

How Do We Determine if Statutory Regulation is the Most Appropriate Way to Regulate Health Professions?

Discussion document

Submissions analysis

Background

On 22 January 2010 the Ministry of Health (the Ministry) released a discussion document *How Do We Determine if Statutory Regulation is the Most Appropriate Way to Regulate Health Professions?* This discussion document was released in response to Recommendation 16 of the Director-General of Health (the Director-General) recently completed review of the operation of the Health Practitioners Competence Assurance Act 2003 (the Act). During this review, concerns were raised that New Zealand has 'a proliferation of registration authorities'. The Director-General therefore recommended that the Ministry review the criteria it uses to advise the Minister whether regulation is justified.

The purpose of this discussion document was to:

- outline the policy principles that are relevant to regulating health professions
- discuss the Ministry's current criteria for regulation and those used in similar jurisdictions
- propose revised criteria to assist the Ministry in advising the Minister whether a profession 'poses a risk of harm' or 'it is otherwise in the public interest' to regulate that profession.

The discussion document asked a series of specific questions, primarily focused on proposed principles, criteria and guidelines for determining whether a new profession should be regulated under the Act. It was not the intention of this consultation process to consider whether it was appropriate for existing regulated professions to remain regulated or to review the wider policy settings of statutory regulation. A more comprehensive review of the Act is scheduled to begin in 2012 and these issues may be considered as part of that review.

Analysis

The discussion document was released for consultation on the Ministry's web site on 22 January 2010. The closing date for submissions was initially 5 March 2010, but a number of groups requested extensions. Extensions to 26 March 2010 were agreed. The Ministry wrote to 115 groups to advise of the consultation. These groups included regulatory authorities, currently unregulated professions that have expressed interest in or have applications in progress for regulation, District Health Boards, training institutions, health professional associations and professional colleges.

The Ministry received 77 submissions from across the range of groups advised of the consultation. A list of submitters is attached to this analysis report. Based solely on the 115 letters sent out by the Ministry, this gives a response rate of 67%. It is not known how many more people received the discussion document through other avenues and networks.

Not all submitters responded to all questions. Because the number of respondents can vary significantly between sections, each section of this analysis states the number of respondents to that section. Percentages are calculated based on the section's total number rather than the total number of submissions.

Principles underlying regulation

Number of responses to this section = 69.

Three overriding principles were proposed.

- I. The health services concerned pose a risk of harm to the public, or it is otherwise in the public interest that the health services be regulated as a health profession under the Act.
- II. The profession delivers a health service as defined by the Act (where a health service means a service provided for the purpose of assessing, improving, protecting or managing the physical or mental health of individuals or groups of individuals).
- III. Regulation under the Act is the most appropriate means to regulate the profession.

Most respondents agreed that the proposed principles were appropriate (86%¹).

The most common type of comment relating to the principles was around definitions: 'risk of harm', 'in the public interest', 'health service', 'profession', and 'most appropriate means', and how the principles will be applied (25/69; 36%). 'Health service' and 'health profession' are already defined under the HPCA Act. Any change to these definitions should be considered as part of the review of the HPCA Act scheduled to begin in 2012. Other terms could be either more clearly defined or detailed explanation and/or examples provided. Providing explanation and examples may allow for greater flexibility to assess individual circumstances than applying a specific definition.

One respondent suggested that re-ordering the principles to ii), i) then iii) would give a more logical progression through the principles.

Four respondents commented that the importance of education should be represented in the overriding principles. However, this aspect seems to sit better in the second level criteria.

Two respondents raised the issue of professions that may 'straddle' more than just the health sector (e.g. social workers, speech-language therapy, counselling), and felt that the place of these types of professions in relation to the HPCA Act should be considered.

To clarify that the proposed principles and criteria must all be met, the Ministry considers these should become primary and secondary level criteria. The first two proposed principles are primary level criteria. The third proposed principle is focused on the form of regulation and should be moved to the second level criteria. Proposed

¹ This number includes those respondents who stated or clearly implied agreement but excludes those who commented on the principles but it was not absolutely clear.

Criterion 6, on the other hand, should be a primary criterion because it is directly related to situations where the other primary criteria are not met but statutory regulation may be warranted.

Criteria

The number of responses to this section varied as not all submitters commented on all criteria.

General

Around two-thirds of respondents (65%) clearly stated their support for the criteria. Some of these also commented that minor amendments would improve the criteria. As with the principles, the most common comments across all the criteria were around defining terms and explaining how the criteria would be interpreted and applied (30%). These can be addressed in the guidelines to becoming regulated under the Act.

Criterion 1

The activities of the profession must pose a significant risk of harm to the health and safety of the public.

Eighteen respondents commented specifically on Criterion 1, with 67 percent focusing on clarifying definitions and interpretation. These matters can be addressed in the guidelines to becoming regulated under the Act.

From the comments around defining and interpreting Criterion 1, it was clear that this criterion is already addressed in the principles (the first level criteria) and does not need to be replicated in the second level criteria.

Criterion 2

Existing regulatory or other mechanisms fail to address health and safety issues.

Only 13 respondents made comments specific to Criterion 2 and approximately half related to definitions and interpretation. Aside from these matters, the key concerns from approximately half were around what other regulatory mechanisms existed (e.g. self regulation, product regulation and employers' standards) and how appropriate these mechanisms for individual professions. There were mixed views on whether these other mechanisms were likely to be effective and whether such mechanisms should be explored as part of the process to regulate a profession under the Act.

The Ministry considers it is appropriate that other mechanisms for protecting the public are explored when assessing whether a new profession should be regulated under the Act.

Criteria 3 and 4

Regulation is possible to implement for the profession in question.
Regulation is practical to implement for the profession in question.

Only five respondents commented specifically on these criteria. The main concern was that each of these criteria provided a loophole that would allow a profession that posed a risk of harm to the public to avoid regulation under the Act.

These criteria could be amended and explanatory notes added to the guidelines to becoming regulated under the Act to clarify that these criteria are not a means to avoid regulation where regulation is warranted. They are intended to identify potential difficulties that may be associated with regulation and how these may be addressed.

Criterion 5

The benefits to the public of regulation clearly outweigh the potential negative impact of such regulation.

Fifteen respondents commented specifically on Criterion 5. The key concern was around potential difficulties with measuring and demonstrating the costs and benefits of regulation. One respondent commented that this criterion was unnecessary because statutory regulation should be a last resort, once all other avenues to protect the public have been explored and discounted.

While acknowledging that regulation under the Act should be a 'last resort', an analysis of the potential costs and benefits in relation to a specific profession under consideration is an important step in determining decisions about statutory regulation. To assist applicant professions more information about the purpose and interpretation of this criterion could be added to the guidelines to becoming regulated under the Act.

Criterion 6

It is otherwise in the public interest that the provision of health services be regulated as a profession.

Only four respondents commented specifically on Criterion 6. Two felt this criterion was a repetition of Criterion 5 and two commented that this criterion was needed as a 'catch all' criteria. It is important that there is a criterion for instances where regulation seems necessary but the usual criteria do not fit the circumstances. It is not intended that Criterion 6 should be used in most cases. As this criterion is related to professions or situations where the primary level criteria are not met, this criterion should be included in the primary criteria rather than the second level criteria.

Additional criteria

The discussion document asked whether any other criteria should be added to those proposed in the discussion document. The comments provided here were generally around clarifying definitions and interpretation of the proposed criteria rather than proposing additional criteria. These comments have, therefore, been incorporated elsewhere in this analysis, particularly into the criteria-specific comments above.

Meet all criteria

Fifty-six respondents (73%) commented on whether a profession should be required to meet all of Criteria 1-5 when applying for regulation under the Act. While 29 respondents stated that criteria 1-5 should all be met (52%), there was no clear agreement among the remaining respondents on which criteria should be met.

Taking into account the responses to this question, and other comments elsewhere in the submissions, it may be preferable to apply the criteria as a measure rather

than a 'meet' or 'does not meet' rule. This would allow a degree of flexibility in assessing an individual profession's circumstances. This flexibility should not be seen as a means of lowering the threshold for regulation.

Risk of harm

Number of responses to this section = 55.

The discussion document asked whether a profession must be involved in at least two of the following activities to establish a risk of harm:

- invasive procedures (such as cutting under the skin)
- clinical intervention with the potential for harm
- making decisions or exercising judgement which can substantially impact on patient health or welfare, including situations where individuals work autonomously, ie unsupervised by other health professionals.

Of those who responded to this question, 23 (42%) agreed that a profession must be involved in at least two of these activities and 13 (24%) stated that a profession should be required to be involved in at least one of these activities in order to establish a risk of harm.

Again, comments in this section related to definitions and interpretation rather than how many of these activities establish a risk of harm. These comments are reflected in other parts of this analysis.

Guidelines

Number of responses to this section = 52.

The discussion document asked whether detailed guidelines should be provided to applicant professions. Of the 52 who responded to the question, there was almost unanimous agreement that detailed guidelines should be provided to applicant professions (51/52; 98%).

Other information in the guidelines

Number of responses to this section = 54.

The discussion document asked whether any other information should be provided. Of the 54 respondents to this question, 17 (31%) indicated that no further information was needed.

Ten (19%) stated that a timeframe for processing applications and/or implementing regulation would be helpful. Three respondents (6%) suggested providing a diagrammatic view of the application process. Five respondents (9%) suggested including a Ministry of Health contact and/or contacts for professions that had completed the application process and could offer advice.

Other suggestions included directing applicant professions to look at annual reports for existing regulated professions of a similar size to gain an indication of costs, and information about other forms of regulation and mechanisms for protecting the public.

The guidelines should be a 'living document' that is expanded with new information, including definitions, interpretation and the application process, as appropriate.

Introducing revised criteria

Number of responses to this section = 43.

The discussion document asked whether the respondent had any comments on when the revised criteria should be introduced and views on how the introduction of revised criteria might impact on professions with applications currently placed on hold.

Most of the 43 respondents (86%) focused on the issue of whether those professions with applications for regulation under the HPCA Act already in progress should have to re-apply under any new criteria approved.

Of the 37 respondents who expressed a view on whether or not professions with applications for regulation under the HPCA Act should have to resubmit applications under the new criteria:

- 21 (57%) stated or strongly implied that existing applications should stand and processing should continue (16 from non-applicant professions and 5 from applicant professions)
- 1 (3%) respondent stated that those applicants that had obtained Ministerial approval for regulation but had not completed the other stages of regulation under the HPCA Act should be allowed to continue with the process but other applicants should be required to reapply (this respondent was from an applicant profession that has obtained Ministerial approval for regulation)
- 15 (41%) respondents (14 non-applicants) stated that applicant professions should be required to reapply under the new framework.

Sixteen submitters (37%) responded to the question of when any new criteria should be introduced. Of those 16, 14 respondents (88%) saw no issues around timing and that any changes should be implemented as soon as possible.

Other comments

Comments provided under this section related to a wide range of issues and, for the purposes of this document, have been grouped under the following headings:

- regulatory authorities
- the HPCA Act
- other forms of regulation or recognition
- New Zealand and international models
- regulation under other legislation

Regulatory authorities

Number of responses to this section = 34.

The most common issue commented on was around the merits of blending regulatory authorities with 28 responses. Most of these (82%) were in favour of

some form of amalgamation of regulatory authorities. Two respondents acknowledged that, while there may be benefits to amalgamating regulatory authorities, there may also be some disadvantages, for example, unique professional issues not being adequately addressed.

While attracting far fewer comments, some respondents queried:

- whether existing regulated professions would or should meet the proposed criteria for regulation (3 respondents)
- whether the Minister of Health's power to amalgamate regulatory authorities should remain, be extended or be reduced (2 respondents).

With the exception of decisions about how a new profession should be regulated once approved for regulation, these matters sit outside the scope of this particular review and should be considered for inclusion in the more substantive review of the HPCA Act scheduled to begin in 2012.

The HPCA Act

Number of responses to this section = 11.

There were no common themes among the 11 respondents but some of the issues raised included questions about:

- the regulation of a profession that does not seek regulation itself (2 respondents)
- the Act's protection of title rather than function (1 respondent)
- the need for other forms of regulation such as licensing (3 respondents)
- the recognition of Maori therapies and cultural models (1 respondent)

These matters sit outside the scope of this particular review and should be considered for inclusion in the more substantive review of the HPCA Act scheduled to begin in 2012.

Other forms of regulation or recognition

Number of responses to this section = 18.

The most common themes among the 18 respondents were:

- the value of other forms of regulation should be promoted / recognised including licensing and self regulation, (89%)
- the need for alternative recognition for professions not meeting the criteria for regulation to ensure unregulated professions have access to public funding such as ACC and pharmaceutical subsidies (33%).

More information about other forms of regulation could be provided on the HPCA Act web site and in the guidelines to accompany the criteria to become regulated under the Act.

Alternative forms of regulation, such as licensing², should be considered for inclusion in the more substantive review of the HPCA Act scheduled to begin in 2012. It should also be noted that the Health and Disability Commissioner Act provides and applies to all health services and providers regardless of whether they are regulated or not.

The Ministry could discuss with other relevant agencies that regulation under the HPCA Act is not necessarily an adequate criteria to determine a particular professions access to public funding. Non-regulated professions are already able to seek recognition for ACC funding, which is likely to be the most common avenue of funding being sought by health professions.

New Zealand and international models

Number of responses to this section = 6.

There were no common themes among the 6 respondents but the notable issues raised were:

- the importance of recognising the Treaty of Waitangi and cultural competency when considering regulatory models used in other countries (2 respondents)
- the validity of international regulatory models to New Zealand's specific circumstances such as New Zealand's ACC system (2 respondents).

While acknowledging New Zealand's specific circumstances, such as the Treaty of Waitangi and ACC system, there are always lessons to be learnt from regulatory models in other countries. In developing any policy or legislation, New Zealand needs to continue to look at what is being done in other countries and consider how this fits, or could be modified to fit, the New Zealand context. In particular, New Zealand must remain aware of the interrelationships between New Zealand and Australian health professional authorities and the commitment of both Governments to the freedom of movement and employment between the two countries. This means that, wherever possible both countries need to try to avoid incompatible regulatory requirements while still recognising each country's individual circumstances.

Regulation under other legislation

Number of responses to this section = 2.

While only commented on by two respondents, the issue of health-related professions regulated under other legislation is worth noting. Social workers, including health social workers, are regulated under the Social Workers Registration Act 2003 not the HPCA Act. The respondents suggest that consideration be given to how to amend the Social Workers Registration Act to better align with the other relevant legislation.

The Social Workers Registration Act is administered by the Ministry of Social Development, but the Ministry would be interested in being informed if any work was

² Australia has carried out an extensive review of health regulation and found no need to introduce a licensing regime.

to be done to align regulatory requirements of professions working across sectors. The Ministry of Health will discuss this with the Ministry of Social Development.

Conclusion

Overall respondents were supportive of the proposed criteria and suggested ways to improve the criteria. Based on the submissions the following key changes have been made to the criteria and guidelines:

- the principles and criteria have been renamed primary and secondary criteria
- proposed criterion 1 has been moved from the second level criteria to the primary criteria
- the third proposed principle has been moved to the secondary criteria
- the guidelines have been modified to assist with interpreting the criteria and what matters might be taken into account when considering a profession for regulation under the Act.

As requested by some respondents, information about processing applications will be developed and provided with the new criteria if the new criteria are approved by the Minister. This information will include the steps involved in processing an application for regulation under the Act, an expected timeframe and Ministry contact details.

List of submitters

Where a submission was from an organisation, the organisation name is recorded. Where a submission was from an individual, the individual's name and, where known, profession is recorded.

Regulatory authorities

1. Medical Council of New Zealand
2. Occupational Therapy Board of New Zealand
3. Midwifery Council of New Zealand
4. Pharmacy Council of New Zealand
5. Health Regulatory Authorities of New Zealand
6. Psychotherapists Board of Aotearoa New Zealand
7. New Zealand Psychologists Board
8. Nursing Council of New Zealand
9. Physiotherapy Board of New Zealand
10. Osteopathic Council of New Zealand
11. Dietitians Board
12. Podiatrists Board of New Zealand
13. Dental Council of New Zealand
14. Medical Sciences Secretariat

Tertiary institutions

15. Faculty of Health and Environmental Sciences, Auckland University of Technology
16. Faculty of Medical and Health Sciences, University of Auckland
17. Department of Sport and Exercise Science, University of Auckland
18. School of Applied Sciences and Allied Health, Christchurch Polytechnic Institute of Technology
19. Faculty of Health and Environmental Sciences, Auckland University of Technology
20. Graduate School of Nursing, Midwifery and Health, Victoria University of Wellington
21. Tertiary Council for Physical Activity, Sport and Exercise, University of Otago

Professional College

22. Naturopathic College of New Zealand
23. Royal Australasian College of Physicians
24. Royal Australasian College of Surgeons
25. College of Physiotherapy
26. Royal New Zealand College of General Practitioners
27. New Zealand College of Midwives
28. Australian College of Ambulance Professionals

District Health Boards

29. Lakes District Health Board
30. Mental Health Services, Canterbury District Health Board
31. Clinical Partners to the Chief Executive, Auckland District Health Board
32. Professional Advisors Group, Southland District Health Board
33. Allied Health, Waitemata District Health Board
34. Chief Executive, Hawkes Bay District Health Board
35. Allied Technical and Scientific, Capital & Coast District Health Board
36. Chief Medical Officer, Counties Manukau District Health Board
37. Hospital Support and Laboratories, Canterbury District Health Board

Professions with applications on hold

38. Clinical Physiologists Registration Board

39. New Zealand Institute of Acupuncture
40. New Zealand Anaesthetic Technicians' Society
41. New Zealand Acupuncture Standards Authority
42. New Zealand Register of Acupuncturists
43. Register of New Zealand Traditional Chinese Medicine Practitioners
44. New Zealand Speech-language Therapists' Association

Professional associations, groups

45. New Zealand Sterile Services Association
46. New Zealand Tertiary Council for Physical Activity, Sport and Exercise
47. New Zealand Board of Dialysis Practice
48. Massage New Zealand
49. New Zealand Association of Medical Herbalists
50. New Zealand Chinese Medicine and Acupuncture Society
51. New Zealand Association of Counsellors
52. Natural Health Council New Zealand
53. New Zealand Society for Music Therapy
54. New Zealand Council of Homeopaths
55. Aotearoa New Zealand Association of Social Workers
56. New Zealand Council of Traditional Chinese Medicine
57. New Zealand Medical Association
58. New Zealand Society of Anaesthetists
59. New Zealand Nurses Organisation
60. New Zealand Institute of Professional Counselling

Others

61. C Miller, Clinical Psychologist
62. L Lord, Anaesthetic Technician
63. M Stuart, Fellow, Australia and New Zealand College of Anaesthetists
64. M Laslett, Fellow, New Zealand College of Physicians
65. M MacKenzie, Registered Nurse
66. Massage Educator's Group
67. Relationship Services
68. Te Rau Matatini
69. Pathways
70. K Crocket, Counsellor
71. Pharmac
72. Diabetes New Zealand
73. Women's Health Action Trust
74. Career Development Association of New Zealand
75. Sport and Exercise Science New Zealand
76. Health and Disability Commissioner
77. New Zealand Health Trust