

Protocol for Methadone Maintenance Treatment in New Zealand

Draft for Comment

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MANATŪ HAUORA

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Background

This draft protocol been developed to replace the existing document entitled *National Protocol for Methadone Treatment in New Zealand* and shaped in consultation with a wide reference group. We would like to thank all those people who have contributed. A list is included as Appendix 6.

During the development of this draft protocol, the reference group raised some issues which are not strictly the domain of a protocol but which need to be addressed in other arenas. These are listed below so that readers are aware that these concerns are already being addressed and so can direct their comments more specifically on the content of this document.

Funding

Some changes from the existing protocol which are proposed in this document have funding implications. These are being addressed with appropriate people in the shared support agencies of the DHBs. The tenor of the final document will reflect funding intentions.

Māori

While comment on this document was sought from Māori, there may be aspects of the document which need to reflect Māori realities more effectively. Ministry of Health staff will be consulting with Māori consumers/tangata whai ora and providers to address these issues.

Protocol vs guidelines

There was considerable debate about whether the existing title of 'Protocol' was too strong and implied a legal status that the document did not have. Following legal advice that there is no legal difference between a 'protocol' and a 'guideline', the decision has been made to leave the word 'protocol' in the title of the document. The word 'maintenance' has been added to the title to minimise any confusion with the use of methadone for any other purpose such as pain relief.

National consistency vs regional responsiveness

In general, providers would like to be able to adapt aspects of the protocol to allow more local flexibility in service provision, while consumers/tangata whai ora see themselves as being disadvantaged by what are perceived to be major differences in approach to methadone maintenance throughout the country. This is particularly evident when people are transferring from one programme to another. This protocol is the basis for national consistency. This protocol is expected to prevail over any local protocols made under it. Such local protocols may enhance the terms of this protocol but shall not detract from them.

Audit

An audit tool for methadone services is currently available. The Ministry of Health acknowledges that a review of the audit tool and the audit process will need to happen as a result of this review of the methadone protocol.

Alternative pharmacotherapies

A range of alternative pharmacotherapies was considered in the development of this document. However, all those currently being considered are either not available in New Zealand or still being tested for safety and efficacy. As a result, this document deals exclusively with methadone maintenance treatment.

Specifically this document does *not* endorse the use of long acting morphine to treat dependence.

Specific references

We have not included any reference to specific training courses or methadone formulations as these tend to change over time and make the protocol out of date.

The Treaty of Waitangi

Any discussion of partnership between Māori and a Crown entity has to start with the Treaty of Waitangi. The relationship between Māori and the Crown is based on the underlying premise of the Treaty, that Māori continue to live in Aotearoa as Māori.

The relationship between Māori and the Crown in the health and disability sector has formed around three key principles:

Partnership: a relationship between Māori and the Crown of good faith, mutual respect and understanding, and shared decision-making. Partnership is balanced by the principles of kawanatanga.

Participation: the Crown and Māori will work together to ensure Māori (including whānau, hapu, iwi, and communities) participate at all levels of the health and disability sector. This includes the development of Māori provider and Kaupapa Māori mental health services, including alcohol and other drug services.

Protection: the Crown actively contributes to improving the health status of Māori and ensures equal access to mental health services and alcohol and other drug services.

Objectives for Opioid Treatment

The objectives of methadone maintenance treatment (MMT) provision in New Zealand, in line with the National Drug Policy, are to improve the health of New Zealanders by minimising the harm associated with the use of opioid drugs, and in particular to:

- assist individuals to achieve a successful withdrawal from opioids (including methadone treatment where appropriate)
- reduce the spread of infectious diseases associated with injecting drug use, especially hepatitis B and C and HIV/AIDS
- reduce crime associated with illegal opioid use
- reduce the mortality and morbidity resulting from the misuse of opioid drugs
- reduce episodes of drug misuse and future chances of relapse into drug misuse
- improve the health of service users
- improve overall personal and social functioning of service users within the context of their family/whānau
- minimise the negative impact of drug use on the children of people who are opiate dependent.

All MMT providers need to balance these objectives with staff and service user safety factors.

1 Specialist Methadone Treatment Services

- 1.0 Specialist methadone treatment services (specialist services) are those that have been specified by the Minister under section 24(5) of the Misuse of Drugs Act 1975 and notified in the *New Zealand Gazette* (published by the Department of Internal Affairs). They are the entry point for all people requiring MMT, unless there are exceptional circumstances.
- 1.1 Specialist services provide services for those who:
- need dose stabilisation on MMT
 - have the highest level of opioid dependence
 - are the most unstable in terms of opioid use
 - need high levels of specialist intervention to make the changes needed.
- 1.2 Once a person on a specialist service MMT programme has a stabilised methadone dose, consideration should be given to moving that person from specialist methadone services to the care of a gazetted medical practitioner working in the community (usually a general practitioner) who can manage them within a normalised community environment.
- 1.3 The role of specialist services is:
- assessment within a holistic (biopsychosocial) model
 - stabilisation on an appropriate dose
 - transfer of people on a stabilised dose to the care of GPs
 - provision of psychological treatment services for people who receive MMT from specialist services and GPs
 - treatment and management of people whose lifestyles or conditions make them unsuitable for transfer to GP care.

Entry into specialist services

Eligibility requirements

- 1.4 People receiving MMT should be at least 16 years old and preferably over 18 years old.
- 1.5 The diagnostic criteria for opioid dependence, such as those outlined in the *DSM IV* and *ICD-10*, must be met.

Criteria for priority admission into specialist services

1.6 People who require immediate access to opioid treatment services include:

- pregnant opioid-dependent women
- people with serious medical conditions such as HIV/AIDS that can be stabilised or improved by opioid treatment
- people who are caring for young children, especially if those children are under five years of age or they have sole responsibility for the children
- partners of service users
- clients transferring within New Zealand.

1.7 Further criteria for priority admission need to be developed for each service to reflect the particular needs of each area.

Assessment

1.8 The goals of assessment are to examine the person's needs and determine their suitability for treatment. The assessment will include:

- a drug-use history, including alcohol, benzodiazepines, tobacco, legally prescribed drugs and other drugs as well as opiates
- assessment of risk-taking behaviours associated with drug use
- observation of clinical symptoms related to drug use, including intoxication or withdrawal
- looking for physical evidence of drug use such as needle marks and associated bruising
- the person's medical history and current status
- a psychiatric and psychological history
- other relevant information, including legal/forensic history, family/whānau history and personal/developmental history
- urine drug screening
- blood testing, in particular for HIV, hepatitis B and C and liver functions
- any restriction notices under section 25 of the Misuse of Drugs Act 1975 or section 49 of the Medicines Act 1981.

1.9 A person is accepted for opioid treatment based on a team decision which, at a minimum, consists of the medical officer and one other staff member.

1.10 The true identity of the person must be confirmed with, for example, their passport, driver's licence or birth certificate. Care should be taken to ensure that they are not receiving any other opioid treatment or drug treatment that could potentiate the opiate dose.

- 1.11 Each person is informed of treatment options and the side effects and considers them at the time of assessment.
- 1.12 The person consents to the conditions of treatment.
- 1.13 Processes for moving out to the care of an authorised or gazetted general practitioner are clarified for people on MMT.

Eligibility restrictions

- 1.14 Access to treatment may not be possible for those cannot accept and work within the specialist service's safety requirements (see section 8).

Stabilisation and treatment

- 1.15 Once the person is assessed as being appropriate for the MMT programme, they will be started on a stabilisation process if there is a place on the MMT programme. If there is to be a delay before the person can receive MMT, specialist services should provide consumers/tangata whai ora with advice, support and information on alternatives to MMT.

Stabilisation

- 1.16 Stabilisation is a process which allows the person to make best use of MMT. The decision about what level of stabilisation is most appropriate for an individual needs to be made jointly by the clinician and the consumer/tangata whai ora. At a minimum, stabilisation would mean that the person can cope on a consistent regular dose of methadone without the need for constant dose changes and reviews. For some people this will take a considerable time to achieve, and they will need considerable input from a variety of staff in the specialist service.
- 1.17 A case manager will be assigned to be responsible for co-ordinating each person's care and may provide some or all the interventions planned. When the person is transferred to a GP working under authority from the specialist service, the GP becomes the case manager but may work closely with a clinic counsellor.
- 1.18 When a person enters a specialist services MMT programme, they should:
 - have an initial treatment plan
 - be stabilised on a comfortable dose of methadone
 - have their acute medical problems addressed
 - have other needs identified and referrals made to the appropriate services, such as mental health or specialist medical services
 - begin to set treatment goals in collaboration with their case manager and/or doctor

- have the physical and social needs of their children considered
- have partners and family/whānau involved where appropriate
- be made aware of their rights as well as their obligations/responsibilities to the service
- have information given to them about the effects of methadone and any other medication prescribed by the service
- be informed of the interactive effects of methadone with alcohol and other drugs.

The treatment plan

- 1.19 There will be a written treatment plan developed in collaboration with the consumer/tangata whai ora. The plan will state the person's goals and a suggested time-frame for achieving the goals. It will also need to give consideration to alternatives to MMT such as detoxification and residential treatment, as well as the person's suitability to their programme's requirements.
- 1.20 The plan will also contain information about the agreed takeaway regime for the individual and the conditions under which this will be altered.
- 1.21 Copies of the plan should be given to the person and be regularly updated.
- 1.22 When a person first enters treatment, their caseworker should see them once every week for the first three weeks, or more frequently, to continue the initial assessment and offer a counselling relationship.
- 1.23 There may be situations where the consumer/tangata whai ora wishes to go on an MMT programme but does not want to undergo counselling. In such situations, once dose stability has been established, the caseworker and consumer/tangata whai ora need to agree the conditions under which the person will be medically safe enough to be moved from the care of the specialist service to either a gazetted medical practitioner or one working under authority.

First methadone dose

- 1.24 Initial doses of methadone should be based on the individual's history of quantity, frequency and route of administration of opiates and should also take into account the person's hepatic and renal functioning. There may be some withdrawal symptoms that are not covered by the first dose. Steady state methadone blood levels are not generally achieved until after five days' dosing.
- 1.25 The first dose should never be higher than 40 mg. Initial doses will generally be in the range of 15–35 mg per day and are to be increased by no more than 5–10 mg per day until the maintenance dose is achieved. This increment may be too high for some people. Care needs to be taken to ensure the person's safety.

- 1.26 Following the first methadone dose, the caseworker or doctor should observe the person's response to methadone, both immediately and after three to four hours.
- 1.27 Specialist services should advise people not to drive or operate heavy machinery when having their dose increased. Once a stable level has been achieved, methadone is unlikely to cause impairment. The Land Transport Safety Authority will have up to date information on the legality of driving or operating heavy machinery under these circumstances.

Subsequent methadone doses

- 1.28 Maximum methadone doses will generally be in the range of 60–120 mg daily. Sometimes higher doses or, rarely, more frequent doses may be required to achieve stability, with serum methadone level monitoring as recommended. In some cases lower doses may be adequate.
- 1.29 Serum methadone levels (trough) should be obtained to avoid unnecessary dose increases and when:
- doses are higher than 120 mg daily
 - the person experiences withdrawal symptoms 15 to 24 hours after the last dose
 - considering whether to prescribe more than 50 mg per day for a pregnant woman
 - more than one daily dose is being considered
 - serious liver disease is present and there may be methadone accumulation in the liver.
- 1.30 The dose of methadone should be sufficient to provide for clinical stability, minimisation of withdrawal symptoms and retention in treatment.
- 1.31 Methadone should never be given to a person intoxicated with drugs or alcohol. Specialist services and pharmacies involved in the dispensing of methadone should develop local protocols for dealing with people suspected of being intoxicated.
- 1.32 Methadone doses that are to be consumed on the premises must be swallowed in front of a specialist services staff member or pharmacist to ensure that there is no diversion.
- 1.33 Care should be taken to minimise the possibility of takeaway doses of methadone being used for illegal purposes or against medical advice.
- 1.34 Sedative/hypnotic drugs will only be prescribed in addition to methadone at safe therapeutic levels. Careful monitoring must take place to ensure there is no further drug supplementation, and frequent dispensing is necessary. The prescribing of these drugs will generally be an exception and will require a case management team decision.

- 1.35 Specialist services will develop local protocols around the prescription and use of other drugs while the person is on MMT.
- 1.36 For drug interactions associated with methadone, see Appendix 2. For the role of the pharmacist in dispensing takeaway doses, see section 5.

Comprehensive management

- 1.37 The prescription of methadone as part of a maintenance process should not be seen as an isolated intervention but as part of a comprehensive care programme. It is important to identify and address other problems such as medical, social, mental health or legal problems. This can be done either by the staff within the specialist services or through liaison with other services.
- 1.38 As part of a comprehensive programme of care, clients will:
- be fully informed about their service provider and treatment, including options, other drug interactions and side effects
 - give informed consent to their treatment
 - participate in decision-making about treatment, case management and all other relevant aspects of service provision.

Reviews by the prescribing doctor

- 1.39 People receiving methadone should be seen by the prescribing doctor at least once during the first seven days of treatment.
- 1.40 They should be seen as required by the prescribing doctor until a stable and clinically effective methadone dose is achieved.
- 1.41 Once a stable and clinically effective methadone dose is achieved, clients should continue to be seen by the prescribing doctor at least once every three months.

Reviews by the caseworker

- 1.42 People receiving methadone should be seen at least once a week for the first month or until a stable methadone dose is achieved.
- 1.43 Then they should be seen at least once a month for the second and third months. More frequent appointments can be made at the request of the individual or the medical practitioner, or as their treatment plan suggests.
- 1.44 After the first four months of treatment, people on MMT should be seen at least once every three months. The caseworker may offer each person a monthly or more regular appointment, depending on their needs.

1.45 Monthly monitoring sessions may include:

- discussion about issues relating to intoxication and polysubstance use and abuse
- consideration of the need for dose adjustment and takeaways
- referral for medical issues and dose adjustment where needed
- addressing behaviour changes – lapses, relapses
- management of co-existing disorders
- information about self-help groups and other support services available
- urine screens
- formal counselling as required.

Reviews by the case management team

1.46 The case management team consists of at least the caseworker and the prescribing doctor. Consultation with the pharmacist and authorised GP (if one is involved) should also occur. The consumers/tangata whai ora and their significant others may also be involved.

1.47 The case management team reviews treatment progress, measuring treatment outcomes against individual treatment goals and reviewing safety.

1.48 Each client should be reviewed by the case management team at least every six months in treatment.

1.49 Six-monthly reviews will include a summary of the areas covered in the monthly reviews and result in:

- an update of the treatment plan, with a copy provided to the consumer/tangata whai ora
- consideration of movement out to either an authorised (if this is not already the case) or gazetted GP.

1.50 A comprehensive medical review may be required where the person is seriously ill.

1.51 Information on general health and welfare issues, including family/whānau and parenting skills, may be given as appropriate during reviews. People receiving MMT should also be made aware of other health and social services available to them in the community.

Transfer of consumers/tangata whai ora to the primary health sector

- 1.52 MMT treatment for opioid dependence is recognised as appropriate in the primary care/general practice setting, providing certain conditions are met. The legislative requirements are outlined in Appendix 1.
- 1.53 The benefits of transferring the patient to the primary health sector include:
- allowing specialist services to focus on those consumers/tangata whai ora with the highest level of opioid dependence and the most need for intensive specialist intervention
 - improving access to specialist services by moving people on more quickly with a consequent reduction in waiting lists
 - improved social integration by normalisation of treatment for the service user, ie, not having to attend a ‘drug clinic’
 - a more holistic management of the person by the GP
 - GPs gaining an understanding of the patient’s drug-related issues and developing expertise in the treatment of opioid dependence.
- 1.54 Before any transfer takes place, patients must be given a comprehensive assessment by a specialist service. This assessment will provide a diagnosis, identify other issues and determine their suitability and priority for treatment.
- 1.55 For those identified as opioid dependent, the service should consider transferring them once they have achieved a stabilised dose of methadone on a MMT programme.
- 1.56 Transfers from a specialist service to primary care may be to a gazetted GP or an authorised GP.
- 1.57 Local protocols should be developed with gazetted GPs and GPs working under authority for returning people who have become destabilised to the care of specialist services.

Transfer to authorised GP

- 1.58 In many cases, initial transfer to primary care will be to a GP working under the authority of the specialist service. In this case, the specialist service remains the responsible provider, while the GP prescribes methadone in accordance with written terms and conditions laid down by the service in relation to specified clients.
- 1.59 A form for authorising GPs from specialist services can be found on the Medsafe website – www.medsafe.govt.nz.

Transfer to gazetted GPs

- 1.60 Once a person is transferred to a gazetted GP (for definition see page 56), the GP will be responsible for implementing systems to ensure safety and progress in treatment. These systems may include random urine drug screens and management of a methadone takeaway regime that ensures the safety of the individual, their family/whānau and the community.
- 1.61 It is expected that GPs who provide services to people on MMT will have formal, agreed relationships with gazetted specialist services. There will be clear agreements in particular as to the management of people who destabilise and need specialist support.
- 1.62 In the interest of fairness, and to avoid problems whereby patients may put pressure on individual GPs to bypass a waiting list for methadone treatment, the GP should never prescribe methadone to patients unless they have been referred by a gazetted specialist service.
- 1.63 In general, gazetted GPs will be working within a broader primary care team which includes the practice nurse and often other professionals. The consumer/tangata whai ora may be supported by non-medical staff in the primary care team as appropriate.

Requirements on the GP when accepting a transfer from a specialist methadone service

- 1.64 The general practitioner may either be gazetted or working under authority.
- 1.65 The general practitioner must confirm the person's true identity.
- 1.66 Care should be taken to ensure that they are not receiving any other substitution pharmacotherapy for opioid dependence.
- 1.67 The general practitioner should have a formal relationship with the local specialist service and a process for moving people back into the care of specialist services should they destabilise and need specialist support.
- 1.68 The general practitioner should have an awareness of, and in some cases provide, the support services needed by consumers/tangata whai ora.
- 1.69 Consumers/tangata whai ora must be informed of the conditions under which they can be returned to the care of specialist services and their ability to access psychosocial services provided by the specialist services.
- 1.70 People who are HIV/AIDS positive may be effectively prescribed methadone by a GP. Furthermore, GPs should offer all their methadone patients HIV and HCV testing as appropriate.

1.71 If the gazetted GP does not comply with the requirements of their gazetting and this protocol, the Minister of Health can and will revoke their gazetting.

2 Methadone Maintenance Treatment

Prescribing process

The prescribing process described below applies to all prescribers whether, gazetted to prescribe or working under authority.

- 2.0 Methadone prescriptions are to be written on the approved H572M forms unless the provider has the written authorisation of the Director-General of Health to use computer generated forms.
- 2.1 Methadone prescriptions are to be posted or couriered to the pharmacy rather than given to the service user.
- 2.2 The prescriber is responsible for notifying the pharmacist of any changes in dose and for arranging the transfer of methadone to other pharmacies (see section 5).
- 2.3 Prescriptions should be started on a day of the week that the person usually consumes methadone and not on a day he or she has a takeaway dose ((for definition see page 56).
- 2.4 Prescribers should ensure that no prescription ends during a takeaway period.
- 2.5 As far as possible, starting prescriptions on a Saturday, Sunday or public holiday should be avoided unless the prescriber is prepared to be contactable in case any questions arise and has an arrangement with the pharmacist to dispense on these days.
- 2.6 The days that takeaway doses are to be dispensed should be clearly specified on the prescription.

Takeaway methadone doses

- 2.7 Takeaway doses of methadone (takeaways) refer to any doses that are not consumed at the specialist service, doctor's surgery or pharmacy premises.
- 2.8 The provision of takeaways should be based on clinical decision-making and consultation with the consumer/tangata whai ora. To protect the individual and the community, takeaways are only allowable under the conditions outlined here and should be dispensed in the least restrictive regime that is clinically appropriate in consultation with the consumer/tangata whai ora. At a minimum, individuals will demonstrate an ability to comply with the safety requirements of the service.

- 2.9 Specialist services and gazetted GPs will specify their safety requirements around takeaways in writing and ensure copies of the information are provided to the consumer/tangata whai ora.

Safety requirements for dispensing

- 2.10 The following requirements apply to all methadone dispensing but need to be particularly considered when giving a person takeaways.

- 2.11 Safety requirements must include processes that ensure:

- potential to overdose is limited
- the person is not intoxicated with other drugs
- the person is advised on safe storage practices so as to enhance the safety of children and others in the household
- potential for methadone diversion is limited
- there is no evidence of serious behavioural problems
- the person is generally stable (for definition of stabilisation page 56).

- 2.12 Compliance with safety requirements can be assessed by some or all of the following:

- consulting with the person's case manager or, in the case of a gazetted GP, with members of the primary care team as appropriate
- assessment of the ability of the consumer/tangata whai ora to take responsibility for their takeaways
- an absence of drug-seeking behaviour patterns
- urine drug screening showing positive for methadone and nil for other opiates
- whether the person attends case management appointment
- whether the person attends doctor's appointments
- consulting with the dispensing pharmacist or pharmacy.

- 2.13 Access to takeaways can be refused by the specialist services or gazetted GP if there is evidence that the person is selling, injecting or otherwise diverting their methadone. If such behaviour persists, the person may be involuntarily withdrawn from the programme.

Dispensing arrangements

- 2.14 Takeaway methadone arrangements are to be reviewed regularly. If the medical practitioner is working under authority, arrangements must be made known to the service or the gazetted medical practitioner. Whenever the prescriber considers that the patient is not meeting the safety requirements as outlined in para 2.11 of this protocol, these takeaway arrangements should be revoked.

Dose replacement policy

- 2.15 Prescribers will not give replacement doses of methadone when doses are lost or stolen except in exceptional circumstances that can be verified. When requests are made for replacement doses, the prescriber needs to review their takeaway arrangements and check their dose is adequate.
- 2.16 The pharmacist may make the decision to replace the vomited dose if the person vomits within approximately 30 minutes of consuming the dose. The range of replacement for vomited doses will be between 50 percent and 100 percent.
- 2.17 The pharmacist will notify the prescriber in all cases where a vomited dose has been replaced. This should be recorded in the clinical notes.
- 2.18 In general, the methadone prescription should clearly state when the person is to take their dose on the premises. Sometimes a special request will be made to have a takeaway dose of methadone. These requests must first be approved by the person's doctor. If granted, the approval may be telephoned through to the dispensing pharmacy.
- 2.19 Written confirmation of this approval must then be provided to the dispensing pharmacy by the prescribing medical practitioner within two business days of communicating that approval. The confirmation is required to:
- ensure that the dispensing pharmacist has documented evidence of the approval given
 - comply with the requirements of regulation 34 of the Misuse of Drugs Regulations 1977.

Other drug prescribing

- 2.20 Medical practitioners working under authority should not prescribe hypnotics, anxiolytics or strong analgesia without consulting the authorising medical practitioner.

Last methadone dose

- 2.21 Medical practitioners working under authority and dispensing pharmacies must notify their gazetted methadone treatment service or practitioner when the patient and/or GP terminates methadone treatment.

3 Treatment Termination

Voluntary treatment termination

- 3.0 The best outcomes occur when the consumer/tangata whai ora and the prescriber agree on the methadone withdrawal regime. Withdrawal should only be considered when the person is reasonably stable and has achieved some of their treatment goals.
- 3.1 Sometimes an involuntary reduction in methadone dose may occur, such as when the person has to serve a prison sentence longer than the period of withdrawal from methadone (see Prison Protocol in Appendix 4) or when the person is discharged from treatment for unacceptable behaviour. Services need to have a management plan for these circumstances.
- 3.2 Planned withdrawal from methadone should involve the offer of a high level of psychosocial and medical support, medical supervision and a flexible end point. The period after treatment termination is particularly important if the person is to remain drug free. They may need more intensive counselling or psychotherapy and information on relapse and relapse prevention.
- 3.3 Ongoing support should be available to people after methadone treatment has been terminated including relapse prevention to help maintain their stability and reduce the likelihood of relapse.
- 3.4 A person who has completed withdrawal from methadone should have access back into methadone treatment if they are not able to maintain stability. This access back into treatment, without having to be placed on a waiting list, should be negotiated between the specialist service and the consumer/tangata whai ora and should be for a realistic finite period following the last dose.

Involuntary treatment termination

- 3.5 Methadone treatment providers may discharge those people who do not fulfil the safety requirements or for whom methadone is not considered an effective treatment. People may be discharged in the following situations:
 - regular overdose or intoxication from psycho-active drugs. It is important to note that relapse is a feature of addiction and this should be taken into account
 - behaviour that is not acceptable to the specialist service or prescriber (eg, violence or threat of violence to staff or other consumers/tangata whai ora)
 - supply of drugs to others on or around the treatment provider's premises or the pharmacy's premises
 - supply of methadone to others
 - inability to keep to the safety requirements of the MMT provider

- repeated failure to keep appointments
 - inappropriate use of the methadone such as injecting oral doses.
- 3.6 Detoxification programmes, whether inpatient or outpatient, should be offered with an involuntary discharge.
- 3.7 The decision to discharge a person involuntarily should be made by the prescribing doctor in consultation with the case manager and service manager or the primary care team (whichever applies).
- 3.8 When involuntarily discharged, the consumer/tangata whai ora will be:
- informed of other treatment options available
 - given the reasons for the discharge in writing
 - given a specified period of stand-down as agreed by the team
 - given an outline of the service's complaints procedure for review of the decision
 - offered consumer/tangata whai ora support during the process.
- 3.9 Each case of involuntary discharge should be reviewed to determine how best to re-engage the person in treatment.

4 Ongoing Support Services

- 4.0 The following support services should be either provided or made available by both specialist services or gazetted GPs. In either case they may either be directly provided or the person may be referred to the appropriate service. In the case of the gazetted GP, they will usually be working within the context of a wider primary care team which may have the resources to be able to directly provide some of the supports identified.
- 4.1 People receiving MMT should receive information and education on health issues, especially on how to reduce the spread of infectious diseases such as HIV/AIDS, hepatitis B and C, and sexually transmitted diseases.
- 4.2 Information on general health and welfare issues should be available and accessible and may be given as appropriate. People should be made aware of other health and social services available to them in the community; for example, family planning agencies, budget services and child-care facilities.
- 4.3 Counselling or psychotherapy should be offered, either by the service or by another agency.
- 4.4 Specialist services should provide a crisis intervention service, or access to one, so that people can achieve stability while in treatment. Gazetted GPs should make people on MMT aware of the after-hours emergency services available to them in the case of an overdose or other emergency.
- 4.5 Information and/or classes and support in the areas of child development and parenting should be available and accessible to all parents. This should include issues around keeping children safe while parents are using drugs, or during relapse.
- 4.6 In usual circumstances, methadone treatment should continue until goals agreed by the person and the service goals are achieved.

Relapse prevention

- 4.7 People should be offered support and assistance to maintain the stability in their lifestyle gained from methadone treatment.
- 4.8 In some cases medical support such as the use of naltrexone may be warranted.
- 4.9 The caseworker or primary care team and consumer/tangata whai ora should work towards goals that relate to sustained reduction of intake or, abstinence from, opioids or other illicit drugs, support for healthy lifestyles and the development of new interpersonal problem-solving skills.

Urine drug screens

4.10 Urine drug screens can provide information helpful in determining safety and progress in relation to treatment goals. However, their utility is limited for several reasons:

- Urine samples may not be a reliable indication of drug use if urination is not observed, but many patients find supervised urine collection demeaning
- False positive and false negative results do occur.

4.11 Specialist services may obtain urine samples for drug screening to test for the presence of psychoactive drugs including methadone. Samples will be taken at the initial assessment and from time to time as required for monitoring purposes.

4.12 When urine samples are taken, procedures should be in place that ensure the integrity of the specimen. It may be necessary to observe the passage of urine on some occasions. For this to happen there should be an appropriate environment for taking urine samples, and staff of the appropriate gender should be involved.

HIV and hepatitis testing and education

4.13 People commencing on methadone will tend to have high rates of blood borne infections. Over half can be expected to test positive for hepatitis C, while less than 1 percent can be expected to test positive for HIV. Some people will have protection from hepatitis B due to previous infection, others will be protected through immunisation. Because of the risk of future hepatitis B infection, all those who do not have protective levels of antibody should be offered vaccination. There needs to be adequate testing and treatment, through the specialist service or a GP, for people on methadone substitution programmes.

4.14 All MMT providers should be trained in providing education on HIV and hepatitis issues.

4.15 HIV and hepatitis B and C tests should be offered as part of the initial assessment by specialist services. Testing can only be done with consent. If the person chooses not to take the test, it should not influence their access to methadone treatment.

4.16 The MMT provider should offer follow-up HIV and hepatitis testing at appropriate periods, especially where high-risk behaviours continue to occur. People who have tested positive to hepatitis C do not need to have the test repeated but will need regular monitoring of liver function tests. People who do not have protective levels of hepatitis B antibodies should be immunised.

4.17 All people having an HIV test must agree to and receive pre- and post-HIV test counselling. Those having the test for hepatitis C should also receive pre- and post-HCV test counselling.

- 4.18 In order to preserve privacy, the use of a code on the blood form is recommended for people taking the test.
- 4.19 All results of HIV and hepatitis testing should remain confidential to the individual and the MMT provider.
- 4.20 Hepatitis B vaccinations should be offered to all people who are not immune. Partners and families should also be offered immunisation if they have independent risk factors.
- 4.21 Those with hepatitis C and hepatitis B carriers should be referred to a gastroenterologist. People who are HIV/AIDS positive should similarly be referred to an HIV service or the appropriate specialist physician.

5 Community Pharmacist Dispensing of Methadone

Pharmacists provide an important function in supporting the community-based management of people on MMT programmes. The community pharmacist works alongside the methadone services and general practitioner.

Joint responsibilities of pharmacists and prescribers

- 5.0 Pharmacists and prescribers are part of the team of people working with consumers/tangata whai ora in the process of MMT.
- 5.1 Prescribers should:
- acknowledge the pharmacist as an integral part of a multidisciplinary team caring for methadone service users.
 - adhere to the guidelines on prescribing set out in section 2 of this document.
 - provide support to community pharmacies dispensing methadone, including ongoing consultancy where necessary/required.
- 5.2 The pharmacist should dispense medication in accordance with the prescription and relevant legislation and maintain confidentiality of the personal information and treatment.
- 5.3 In addition, the pharmacist should provide the following services:
- 5.3.1 Supervise consumption of methadone on the pharmacy premises on the days the pharmacy is open and arrange for the collection of takeaway doses for the days the pharmacy is closed, or deliver those doses to the methadone service, prescribing GP or after-hours pharmacy, where appropriate.
- 5.3.2 Liaise with the methadone service on a regular basis and maintain a communication network with the dispensing nurse, caseworkers and prescribing medical officers or GP and after-hours pharmacy, where appropriate.
- 5.3.3 Listen and be aware of any problems that the person may be having and communicate these to the caseworker or the prescribing GP.
- 5.3.4 Liaise with the Medicines Control Advisor regarding the specialist service and any problems involved.
- 5.3.5 Direct the person back to the service or prescribing GP, if they have any problems (eg, nausea, drowsiness) due to the methadone formulation.

- 5.3.6 Deliver the first dose to the methadone service or prescribing GP, if requested, so that the person can be observed taking the methadone.

Methadone formulation

- 5.4 Pharmacists will use an appropriate commercial methadone formulation. If the commercial formulations cannot be taken by a particular patient, or the volume of stock to be kept on the premises is impracticable and poses a security risk (eg, 10 or more people being supplied on a regular basis), then an extemporaneous formulation may be prepared.
- 5.5 Extemporaneous formulations should be prepared to the same formulation as the currently funded commercially available formulation.
- 5.6 When preparing methadone formulations, pharmacists will comply with the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 3: Compounding and Dispensing, 1993.

Procedures for administration and dispensing

- 5.7 Pharmacists will comply with all regulations regarding controlled drugs, including the requirements for recording, storage and telephoned prescriptions and authorisations as detailed below.
- 5.8 There are two ways in which a person can receive their medication: as an administered dose consumed under observation or as a dispensed dose taken away to be consumed. A takeaway dose of methadone is any dose that is not consumed under observation.
- 5.9 A pharmacist must ensure that the correct medication is given to the right person in the right dose at the right time. This should include:
- ensuring the legality of the prescription
 - sighting of photographic identification if the person is not known to the pharmacist
 - assessment of person for intoxication/withdrawal
 - following correct labelling, record keeping and filing procedures
 - observation of dose consumption where required.
- 5.10 Where pharmacists are dispensing to more than 10 people on a regular basis, an automatic self-zeroing dose-measuring pump/burette should be used to facilitate measuring many doses and to minimise dose errors.
- 5.11 Unused methadone or the next day's doses must never be left on the dispensary bench overnight. It is recommended that, when filling the dose-measuring pump/burette for dispensing, the pharmacist uses sufficient for one day's supply

only. Any unused methadone formulation remaining in dose-measuring pumps/burettes and stock bottles must be returned to the controlled drug safe at the close of business for the day. The dose-measuring pump/burette must be cleaned and stored appropriately for use the next day.

Administration of consumed dose

5.12 The person receiving MMT must consume a full dose of methadone under observation at the time of each administration. The procedure should include:

- measuring the dose into a disposable cup
- administering the dose to the person
- observing dose consumption by having the person speak and/or drink additional fluid after swallowing the dose
- safely disposing of the disposable cup. This should not be recycled.

Takeaway doses of methadone

5.13 Takeaway doses of methadone should be diluted to at least 50 ml.

5.14 Takeaway doses must be measured into bottles with child resistant closures (CRCs). Exceptions apply as per section G, Pharmaceutical Schedule.

5.15 Pharmacists should ensure that those receiving methadone can open *and close* CRCs *correctly*, and are aware of the need for these CRCs. Pharmacists should emphasise the importance of storing takeaway doses in a cool place, out of sight and out of reach from children (preferably locked away).

5.16 Where a dose is being dispensed to an agent, there must be written notification of the agent's approval to collect the dose(s) from a GP or specialist service case manager. The prescriber must be notified that the agent collected the dose.

Delivery of methadone

5.17 In some cases pharmacies may be required to deliver methadone for consumption. This would apply most often in situations where the person is in police custody or in prison. Pharmacies should have a delivery plan that maximises the safety of the pharmacy staff and ensures that the correct person receives the appropriate dose of medication.

Telephoned methadone prescriptions and authorisation of takeaway doses

- 5.18 All pharmacists must confirm a telephone authorisation has actually originated from the clinic by calling back the clinic immediately.
- 5.19 In accordance with regulation 34 of the Misuse of Drugs Regulations 1977, any changes in methadone dose given by telephone must be confirmed by a new prescription within two days of the telephone call advising of the change.
- 5.20 A change in dispensing from ‘consume on premises’ to ‘takeaway dose’ does not require a new prescription but does require some form of written authorisation. This written authorisation should be immediately faxed through to the pharmacy. A sample authorisation is available on the Medsafe website at www.medsafe.govt.nz.

Cancellation of administered or dispensed doses

- 5.21 GPs, methadone service clinical staff (including case managers, pharmacists and clinical supervisors) or the dispensing pharmacist may cancel doses of methadone or cancel takeaway arrangements for people to:
- prevent a person from receiving a double dose of medication
 - prevent an intoxicated person from receiving additional medication
 - prevent situations that may endanger a person’s health and life
 - ensure that an accurate medication serum level is obtained
 - re-establish contact with a service user where all other attempts have failed.
- 5.22 All cancellation of methadone doses will be in writing, or through provision of a new H572M prescription.
- 5.23 Any of the above persons who initiate a methadone dose cancellation must notify the person directly of any cancellation. If direct contact is unable to be made with the person, a confidential letter will be sent to the person, via the pharmacy, outlining the reasons for this intervention.
- 5.24 When a pharmacist cancels a methadone dose, they must notify the appropriate prescriber or specialist service case manager by phone on the day on which the dose was cancelled and follow up by providing written (email, letter or fax) verification of the intervention and the reason for that intervention within two business days.

Risk management

- 5.25 The pharmacist must notify the prescriber by phone or in writing each time the person:
- fails to present for dosing
 - presents as intoxicated at the point of dispensing
 - exhibits abusive or threatening behaviour
 - diverts their methadone or makes a serious attempt to divert their methadone
 - is believed to have administered takeaway oral methadone intravenously
 - exhibits withdrawal symptoms
 - deteriorates in their physical, emotional or mental state.
- 5.26 The pharmacist must contact the prescriber for clarification of any administration/dispensing instructions that are unclear on the prescription.
- 5.27 The pharmacist must not dispense to a service user who has not collected their medication for three consecutive days or to any service user(s) whose presentation for dosing deviates from the administration/dispensing pattern outlined on the prescription.
- 5.28 Where a person has not collected their medication for three consecutive days, the pharmacist will notify the prescriber.
- 5.29 Where a pharmacist has administered an underdosage of methadone to a service user, the balance of the methadone dose should be given within the same day.
- 5.30 Where a pharmacist has administered an overdose dose of methadone to a service user, the pharmacist will:
- immediately advise the person of the medication error and the need for the person to be seen by the service or prescriber within three to four hours
 - advise the prescriber of the medication error if the person has already left the pharmacy. The prescriber (or person delegated) will make every effort to contact the person to advise and request the person to attend for a medical appointment
 - notify the prescriber in writing of the incident and actions taken.
- 5.31 Pharmacists must have procedures in place for the management of abusive behaviour or other incidents.

6 Use of Methadone in Pregnancy

- 6.0 Methadone maintenance treatment during pregnancy can improve the health of the mother and the chances of a full-term healthy baby. The main risk to the health of the fetus is for the pregnant women to start and stop opioid use, particularly where this involves the opioid withdrawal syndrome. Pregnant women are a priority group for methadone maintenance treatment.
- 6.1 Pregnant women may be being managed by a specialist service, an authorised GP or a gazetted GP. In each case, the responsible clinician will ensure each woman has information regarding the effect of MMT on the fetus.
- 6.2 If a pregnant woman is stable on methadone and is being managed by a GP, she does not need to be referred back to the specialist service. However, the specialist service may provide support for the GP as part of the consultation/liaison role expected of all services.
- 6.3 Both GPs and specialist services will ensure that the pregnant woman has appropriate antenatal and postnatal care, which in many cases means referral to an obstetrician.
- 6.4 Each specialist service will have a local protocol for the management of pregnant opiate-using women. This local protocol should include liaison arrangements with the GP, obstetrician, paediatrician, midwife, postnatal nurses and pharmacists.
- 6.5 Methadone services are to educate opiate users, GPs, obstetricians, paediatricians, midwives and pharmacists about the benefits to mother, fetus and baby of well-managed methadone treatment.
- 6.6 Breastfeeding is recommended for women having methadone treatment in the postnatal period, except when contraindicated for other medical reasons.
- 6.7 When women enter MMT, they should be informed about the effects of methadone on any fetus if they happen to become pregnant. See Appendix 3 for further information on pharmacokinetics.

7 Treatment of Pain in Methadone Recipients

- 7.0 For acute pain, methadone when prescribed as a methadone substitution treatment should not be considered as analgesia on its own.
- 7.1 For most people receiving methadone treatment, effective analgesia is achieved by conventional doses of opiates or other drugs additional to maintenance methadone. However, in some cases there may be cross-tolerance to pain relief. In such cases, expert advice should be sought from a pain professional.
- 7.2 For surgical procedures, full MMT doses can be administered throughout the hospital stay, and additional opiates given as is appropriate for the procedure.
- 7.3 Cross-tolerance with opioid surgical premedications can occur in the methadone-maintained individual so that higher doses of these agents may be indicated; however these should be instituted with caution, especially if the person has hepatitis C.
- 7.4 Note that mixed agonist-antagonist drugs, such as pentazocine (Fortral) and buprenorphine, can produce opioid withdrawal symptoms when used with MMT.
- 7.5 Consumers/tangata whai ora should inform their MMT provider if they are planning to undergo surgical or medical treatment. The treatment provider should then liaise with the medical or surgical service to confirm the timing and dose of methadone before and after the event and to ensure the methadone treatment is uninterrupted during hospital admission and convalescence.
- 7.6 There may be other instances where MMT providers, with the agreement of the consumer/tangata whai ora, may need to advise hospital staff, dentists or other health professionals regarding MMT and pain management for those on MMT when the consumer/tangata whai ora is undergoing treatment that may require pain medication.
- 7.7 People receiving methadone treatment may have hepatitis C, and subsequently their liver function may be impaired. This must be taken into account when the use of drugs metabolised in the liver is considered. The dose of paracetamol, for example, needs to be well within the standard 4 g per day. For general pain relief, non-steroidal anti-inflammatory agents (ibuprofen has a low risk of gastric irritation) should be considered as a suitable alternative to regular use of paracetamol with or without codeine.
- 7.8 For chronic, non-malignant pain syndrome in opioid-dependent people, there should be dual consultation and liaison between pain and methadone treatment services and GPs.

8 Administrative Expectations of Specialist Services

Outcomes of methadone maintenance treatment by specialist services

- 8.0 Each specialist service should clearly state their philosophy and expected outcomes for people receiving treatment for dependence on controlled drugs.
- 8.1 Outcomes should reflect the objectives of opioid treatment identified at the beginning of this document.
- 8.2 It is expected that specialist services will annually review their performance against these outcomes through the use of the Ministry of Health's Audit Tool for Methadone Services or an approved treatment index.

Staffing of specialist services

- 8.3 Specialist service staff should have:
- ongoing specialist training relating to the treatment of opioid dependence
 - awareness of key documents relevant to the treatment of people with severe mental health and alcohol and other drug problems
 - positive attitudes, including a high level of empathy with the consumer/tangata whai ora
 - management skills that are specific to the opioid-using population
 - training and cultural support in working with diversity, including working with Māori and Pacific peoples and people of other cultures
 - training in the assessment and treatment of other addictions and of polydrug abuse and drug interactions
 - training in the recognition of co-morbid mental illness
 - ongoing clinical supervision and support.
- 8.4 Specialist services should employ staff who have been trained and supervised in working with opioid-dependent people. In addition, small specialist services should have a formal relationship with other services to support the advancement of their work and the treatment of consumers/tangata whai ora.

- 8.5 At least one staff member in a specialist service should have significant experience and competence in the provision of methadone maintenance treatment. This staff member should also be well informed about the available outreach services and information about safe practices for opioid users.
- 8.6 All staff should be willing to work with all service users, regardless of race, ethnicity, age, disability, sexual orientation, gender or health status, and be sensitive to these issues.
- 8.7 Where possible and appropriate, services should match staff to client demographics so that cultural/gender/sexuality characteristics can be more easily taken into account and the consumer/tangata whai ora feels safe.
- 8.8 Tangata whai ora should be treated in accordance with the partnership principles of the Treaty of Waitangi.
- 8.9 At least one staff member from each service should be supported to attend an annual national workshop of opioid treatment providers. Staff should have ongoing training in issues related to methadone maintenance treatment.

Administration

- 8.10 Specialist services may develop their own local protocols and procedures provided they are consistent with, and not in conflict with, this National Protocol and relevant legislation, codes of practice and accountability requirements (see Appendix 5).
- 8.11 Specialist services should develop a system for resolving disputes between staff.

Record keeping

- 8.12 Records must be held for all service users, and must include:
 - National Health Index Number (NHI)
 - confirmation of name, address and date of birth
 - gender and ethnicity
 - details of the initial assessment before commencing opioid treatment
 - the date treatment began
 - a written medical assessment, including hepatitis serology, liver function and other laboratory tests
 - methadone dose and dispensing arrangements
 - the names of case manager and doctor
 - the name, address, telephone number and fax number of the pharmacy dispensing opioid prescriptions for that person

- the treatment plan and progress notes
- the discharge date and factors involved in discharge if this occurs
- review summaries of treatment progress
- consent forms (for treatment, disclosure of personal information, etc)
- copies of GP authorisation forms for those in GP-managed treatment, and treatment review forms
- details of any transfers either between services or to a gazetted general practitioner, or refusal of such a transfer and related factors
- any restriction notices under section 25 of the Misuse of Drugs Act 1975.

8.13 The service user must receive:

- a copy of their treatment plan
- information about confidentiality and situations under which the service may need to break that confidentiality
- information about the range of treatment options available
- information about methadone as a substance and side effects
- information about their rights as consumer/tangata whai ora, including their rights under the Code of Health and Disability Services Consumers' Rights and relevant patient and consumer advocacy contacts
- information about the service's complaints procedure
- information about their obligations as consumer/tangata whai ora.

Reporting requirements

8.14 Specialist services must send complete, timely and accurate information to the Mental Health Information National Collection. Services will also collect and forward statistical data related to waiting lists and times as required by the Ministry of Health.

Service user rights

8.15 Each person should receive a description of the treatment the service offers.

8.16 People should receive a copy of their rights and responsibilities while in treatment.

8.17 All opioid treatment services must comply with the National Mental Health Sector Standards that include sections on consumer/tangata whai ora involvement in services.

- 8.18 Consumers/tangata whai ora should be given clear verbal and written information about both voluntary and involuntary withdrawal processes and the conditions under which an involuntary withdrawal might be activated.

Complaints procedure

- 8.19 Services will have clear written procedures that are available and accessible for individuals to seek a review of their situation, particularly when a person is involuntarily discharged or refused access to a local specialist service. Specialist services may limit the number of reviews available or make a time period before new reviews are accepted.

Psychosocial treatment

- 8.20 Specialist services are contracted to provide a holistic service for people who are opioid dependent and either undergoing assessment and stabilisation of dose before moving on to gazetted GPs, or receiving a range of services to help in their recovery in addition to their maintenance methadone or other pharmacotherapy.
- 8.21 Each person should have an allocated caseworker who will take the responsibility for the development of a treatment plan with the person that is matched to their needs and defines clear outcomes for treatment.
- 8.22 Each specialist service will have a clear local protocol for review of all service users, which will include plans for movement of the person to authorised or gazetted medical practitioners as soon as possible.
- 8.23 To ensure that there is appropriate management, a multidisciplinary team should be involved in the overview of all cases. Services should have protocols to ensure that there are appropriate reviews of treatment progress, measurement of treatment outcomes against individual treatment goals and review of safety.

Safety requirements of services

- 8.24 Safety requirements of services are set out in the National Mental Health Sector Standards.
- 8.25 Services need to balance the safety needs of consumers/tangata whai ora and their family/whānau, service staff, pharmacy staff and the general public.
- 8.26 Each service should develop a set of safety requirements, which cover the areas of personal safety of consumers/tangata whai ora and staff as well as prescribing, dispensing, and takeaways. These safety requirements must be made clear to the consumer/tangata whai ora as part of their initial assessment.

Local protocol requirements

8.27 Services should develop local protocols which cover processes around:

- access to services
- management of pregnant women
- management of people suspected of being intoxicated or of diverting their methadone
- management of aggression or violence
- transfer of people to the care of gazetted GPs and GPs under authority and process for returning them to the care of specialist services
- transfer of people between specialist services
- review of progress of consumers/tangata whai ora
- involuntary termination
- measurement of outcomes for consumers/tangata whai ora
- review of safety issues.

External review

8.28 The Ministry of Health or the District Health Board may at any time request an external audit based on the Audit Tool for Methadone Treatment Services. Copies of the Audit Tool are available from the Ministry of Health.

9 Application for Approval to Offer Methadone Treatment in New Zealand

- 9.0 It is an offence for a medical practitioner to prescribe controlled drugs for the treatment of dependence unless the person is approved under the Misuse of Drugs Act 1975 (see Appendix 1).
- 9.1 Approval to prescribe will only be given to services or medical practitioners that fulfil the criteria set out by the Ministry of Health. In recommending services or medical practitioners for approval, the Ministry of Health will be guided by this protocol and other approved standards and processes. Existing approved services must ensure they comply with this protocol to ensure continuation of gazettal.
- 9.2 An application form for services or medical practitioners wishing to apply for gazettal under the Misuse of Drugs Act can be found on the Medsafe web site at www.medsafe.govt.nz. This site also has forms which allow GPs to prescribe under authority.

Gazetting methadone treatment services

- 9.3 The Minister of Health has delegated authority to the Director of Mental Health to gazette certain agencies and medical practitioners so that they may provide services for those assessed as suitable for methadone treatment.
- 9.4 The Director of Mental Health has adopted the criteria outlined below to decide whether to approve an institution as a methadone treatment service under section 24(5)(b) of the Misuse of Drugs Act 1975, or whether a service, which has already been approved, can continue to meet the minimum standards outlined in this protocol and so remain a gazetted service for methadone treatment.
- 9.5 Each application will be considered on its merits. In general, a service which does not meet the requirements of this protocol will not gain approval. However, the Director of Mental Health will consider submissions from organisations or persons wishing to run a specialist service, explaining why deviation from the specified criteria should be permitted.

The criteria

- 9.6 To be approved as an MMT service, the organisation must have a gazetted or authorised medical practitioner working in the service, be a legal entity and be an established health service capable of offering continuity of service to the client group.

- 9.7 The methadone service should have rooms for private interviewing, have secure filing systems and maintain confidentiality according to the Health Information Privacy Code 1994.
- 9.8 The methadone service should undertake to provide the Director of Mental Health with the names of staff who work with people receiving methadone treatment. These staff members should include at least one registered medical practitioner who has been authorised under section 24(5)(a) or 24(2)(c) of the Misuse of Drugs Act 1975 specifically available at the service, and at least one of the following who must be available during work hours:
- a registered psychologist
 - a qualified social worker
 - a registered nurse
 - another health professional (eg, occupational therapist, counsellor with relevant qualifications).
- 9.9 All of the above should have training and/or experience in working with opioid-dependent persons to a level acceptable to the Director of Mental Health.
- 9.10 The service will be responsible for informing the Director of Mental Health of any changes in the list of staff that would mean these minimum criteria are not met.
- 9.11 The service must agree to comply with this protocol. From time to time, services will undergo an external audit process using the Ministry of Health's Audit Tool. (Note that the Audit Tool will be updated after this protocol has been revised.)

Existing services – obligations to maintain the criteria set out in this protocol

- 9.12 If the specialist service cannot fulfil any of the criteria set out above, the organisation or persons running the service should immediately inform the Director of Mental Health. A meeting will be arranged to resolve the situation to the satisfaction of the Director of Mental Health.
- 9.13 Where a service continues to be unable or unwilling to meet the criteria and in the Director of Mental Health's opinion a satisfactory solution has not been found, the Director of Mental Health may take action to revoke the approved status of the methadone treatment service.
- 9.14 Before making a decision as to whether to revoke the approved status of a specialist service, the Director of Mental Health will accept and consider representations made by the organisation or persons running the service as to why the service should retain its approved status.

Criteria for gazetting medical practitioners

9.15 Criteria used by the Ministry of Health in assessing applications for gazetting a medical practitioner include, but are not restricted to:

- the medical practitioner having a current annual practising certificate
- the medical practitioner having a practising certificate that has never been revoked
- the medical practitioner's experience in providing treatment to people who are dependent on controlled drugs. In most cases this experience will be through working under the authority of a specialist service
- the medical practitioner's agreement to comply with the requirements of this protocol.

9.16 In addition, medical practitioners seeking to be gazetted will be expected, as part of their continuing medical training, to keep up to date on MMT and related issues.

Medical practitioners working under authority

9.17 Medical practitioners working under authority are those who are working with particular people in accordance with the terms and conditions set out in the Misuse of Drugs Act (see Appendix 1).

9.18 This allows for methadone services to increase their medical capacity by using GPs working under authority to see more stable people, and for authorised medical practitioners to take breaks as appropriate while ensuring that their patients get the care from a legally authorised person.

9.19 GPs are suitable for managing methadone patients when they have knowledge of this protocol and can work within the protocol's requirements.

9.20 More specifically, the authorised GP prescriber needs to be familiar with:

- legal implications of the authorisation (authorisation is only for the named patients, for a set period, and in accordance with such terms and conditions as specified by the authorising medical practitioner)
- treatment aims of the service
- service policies, philosophy and procedures
- appropriate record keeping
- current methadone treatment issues
- HIV/AIDS and hepatitis B and C treatment and prevention issues.

9.21 Conditions under which people can be transferred to the care of an authorised GP should be clearly set out in specialist service local protocols. These conditions should reflect best clinical practice and have consideration for the safety of the service user and the authorised medical practitioner.

Obligations of specialist services and gazetted medical practitioners to GPs working under authority

- 9.22 There should be recognition of the varying levels of GPs' expertise in prescribing methadone. In some situations, the specialist services or gazetted medical practitioner will specify the dose, dispensing frequency or takeaway regime in order to provide guidance and ensure that safety requirements are met. In other situations, only the written authority will be required from the gazetted service's authorising medical practitioner. Consideration must be given to the overall responsibility that the gazetted medical practitioner has in supervising this situation.
- 9.23 The responsibilities of the gazetted medical practitioner or specialist service to the GP working under authority include ensuring:
- that proper authorisation is given to each GP for the named patient and that this is updated at three-monthly intervals
 - that, where authorisation is sought for longer than three months, approval is obtained through a Medical Officer of Health appointed by the Ministry of Health
 - GPs have other information such as the safety aspects for methadone prescribing, suggested frequency of consultations, and methods of assessment and monitoring.
- 9.24 Because specialist services work with GPs under authority for a long period of time, the services also have a responsibility to:
- be available to discuss management problems with the GP
 - co-ordinate regular meetings with this group of GPs
 - review patients at six monthly intervals or at the request of the GP
 - take back into the service any patient whom the GP is no longer able to manage.

Revocation of authority

- 9.25 If the GP working under authority does not comply with the requirements stated on the authorisation form and in section 24(2)(d) of the Misuse of Drugs Act 1975, then the authority can and will be revoked with the referring methadone service taking the person back under their direct care (see Appendix 1).

Appendix 1: Misuse of Drugs Act 1975 Section 24

24 Treatment of persons dependent on controlled drugs

- (1) Every medical practitioner commits an offence against this Act who, except as provided in subsection (2) of this section, prescribes, administers, or supplies any controlled drug for or to any person, whom the practitioner has reason to believe is dependent on that or any other controlled drug, in the course, or for the purpose, of treatment for dependency.
- (1A) Every registered midwife or designated prescriber commits an offence against this Act who prescribes, administers, or supplies any controlled drug for or to any person, whom the midwife or prescriber has reason to believe is dependent on that or any other controlled drug, in the course, or for the purpose, of treatment for dependency.
- (2) A medical practitioner may prescribe, administer, or supply any controlled drug for or to any such person if the medical practitioner –
 - (a) is for the time being a medical practitioner approved by the Minister under subsection (5)(a) and is acting in accordance with any general or specific directions imposed by the Minister under that approval; or
 - (b) is working in a place specified under subsection (5)(b) and is authorised, by a medical practitioner approved under subsection (5)(a) who is working in the same place, to prescribe controlled drugs; or
 - (c) is acting in the medical practitioner's capacity as a medical officer employed in a place specified under subsection (5)(b), and is authorised in writing by the chief executive of the organisation that runs that place (acting under the general or specific direction of a Medical Officer of Health) to prescribe controlled drugs; or
 - (d) is acting in relation to a particular patient during the period prescribed in, and in accordance with the terms and conditions of, a permission in writing given by an approved medical practitioner (as described in paragraph (a)) or an authorised medical officer (as described in paragraph (c)).
- (3) Except with the concurrence of the Medical Officer of Health, no permission given under paragraph (d) of subsection (2) of this section shall be expressed to apply for any period longer than 3 months, but any such permission may from time to time be renewed by the approved medical practitioner or by the authorised medical officer, or any other medical officer similarly authorised and employed in the same hospital, for a period not exceeding, except as aforesaid, 3 months at any one time.
- (4) Any authority or permission given or renewed pursuant to subsection (2) or subsection (3) of this section may, by notice in writing to the person to whom the authority or permission was given, be withdrawn at any time by the person who gave or renewed the authority or permission, and shall be deemed to have been so

withdrawn when the notice specifying the hospital, health centre, clinic, or place, in or from which the authority or permission was given or renewed, or specifying the medical practitioner by whom the authority or permission was given, as the case may require, is revoked, or, in the case of an authority under paragraph (b) of the said subsection (2), such medical practitioner dies or ceases to work in the hospital, health centre, clinic, or place to which the authority relates.

- (5) The Minister may from time to time, by notice in the Gazette, do any 1 or more of the following:
 - (a) approve any medical practitioner as a medical practitioner who may, subject to any general or specific conditions imposed by the Minister on the recommendation of the Director-General of Health, prescribe, administer, or supply controlled drugs for the purpose of this section:
 - (b) specify by name or description any licensed hospital (within the meaning of the Hospitals Act 1957), or any health centre, clinic, or similar place, as a place at which controlled drugs may be prescribed, administered, or supplied for the purpose of this section:
 - (c) revoke any approval or specification under this section.
- (6) Nothing in the preceding provisions of this section shall apply to –
 - (a) The treatment of a patient, within the meaning of the Alcoholism and Drug Addiction Act 1966, while he is in an institution, within the meaning of that Act:
 - (b) The emergency treatment of a patient in any hospital within the meaning of the Hospitals Act 1957, for a period not exceeding 3 days:
 - (c) The treatment of any restricted person within the meaning of section 25 of this Act.

Appendix 2: Drug Interactions Associated with Methadone

The drugs listed below are known to affect methadone metabolism and should therefore be used with caution by those being treated with methadone.

Note: Those with hepatitis C may have impaired liver function. This needs to be taken into account when the use of drugs metabolised in the liver is considered. The dose of paracetamol, for example, needs to be well within the standard 4 g per day. For more information on the management of people with HIV or hepatitis, see section 4 in this document.

Drug	Status of effect	Mechanism	Interaction
Alcohol	Clinically important	Increased sedation, increased respiratory depression; combination may also have increased hepatotoxic potential	Additive central nervous system depression
Benzodiazepines	Clinically important	Enhanced sedative effect	Additive CNS depression
Buprenorphine	Clinically important	Antagonist effect or enhanced sedative and respiratory depression	Partial agonist of opiate receptors
Carbamazepine	Clinically important	Reduced methadone levels	Stimulates hepatic enzymes involved in methadone metabolism
Chlormethiazole	Clinically important	Enhanced sedative effect	Additive CNS depression
Cimetidine	Two cases have been shown in patients taking methadone as analgesia	Possible increase in methadone plasma levels	Inhibits hepatic enzymes involved in methadone metabolism
Cisapride, domperidone, metoclopramid	Theoretical	Theoretically might increase the speed of onset of methadone absorption, but not the extent	Possibly by reversing the delayed gastric emptying associated with opioids
Cyclizine and other sedating anti-histamines	Clinically important	Anecdotal reports of injection of cyclizine with opiates causing hallucinations	Additive psychoactive effects; anti-muscarinic effects at high doses
Desipramine	Clinically important	Raised desipramine levels by up to a factor of two	Unknown interaction not seen with other tricyclic antidepressants
Other tricyclic antidepressants	Theoretical	Enhanced sedative effect, which is dependent	Additive CNS dose depression

Drug	Status of effect	Mechanism	Interaction
Erythromycin	In theory should interact but combination has not been studied	Increase in methadone levels	Decreased methadone metabolism
Fluconazole	In theory the same as ketoconazole		
Fluoxetine	Clinically important	Raised methadone levels, but not as significant as for fluvoxamine	Decreased methadone metabolism
Fluvoxamine, other SSRI	Clinically important, theoretical	Raised plasma methadone levels	Decreased methadone metabolism
Grapefruit juice	Should interact in theory and there have been several anecdotal reports	Raised methadone levels	Decreased methadone metabolism
Indinavir	Clinically important	Raised methadone levels	Decreased methadone metabolism
Ketoconazole	Clinically important	Raised methadone levels	Decreased methadone metabolism
MAOI (including selegiline and moclobemide)	Severe with pethidine though unlikely with methadone and has never been described	CNS excitation delirium, hyperpyrexia, convulsions, hypotension or respiratory depression	Unclear; avoid the combination if possible
Naltrexone	Clinically important	Blocks effect of methadone (long acting)	Opiate antagonist – competes for opiate receptors
Naloxone	Clinically important	Blocks effect of methadone (short acting), but may be needed if overdose suspected	Opiate antagonist – competes for opiate receptors
Nevirapine	Clinically important	Decreased methadone levels	Increased methadone metabolism
Nifedipine	Has been demonstrated <i>in vitro</i> only	Increased nifedipine levels; no effect on methadone levels	Methadone increases the metabolism of nifedipine
Omeprazole	To date, demonstrated only in animals	Increased methadone levels	Possibly affects methadone absorption from the gut
Phenobarbitone	Clinically important	Reduced methadone levels; increased sedation; additive CNS depression	Barbiturates stimulate hepatic enzymes involved in methadone metabolism
Phenytoin	Clinically important	Reduced methadone levels	Phenytoin stimulates hepatic enzymes involved in methadone metabolism

Drug	Status of effect	Mechanism	Interaction
Rifampicin	Very important: most patients are likely to be affected	Reduced methadone levels	Rifampicin stimulates hepatic enzymes involved in methadone metabolism
Rifabutin	Occasionally clinically important	Decreased methadone levels	Increased methadone metabolism
Ritonavir	Clinically important	Ritonavir may increase plasma methadone levels	Inhibits methadone metabolism
Other protease inhibitors	Theoretical	May raise or lower methadone plasma levels	Inhibits methadone metabolism
Urine acidifiers (eg, ascorbic acid/ vitamin C)	Clinically important	Reduced plasma methadone levels	Raised urinary excretion of methadone
Urine alkalinisers (eg, sodium bicarbonate)	Clinically important	Increased plasma methadone levels Reduced urinary excretion of methadone	
Zidovudine	Clinically important	Raised plasma levels of zidovudine; no effects on methadone levels	Unknown
Zopiclone	Clinically important	Enhanced sedative effects	Additive CNS depression
Other opiates	Clinically important	Enhanced sedative effect	Additive CNS depression; enhanced respiratory depression
Other CNS depressant drugs (eg, neuroleptics, hyoscine)	Clinically important	Enhanced sedative effects which is dose dependent	Additive CNS depression

Adapted from Drug Misuse and Dependence: – Guidelines on clinical management, Department of Health, United Kingdom, 1999.

Appendix 3: Pharmacokinetics

- 1 Methadone is plasma protein bound 85 percent, with a Vd of 5 l/kg. It is metabolised chiefly in the liver and excreted as glucuronides. Methadone is reabsorbed in the renal tubules, and this reabsorption decreases as the urinary pH decreases. The kidneys are the major route of excretion only when the dose exceeds 50 mg/day. Methadone metabolites are also excreted in the faeces via the bile.
- 2 Methadone and morphine differ chemically, but their actions and analgesic potency are similar. For intramuscular administration, 7.5-10 mg methadone is equivalent to 10 mg morphine. For oral administration, 60 mg morphine is approximately equi-analgesic to 20 mg of methadone. Furthermore, there is a slower development of tolerance and dependence with methadone than with morphine.
- 3 Methadone accumulates in the body on repeated administration.
- 4 Symptoms of methadone overdose in the adult:

Pinpoint pupils	hypothermia
respiratory depression	bradycardia
bradycardia	hypotension
pulmonary oedema (not always)	seizures
coma	

Rhabdomyolysis, myoglobinuria, muscle necrosis, and renal failure may occur secondary to methadone intoxication and may result from muscle damage related to prolonged coma and immobilisation or from a direct toxic effect of methadone.

Treatment

Ensure that the airway is clear and perform emergency cardiopulmonary resuscitation as necessary. Take the person to hospital as soon as possible where treatment with an infusion of naloxone can be commenced.

Overdose patients should remain in hospital for 24 to 72 hours due to methadone's long half life.

Toxic dose level of methadone

- For non-tolerant adults, doses of 50 mg of methadone or less have been known to be fatal, including doses taken orally. Potentially lethal overdoses of methadone can occur within 0.5 to 6 h after ingestion by non-tolerant or partially tolerant individuals.
- Parenteral administration of methadone has a similar onset to morphine with peak plasma levels within 0.25–2 h and duration of action 4–6 h. Parenteral methadone is approximately twice as potent as oral methadone but still has a long half life.

- Oral methadone has a much longer onset (single dose: measurable amounts in the plasma at 0.5 h, peak levels at 4 h) and duration of action (single dose: half-life 10 to 18 h or longer).
- The blood methadone concentration of victims of methadone overdose overlaps that for methadone maintenance subjects. The plasma concentration peaks (74 ng/ml) 1-2 h after high doses and 4 h after an oral dose of 15 mg methadone. Blood levels decline, so that at 24 h, the plasma levels equal 40 percent of peak levels (30 ng/ml).

5 Children who ingest methadone

The fatal dose of methadone in children is 10-20 mg.

- Symptoms of opioid overdose in children are similar to those in adults, with pupillary miosis; however, the pupils may be normoreactive or, rarely, fixed and dilated. Infants may have drowsiness, coma and apnoea. Children are usually, but not always, symptomatic.
- Known or suspected methadone-intoxicated children should be hospitalised, since respiratory depression may be observed for as long as 48 h after ingestion. Successful resuscitation with a narcotic antagonist may be followed by relapse. Treatment must include establishment of an airway, maintenance of adequate respiratory ventilation, precise supportive care to maintain fluid and electrolyte balance, naloxone, emptying of the upper and lower gastrointestinal tracts, and prevention of aspiration of gastric contents.

6 Use in pregnancy and lactation

- Methadone crosses the placenta, and in sufficient doses, usually more than 30 mg maternal daily may cause respiratory depression in the newborn infant. Ventilatory support, as required, is recommended in the management of respiratory depression of the newborn. The use of naloxone is contraindicated, as it may precipitate a severe abstinence syndrome.
- Withdrawal symptoms (Neonatal Abstinence Syndrome) in the methadone infant can be moderately severe if not appropriately treated. The newborn infant should therefore be under the care of an experienced paediatrician.
- Methadone metabolism in the mother may be increased during pregnancy, leading to lower plasma methadone concentrations and, in some cases, symptoms of methadone withdrawal. In such cases, the methadone may need to be increased or given in divided doses.
- Breastfeeding is not contraindicated as the amount of methadone present in breast milk is minute and unlikely to harm the infant in the first three to six months of life. The benefits of breastfeeding outweigh the risks (excepting maternal HIV positive status) and therefore is to be encouraged.
- Assuming identification and safe management of Neonatal Abstinence Syndrome, there is no evidence to suggest that pregnancy outcomes or neonatal wellbeing is adversely affected by usual maternal doses of methadone.

Appendix 4: Prison Opioid Substitution and Detoxification Protocol (Agreed May 2000)

1 Preamble

This protocol:

- supersedes the current Protocol for Methadone Treatment in Prisons
- forms an appendix to the National Protocol for Methadone Treatment In New Zealand
- constitutes an agreement between the Department of Corrections, the Ministry of Health and the Health Funding Authority.

2 Aims and objectives

Methadone treatment programmes have been extensively evaluated and show conclusively that clients maintained in treatment show a dramatic reduction in criminal activity over time.

In line with this information, treatment is being offered to clients on opioid substitution as outlined in the following document.

In doing this prisons will also endeavour to manage inmates who arrive in prison and who are on an opioid substitution programme according to their individual clinical and custodial management needs, and in accordance with this protocol.

3 Eligibility

3.1 Methadone maintenance

Methadone maintenance will be provided only to those people on a bona fide methadone treatment programme prior to being committed to custody, in accordance with the following conditions:

- (a) *Remand* inmates are maintained on methadone.
- (b) *Sentenced* inmates are withdrawn from methadone, in accordance with the procedure in section 7, with the following exceptions:

- Maintain inmates who would be released before they are completely withdrawn from methadone.
- Maintain inmates who are pregnant if that is recommended by their obstetrician in consultation with the prescriber and the prison medical officer.
- Maintain HIV positive inmates if that it is recommended by specialist medical practitioner in consultation with the prescriber and the prison medical officer.
- Maintain inmates receiving interferon treatment for Hepatitis C if that is recommended by a specialist medical practitioner in consultation with the prescriber and the prison medical officer.
- Maintain inmates who have been granted leave by the Court to apply for release to home detention but whose application is yet to be determined by the District Prisons Board.

3.2 Methadone prescribed for pain relief

Inmates who arrive at prison and who are receiving methadone as a legitimate treatment for pain shall continue to receive this.

Any continued prescription of methadone for this purpose is the clinical responsibility of the pain clinic/prescribing agency, in consultation with prison health staff.

Methadone for pain will be delivered in accordance with appropriate clinical guidelines.

3.3 Eligibility for other opioid substitution medications

Inmates who arrive at prison and who have been prescribed other opioid substitution medications, whether through a clinic or a gazetted GP, shall continue to receive this medication, subject to the provisions in section 6.3.

4 Funding

The Health Funding Authority will continue to fund inmates who are maintained or withdrawn from opioid substitution in prisons.

Inmates retain their opioid substitution provider client place while they are being maintained or until they are withdrawn from opioid substitution drugs.

5 On reception

When inmates receiving opioid substitution are received into prison, the prison medical officer or their representative will notify the community methadone clinic or other prescriber within four hours. After hours or at weekends or public holidays, the notification will be made as soon as possible.

6 Joint inmate management model

6.1 General methadone treatment

Methadone treatment will be managed by the inmate's methadone prescriber clinic of origin in conjunction with the prison medical officer.

Community methadone prescribers clinic of origin will have clinical responsibility for the methadone treatment of inmates. However, all decisions relating to dose adjustments will be in consultation with the prison medical officer.

Responsibility for writing prescriptions and medical supervision (including re-subscription) will be in accordance with Table 1 below.

6.2 Managing out of region methadone inmates

Methadone treatment for out of region inmates will be managed by the inmate's methadone prescriber clinic of origin in conjunction with the prison medical officer.

Community methadone prescriber clinics of origin will have clinical responsibility for the methadone treatment of out of region inmates. However, all decisions relating to dose adjustments will be in consultation with the prison medical officer.

If an inmate is out of region, the Medical Officer in the receiving prison will be temporarily authorised to prescribe for the treatment of drug dependence by the person's normal methadone prescriber clinic of origin in accordance with section 24, Misuse of Drugs Act 1975.

Responsibility for scripting and medical supervision (including re-subscription) for out of region inmates will be in accordance with Table 1 below.

Table 1: Responsibility for opioid substitution prescribing and medical supervision (including re-subscription)

Client category	Local clients	Out of region clients
Sentenced inmate being withdrawn from methadone	Clinic of origin/gazetted GP/ authorised GP (client place kept until withdrawal completed)	Clinic of origin/gazetted GP/ authorised GP (client place kept until withdrawal completed)
Methadone maintained short sentence and remand inmate who is expected to be released before their next three-monthly check-up comes up	Clinic of origin/gazetted GP/ authorised GP (client place kept by clinic to ensure that inmate remains on the methadone programme following release from prison)	Clinic of origin/gazetted GP/ authorised GP (client place kept)
Methadone maintained short sentence and remand inmate who is expected to be released after their next three-monthly check-up comes up	Prison doctor under authority from local prescriber (client place kept)	Prison doctor under authority from methadone prescriber clinic of origin (client place kept)
Other methadone maintained sentenced inmates (pregnancy, HIV+, interferon)	Prison doctor under authority from local prescriber (client place kept)	Prison doctor under authority from methadone prescriber clinic of origin (client place kept)
People on alternative medications prescribed for opioid dependence or withdrawal	On a case by case basis in consultation with prescriber in accordance with this protocol (client place kept if applicable)	On a case by case basis in consultation with prescriber in accordance with this protocol (client place kept if applicable)

6.3 Management of other opioid substitution medications

Other opioid substitution medications should be assessed and managed on a case by case basis by the inmate’s prescriber in conjunction with the prison medical officer and in accordance with this protocol.

Community prescribers will have clinical responsibility for the opioid substitution treatment of inmates. However, all decisions relating to dose adjustments will be in consultation with the prison medical officer.

7 Procedures for managed withdrawal

7.1 General methadone withdrawal

Inmates will be withdrawn from methadone according to the following managed withdrawal guidelines:

- The methadone dose is reduced by 5mg per day until the daily dose is reduced to 25 mg.
- After reaching 25 mg, the methadone dose is reduced by 2.5 mg per day until complete withdrawal is achieved.

- Medication to address withdrawal symptoms is provided as necessary.
- Psychosocial support is provided as necessary.

Inmates may elect to withdraw from methadone without a managed withdrawal programme (that is immediately) with assistance to minimise the side effects of the withdrawal.

Where there are exceptional clinical circumstances the General Manager, Public Prisons Service may approve an extended withdrawal programme. For inmates in the Auckland Contract Remand Prison, the General Manager Auckland Contract Remand Prison may approve an extended withdrawal programme.

Methadone clinics will take over the management of gazetted or authorised GP clients in situations where the gazetted or authorised GP has an objection to their client withdrawing from any opioid substitute.

7.2 Withdrawal from other opioid substitutes

Withdrawal from other opioid substitution medications should be managed on a case by case basis, by the inmate's prescriber, in conjunction with the prison medical officer, and in accordance with this protocol.

8 Opioid substitution administration

8.1 Methadone administration

Where possible opioid substitution medications will be administered in the prison health clinic.

Prison health staff will administer the opioid substitution medications. Opioid substitution medications will be issued daily, and in the morning where possible.

Opioid substitution medications will be administered in accordance with principles of safe practice.

8.2 Administration of other opioid substitutes

The procedures for the administration of other opioid substitution medications should be determined on case by case basis, by the inmate's prescriber, in conjunction with the prison medical officer, and in accordance with this protocol.

9 Training for prison and community opioid substitution treatment staff

The Prisons Service and opioid substitution providers will ensure that their health staff are appropriately trained to comply safely with the provisions of this protocol.

10 Confidentiality and records

All communications concerning opioid substitution in prisons will comply with the Health Privacy Code.

Appendix 5: Relevant Legislation and Codes of Practice

Services and medical practitioners gazetted under section 24 of the Misuse of Drugs Act 1975 are expected to comply with the legislation and guidelines outlined in the Mental Health Purchase Framework and Service Specifications, in particular:

Legislation

Alcoholism and Drug Addiction Act 1966
Criminal Justice Act 1985
Health (Needles and Syringes) Regulations 1987
Medicines Act 1981
Medicines Regulations 1984
Misuse of Drugs Act 1975
Misuse of Drugs Regulations 1977
New Zealand Public Health and Disability Act 2000
Official Information Act 1982
Privacy Act 1993 (Health Information Privacy Code 1994)

Ministry of Health and other relevant guidelines

Alcohol and Drug Service Accreditation Standards
Audit Tool for Methadone Services 1994
Guidelines for Cultural Assessment in Mental Health Services 1995
Guidelines for Effective Consumer Participation in Mental Health Services 1995
Guidelines for the Management of Patients with Co-existing Psychiatric and Substance-use Disorders 1994
Guidelines for the Management of Suicidal Patients 1993
Involving Families Guidance Notes: Guidance for involving families and whānau of mental health consumers/tangata whai ora in care, assessment and treatment processes 2000
Medical Aspects of Fitness to Drive: A guide for medical practitioners 1999 (currently being updated)
Methadone in Prisons
National Mental Health Sector Standards (Standards New Zealand)
New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 3: Compounding and Dispensing, 1993
Recovery Competencies for New Zealand Mental Health Workers 2001

Professional codes of ethics and standards of practice

Applicable to:

- medical practitioners, including psychiatrists
- recognised counsellors
- registered nurses
- social workers
- occupational therapists
- registered psychologists
- pharmacists.

Appendix 6: List of Contributors

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Appendix 7: Glossary

Authorised Medical Practitioner	An authorised medical practitioner, typically a general practitioner, is a medical practitioner who is authorised by a specialist services to provide MMT to specified people.
Case Manager	A case manager is someone assigned to be responsible for co-ordinating the care and treatment of a consumers/tangata whai ora and may provide some or all the interventions planned. When the person is transferred to a GP working under authority from the specialist service, the GP becomes the case manager but may work closely with a clinic counsellor.
Diversion of methadone	Diversion is defined as selling, injecting or otherwise using their prescribed methadone illegal purposes or against medical advice.
Gazetted Medical Practitioner	A gazetted medical practitioner is one who has been approved by the Ministry of Health under section 24(5)(a) of the Misuse of Drugs Act 1975 to prescribe, administer, or supply controlled drugs for the treatment of dependence. In this document, reference is made almost exclusively to gazetted GPs.
Specialist Service(s)	Specialist methadone treatment services (specialist services) are those which have been specified by the Minister under section 24(5) of the Misuse of Drugs Act 1975 and notified in the New Zealand Gazette (published by the Department of Internal Affairs).
Stabilisation	Stabilisation is a process which allows the person to make best use of the MMT. The decision about what level of stabilisation is most appropriate for an individual needs to be made jointly by the clinician in consultation with the consumer/tangata whai ora. At a minimum, stabilisation would mean that the person can cope on a consistent regular dose of methadone without the need for constant dose changes and reviews. For some people this will take a considerable time to achieve, and they will need considerable input from a variety of staff in the specialist service.
Takeaways	Takeaway doses of methadone refer to any doses that are not consumed on the methadone clinic or pharmacy premises.