Regulatory Impact Statement: Overview of required information

Regulatory Impact Statement

Amending references to health practitioners in relation to opioid substitution treatment and certification of cause of death

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry of Health.

It provides an analysis of options to change two unnecessarily restrictive statutory references from medical practitioners to health practitioners. The net impact is to ease regulatory restrictions in the health sector.

It has not been possible to quantify the benefits of the proposed change. However, there are clear benefits and identifiable costs are minimal.

The proposal does not:

- impose additional costs on businesses
- impair private property rights, market competition, or the incentives on businesses to innovate and invest, or
- override fundamental common law principles.

Brenda Wraight
Director, Health Workforce New Zealand

[Signature] [Date]

Status quo and problem definition

1. At present, certain statutory functions are reserved to medical practitioners. For example, the Holidays Act 2003 only allows medical practitioners to provide a certificate as proof of sickness, and the Land Transport Act 1998 only allows medical practitioners and optometrists to provide medical reports on persons unfit to drive. These restrictions impose unnecessary costs on practitioners and the public.

2. Currently, practitioners with the competencies and knowledge to perform a particular statutory responsibility are unable to legally do so. This creates unnecessary costs for the public, who must often wait and pay to see a doctor when another practitioner could carry out an examination or assessment in a more timely and cost-effective manner. The current legislation also creates a barrier to innovative practice, and with practitioners making the best use of their time and resources. As the demand for health services continues to grow, it is becoming increasingly important that barriers to innovation and greater efficiency in service delivery are removed.

3. Without change to statutory provisions, health services will continue to 'work around' the legal requirements. For instance, a nurse, nurse practitioner or allied health professional may undertake a clinical assessment but a medical practitioner will sign the associated form. Such situations are onerous for the service, inefficient, a barrier to innovative practice, and may place the medical practitioner in a legally risky situation.

4. A working group convened by the Ministry of Health in 2010 compiled a list of 59 legislative provisions that unnecessarily restricts particular activities, powers or rights to doctors. Health sector and government agency stakeholders then identified provisions in eight Acts as priorities for change because they would have a significant impact on practice and service delivery.

5. In October 2011 Cabinet agreed to make six of the amendments, which all replaced the term 'medical practitioner' with 'health practitioner' [SOC Min (11) 21/4]. These amendments have been drafted as the Health Practitioners (Statutory References to Medical Practitioners) Bill, which is an omnibus bill that will amend the Health Practitioners Competence Assurance Act 2003 (HPCA Act) and each relevant statute.

6. The current paper covers two further proposed amendments, one of which was on the list of eight priority statues for change, and one of which has been proposed by the mental health and addiction sector. Proposed amendments are listed in Table 1 below.

Table 1: Legislative Provisions to Address

Department Responsible	Legislation	References Identified
Ministry of Health	Burial and Cremation Act 1964	• Only doctors can sign Medical Certificate of Cause of Death (MCCD)
Ministry of Health	Misuse of Drugs Act 1973	• Only doctors can prescribe controlled drugs

Authority to sign MCCD

7. In the case of the Burial and Cremation Act, only doctors can sign the Medical Certificate of Cause of Death (MCCD). Problems arise, particularly in remote places and outside normal working hours, when a doctor is not available to sign the MCCD. The effect of the MCCD not being signed is that the undertaker and/or family does not have the legal right to remove the body and prepare it for burial, cremation or tangi. The impact of restrictions on death certification is most obvious outside normal working hours, when removal and preparation of the deceased for burial is delayed.

8. The problem with the status quo is that, where a doctor is not available to sign the MCCD, the family may not be able to uplift the body and progress either burial or cremation. Often the MCCD is not signed for several days after the death, often due to high doctor workloads or difficulty contacting the attending doctor. In some cases the nurse is the health practitioner who is most knowledgeable the patient's health status.

9. In some cases doctors can be pressured to sign an MCCD in situations where they do not necessarily have the information to properly assess the cause of death. In addition, some employers in the aged residential care sector have signalled a reluctance to hire health practitioners who are not doctors because of restrictions around death certification.

Nurse prescribing for OST

10. In the case of limitations on prescribing for opioid substitution treatment (OST) to registered doctors set out in the Misuse of Drugs Act, the problem that exists is that there is significant unmet need for OST. Approximately 5000 people who are addicted to opiates are not accessing OST. As well as affecting quality of life this also contributes to crime committed by addicts to support their habit. OST has a clear track record of preventing and reducing the health, social and economic harms that are linked to the use of opioid drugs.

11. The small number of registered doctors in addiction treatment means that access to OST is difficult and often is delayed more than is medically and socially appropriate.

Objectives

12. The objectives of the proposed legislative changes are to make it easier for the public to access statutory services from health practitioners; and to facilitate timely and effective treatment for patients.

Regulatory impact analysis

13. As the problem in both cases set out above is caused by statutory references, solving it will require statutory change. Two options have been identified:

    Option one: changing references to 'medical practitioners', so they become references to 'health practitioners';

    Option two: adding references to other specific practitioners where 'medical practitioners' are currently specified.

14. Neither option imposes costs on patients or practitioners.

15. Either option would allow a wider variety of practitioners to carry out certification of death or prescribe for OST, with benefits to the public in terms of faster access to appropriate services and reduced delays. The changes would also facilitate increased productivity overall, through better use of practitioners' expertise and time.

16. It is not possible to quantify the benefits of these changes ex ante. However, there are clear benefits in terms of service delivery and access.

17. The Ministry of Health prefers option one for certification of death, as it addresses the immediate issue while also allowing for future flexibility as practice changes and roles are developed. In this case there is no need to specify particular classes of practitioner, as a practitioner's competence to carry out a statutory function will be governed through a scope of practice.

18. The Ministry prefers option two for prescribing of opioid substitutes. In this case it is appropriate to clearly circumscribe and limit which groups can prescribe for OST because the drugs involved are dangerous and can be diverted, i.e. traded on the black market.

Consultation

Authority to sign MCCD

19. As noted above, the ability to sign the Medical Certificate of Cause of Death (MCCD) through the Burial and Cremation Act was identified through a sector consultation process as one of the top eight priority statutes for change.

20. The Law Commission then began its review of the Burial and Cremation Act. The Commission published an Issues Paper for wide consultation in May 2011. The Issues Paper focused on death certification and specifically asked (among other questions) whether the authority to sign MCCDs should be extended to nurse practitioners who had been the person's lead carer. Of 21 submissions that addressed this question, five were opposed.

21. Overall, the sector was in favour of the proposed amendments as they would improve efficiency, reduce some of the workload burden on doctors, and enable other professions to use more of their skills. Submitters from nursing organisations and legal/coroner perspectives were supportive of the proposed changes, while some medical practitioner and groups opposed the changes. The arguments of those in opposition were somewhat opaque, but the implied reasons were related to standard of care and standard of completion of the MCCD.

Nurse prescribing for OST

22. Health sector stakeholders were consulted separately on the proposal to widen the ability to prescribe controlled drugs to treat drug dependency in 2013. Of eleven directly-affected workforce groups that responded, one (New Zealand Medical Association or NZMA) opposed the proposal. Although they opposed the proposal in its current form, NZMA noted that under controlled settings, extending delegated prescribing rights to suitably trained nurses to prescribe OST drugs may be appropriate.

23. Interested government agencies were also consulted on the proposals. Those agencies did not request any changes to the paper or the Regulatory Impact Statement.

Risks

24. There are some perceived risks associated with the proposed amendments raised in consultation. At a high level these were:

    - Other health practitioners who are not subject to the same accountability mechanisms as doctors, will be undertaking statutory functions beyond their competence, and this will be a risk to patient and public safety
    - Other health practitioners have not had the same level of training as doctors
    - Other health practitioners may not have trained in diagnosis and therefore should not be undertaking death certification or prescribing.

Authority to sign MCCD

25. Consultation demonstrated that there was a perception held by some that other health professionals may be less responsible than medical practitioners in performing the activities and may apply less rigour when certifying death. There is no substantive evidence that this will occur. The safeguards on medical practitioner conduct and performance apply equally to all health practitioners regulated under the HPCA Act. Each health regulatory authority operates a complaints system for its workforce.

26. Health practitioners are governed by the HPCA Act, which requires that health practitioners may legally only undertake professional functions within their scope of practice. Existing safeguards on practitioner competence and practice through the HPCA Act and the Code of Health and Disability Services Consumers' Rights will still apply. Under section 8 of the HPCA Act, health regulatory authorities are responsible for ensuring that health practitioners are fit and competent to practice and ensure that they do not practise outside their scope. Therefore, only health practitioners qualified to undertake the specific activity would be able to do so under the law changes proposed.

27. In some cases, decisions based on the advice of health practitioners are open to legal challenge and practitioners may need to defend their advice in court. All health practitioners covered by the HPCA Act are accountable for their practice. Health practitioners cannot be compelled to perform activities for which they do not feel sufficiently competent. Those that choose to perform the statutory functions must be prepared to defend their practice.

28. The nature of the activity and scopes of practice will limit which types of health practitioner can perform the activities, just as they currently ensure only medical practitioners with an appropriate scope of practice can perform the activities now. For example, conducting physical examinations of children suspected of being victims of abuse would fall within the scopes of practice of general practitioners, some medical specialists, nurse practitioners, and registered nurses. It would not fall within the scope of practice of other health practitioners such as dieticians, dental therapists or medical laboratory scientists.

29. The requirement that only appropriately qualified health practitioners can perform the statutory functions would be emphasised through the interpretation section of the relevant Acts. The definition of a health practitioner in the interpretation sections will specify that they must be working within their scope of practice.

30. Submitters have emphasised the importance of newly authorised practitioners receiving appropriate training, credentialed competence, guidelines and scopes of practice.

Nurse prescribing for OST

31. An argument raised by some doctors has been a perceived risk that approved nurses, when asked to prescribe a controlled drug, may not be capable of providing a complete and thorough health assessment for the patient including specialist diagnosis, considering the full range of mental and physical health issues, to a standard comparable to that expected of a medical practitioner. The concerns around widening the group who can prescribe controlled drugs, which are by definition dangerous, have led the Ministry to restrict this proposal only to suitably qualified health professionals. Only doctors and nurses who are authorised by their regulatory authority to undertake comprehensive health assessment, undertake diagnosis and prescribe treatments on a broad range of health issues and problems, will be legally able to prescribe opioids for dependency. In addition, only nurses who are working in a specialist service with the approval of that service's lead medical practitioner will be able to prescribe.

32. Currently nurse prescribers in New Zealand hold level 8 National Qualifications Framework qualifications (Masters level), which reflect education in physiology, pharmacology, advanced health assessment/diagnosis and prescribing. Other nurses prescribing for opiate dependency will be required to have level 8 qualifications and credentialed to work in an approved service.

33. Any complaints against nurse prescribers will be dealt with by the Nursing Council under the Health Practitioners Competence Assurance Act. If a complaint arises about a nurse's prescribing, the Nursing Council will act in accordance with the HPCA Act in dealing with such complaints. The Council has a range of potential responses to inappropriate prescribing according to the circumstances – from support to training to deregistration.

34. The list of medicines that could be prescribed by nurses under the amended MODA would be limited to a small group of medicines that would be included in a schedule to the Misuse of Drugs Regulations. The list of nurses with the ability to prescribe OST would be published in the Gazette pursuant to section 24(7)(a) MODA or an equivalent new subsection.

35. An amendment would also be required to regulation 21(4B) to enable the prescribing for a period of supply greater than three days by a nurse in an OST setting.

36. This risk could be further mitigated by enabling central monitoring of buprenorphine prescribed by all prescribers for OST (as central monitoring of methadone is currently enabled). This would enhance accountability for those prescriptions and would be achieved by amending Misuse of Drugs Regulations 29(1) and 35(2).

37. The current preparation of buprenorphine prescribed in OST settings has the trade name suboxone, which is a combination of buprenorphine (Class C4 controlled drug) and naloxone. Prescriptions for Class B drugs must be written on a triplicate controlled drugs prescription form that ensure a copy goes to the Medical Officer of Health, Medicines Control. Buprenorphine prescriptions are exempted by regulation 29(1)(a)(ii). Officials propose that this exemption be removed so that prescriptions for buprenorphine must be written on a triplicate prescription form, enhancing accountability[1]. To further strengthen accountability, regulation 35(2) should be amended to require dispensings of buprenorphine to be reported to the Medical Officer of Health, Medicines Control (this is already required for methadone).

38. The effect of amendments to regulation 29(1) and 35(2) would be to put tight requirements around what information must be included in each script e.g. full details of the prescriber and patient, and ensure that each prescription for OST is copied to the Medical Officer of Health, Medicines Control in the Ministry of Health.

39. Finally, stakeholders note that nurse prescribers should only be able to prescribe up to the level indicated in the Ministry's OST Guidelines, which are promulgated to all DHBs. The requirement would be communicated through the Nursing Council. Compliance with the guidelines could be monitored through the reporting of relevant dispensing to the Medical Officer of Health, Medicines Control.

40. Officials anticipate that there will be costs associated with this proposal, but these will be minimal for the next few years. The Ministry estimates that there are likely to be up to three nurses eligible to prescribe for OST by the time the Amendment Bill is passed. This number will slowly increase over time to meet the demand. The additional cost will be in pharmaceutical prescribing will be balanced by reduced harm to individuals through quicker access to safe treatment, and reduced costs in healthcare and the police/justice sector (opioid addicts often commit crime to fund their habit, and of course non-prescribed possession of most opioids is illegal).

Communications

41. Much of the perceived risk can be mitigated by communications to ensure that health practitioners know what scope of practice is required to perform the statutory functions, and legal and professional obligations associated with performing the activities. These communications will be delivered through the respective regulatory authorities.

42. In the case of the Misuse of Drugs Act, any nurse who is appropriately qualified to prescribe controlled drugs would need to be specified by name, by notice in the Gazette, just as medical practitioners are currently required to be.

43. Existing communications and guidelines for medical practitioners on the functions will be updated to reflect the changes. Some targeted public education may also be appropriate to inform people of the changes, for example through notices in practices and clinics.

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[1] An additional amendment to regulation 29(1)(b) would provide a mechanism to approve prescribers working within an OST clinic to print these prescriptions with computer text (rather than hand writing) for buprenorphine, which would reflect the current status for prescriptions written for methadone).

Conclusions and recommendations

44. The Ministry recommends amending the Burial and Cremations Act 1964 so that references to ‘medical practitioners’ become references to ‘health practitioners’. The Ministry also recommends amending the Misuse of Drugs Act 1975 section 24 so that specified medical practitioners and nurses in specified settings can prescribe for opioid substitution treatment.

45. The general reference to health practitioners also allows flexibility for the future and avoids the possibility of having to make a similar legislative change in the future.

Implementation

46. Legislation will be required to implement the changes. The amendments will be incorporated into the Health Practitioner (Statutory References) Bill. This bill has a priority 5 on the legislative programme.

Monitoring, evaluation and review

47. The Ministry will monitor the impact of the legislative changes through central monitoring functions. The proposed change is expected to have benefits, small costs in pharmaceutical subsidies, and no costs to patients.