Regulatory Impact Statement: Amendments to improve safe access to opioids

Coversheet

Purpose of Document	
Decision sought:	Analysis to support an amendment to the Misuse of Drugs Regulations 1977 to adjust prescribing limits for opioids and other controlled drugs
Advising agencies:	Manatū Hauora
Proposing Ministers:	Hon Dr Ayesha Verrall, Minister of Health
Date finalised:	11 July 2023

Problem Definition

The Misuse of Drugs Regulations 1977 set limits on the amount of controlled drugs that can be prescribed, reflecting the likely harms of any overdose, overmedication or misuse such as further supply for criminal purposes. Setting appropriate limits can be challenging, reflecting the need to ensure health needs are met while minimising potential harms. It has been identified that recent amendments to these Regulations have resulted in inappropriate limits for some opioids.

Current limits are also complex, sometimes arbitrary, can be a barrier to accessing health services, and for some prescribers not reflective of their competence. Navigating these limits can be challenging for both clinicians and consumers as they do not always provide a reasonable framework for services to be delivered.

Executive Summary

A number of controls and safeguards exist to manage the risk of inappropriate access to opioids, both regulatory and non-regulatory. These include regulations that set out prescribing authorities, clinical guidance that sets out appropriate practices, clinical support systems in provider settings, monitoring systems to review potential inappropriate prescribing, and professional sanctions where inappropriate prescribing occurs.

Amendments to the Misuse of Drugs Regulations 1977 made in 2022 [CAB-22-MIN-0526] increased the amount of Class B controlled drugs that could be prescribed at one time, from one month to 3 months. Many prescription opioids (such as fentanyl and oxycodone) are Class B controlled drugs.

In early 2023, Manatū Hauora conducted a review of opioid controls (the review) following concerns raised by some clinicians that the 2022 amendments could have increased the risk of overprescribing opioids. As part of this review a cross-agency working group was established. Members of the working group came from government agencies that provide, or have oversight responsibilities for the provision of, health services.

The intent of the review was to determine whether the existing controls are effectively managing the risk of opioid harm and enabling safe patient access. The review highlighted that the most important controls to provide for safe access are non-regulatory:

- standards and guidelines provided to professions on appropriate prescribing practice
- and a robust monitoring system to identify inappropriate prescribing and intervene when necessary.

The review did identify several potential improvements to regulations to reduce the risk of harm from overprescribing of **all** opioids. These include specific amendments to prescribing regulations for opioids, and broader amendments to prescribing regulations for all controlled drugs. The recommended amendments to the Misuse of Drugs Regulations 1977 are to:

- create a single prescribing limit for Class B and C opioids, of one month
- establish an exemption to the one month limit for prescriptions written by Opioid Substitution Treatment (OST) providers, i.e. allow the Medical Officer of Health to authorise OST prescriptions for up to 3 months
- align controlled drug prescribing limits for all controlled drug prescribers
- align prescribing limits for physical and electronic prescriptions.

Limitations and Constraints on Analysis

High level dispensing data was obtained through the Pharmaceutical Data web tool, which provides dispensing information for prescriptions funded by Pharmac. The limitations of this data are that it only provides an overview of prescribing up to the end of 2021 and it does not account for non-funded prescriptions (although this would be a small minority of prescriptions).

Te Whatu Ora facilitated a data request to a new database that provides up-to-date prescribing and dispensing data for all medicines, the Medicines Data Repository (MDR). While the MDR is functional it is currently in a transitional phase so the data could not be extracted in time for this analysis. Work is already underway to better resource this new database.

Where data could not be obtained, the analysis relied on assumptions regarding prescribing behaviours. These assumptions came from input from clinical advisors within Manatū Hauora, the Safe Access to Opioids Working Group, and engagement with stakeholders.

Responsible Manager(s) (completed by relevant manager)

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11 July 2023

Quality Assurance (completed by QA panel)	
Reviewing Agency:	Papers and Regulatory Committee (PARC), Ministry of Health
Panel Assessment & Comment:	The Ministry of Health QA panel has reviewed the Impact Statement titled "*Amendments to improve safe access to opioids"* produced by the Ministry of Health and dated 11 July 2023. The panel considers that the Impact Statement **Partially Meets** the quality assurance criteria. The Impact Statement is clear, complete and consulted. The Impact Statement does not make a convincing case that the regulatory proposals will achieve the desired objectives. However, the improved monitoring and future regulatory mechanisms described in the Impact Statement are likely to address the identified issues.

Section 1: Diagnosing the policy problem

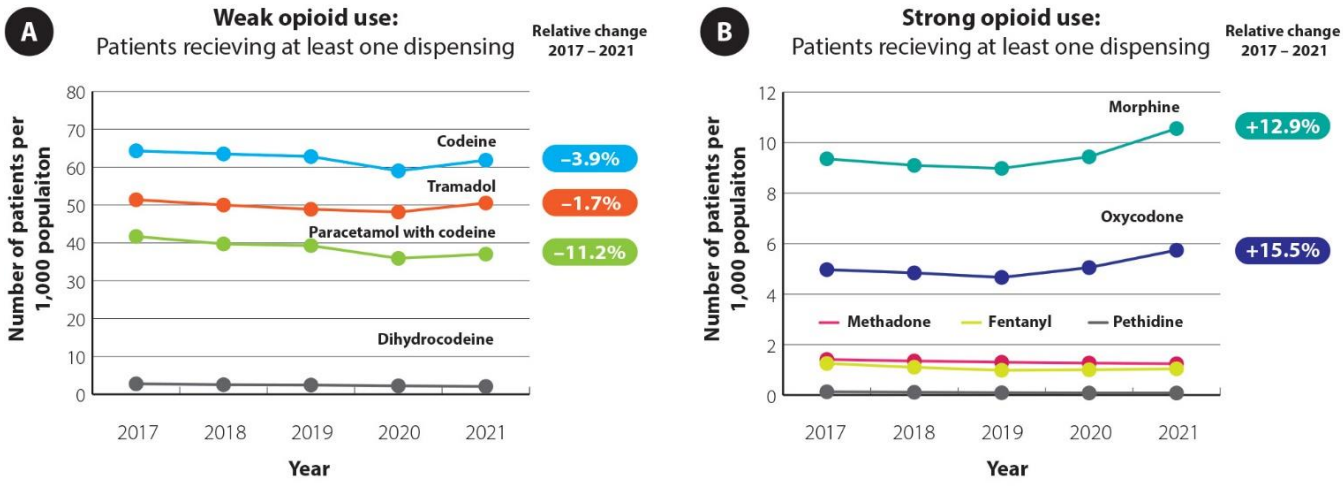
What is the context behind the policy problem and how is the status quo expected to develop?

Prescription opioids

Opioids (e.g. codeine or fentanyl) are important or essential pain medicines for many; however, they can also be addictive and cause significant harm when misused. Caution is therefore needed when prescribing opioids. They should only be prescribed in-line with best practice clinical guidelines to ensure appropriate access for patients to manage their pain. They are generally recommended for moderate to severe acute pain and for cancer pain. They are not recommended for chronic non-cancer pain due to concerns over the long-term efficacy and safety of treatment, including the risk of abuse, misuse and dependence.

There has been international concern over increases in opioid prescribing which has led to sharp increases in prescription opioid-related deaths and overdoses. Regulators have implemented various legislative changes and regulatory actions with the aim of limiting opioid harm in their jurisdictions.

Overall opioid use in New Zealand marginally declined between 2017 and 2021, however a small increase occurred between 2020 and 2021.



New Zealand has so far avoided the same level of harm experienced in other countries caused by inappropriate access to and misuse of prescription opioids.

Most prescribers of controlled drugs, such as opioids, prescribe safely and in the best interests of their patients. However, there are concerns among some New Zealand health professionals that even a small amount of inappropriate prescribing could lead to an increase in the misuse of prescription opioids and subsequent harm.

Recent changes to regulation of opioids

A number of controls and safeguards exist to manage the risk of inappropriate access to opioids. These include regulations that set out rules for prescribing and dispensing, clinical guidance that sets out appropriate practices, clinical support systems in provider settings, monitoring systems to review potential inappropriate prescribing, and professional sanctions where inappropriate prescribing occurs.

The Misuse of Drugs Regulations 1977 (the Regulations) set out the requirements for prescribing and dispensing controlled drugs, including opioids. The Regulations were created to provide additional controls for medicines that are considered to have a high risk of causing harm. The maximum period of supply, which limits how much of a controlled drug a health professional can prescribe, is one such control. The Regulations determine the maximum

period of supply for each type of prescriber (medical practitioner, nurse practitioner, midwife, etc.) and for each Class (A, B, C) of controlled drug.

Drugs are classified within the schedules of the Misuse of Drugs Act 1975 by their potential risk of harm, as either A (very high risk), B (high risk), or C (moderate risk). Medical practitioners, nurse practitioners and dentists are authorised to prescribe any Class of controlled drug under the Regulations (except for some subsets of controlled drugs that require Ministerial approval to prescribe).

Designated prescriber nurses, designated prescriber pharmacists and midwives are only authorised to prescribe specific controlled drugs that are listed in their schedules within the Regulations. These schedules contain a combination of Class B and C controlled drugs, primarily opioids and benzodiazepines.

Current prescribing maximums for controlled drugs by profession[1]

Profession	**Maximum period of supply (length of prescription)**	
	Physical prescription	**Electronic prescription (through NZePS)**
Medical practitioners:		
- Class B	1 month	3 months
- Class C	3 months	3 months
Nurse practitioners:		
- Class B	1 month	3 months
- Class C	3 months	3 months
Midwives:		
- Class B	1 month	3 months
- Class C	1 month	1 month
Designated prescriber nurses:		
- Class B	7 days	3 months
- Class C	7 days	7 days
Designated prescriber pharmacists:		
- Class B	3 days	3 months
- Class C	3 days	3 days

[1] These prescribing maximums are set by the Misuse of Drugs of Regulations 1977 (following the 2022 amendments). These are for a single prescription, a prescriber can issue subsequent prescriptions indefinitely.

Dentists: - Class B - Class C	 7 days 7 days	 7 days 7 days

In December 2022, the Misuse of Drugs Amendment Regulations 2022 (the 2022 amendments) came into force. These amendments increased the amount of Class B controlled drugs that certain professions could prescribe on a single prescription to a maximum of 3 months' supply. This increase was only applied to electronic prescriptions issued through the New Zealand ePrescription Service (NZePS).[2]

This change was made to increase access by reducing the frequency a patient would need to obtain a prescription for their medicines when dealing with a chronic condition. The primary intent of the amendments was to increase access to medicines used to treat attention deficit hyperactivity disorder (ADHD). The previous limits caused difficulties for ADHD patients in accessing their medicines and unnecessarily increased general practitioner and mental health practitioner workloads. Medicines used to treat ADHD include Class B amphetamines such as dexamphetamine or methylphenidate. While these drugs are controlled similarly to many opioids, they do not have the same risk profile. Treatment for ADHD is also usually long term, unlike acute pain treatment, so longer length prescribing is more appropriate.

However, some clinicians raised concerns after the 2022 amendments that the change in the maximum period of supply could increase the risk of harm from inappropriate prescribing of opioids (many prescription opioids are also Class B controlled drugs). Potential risks include:

- **medicine stockpiling** where drugs that extend beyond a patient's need are unused, which then may be used inappropriately or wasted
- **diversion of medicines** where the drug is prescribed to a person with a legitimate need but is then passed on to others without a legitimate need
- **addiction** arising from longer prescriptions.

Review of safe opioid access

In response to the concerns raised, Manatū Hauora reviewed the existing controls to determine if they are effectively managing the risk of opioid harm while enabling safe patient access.

The Safe Access to Opioids Working Group (the Working Group), made up of representatives from Manatū Hauora, Te Aka Whai Ora, Te Whatu Ora, Pharmac and Te Tāhū Hauora | Health Quality and Safety Commission was established in January 2023 to support the review.

While there was not a clear consensus amongst the Working Group that the 2022 amendments had significantly increased the risk of harm associated with Class B opioids, the Working Group agreed the maximum prescribing limit set by 2022 amendments are not appropriate given the risk profile of opioids.

[2] The NZePS enables a prescription to be generated by the prescriber, transmitted to the NZePS health information exchange broker, and downloaded electronically at a community pharmacy.

Through the review, the following controls have been identified as needing improvement to manage safe access to opioids:

- amending opioid prescribing regulation to be more in line with best practice and enable practitioners to prescribe appropriately
- more comprehensive monitoring capability, including further investment to take advantage of technology advances
- in the longer term, create a better mechanism for establishing prescribing and dispensing rules and guidelines for high-risk medicines.

Amending prescribing regulations for opioids, and controlled drugs in general, will require amendments to the Misuse of Drugs Regulations 1977.

The improvements to non-regulatory controls, that were identified in the review, will be progressed separately to the amendments. The review found that improvements to non-regulatory controls, such as monitoring and clinical guidance, will likely have a much stronger impact on safe prescribing practices than amending the Regulations.

Comprehensive monitoring capability

Medicines Control is a regulatory team within Medsafe that oversees the local distribution chain of medicines and controlled drugs within New Zealand. This includes monitoring how controlled drugs are prescribed.

Currently, Medicines Control will only become aware of inappropriate prescribing practices if someone reports a concern about a practitioner or organisation, or in response to a trigger (for example, through information identified during an audit process). This means that inappropriate prescribing can go on for some time, before it is reported, or it can go unreported. The Working Group identified the need for improved monitoring, to manage compliance with best practice, as essential for managing safe access to opioids.

Medicines Control does not currently have access to tools to easily monitor and identify inappropriate prescribing. Work is in progress to implement tools that will enable Medsafe to monitor the prescribing data more effectively (including in real time). This implementation is currently underway and is expected to be completed in 2023.

The Medicines Data Repository (MDR) is a database of prescribed and dispensed medicines information, currently managed by Te Whatu Ora. It is based on real-time information received directly from the NZePS.

Use of the MDR will enhance Medsafe monitoring capabilities by providing:

- a single source for prescribing data on all medicines and controlled drugs (NZePS data),
- real-time data,
- the ability to readily search large quantities of data across prescribers, pharmacies and medicines.

Real-time information on prescribing behaviours would help to identify inappropriate prescribing before significant harm is caused. This is essential information for professional regulators to be confident in the practices of the professions they regulate.

However, further investment is required to achieve more comprehensive monitoring. Manatū Hauora is committed to a more sophisticated level of monitoring capability and is exploring how resources could be allocated to achieve this.

A better mechanism for prescribing and dispensing rules

The prescribing regulations in the Misuse of Drugs Regulations were created to provide extra protections for medicines that are considered to have a high risk of causing harm, including dependence and abuse. These regulations were developed to restrict access to potentially harmful substances, rather than facilitating safe access to important medicines.

The restrictions set out within the regulations are also frequently criticised for being arbitrary, impractical, and not reflective of clinical views. Frequent amendments are necessary to these Regulations to adapt to changing models of care, best prescribing practices, access to new medicines and technology. Changing regulations also requires an extensive amendment process involving consultation, Ministerial agreement, the drafting of new regulations by Parliamentary Counsel Office, and approval by Cabinet.

There is an opportunity for significant change to the mechanism used for prescribing and dispensing rules through the new regulatory regime being proposed by the Therapeutic Products Bill (the TPB). This mechanism would be more appropriate than regulation for several reasons:

- **More responsive**: the rules would be created under the authority of the Therapeutic Products Regulator; the amendment process would be faster.
- **Better for patients**: the rules would be created to ensure safe access to opioids, which means that the impact on patients would be central to any restrictions.
- Allows a **more flexible** approach to prescribing authority that could enable a clinical review process for prescribing outside of normal parameters.
- Rules would be developed by those with the relevant clinical skills and experience; this would provide practitioners with the most up to date direction on **best practice**.

Work is underway to explore how this could be achieved under the new Therapeutic regulatory regime.

What is the policy problem or opportunity?

Current prescribing regulations for opioids, and other controlled drugs, are not appropriate to manage the risk of harm associated with these drugs, competencies of the prescribers, and the additional controls over prescribing outside regulation. The prescribing limits (also referred to as maximum periods of supply) within the Misuse of Drugs Regulations are complex and sometimes arbitrary, which can cause difficulties for prescribers.

Current limits for opioid prescribing are not appropriate

The 2022 amendments increased the amount of Class B controlled drugs that can be prescribed on a single prescription. This increased the maximum prescribing amount for Class B opioids to 3 months, which a recent review has identified is an inappropriate length of time for these drugs, in most circumstances. The 2022 amendments were intended to increase access for those with chronic conditions however clinical feedback has recommended that opioids are only appropriate for short term use.

Although 3 months is an inappropriate prescribing limit for Class B opioids, the review noted that due to additional controls it is highly unlikely that prescribing practise was substantively affected. Along with clinical standards and guidelines set by the professional regulators (such as the Medical Council), there are further controls set by the Pharmaceutical Schedule (administered by Pharmac) which limits funding to one month for Class B opioid

prescriptions. Returning the prescribing limits for Class B opioids back to one month would realign the Regulations with the Pharmac Schedule.

Opioids should be prescribed with caution and only for as long as is necessary. The findings of the Working Group, which was confirmed through engagement, is that opioids are not appropriate to treat chronic pain. While the Regulations do not dictate prescribing practises, the current Regulations allow too much of an opioid to be prescribed at once. Given the additional controls over prescribing practice there is also little utility in having different prescribing maximums for each profession.

If opioids (Class B or C) are prescribed, it should be at the lowest potency and dose to adequately manage pain, for the shortest possible duration.[3] One month is a more appropriate limit, which ensures regular clinical review, to be certain that a patient still requires opioids before being prescribed them further.

The review also identified that, for some prescribers, the current regulations allow longer prescriptions for Class B drugs than for Class C drugs, which needs to be rectified.

An exemption can be made for Opioid Substitution Treatment

The increase in prescribing limits, due to the 2022 amendments, did enable greater access to Opioid Substitution Treatment (OST) services, which can be maintained through an exception to any reduced prescribing limit for opioids.

OST services help people who have an opioid dependence to access treatment, including substitution therapy, which provides them with the opportunity to recover their health and wellbeing. Specialist OST services are specified by the Minister of Health under section 24A of the Misuse of Drugs Act 1975. OST services in Aotearoa are expected to provide a standardised approach underpinned by concepts of centring the person, family and whānau at the heart of treatment, recovery, wellbeing and citizenship.

A specialist service and the lead clinician of that service must be authorised under section 24A to provide OST services. Section 24A also allows the specified lead clinician to authorise other practitioners within the service to provide OST services. They must also adhere to the New Zealand Practice Guidelines for Opioid Substitution Treatment, issued by Manatū Hauora. This high level of oversight, over both the provider and service user, greatly reduces the risk of inappropriate prescribing of opioids.

Regulation should provide a reasonable framework for health service delivery

Controlled drug prescribing regulations should provide a reasonable framework that balances safety and access, and enables practitioners to provide the necessary care to their patients. The Regulations establish limits for the prescribing of controlled drugs. They are not intended to be a clinical guideline for prescribers on what is appropriate in specific circumstances.

There is an opportunity to amend the Regulations to provide more flexibility for managing safe access to controlled drug medicines. Responsible authorities (RAs) are statutory bodies (such as the Medical Council or Nursing Council) that ensure registered health practitioners are fully competent in the practice of their profession.[4] The functions of an RA include setting standards of clinical competence and promoting education and training within their

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[3] Best Practice Advocacy Centre New Zealand (bpac), https://bpac.org.nz/2022/opioids.aspx

[4] Health Practitioners Competence Assurance Act 2003

professions. Increasing prescribing limits in the Regulations will provide the RAs with the flexibility to more easily adjust their standards and education programmes when appropriate.

Clearer prescribing regulations will improve confidence in the system

The prescribing limits set by regulations are complex, sometimes arbitrary, and for some prescribers are not reflective of their competence. Navigating these limits can be challenging for both clinicians and consumers as they do not provide a reasonable framework for services to be delivered. This particularly affects those with limited access to specialist services, such as those in rural or remote areas, as they may primarily have access to prescribers with more restrictive prescribing limits (such as designated prescribers).

The variation in prescribing limits across professions, and for different types of drugs, has created unnecessary confusion for the health sector (this confusion was evident during engagement). This issue could be easily addressed through setting consistent limits across professions, combined with clearly communicated prescribing rules and standards.

What objectives are sought in relation to the policy problem?

The desired outcome is for prescribing limits set in the Regulations to provide a reasonable and clear framework to enable safe access to controlled drugs, particularly high-risk drugs like opioids. Right-touch regulation will appropriately balance access to controlled drugs with their risk of harm. The main objectives are to:

- ensure regular clinical review of people using prescription opioids
- maintain access to important medicines
- reduce pressure on medical and nurse practitioners
- fully utilise the skills of the available workforce
- provide flexibility for professional regulators to establish standards and best practice for their workforce.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

- *Safety*
  The option should set reasonable prescribing limits for controlled drugs that ensure appropriate clinical review is taking place to minimise the risk of diversion and patients developing dependence.

- *Access*
  Prescribing limits should not unreasonably limit access to controlled drugs. The option should also ensure that authorised prescribers are able to provide services that their patients need.

- *Cost to consumers*
  The option should not significantly increase costs of accessing health services.

- *Complexity of rules*
  The rules set by prescribing regulations need to be clear and understandable for both clinicians and the public. Straightforward rules would also aide monitoring and enforcement.

What scope will options be considered within?

The scope of feasible options was informed by the Working Group and stakeholder engagement. The targeted stakeholders included prescribers and dispensers of opioids, pain specialists, professional regulators and patient advocacy groups. Feedback from stakeholders indicated that improving monitoring capability and clinical guidance related to opioids would be beneficial. However, there was strong support for also amending current prescribing regulations.

The review determined that any option would need to:

- improve monitoring processes and capabilities, and prescribing guidance
- adjust the prescribing maximums for opioids to a more reasonable amount
- adjust prescribing regulations for all controlled drug prescribers to establish consistent maximums across professions.

Further regulatory amendments, outside of those within the current proposals, were tested during engagement. These included implementing a peer review process for long term opioid prescribing, an exemption from opioid prescribing limits for palliative care and cancer pain treatment and establishing a reduced dispensing maximum for opioids. These were based on similar regulatory actions taken by other countries, such as Australia, in response to opioid harms. However, it was determined that potential benefits of these options would be outweighed by difficulties in implementation and may place a burden on the health workforce.

The review also confirmed that the primary intent of the 2022 amendments, to increase access to ADHD medicines, had been successful. Further amendments to ADHD prescribing regulations were not considered.

What options are being considered?

Option One – [*Counterfactual*]

Under this option, no changes will be made to the Misuse of Drugs Regulations 1977.

This option will not address any increased potential for harm from overprescribing Class B opioids as there would be nothing in law to stop the issuing of a 3-month prescription for a Class B opioid.

Those who need these opioids for longer periods (cancer patients and those in palliative care) will face fewer impediments to accessing them. However, they may not get the level of clinical review required to manage their opioid use as the Regulations would not require it.

Under this option there would be the potential for more medicine wastage, stockpiling and an increased risk of diversion due to the amount of Class B opioids that could be accessed beyond clinical need.

Non-regulatory improvements will continue to be made to monitoring both in process and capability, clinical guidance will be issued to improve both public and clinical understanding of appropriate opioid prescribing.

This option would not address existing inconsistencies in prescribing limits for different professions that are causing confusion and reducing access to medicines.

Option Two – [*Small regulation change*]

Under this option, the Misuse of Drugs Regulations 1977 will be amended to reduce the maximum prescribing limit for Class B opioids from 3 months to one month. The effect of this will be to reverse the change made to Class B opioid prescribing limits by the amendments in 2022.

This will address the perceived risk of harm from allowing 3-month prescriptions for Class B opioids, however it will not address the risk from over prescribing of Class C opioids or the inconsistencies in prescribing limits.

Those who need Class B opioids for longer periods (cancer patients and those in palliative care) will face more impediments to accessing them. However, they will get the level of clinical review required to manage their opioid use.

This option reduces the risk of medicine wastage, stockpiling and diversion as fewer Class B opioids will be able to be accessed on a single prescription.

Under this option non-regulatory improvements will be made. This includes improvements to monitoring (both in process and capability) and new guidance to improve public and clinician understanding of appropriate opioid prescribing.

This option would not address existing inconsistencies in prescribing limits for different professions that are causing confusion and reducing access to medicines.

Option Three - [*Comprehensive regulation change*]

A comprehensive amendment to the Misuse of Drugs Regulations 1977 to:

- create a single prescribing limit for Class B and C opioids, of one month

- establish an exemption to the one month limit for prescriptions written by OST providers, i.e. allow the Medical Officer of Health to authorise OST prescriptions for up to 3 months
- align controlled drug prescribing limits for all controlled drug prescribers
- align prescribing limits for physical and electronic prescriptions.

This will set the maximum prescribing limit for **all** controlled opioids at a level that will reduce the potential for harm from overprescribing.

Those who need these opioids for longer periods (cancer patients and those in palliative care) could face more impediments to accessing them. However, they will get the level of clinical review required to manage their opioid use.

This option will help prevent medicine waste, stockpiling and potential for diversion by reducing the amount of opioids available.

This option would address existing inconsistencies in prescribing limits for different professions that are causing confusion and reducing access to medicines. This will reduce the costs for consumers who access their medicines through these prescribers.

How do the options compare to the status quo/counterfactual?

Key:					
++	much better than counterfactual	0	about the same as counterfactual	-	worse than counterfactual
+	better than counterfactual			- -	much worse than counterfactual

	Option One – *counterfactual*	Option Two – *small regulation change*	Option Three - *comprehensive regulation change*
Safety	**0** Improvements outside of regulation will progress. Improved monitoring, better clinical guidance and public education will all lead to safer opioid access. However, inappropriately long opioid prescriptions will be possible, increasing the potential for harm. Those who do need opioids over a longer period (cancer patients and those in palliative care) may not get the level of clinical review required to manage their health. Will not address the potential for harm from inappropriate Class C opioid prescribing amounts.	**+** Returning the maximum period of supply to 1 month for Class B opioids will address any increase in risk of inappropriately long prescriptions being issued (only for Class B opioids) thereby reducing potential harm. Will not address the potential for harm from inappropriate Class C opioid prescribing amounts.	**+ +** Returning the maximum period of supply to 1 month for Class B opioids will address any increase in risk of inappropriately long prescriptions being issued (only for Class B opioids) thereby reducing potential harm. Incorporating Class C opioids into the 1 month maximum will reduce the potential harm from these substances. Increased restrictions on maximum prescriptions for opioids will help prevent stockpiling within the community and reduce medicine waste. It will reduce the amount of opioids available for diversion.
Access	**0** Likely no impact on ability to access opioids. While regulations will still allow 3	**-** As this option would only impact Class B opioids there is unlikely to be any impact	**- -** Limits access to Class C opioids for those used to receiving three months

	month prescribing of Class B opioids, funding criteria, professional standards and clinical guidance will mean most prescribers will not issue three month prescriptions.	on access, prescribers have not changed behaviour since three-month prescriptions were allowed. Those who may need class B opioids over a longer period will face additional impediments to access prescriptions.	prescriptions from medical or nurse practitioners Will also remove some barriers to accessing controlled drugs (including opioids) through increasing prescribing maximums for designated prescribers, dentists and midwives. However, this impact will likely be minimal as practice is dependent on guidance and standards issued by professional regulators. Those who may need opioids over a longer period will face additional impediments to access prescriptions. Particularly those who currently use Class C opioids. Would allow longer opioid prescription for OST services in some cases to ensure uninterrupted access to treatment
Complexity of regulation	**0** This option would not address existing inconsistencies in prescribing regulations that are causing confusion.	**0** This option would not address existing inconsistencies in prescribing regulations.	**+ +** This option will significantly simplify the maximum prescribing limits across different types of prescribers This will set consistent maximums in legislation for prescribers and allow practice to be determined by clinical guidelines and standards set by professional regulators

Cost to consumers	**0** No cost impact to consumers, some costs remain due to different limits between professions.	**-** Since the 2022 amendments Pharmac funding criteria has not been amended to fund 3-month prescriptions for Class B opioids so no impact on current costs of filling prescriptions. Patients whose clinical conditions require longer term opioid use (cancer and palliative patients) will face additional costs due to more frequent prescribing required.	**-** Due to the reduced maximum prescribing amount for Class C opioids, there will be a potential increase in costs if more than 1 month of opioid required due to more frequent appointments with prescribers. There is potential for a reduction in costs for some consumers associated with the increase in prescribing limits for some prescribers.
Overall assessment	**0** Improvements will continue to be made to the controls (outside of regulations) that can impact access to opioids and other controlled drugs. These improvements will likely increase safety of opioid prescribing however issues with the prescribing limits on opioids being too high will remain unresolved. Additional regulatory issues such as inconsistent and complex prescribing limits for some prescribers would also remain.	**0** This option will address the immediate concerns raised following amendments in 2022 that increased the maximum prescribing amount for some opioids. This option will not address many of the safety issues from prescribing limits on opioids that were identified in the review.	**+** This option will result in more appropriate regulation for opioid prescribing. This will ensure that prescribers are required to review patients currently on opioids, at least once per month. The tighter controls on opioids may also result in improved prescribing practices. This option will address the complex prescribing limits that many practitioners find confusing, and will provide a more flexible regulatory framework, with appropriate limits.

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Option 3 is the preferred approach

A comprehensive amendment to the Regulations is the preferred approach as it addresses the key issues with the regulations that were identified by Manatū Hauora's recent review. Creating a specific prescribing limit for opioids (both Class B and C) will provide a safer maximum which is suitable for most situations and will decrease the risk associated with inappropriate prescribing.

It also sends a clear signal about the level of risk these medicines pose.

Option 3 is also the preferred option to improve access to medicines through designated prescribers and to address the inconsistencies and complexities in the current regulations.

While this is the preferred approach, it is acknowledged that regulatory change will not have a significant impact on improving safe prescribing practices for opioids, or other controlled drugs. The prescribing limit, within regulation, is still higher than the clinically recommended maximum in most circumstances and there is no regulation preventing indefinite repeat prescriptions.

Continued investment in improved monitoring system combined with better enforcement and strengthened clinical guidance will likely have the largest effect on prescribing practices and ensuring medicines are being delivered safely.

Section 3: Delivering an option

How will the new arrangements be implemented?

The preferred option would be given effect through an amendment to the Misuse of Drugs Regulations 1977.

Implementation of the regulation changes will not require significant changes in practice for most clinicians, as the proposals will only affect maximum prescribing amounts.

Manatū Hauora would develop a communications plan along with relevant health agencies, responsible authorities (professional regulators), and professional bodies to ensure these changes are well communicated to the health workforce and the public.

It is important to communicate the rationale and impact of the new regulations as well as the other improvements which are happening alongside, such as improved monitoring capabilities.

How will the new arrangements be monitored, evaluated, and reviewed?

Manatū Hauora and Te Whatu Ora would closely monitor the impacts of the new regulations through the new monitoring system currently being implemented, the Medicines Data Repository. The transition to this new system is currently being finalised and expected to be completed in August 2023. Further development of Manatū Hauora's monitoring capability has been prioritised.

Manatū Hauora will carry out a review of controlled drug access 12 months after commencement of the amendment regulations. This review will focus on the impacts of the amendments on patient access and prescriber behaviour. It will also assess the progress of implementing improved monitoring capabilities across Manatū Hauora and Te Whatu Ora.