Professional Advisory Services Fee payments, and Final LTC Professional Advisory Services Fee payments owed to the Provider on the assumption that the Supply 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 Product Supply Services Fee payable for the Supply 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 Supplied has Repeat Items available or is a Repeat Item).
- 27.3 The DHB will, each Quarter, review the LTC Professional Advisory Service Fees paid to the Provider in respect of each Pharmaceutical to determine whether any Pharmaceuticals that the DHB assumed were Supplied as part of a Negative A3 or J3 Transaction were in fact not Supplied as part of a Negative A3 or J3 Transaction.
- 27.4 If the DHB determines that a Pharmaceutical was assumed to have been Supplied as part of a Negative A3 or J3 Transaction, but was not in fact Supplied as part of a Negative A3 or J3 Transaction, the DHB will pay the Provider a LTC Professional Advisory Services Fee for the Supply of the Pharmaceutical on the first Business Day after the review is complete.
- 27.5 The LTC Professional Advisory Services Fee for the Pharmaceutical is calculated as follows:
- $$R = (IRVU \times ISF) \times GST - RITV$$
- where:
- R = the LTC Professional Advisory Services Fee (inclusive of GST) that the DHB will pay the Provider
 - IRVU = the relative value unit (IRVU) assigned to the Supply, which is 1.01
 - ISF = the initial base service fee for the Supply, which is \$4.43 (GST exclusive)
 - GST = 1.15 (or such other amount as correctly reflects the GST rate at the time of Supply)
 - RITV = the GST inclusive amount of the Transaction Sequence excluding the Professional Advisory Services Fee (which is treated as a positive amount)
- 27.6 To avoid doubt, the review will not affect any other payments that the DHB has paid to the Provider, nor will it mean that the IRVU, that was applied in relation to the Supply of Initial Items that were Supplied 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.

28. Definitions that apply to this Schedule

28.1 In this 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 Pharmacist Services Protocol

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

LTC Annual Cap has the meaning set out in clause 6(1)

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

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

LTC Pharmacist Services Protocol means the publication entitled "LTC Pharmacist Services Protocol", which is available at www.tas.health.nz (or any other website advised by the DHB), as amended by the DHB from time to time following engagement with provider representative groups

LTC Product Supply Services Fee means the fee paid in accordance clause 12

LTC Professional Advisory Services Fee means the fee paid in respect of the Supply of Initial Items in accordance with clause 14, and the fee paid in respect of the Supply of Repeat Items in accordance with clause 15

LTC Service Patient Eligibility Assessment Form means the form used by providers to assess Service Users for eligibility to receive LTC Pharmacist 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 Pharmacist Services from the Provider in accordance with this Schedule.

SCHEDULE 3B.2
COMMUNITY RESIDENTIAL CARE PHARMACIST SERVICES

1. Background and service objectives

- 1.1 The DHB wishes to fund Community Residential Care (CRC) Pharmacist Services for Service Users living in community residential care.
- 1.2 CRC Pharmacist Services are community based health services that:
- (a) provide CRC Service Users with the best quality and most cost-effective community pharmacist services, within available funding, based on established professional and quality management standards and codes of practice;
 - (b) provide pharmacist 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 The DHB will fund the Provider to provide CRC Pharmacist Services to Service Users who are:
- (a) people living in a CRC Service who require community residential support services and who 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 a Oranga Tamariki Care & Protection or Youth Justice Residence under section 364 of the Oranga Tamariki Act 1989 and:
 - (i) have behavioural problems; or
 - (ii) have committed an offence.

3. Access

- 3.1 The Provider must:
- (a) provide CRC Pharmacist 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 Pharmacist Services to CRC Service Users that meets the CRC Service Users' reasonable needs; and
 - (c) provide CRC Pharmacist Services during normal business hours to minimise the need for after hours pharmacist 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 Pharmacist Services include:

- (a) Supplying Pharmaceuticals in accordance with clauses 2 to 5 of Schedule 1;
- (b) providing information, advice, and services in accordance with Schedule 2;
- (c) maintaining an accurate dispensing record and medication profile for every CRC Service User, and:
 - (i) making this profile available, if requested, to the CRC Service User, and members of the CRC Service User's multi-disciplinary team; and
 - (ii) transferring it to any other another provider or CRC Service that the CRC Service User transfers to; and
- (d) synchronisation and reconciliation services, as appropriate, for each CRC Service User.

5. Delivery times

5.1 Unless the DHB agrees otherwise in writing, in order to minimise unnecessary Supply and waste of Pharmaceuticals, the Provider must not deliver Pharmaceuticals to a CRC Service Provider earlier than three 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 supply 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 Pharmacist 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) start date of CRC Pharmacist Services;
- (c) end date of CRC Pharmacist Services, if applicable;
- (d) the name of the CRC Service Provider (in which the CRC Service User to whom the Provider is providing CRC Pharmacist 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 11 of Schedule 1; and
- (b) the CRC Service Providers providing services to the Provider's CRC Service Users.

8. Additional claiming and payment rules for CRC Pharmacist Services

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

- (a) Service Users that receive:
 - (i) ARRC Pharmacist Services;
 - (ii) LTC Pharmacist 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 Supplied 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;
- (c) for Pharmacist Clozapine Services, in accordance with Schedule 3A.4; and
- (d) for Special Foods Services, in accordance with Schedule 3B.4.

8.3 Subject to clause 8.1, if the Provider makes a claim under this Schedule in relation to the Supply of a Pharmaceutical to, or for, a CRC Service User, the Provider must not claim, and the DHB will not pay:

- (a) for the Supply of the Pharmaceutical under Schedule 1;
- (b) for providing Professional Advisory Services in relation to the Supply of the Pharmaceutical under Schedule 2; or
- (c) for the provision of any other Population Service under a Service Schedule in Schedule 3.

8.4 If the Provider Supplies an Unregistered Medicine in accordance with this Schedule, the DHB will pay the Provider an additional payment for Supplying the Unregistered Medicine in accordance with clause 19 of Schedule 1, and clause 20 of Schedule 2.

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 Pharmacist Services

9.1 The DHB will pay the Provider a CRC Pharmacist Services Fee for each Pharmaceutical that the Provider Supplies to a Service User and claims in accordance with this Schedule.

9.2 The CRC Pharmacist Services Fee is calculated as follows:

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

where:

- R = the CRC Pharmacist Services Fee that the DHB 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 Supply
- 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 listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- 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 at the date of Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

9.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

10. Definitions that apply to this Schedule

10.1 In this 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 provide CRC Service Users with accommodation (either in a large facility or 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 PHARMACIST SERVICES

1. Background and Service objectives

1.1 The DHB wishes to fund Pharmacist Services for ARRC Service Users in ARRC Facilities:

- (a) to ensure appropriate pharmacist services and advice are provided to ARRC Service Users and to those Service Users' ARRC Providers; and
- (b) as part of an integrated community based 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 Supply and waste, of Pharmaceuticals; and
 - (iv) ensures ARRC Service User and Staff safety.

2. Eligible Service Users

2.1 The DHB will fund the Provider to provide ARRC Pharmacist 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 Pharmacist 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 Pharmacist Services to ARRC Service Users that meets the Service Users' reasonable needs; and
- (c) provide ARRC Pharmacist Services during normal business hours to minimise the need for after hours pharmacist 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 Pharmacist Services include:

- (a) Supplying Pharmaceuticals in accordance with clauses 2 to 5 of Schedule 1;
- (b) providing information, advice, and counselling services in accordance with Schedule 2;
- (c) implementing systems for the distribution and administration of Pharmaceuticals to ARRC Service Users' ARRC Providers that support the guidelines issued by the Ministry about medicines care for residential aged care;

- (d) maintaining an accurate medication profile for every ARRC Service User and:
 - (i) making it available, if requested, to the ARRC Service User and members of the ARRC Service User's multi-disciplinary team; and
 - (ii) transferring it to any other provider, ARRC Provider, or secondary care Practitioner that the ARRC Service User transfers to;
- (e) synchronisation, reconciliation, and review services, as appropriate for each ARRC Service User;
- (f) 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;
- (g) 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
- (h) providing a delivery service to ARRC Service Users in ARRC Facilities.

5. Delivery times

- 5.1 Unless the DHB agrees otherwise in writing, in order to minimise unnecessary Supply and waste of Pharmaceuticals, the Provider must not deliver a Pharmaceutical to an ARRC Service User in an ARRC Facility earlier than three 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 the DHB 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 Pharmacist 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 the DHB about, within one month of the date on which the Provider first provides ARRC Pharmacist 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 11 of Schedule 1;
 - (b) palliative care providers;
 - (c) pain management service providers; and
 - (d) the ARRC Providers of the relevant ARRC Facilities.

8. Additional claiming and payment rules for ARRC Pharmacist 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 Supplied 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;
 - (c) for Pharmacist Clozapine Services, in accordance with Schedule 3A.4; and
 - (d) for Special Foods Services, in accordance with Schedule 3B.4.
- 8.2 Subject to clause 8.1, if the Provider makes a claim under this Schedule in relation to the Supply of a Pharmaceutical to, or for, an ARRC Service User, the Provider must not claim, and the DHB will not pay:
- (a) for the Supply of the Pharmaceutical under Schedule 1;
 - (b) for providing Professional Advisory Services in relation to the Supply of the Pharmaceutical under Schedule 2; or
 - (c) for the provision of any other Population Service under a Service Schedule in Schedule 3.
- 8.3 If the Provider Supplies an Unregistered Medicine in accordance with this Schedule, the DHB will pay the Provider an additional payment for Supplying the Unregistered Medicine in accordance with clause 19 of Schedule 1, and clause 20 of Schedule 2.
- 8.4 The Provider must provide the date of birth of each ARRC Service User for which the Provider submits a claim.

9. ARRC Pharmacist Services Fee

- 9.1 The DHB will pay the Provider an ARRC Pharmacist Services Fee for each Pharmaceutical that the Provider Supplies in accordance with this Schedule.

9.2 The ARRC Pharmacist Services Fee is calculated as follows:

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

where:

- R = the ARRC Pharmacist Services Fee that the DHB will pay the Provider (if R is a positive number)
- Sc = the GST exclusive subsidy specified for the Pharmaceutical in the Pharmaceutical Schedule as at the date of Supply
- 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 listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Pharmaceutical, which is \$1.01
- 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 at the date of Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

9.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

10. Definitions that apply to this Schedule

10.1 In this 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 Pharmacist Services to ARRC Service Users

ARRC Provider means a provider who has an agreement with the DHB to provide ARRC Pharmacist Services

ARRC Service User means a Service User who has been needs assessed as requiring long-term residential care in a hospital or rest home indefinitely under the Social Security Act 1964, and is receiving ARRC Pharmacist Services from an ARRC Provider in an ARRC Facility.

SCHEDULE 3B.4
SPECIAL FOODS SERVICES

1. Background and service objectives

- 1.1 The DHB wishes to fund Special Foods Services to enable Service Users 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, subject to the conditions set out in clause 9 of Schedule 1.

4. Service components

- 4.1 The Provider must Supply Special Foods in accordance with the relevant clauses in Schedules 1 and 2 and, in particular, with clauses 2 to 5 of Schedule 1, and clauses 2 to 5 of Schedule 2, if applicable.

5. Service linkages

- 5.1 The Provider must have effective links with:
- (a) the service providers and organisations specified in clause 11 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.

6. Additional claiming and payment rules for Special Foods Services

- 6.1 The Provider must charge a Service User only one Co-payment if the Service User receives more than one flavour of the same type of Special Food listed in the Oral Supplements/Complete Diet section of the Pharmaceutical Schedule.
- 6.2 If the Provider provides NPPA Services A, NPPA Services B, or Extemporaneously Compounded Preparations Services to a Service User in accordance with this Schedule, the Provider must claim for each Pharmaceuticals Supplied to the Service User in accordance with the relevant provisions in Schedule 1.
- 6.3 If the Provider Supplies an Unregistered Medicine in accordance with this Schedule, the DHB will pay the Provider an additional payment for Supplying the Unregistered Medicine in accordance with clause 19 of Schedule 1, and clause 20 of Schedule 2.

7. Special Foods Services Fee

- 7.1 The DHB will pay the Provider a Special Foods Services Fee for each Special Food that the Provider Supplies to a Service User in accordance with this Schedule.

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 the DHB 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 Supply
- M = a margin towards the procurement and stockholding costs for the Special Food, which is:
- (a) 0.03 if the Pharmaceutical Schedule Pack Subsidy for the Special Food is less than \$150.00; and
 - (b) 0.04 if the Pharmaceutical Schedule Pack Subsidy for the Special Food is \$150.00 or more
- PF = the Per Pack Fee listed in the Pharmaceutical Schedule (which is pro-rated if less than the full pack of the relevant Pharmaceutical, as listed in the Pharmaceutical Schedule, is Supplied)
- HF = the Handling Fee for the Special Food, which is \$1.01
- 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 Supply)
- CoP = the Co-payment payable by 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) the DHB will be entitled to recover that amount from the Provider (including by way of set-off).

7.4 The DHB will not recover (nor be entitled to recover) the amount "R" if the Supply of the Pharmaceutical is a Negative A3 or J3 Transaction.

8. Definitions that apply to this Schedule

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

Special Foods means the special foods listed in Section D of the Pharmaceutical Schedule.

SCHEDULE 3B.5
COMMUNITY PHARMACIST ANTI-COAGULATION MANAGEMENT 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 Pharmacist 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 in the community;
 - (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 those the practice has 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 CPAM Service Users are Eligible Persons who:
- (a) have a Medical Practitioner
 - (b) are referred by a Medical Practitioner who delegates point-of-care warfarin testing, dose adjustment and associated patient counselling to the Provider, and:
 - (i) are taking warfarin medication;
 - (ii) require warfarin loading, and initial stabilisation; or
 - (iii) have overlapping warfarin medication with low molecular weight heparin (LMWH);
 - (c) are mobile and able to access CPAM Services;
 - (d) consent to registration in the CPAM Service; and

- (e) does not:
 - (i) reside in an Aged Residential Care Facility (unless otherwise agreed by the DHB that CPAM Services may be provided in this setting); or
 - (ii) have anti-phospholipid syndrome, anti-cardiolipid syndrome, lupus anti-coagulant syndrome, and/or receiving active anti-neoplastic treatment.

3. Exit criteria

3.1 The Provider must disenrol a Service User if:

- (a) the Service User chooses to exit the CPAM Service, leaves the district, 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 the DHB, 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 7 of Schedule 2 and the availability of an accredited Pharmacist.

5. Service components

5.1 The Provider must provide CPAM Services in accordance with Schedule 2 and, in particular, clauses 2 to 5 of Schedule 2, if applicable.

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 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 test and providing advice on the dose of warfarin to take each day until the next test as a hard copy dosing calendar;

- (g) giving the Service User counselling and education about warfarin medication, 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 is less than 1.5 and 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 individual patients 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 review 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) the Provider must 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 the Provider may compare test results on selected Service Users;
- (c) there must be access to a private area within the Premises for testing and counselling; and
- (d) a Quarterly CPAM Service evaluation will be undertaken to determine quality outcomes and measures as measured against goals determined by the Ministry 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 Practising Certificate without restrictions; and
- (b) at least two pharmacists per Premises must have attended an accredited CPAM Services training course and be accredited to provide CPAM Services, such accreditation to be re-certified biennially.

8.2 If there is a reason that the requirements in clause 8.1 cannot be met, (eg, the pharmacist is a sole operator) the DHB must be satisfied the Provider can guarantee safety and quality of the service in the event of unexpected absence or leave.

9. Safety

- 9.1 The Medical Practitioner retains overall responsibility for the Service User's management, 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.

10. Reporting requirements

- 10.1 The Provider must record each Service User's NHI Number and, if requested by the DHB, will provide NHI number information to the DHB for more detailed analysis.
- 10.2 The Provider will be advised of any additional reporting requirements.
- 10.3 The Provider must report quarterly to the DHB as follows, using an agreed reporting template:

Reporting Period	Report Due
1 July – 30 September	20 October
1 October – 31 December	20 January
1 January – 31 March	20 April

1 April – 30 June	20 July
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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@moh.govt.nz

Performance Reporting Team
Sector Services
Ministry of Health
Private Bag 1942
Dunedin 9054

11. CPAM Services Fee

11.1 The DHB will pay the Provider a Product Supply Services Fee for each Pharmaceutical that the Provider Supplies to a Service User and claims in accordance with this Agreement, in accordance with Schedule 1.

11.2 The DHB 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) \$45.00 per month for each CPAM Service User to whom the Provider provided CPAM Services in the month.

11.3 The DHB 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) DHB 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.

DRAFT FOR DHB CONSULTATION

SCHEDULE 3B.6
SMOKING CESSATION SERVICES

1. Background and service objectives

- 1.1 The DHB 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 Service Users are Eligible Persons who:
- (a) present with a Prescription for a smoking cessation medicine;
 - (b) present to purchase a smoking cessation product from the Provider;
 - (c) ask the Provider to register them in the programme; or
 - (d) present and to whom the Provider provides subsidised NRT 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 a Service User in excess of the Cap described in clause 3(1).

3. Cap on number of Service Users

- 3.1 The DHB will notify the Provider in writing 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 the DHB receives an application from the Provider requesting an increase in the Cap, the DHB 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 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 The DHB 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, and 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 the Ministry.

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).

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>.
- 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 the Ministry concerning helping people to stop smoking.

10. Quarterly reporting requirements

- 10.1 The Provider must, for each Service User:
- (a) prepare and submit a quarterly report containing the information set out in Table 1; and
 - (b) submit this report to the DHB 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 the 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 cover all Service Users who set a TQD in the second Quarter, including quit outcomes for each Service User (refer to Table 1, Part C below).

Table 1

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 • No 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>
Medication use (Yes/No):	<ul style="list-style-type: none"> • NRT (nicotine patches, gum, and lozenges) • Bupropion • Nortriptyline • Varenicline <p>Specify whether the Service User used any of these medicines during the first three months of receiving the Smoking Cessation Services.</p>
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")/ 	<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
"abstainer")	
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 [b] Yes, just a few puffs [c] Yes, between 1 and 5 cigarettes [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 not 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 [b] Yes, just a few puffs [c] Yes, between 1 and 5 cigarettes [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 reporting requirements

- 11.1 The Provider must submit a year-end report containing the information set out in Table 2 by 31 July each year.

Table 2

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.

12. Smoking Cessation Services Fee

- 12.1 The Provider may claim for providing Smoking Cessation Services to 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 On receipt of a valid invoice that complies with the requirements set out in clause 12.1, the DHB 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.
- 12.3 The DHB will pay a Smoking Cessation Services Fee on the 20th day of the month following the month in which the DHB received the invoice.
- 12.4 The DHB 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.
- 12.5 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.8, 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 PHARMACIST SERVICES]

1. [Insert]

1.1 [Insert]

DRAFT FOR DHB CONSULTATION

**CLOZAPINE SERVICES PROTOCOL
(MONITORED THERAPY MEDICINE SERVICES)**

Dispensing Clozapine

1. On receipt of a Prescription Form for clozapine, check patient details, and if the Service User is a new patient, obtain the following information:
 - (a) name of Service User and/or caregiver;
 - (b) address;
 - (c) contact telephone numbers;
 - (d) NHI Number (required to access the blood monitoring database);
 - (e) date of birth (DOB);
 - (f) Community Services Card (CSC) status;
 - (g) High Use Health Card (HUHC) status;
 - (h) Prescriber's name and contact telephone number;
 - (i) name of liaison person agreed with Prescriber together with contact telephone numbers (if appropriate);
 - (j) community mental health team that the Service User is under together with contact telephone numbers (if appropriate);
 - (k) current dosage of clozapine;
 - (l) other prescribed and over the counter medications;
 - (m) date and result of the most recent blood test;
 - (n) due date for next blood test;
 - (o) name of laboratory where blood test results can be obtained from together with contact telephone numbers;
 - (p) base line blood test (i.e. test prior to and within seven days of commencing clozapine treatment). Available from the supplier(s) of clozapine or an agent thereof; and
 - (q) stage in treatment, (i.e. how many weeks has the patient been receiving clozapine). Available from the supplier(s) of clozapine or an agent thereof.
2. Record this information on a file for each Service User (see section 3 below).
3. Check the patient is registered with the supplier(s) of clozapine by contacting the supplier(s) of clozapine, or an agent thereof, either:
 - (a) by accessing their database; or
 - (b) by contacting them directly.

4. This is to safeguard against Supplying clozapine to Service Users who have been excluded from treatment with clozapine because of a previous incidence of agranulocytosis, hypersensitivity reactions or other medical and clinical conditions.
5. Prescribers are responsible for registering the Service User with the relevant supplier(s) or agent thereof but the Provider must check this has in fact been done. If the Service User does not appear to be registered with the relevant supplier(s) or agent thereof, inform the Prescriber or, if appropriate, the liaison person agreed with the Prescriber. The Provider is required to enter the date of any Supply on the website for a complete record to be available to all providers.
6. Do not supply clozapine to unregistered Service Users.
7. Check that the Prescription Form is written by an authorised Prescriber:
 - (a) The Ministry of Health has directed that clozapine may only be prescribed by:
 - (i) Prescribers who are vocationally registered under the HPCA Act and certified as competent in the branches of psychological medicine or psychiatry by the Medical Council of New Zealand; and
 - (ii) registrars in psychological medicine or psychiatry who are under the supervision of persons of the kind referred to in sub-clause (i) above.
 - (b) The Provider is required to check that the Prescriber is either a specialist or registrar in psychological medicine or psychiatry. The Provider will be provided with a list of the appropriate registrars in its area.
8. Check blood test results:
 - (a) No clozapine prescriptions are to be Supplied unless a satisfactory blood test result is available. (See process for blood test monitoring which is outlined in section 2 below).
9. Quantity of clozapine that may be Supplied:
 - (a) Clozapine will generally be Supplied in lots of 7, 14 or 28 days as dictated by the frequency of blood monitoring or the date of the next blood test.
 - (b) The quantity of clozapine Supplied must not exceed that which is required to take the patient from the date of Supply to the date of the next blood test.
 - (c) If the date of the blood test coincides with the date of Supply, the following applies:
 - (i) for Service Users in the first 18 weeks of treatment, the Provider must only Supply a sufficient quantity of clozapine for seven days; and
 - (ii) for Service Users having blood tests at four-weekly intervals, the Provider must only Supply a sufficient quantity of clozapine for 28 days.
 - (d) If the date of the blood test precedes the date of Supply, then the quantity of clozapine Supplied should only be sufficient to take the Service User up to the date of their next blood test.
 - (e) For Service Users in the first 18 weeks of treatment with clozapine, and if the date of most recent blood test precedes the date of Supply by two days (48 hours), the Provider must only Supply a sufficient quantity of clozapine for five days.

- (f) For Service Users having blood tests at four-weekly intervals and if the date of the most recent blood test precedes the date of Supply by two days (48 hours), the Provider must only Supply a sufficient quantity of clozapine for 26 days.
10. Interval between blood test and Supply:
- (a) Supply should generally take place within 24–72 hours of the date of the most recent blood test for the relevant Service User. This requirement may vary according to the hospital or health service protocol that applies in the Provider's locality. The Provider may need to customise its procedures accordingly.
11. Maximum supply is limited to 28 days:
- (a) In relation to the Supply of clozapine, one month's supply = 28 days. This is to regularise the period of Supply with the blood testing regime and to avoid the involvement of weekends.
12. Record information regarding Supply on patient files:
- (a) Information must include the following:
- (i) Supply date;
 - (ii) total daily dosage;
 - (iii) number of days supplied;
 - (iv) date when next supply is due.
13. Label the container:
- (a) Apply Cautionary and Advisory labels 1 and 9:
- (i) label 1 states that "This medicine may make you sleepy and make it dangerous to drive or operate machinery. Limit alcohol intake.";
 - (ii) label 9 states "Do not stop taking this medicine without consulting your doctor.".
14. Patient advice and counselling:
- (a) Discuss with the individual Service User for whom the prescription is issued or with the carer of such Service User essential advice and counselling on the directions for safe and effective use of clozapine. Advice and counselling must be given in accordance with the requirements of Schedule 2. In this particular case, in addition, the Provider should discuss the:
- (i) importance of compliance;
 - (ii) requirement to consult their Prescriber immediately at the first signs of a cold, influenza, sore throat or other infection;
 - (iii) importance of having their next blood test on the day it falls due;
 - (iv) importance of safe storage for clozapine.
- (b) The Provider must also inform the Service User or their caregiver where a reduced quantity of clozapine has been supplied to coincide with the date of the next blood test.

15. Record and monitor the next Dispensing date:
 - (a) Record the Service User's name and the date of the next Supply in the clozapine diary. Check the clozapine diary daily and follow up on any Service Users who have not had clozapine Supplied by contacting the Prescriber or, if appropriate, the liaison person agreed with the Prescriber.
16. Arrangements for collection or delivery:
 - (a) Put aside for collection, or arrange for delivery where this is required.

Blood Test Monitoring

17. Check that a satisfactory blood test is available for the relevant Service User before Dispensing clozapine.
18. Obtaining blood test results:
 - (a) Blood results may accompany the Prescription Form. A copy of an official laboratory reporting form may be attached to the Prescription Form.
 - (b) Blood results may be written on the actual Prescription Form in the Prescriber's own handwriting. Check that the results are the latest blood test results for that Service User and that the date of the test is annotated on the Prescription Form.
 - (c) Blood results may be obtained direct from the laboratory. In this case a copy of the results must be faxed to the Provider for verification.
 - (d) Blood results may be obtained directly from an appropriate electronic clinical data repository (such as Test Safe or the blood monitoring database monitored by the supplier(s) of clozapine (or an agent thereof)) where the Provider has access to such an electronic data repository.
19. Definition of a recent blood test:
 - (a) As a general guide the most recent blood test results should not be older than 24 – 72 hours at the time of Supplying clozapine. This time frame may vary according to hospital and health service protocol applying in the Provider's locality. The Provider may need to customise its procedures.
20. If no applicable blood results are available then a blood test should be requested through the Prescriber. Clozapine should not be Supplied until a satisfactory blood result is obtained. Supply only as advised by the Prescriber.
21. Record blood test results.
 - (a) Information on blood tests should be entered on a separate record sheet for each Service User. The following information should be recorded:
 - (i) date of blood test;
 - (ii) white blood cell count (WBC);
 - (iii) neutrophil count; and
 - (iv) date when the next blood test is due.

22. If laboratory results are normal, supply a sufficient quantity of clozapine as required to take the Service User up to the date of their next blood test. The Provider will need to refer to the instructions on the Prescription Form and also to the Supply requirements for clozapine.
23. Determining the date of the next blood test:
- (a) For Service Users in the first 18 weeks of treatment with clozapine, the date of the next blood test will be seven days from the last test.
 - (b) For Service Users having tests at four-weekly intervals then the date of the next blood test will be 28 days (four weeks) from the last test.
 - (c) As a general guide the monitoring frequency is reduced to four-weekly intervals after the first 18 weeks if no abnormalities are detected. This may vary so please refer to the hospital and health service protocol applying in the Provider's area.
 - (d) Monitoring of blood at four-weekly intervals should remain in place as long a clozapine treatment continues. More frequent monitoring is required whenever blood tests indicate borderline results.
24. If the laboratory results are abnormal:

If the WBC falls below $3.5 \times 10^9/L$ ($<3500\text{mm}^3$) for a Service User in the first 18 weeks of therapy, or below $3.0 \times 10^9/L$ ($<3000\text{mm}^3$) for a Service User beyond the first 18 weeks and/or neutrophil count falls below $2.0 \times 10^9/L$ ($<2000\text{mm}^3$) for a Service User in the first 18 weeks of therapy, or below $1.5 \times 10^9/L$ ($<1500\text{mm}^3$) for a Service User beyond the first 18 weeks or either have dropped by a substantial amount from the baseline. A substantial drop is defined as a single drop of $3.0 \times 10^9/L$ or more in the WBC.
and/or there are any signs or symptoms of infection occurring
THEN DO NOT SUPPLY CLOZAPINE.
THE PROVIDER MUST CONSULT THE PRESCRIBER.

- (a) Service Users may need to have a differential white blood cell test.
- (b) Supply only as instructed by the Prescriber.
- (c) Notify the relevant supplier(s) or agent thereof in cases where treatment with clozapine is withheld.
- (d) Service Users in whom clozapine has been discontinued for haematological reasons must not be re-exposed to the medicine.

Service User Information Records

25. Every Service User receiving clozapine should have a separate file. These should be kept in alphabetical order and in a secure location within the Provider's dispensary.
26. The information that should be kept on each Service User's file must include the following:
- (a) Service User details (as referred to in section 1.2 above);
 - (b) copies of blood test results from laboratories, kept in order according to date;
 - (c) recording sheets for blood test results and Dispensing details; and
 - (d) delivery details.

27. All actions undertaken in association with the collection, retention and disclosure of health information about a patient receiving clozapine must comply with statutory requirements.
28. The supplier Clozapine website needs to be updated with the date of Supply each time this occurs.

Special Circumstances

29. Missed Doses:
 - (a) If the Provider becomes aware that clozapine therapy has been interrupted and that a Service User has missed more than two days of treatment, then the Provider must notify the Prescriber.
 - (b) Treatment should be re-initiated using the original dose titration schedule. It is important that the first few doses are low. However it may be possible to titrate upwards more quickly than was the case when clozapine was initially begun.
30. Extended supply:
 - (a) In exceptional circumstances, e.g. public holidays, the period of supply may be extended by one or two days. This will only be carried out after consultation with the Prescriber.
 - (b) The maximum quantity of clozapine that can be Supplied at one time must not exceed 28 days' supply.
31. Replacement doses:
 - (a) If a Service User loses their supply of clozapine, the Provider must contact the Prescriber. The Prescriber may decide to issue another Prescription Form. Document the situation on the Service User's file. Annotate on the Prescription Form that the medication was lost. The amount Supplied must only be enough to carry the Service User through until the date of their next blood test. Keep in mind the potential risks if this medicine is being hoarded.
 - (b) If the Prescriber cannot be contacted, some of the following actions may be useful:
 - (i) try to obtain an alternative contact for the Prescriber (e.g. cell phone number);
 - (ii) contact the medical practitioner who is standing in for the Prescriber;
 - (iii) contact the liaison person agreed with the Prescriber; and
 - (iv) contact the Mental Health Service which the Service User is under. Ask to speak to either the psychiatric registrar or house surgeon on call or the key worker/case manager where appropriate.
32. Patients admitted to hospital:
 - (a) If the Provider becomes aware that the Service User is admitted to hospital at any stage during treatment, this should be noted on the Service User's file, and it may be useful for the Provider to contact the hospital pharmacy to confirm the Service User's clozapine treatment record.
 - (b) After the Service User has been discharged it may be useful to question the Service User or their caregiver whether they have any clozapine which is surplus to their requirements and encourage them to return it to the Provider for destruction.