Continuous Improvement in Health and Disability Services

A discussion paper on the review of the Health and Disability Services (Safety) Act 2001

Citation: Ministry of Health. 2007. *Continuous Improvement in Health and Disability Services: A discussion paper on the review of the Health and Disability Services (Safety) Act 2001*. Wellington: Ministry of Health.

Published in July 2007 by the
Ministry of Health
PO Box 5013, Wellington, New Zealand

ISBN 978-0-478-19175-2 (Online)

HP4446

This document is available on the Ministry of Health's website:
http://www.moh.govt.nz

MANATŪ HAUORA

Contents

Introduction 1

The discussion document 1

The submission form 1

Regulatory impact analysis 1

Your submission 1

The review process 2

Discussion Document Health and Disability Services (Safety) Act 3

Background 3

The review 4

Issues for your consideration 6

Submission Form Health and Disability Services (Safety) Act 11

Information about you 11

How to make a submission 15

Appendix 1: Code of Good Regulatory Practice 16

Efficiency 16

Effectiveness 16

Transparency 17

Clarity 18

Equity 18

Introduction

This document consists of a discussion document on certain aspects of the review of the Health and Disability Services (Safety) Act 2001 and a submission form to guide individuals and organisations making a submission.

The discussion document

The discussion document provides information on the current situation, a brief outline of the range of approaches towards healthcare regulation found internationally, what problems there are at the present time, and what the review will consider to address those problems.

The submission form

The submission form, found at the end of this document, asks you questions about the information contained in the discussion document.

Answer as many or as few questions as you wish. Where you can, please provide any examples or summarise your experience in support of your submissions.

Regulatory impact analysis

The discussion document and submission form include substantive regulatory impact analysis elements. A formal regulatory impact analysis (analysis of regulatory proposals), designed to improve the quality of regulatory interventions, is required to support most proposed changes to government regulations. The document outlines problems and options and asks for your input on the impacts of the options. Your feedback on the impact of options, including staying with the status quo, will contribute to the regulatory impact analysis that will help government decision-makers with their decisions.

There is also an appendix with the Code of Good Regulatory Practice. This is referred to in the discussion document.

Your submission

Submissions should be emailed or posted to arrive by Friday 21 September 2007.

Electronic submissions are encouraged as they aid our analysis.

Word or pdf versions of the submission booklet can be downloaded from the Ministry's website: www.moh.govt.nz.

Electronic submissions can be emailed to: safetyactreview@moh.govt.nz.

Postal submissions should be posted to the address on the front cover of this booklet.

Please note

That any submission you make may be the subject of a request under the Official Information Act 1982. The withholding of particular submissions on the grounds of privacy, or for any other reason, will be determined in accordance with that Act.

The submission form asks you to indicate if you:

- are happy for your submission to be released; or
- would like to be consulted prior to release.

The review process

A document providing a summary of submissions will be posted on the Ministry of Health website after the analysis has been completed.

The Ministry will be making recommendations to the Government later this year.

The government will present the amended Health and Disability Services (Safety) Bill to Parliament at a time yet to be determined.

There will be an opportunity to have further input after this consultation at select committee hearings.

Discussion Document
Health and Disability Services (Safety) Act

Background

1. The Health and Disability Services (Safety) Act

The Health and Disability Services (Safety) Act 2001 (the Act) came into force on 1 July 2002, replacing the previous licensing regime for providers of health care services under the Hospitals Act 1957, Disabled Persons Community Welfare Act 1975 and Old People's Homes Regulations 1987.

The main aims of the Act are to keep consumers in health and disability services safe, while encouraging providers to continuously improve those services. The Act is intended to be enabling rather than intensely prescriptive.

The safety regime in this Act is separate from, and in addition to, the regimes under other legislation such as the Building Act 2004, Fire Service Act 1975 and their regulations. Those Acts and regulations are concerned with the overall safety of all buildings and their occupants. The Health and Disability Services (Safety) Act 2001 is concerned with the safety of the healthcare services and disability support services that are provided in and outside of buildings.

2. Certification

The Act establishes a certification regime whereby specified heath and disability services must be certified by the Director-General of Health (DG) in order to provide those services. It is an offence under the Act to provide relevant health and disability services without a current certificate. Since 1 October 2004 all relevant services must have a certificate before they can legally deliver health and disability services.

3. Coverage

The Act applies to hospital care, residential disability care, and rest home care. However, these services are defined so that residential disability services with fewer than five people and day surgical services are not covered.

The Act also applies to any 'specified health or disability services' declared by Order in Council to fall under the Act. Fertility services are the only services to be added to the scope of the Act thus far.

4. Standards

To become certified, services are assessed against standards approved by the Minister of Health. The standards are developed by the sector with public consultation and are focused on outcomes for consumers. For example, while the standards require rooms to be large enough to allow freedom of movement, they do not specify actual dimensions. The current health and disability service standards are:

- Health and Disability Sector Standards
- Infection Control Standard
- Restraint Minimisation and Safe Practice Standard
- National Mental Health Sector Standard.

The DG cannot certify a service unless satisfied that it complies with the relevant standards.

5. Audits against standards

To support their applications for certification, providers give the DG audit reports as evidence of service compliance with the approved standards. Audits are carried out by independent audit agencies designated by the DG. There are currently eight such agencies. Providers choose one of these designated audit agencies (DAAs) and pay for their own audits. The DG uses the audit reports and any other relevant information when deciding whether to certify a service.

6. Improvements since the Act came into force

The Act has resulted in significant improvements in the safety and quality of health and disability services. One of the main differences between the old regime and the current one is a change in focus from details such as the size of rooms and number of hand basins in a facility, to the quality of the health and disability services provided. Upon the implementation of the Act several providers recognised their services were unlikely to meet the required standards and voluntarily discontinued their services. A few other services have since been closed by the DG because of their failure to meet the required service standards.

The review

7. Why we are reviewing the Act

The Minister of Health has asked the Ministry of Health to review the Act. One reason for the review is that the experience of the past five years has shown that the Act does not adequately give effect to some aspects of the policy intent and is ambiguous in places. Most significantly, although the Act makes the DG and the Minister of Health accountable for the safety of health and disability services, it does not provide them with sufficient powers to enforce safety and quality, nor does it provide sufficient incentives and rewards for quality improvements.

8. Scope of the review

For the most part, the aims of the Act will not change. In particular, there is no intention to move away from the focus on quality and continuous improvement of services. The focus on outcomes rather than inputs will be retained, in keeping with the government's Code of Good Regulatory Practice.

In short, rather than focusing on big policy changes, this review is designed to make the legislation work better to achieve the same aims. The review will explore:

- strengthening the DG's enforcement powers
- clarifying the certification process
- clarifying definitions
- extending the coverage of the Act
- the provisions around DAAs
- clarifying the process for exempting providers under the Act.

This review is linked to a separate review of the Health and Disability Service Standards that is currently under way. That review is focused on improving consistency between the four health and disability service standards listed in section 4 above. Standards New Zealand released the draft reviewed standards for public comment in late June 2007. Submissions close in early September 2007 with publication of final approved standards scheduled for December 2007.

9. Scope of this consultation

While there will be opportunities to discuss all of the changes with stakeholders as this review of the Act goes through the legislative change process, there are some issues on which we seek input before we progress further. These issues are:

- establishing sanctions to strengthen the DG's enforcement powers and underpin a streamlined certification process
- extending the coverage of the Act
- the provisions around DAAs.

10. Regulating healthcare

Healthcare and disability support services regulation is a social construct reflective of a country's culture. Different cultures generally deal with regulatory problems using one of two approaches (or a mixture of both). The first approach assumes that all providers are not to be trusted and seek to benefit themselves rather than consumers. Regulators using this approach make extensive use of prescribed inputs and inspections and quickly resort to sanctions or penalties for all non-compliance. The second approach assumes that providers are generally worthy of trust and support and that failure to deliver safe and quality services is attributed to a lack of knowledge or competence. Regulators using this approach focus on providing guidance, support and advice and only use sanctions or penalties as a last resort.

Both approaches have their drawbacks so it is preferable to use a regulatory model that is an amalgam of both approaches. This modern model of healthcare and disability support services regulation is focused on performance improvement with interventions proportionate to the size and importance of the issue. Under this model, information about the regulatory process is freely and widely available and the regulator is mindful of the costs of regulation, including the cost-benefit trade-off of any proposed new regulatory interventions. Regulators using this model use a range of incentives and sanctions to influence service providers to deliver safe and good quality services.

The current Act enables a modern approach to regulating the health and disability sector which is in keeping with the government's Code of Good Regulatory Practice. In particular, the Code emphasises transparency and having efficient and effective regulation that balances the need for effective enforcement with ensuring the benefits of regulation outweigh the costs. Our performance against these principles can be further strengthened in the review of the Act by some adjustment to the certification system.

We will be using the principles in the Code of Good Regulatory Practice to guide the review. A copy of the Code is found in Appendix 1.

Issues for your consideration

11. The proposed infringement regime

a) The current situation

At present there are a number of offences under the Act that are serious and attract large penalties. These offences happen infrequently, and they involve convicting a person through the courts and are used only as a last resort.

For example, it is an offence to provide health care services without a current certificate or while a closing order relating to the premise is in effect. This kind of offence attracts a fine of up to $50,000.

There is also provision for a fine of up to $1000 relating to enforcement, such as intentionally obstructing an authorised person from inspecting a service.

In addition, when a service is unsafe or not meeting standards, the DG *must* cancel the certification and may, under certain circumstances, issue cessation or closing orders.

b) Problems with the current situation

These ways of enforcing compliance have a number of problems for providers, the DG, and ultimately consumers. The problems include:

- the DG has no tool for deterring high frequency and/or low seriousness transgressions such as failing to apply for recertification in time and/or not reporting progress with conditions of certification
- the DG must cancel certification if a provider fails to meet all relevant standards, even if it would be more appropriate to employ some lesser penalty and require the provider to fix the problem.

c) Changes we will consider in the review

We are investigating an infringement regime that allows the DG to use interventions that are proportionate to the seriousness of transgressions and that encourage compliance.

The model we propose is a hierarchy of sanctions that would reflect the seriousness and frequency of infringements. The intention of the sanctions is to encourage

compliance and allow certification and recertification processes to become smoother and faster.

High frequency / low seriousness transgressions

High frequency/low seriousness infringements (such as a provider failing for apply for recertification in time for it to be processed before the current certificate expires) could be subject to a fine. Fines would be set at the lowest level that will encourage compliance. In time, we would hope that fines would never be issued as providers become fully compliant.

Failing to meet standards

More serious problems such as not meeting all of the standards would be assessed for seriousness and risk to consumers and staff. There would be appropriate responses available for the different sorts of failures.

For example, the system could operate as follows:

- Low risk/low seriousness: a shorter certificate length with conditions that the problems be rectified within a certain time.
- Significant risk/moderate seriousness: a statutory manager may take control of a service to restore/maintain safety.
- High risk/high seriousness and offences: closure and/or conviction (as is the case with the current regime).

It is important to note that services will continue to be expected to comply with all relevant standards.

Exemplary providers

We expect that this infringement regime would be complemented by more emphasis on rewarding and encouraging exemplary providers. There are a range of approaches that may be taken such as the current ability to give services longer certification periods and fewer audits. While these are already possible under the Act, we would like to take this opportunity to seek your input on what would reward and encourage exceptional quality and safety.

Questions for your feedback are found in the submission form at the end of this document.

12. Extending the coverage of the Act: Residential disability care

a) The current situation

At present residential disability care is defined as:

> Residential care provided in any premise for five or more people with an intellectual, physical, psychiatric, or sensory disability (or a combination of two or more such disabilities).

Residential disability care services in 'any premises' with fewer than five people are not subject to the Act and therefore are not required to be certified.

b) Problems with the current situation

There is a philosophical view that residences with fewer inhabitants are more appropriate and more like private homes than are residences housing larger numbers and therefore should not be subject to statutory oversight. For instance some express a view that:

> The requirements of certification to improve safety could be seen to impede the 'ordinary' life of people living in them, which is important to the disability sector and people with disabilities. There is therefore a tension between safety and rights that needs to be acknowledged.

Some service providers, however, choose to accommodate fewer than five consumers in each of a large number of residences in order to avoid the need to comply with statutory requirements under the Act. It seems illogical that five or more consumers in residential disability homes have statutory protection while similar consumers in residences with fewer than five people do not benefit from this statutory protection.

c) Changes we will consider in this review

We will consider the desirability of all residential disability services being covered by the Act, even if there are fewer than five consumers in each premise. The proposed new definition of residential care would not, however, include people looking after their own family members.

None of the changes we will consider will impact on other Acts and regulations relating to building and fire safety and residential tenancy protection.

Questions for your feedback are found in the submission form at the end of this document.

13. Extending the coverage of the Act: Day surgical services

a) The current situation

At present, the definition of hospital care is:

> Services that are children's health services, geriatric services, maternity services, medical services, mental health services, or surgical services (or services of two or more of those kinds) provided –
>
> (a) in premises held out by the person providing or intending to provide the services as being capable of accommodating two or more of the people for whom the services are provided for continuous periods of 24 hours or longer; and

(b) in consideration of payment (whether made or to be made, and whether by the Crown, the people for whom the services are provided, or any other person).

b) Problems with the current situation

Day surgical services are becoming increasingly common and many of the safety and quality issues that affect hospital surgical services also affect day surgical services. It therefore seems illogical that day surgical services would be outside the coverage of the Act.

In addition, some day surgical service providers have requested that they be covered by the Act so they can assure their patients of safety and quality and can avail themselves of the quality improvement framework in the Act.

c) Changes we will consider in the review

We would like to remove the part of the definition that says 'for continuous periods of 24 hours or longer', so that day surgery would be covered by the Act.

Questions for your feedback are found in the submission form at the end of this document.

14. The provisions around Designated Audit Agencies (DAAs)

a) The current model

At present, relevant services are audited against Standards every time they need a new certificate, and in the middle of a certification period (surveillance audits). The DG will only give relevant services a certificate if satisfied that the service complies with all the relevant standards. The DG uses the audit reports and any other relevant information when deciding whether to certify a service. The audit reports are a very important piece of evidence for the DG.

Audits are carried out by independent audit agencies, which are private organisations that meet provisions in the Act and are designated by the DG. Providers choose and pay one of the DAAs to conduct their service audits. There are currently eight DAAs.

b) Concerns about the current model

Since the Act came into force, and with most services having one round of audits behind them, some have expressed concerns about a perceived conflict of interest with DAAs being selected and paid for by the services they are auditing. For instance Eileen McKinlay (a lead quality auditor, nurse and academic) said in *Kai Tiaki Nursing New Zealand* magazine (March 2007) that DAAs may be seen as having conflicts of interest and be under pressure to provide "good audits".

Others have expressed concern that there is no consistency between DAAs, such that some providers may be being held to a higher standard than others. Other concerns include the cost of audits, the amount of time auditors spend at their facilities and the

lack of consistency between the way DAAs complete audit reports for the DG. This makes certification decisions difficult.

c) Changes we will consider in this review

When this model of auditing was considered at the time the Act was being written, it was compared to the idea of having a single audit agency for all providers. This could have been: one of the current agencies contracted by the Ministry of Health; a stand-alone government agency, similar in structure to the Education Review Office; or part of the Ministry of Health. Consultation feedback at that time favoured having several agencies because it was thought that a stand-alone agency would be too expensive and that having more than one DAA would encourage competition to keep prices down.

Due to the concerns outlined above and reports that audits are costing more than was expected when the Act came into force, we will be revisiting the other options. That is, the review will consider:

- the current requirements leading to designation and ongoing monitoring of DAAs
- a single audit agency.

Any proposal to adopt a single independent audit agency would need to be preceded by robust machinery of government analysis to define the issues, identify implications (including but not limited to financial implications), and weigh the advantages and disadvantages. This analysis would need to be done in consultation with the State Services Commission.

It is also important to note that whatever model is chosen, providers will continue to be required to pay for audits.

Questions for your feedback are found in the submission form at the end of this document.

Submission Form
Health and Disability Services (Safety) Act

Please note that any submission you make may be the subject of a request under the Official Information Act 1982. The withholding of particular submissions on the grounds of privacy, or for any other reason, will be determined in accordance with that Act.

Please indicate if you (please type X in the appropriate box):

☐	would be happy for your submission to be released; or
☐	would like to be consulted prior to release

Information about you

Part one (optional)

This submission was made by:

Name	
Postal address	
Organisation (if applicable)	
Role/position (if applicable)	

Part two

Which of the following best describes you and your organisation?
(Please type X in the appropriate box.)

☐	Rest home provider	
☐	Residential disability care provider	
☐	Hospital services provider	
☐	Day surgery provider	
☐	Designated audit agency	
☐	District Health Board	
☐	Consumer	
☐	Other (please specify)	

Is your organisation currently covered by the Health and Disability Services (Safety) Act 2001?
(Please type X in the appropriate box.)

	Yes
	No
	Not applicable

Please answer as many or as few questions as you like. Please give reasons for your views. You may attach additional pages for your submission.

The proposed infringement and reward regime

1. Should the Ministry of Health be able to issue fines to encourage providers to comply with the Act, for example to reapply for certification on time and report to the Ministry when required?

2. If so, about how much should those fines be?

3. What impact, if any, would an infringement regime have on you or your organisation?

4. How could the Ministry reward and encourage exceptional quality and safety?

Extending the coverage of the Act

5. Should the Act apply to residential disability care services with fewer than five residents?

6. If so, should there be a lower limit (eg, applying the Act to services for three or more people)? Would a change in the numbers affect your service? If so, how, and what would be the size of the impact?

7. Should the Act apply to day surgical services? Would this affect your service? If so, how and what would be the size of the impact?

Provisions around Designated Audit Agencies (DAAs)

8. Do you think the current model of having several DAAs to choose between should be changed? Why or why not? How would such a change affect you and what would be the size of the impact?

9. If you think we should keep the current model of several DAAs, how can we improve the consistency and quality of audits?

10. If you think we should keep the current model of several DAAs, how can we manage the perceived conflict of interest due to providers being ‘clients’ of DAAs?

11. If there were just one DAA, what sort should it be and why? For example, it could be:
    - within the Ministry of Health
    - a stand alone government agency
    - a private company.

12. Have you encountered concerns with the quality of audits? If so, how often and what sort of problems?

13. Do you have a view on the frequency of audits, including surveillance audits?

Other issues/comments

14. Do you have any further comments to make that have not been covered in the questions set out above?

How to make a submission

Submissions must be received by 21 September 2007.

Electronic submissions are encouraged as they aid our analysis.

Submissions by post

Written submissions should be posted to the address on the front cover of this booklet to arrive by Friday 21 September 2007.

Submissions by email

Word or pdf versions of this submission booklet can be downloaded from the Ministry's website: www.moh.govt.nz.

Electronic submissions can be emailed to: safetyactreview@moh.govt.nz.

Appendix 1: Code of Good Regulatory Practice

Ministry of Economic Development
Originally published 15 November 1997

Efficiency

Adopt and maintain only regulations for which the costs on society are justified by the benefits to society, and that achieve objectives at lowest cost, taking into account alternative approaches to regulation.

Efficiency guidelines

- **Consideration of alternatives to regulation:** regulatory design should include an identification and assessment of the most feasible regulatory and non-regulatory alternative(s) to addressing the problem.
- **Minimum necessary regulation:** when government intervention is desirable, regulatory measures should be the minimum required, and least distorting, in achieving desired outcomes.
- **Regulatory benefits outweigh costs:** in general, proposals with the greatest net benefit to society should be selected and implemented.
- **Reasonable compliance cost:** the compliance burden imposed on society by regulation should be reasonable and fair compared to the expected regulatory benefit.
- **Minimal fiscal impact:** regulators should develop regulatory measures in a way that minimises the financial impact of administration and enforcement.
- **Minimal adverse impact on competition:** regulation should be designed to have a minimal negative impact on competition.
- **International compatibility:** where appropriate, regulatory measures or standards should be compatible with relevant international or internationally accepted standards or practices, in order to maximise the benefits of trade.

Effectiveness

Regulation should be designed to achieve the desired policy outcome.

Effectiveness guidelines

- **Reasonable compliance rate:** A regulation is neither efficient nor effective if it is not complied with or cannot be effectively enforced. Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest possible cost to all parties. Incentive effects should be made explicit in any regulatory proposal.
- **Compatibility with the general body of law,** including the statute which it amends, statutes which apply to it, and the general body of the law of statutory interpretation.

- **Compliance with basic principles** of our legal and constitutional system, including the Treaty of Waitangi, and with New Zealand's international obligations.
- **Flexibility of regulation and standards:** regulatory measures should be capable of revision to enable them to be adjusted and updated as circumstances change.
- **Performance-based requirements that specify outcomes** rather than inputs should be used, unless prescriptive requirements are unavoidable. This will help ensure predictability of regulatory outcomes and facilitate innovation.
- **Review regulations systematically** to ensure they continue to meet their intended objectives efficiently and effectively.

Transparency

The regulation making process should be transparent to both the decision-makers and those affected by regulation.

Transparency guidelines

- **Problem adequately defined:** identifying the nature and extent of the problem is a key step in the process of evaluating the need for government action. Properly done, problem definition will itself suggest potential solutions and eliminate others clearly not suitable.
- **Clear identification of the objective of regulation:** the policy goal should be clearly specified against the problem and have a clear link to government policy.
- **Cost benefit analysis:** regulatory proposals should be subject to a systematic review of the costs and benefit. Resources invested in cost benefit estimation should increase as the potential impact of the regulation increases.
- **Risk assessment:** regulatory proposals should be subject to a risk assessment which should be as detailed as is appropriate in the circumstances.
- **Public consultation** should occur as widely as possible, given the circumstances, in the policy development process. A well-designed and implemented consultation programme can contribute to better quality regulations, identification of the more effective alternatives, lower costs to business and administration, ensure better compliance, and promote faster regulatory responses to changing conditions.
- **Direct approaches to problem:** In general, adopting a direct approach aimed at the root cause of an identified problem will ensure that a more effective and efficient outcome is achieved, compared to an indirect response.

Clarity

Regulatory processes and requirements should be as understandable and accessible as practicable.

Clarity guidelines

- **Make things as simple as possible, but not simpler, in achieving the regulatory objective.**
- **Plain language drafting:** where possible, regulatory instruments should be drafted in plain language to improve clarity and simplicity, reduce uncertainty, and enable those affected to better understand the implications of regulatory measures.
- **Discretion should be kept to a minimum,** but be consistent with the need for the system to be fair. Good regulation should attempt to both minimise and standardise the exercise of bureaucratic discretion, in order to reduce discrepancies between government regulators, reduce uncertainty, and lower compliance costs.
- **Educating the public** as to their regulatory obligations is fundamental in ensuring compliance.

Equity

Regulation should be fair and treat those affected equitably.

Equity guidelines

- **Obligations, standards, and sanctions** should be designed in such a way that they can be imposed impartially and consistently.
- **Regulation should be consistent with the principles** of the New Zealand Bill of Rights Act 1990, and the Human Rights Act 1993, and the expectations of those affected by regulation, as to their legal rights, should be meet.
- **People in like situations should be treated in a similar manner;** similarly, people in disparate positions may be treated differently.
- **Reliance should be able to be placed on processes and procedures of the regulatory system:** a regulatory system is regarded as fair or equitable when individuals agree on the rules of that system, and any outcome of the system is considered just.