Guidelines

Applying for regulation under the Health Practitioners Competence Assurance Act 2003

The Health Practitioners Competence Assurance Act (the **Act**) contains provisions enabling the scope of the Act to be extended to cover other professions that provide health services (refer s 115).

This document discusses the Act's provisions and provides guidance to professions who might seek to apply for regulation under the Act.

The need for regulation is determined based primarily on assessment of the risk of harm to the health and safety of the public. The process for a profession to become regulated is lengthy and is outlined below.

1. The prospective applicant(s) (professional body or bodies) meet with Health Workforce to discuss issues when considering applying.
2. Health Workforce receives a formal application.
3. Health Workforce undertakes a preliminary assessment of the application (against the criteria outlined in Section 4 below) and seeks further information if required.
4. If Health Workforce accepts that the application makes a robust case, it convenes an expert panel to consider the application. This includes an independent assessment of whether the public is at risk of harm and whether it would be in the public interest to regulate the profession.
5. If necessary, discussions may be held between the applicants and existing responsible authorities to seek agreement on whether the proposed new profession can be included in an existing authority.
6. Subject to the Minister of Health's agreement, Health Workforce undertakes a consultation process and analyses submissions.
7. Health Workforce then provides advice to the Minister regarding whether the profession should be regulated and the appropriate responsible authority to regulate it. (Note: If agreement has not been reached regarding an appropriate authority, the Minister may assign the new profession to an existing authority.)
8. If in agreement with the proposal, the Minister seeks agreement from Cabinet.
9. If the proposal is agreed to by Cabinet, an Order in Council is prepared by the Parliamentary Counsel Office. The Order in Council will then be considered by Cabinet and - if agreed - the Minister will recommend to the Governor-General that the profession is designated under the Act.
10. The profession then either joins or is established as a responsible authority.
11. The Minister then appoints members of the responsible authority.

If you are considering applying to become a regulated profession, we suggest that you contact us early for a preliminary discussion. If you have any queries about the criteria or application process, please email info@healthworkforce.govt.nz.

Section 1 - Introduction

There are 17 responsible authorities under the Act. The Act contains provisions enabling its scope to be extended to cover other professions that provide health services. This document discusses these provisions and provides guidance to professions considering applying to become regulated under the Act.

Section 115 of the Act (see Appendix 1) enables the Governor-General, on the advice of the Minister of Health, to designate health services of a particular kind as a health profession under the Act and to either:

- establish an authority for the profession; or
- provide that the designated profession be added to the profession or professions in respect of which an existing authority is appointed – thus creating a 'blended authority'.

The Act does not provide for new, blended, or existing authorities to receive Crown funding. The set up and operational costs of an authority will need to be borne by registrants. The financial viability of any proposed authority may have a bearing on the Minister's decision for the best choice regarding the appointed authority. Applicants may be asked to provide comment on this issue.

Section 2 - Purpose of the Act is paramount

Essentially, any profession applying to become regulated under the Act must show consistency with the purpose of the Act; the principal purpose of which is *to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions* (refer s 3(1)).

Implicit in the Act is the protection of public interest through ensuring that the public can readily find out what services a health practitioner is competent and entitled to provide. This will enable the public to know what health services can be expected from their chosen practitioner, and to know that that practitioner is competent and safe. The concept of providing the public with clear information on the nature of a profession, and the scope of practice and competencies of its practitioners, is reflected in the requirements set out below.

Section 116 of the Act

Section 116 of the Act (see Appendix 1) requires that, before recommending a health service be regulated as a health profession, the Minister must be satisfied that the health services **pose a risk of harm to the public** or that it is otherwise in the **public interest** that the health service be regulated.

The Minister must also be satisfied that the providers of the health services are generally agreed on the following.

- Qualifications for any class of providers of those health services.
- Standards that any class of service providers are expected to meet.
- Competencies for scopes of practice for those health services.

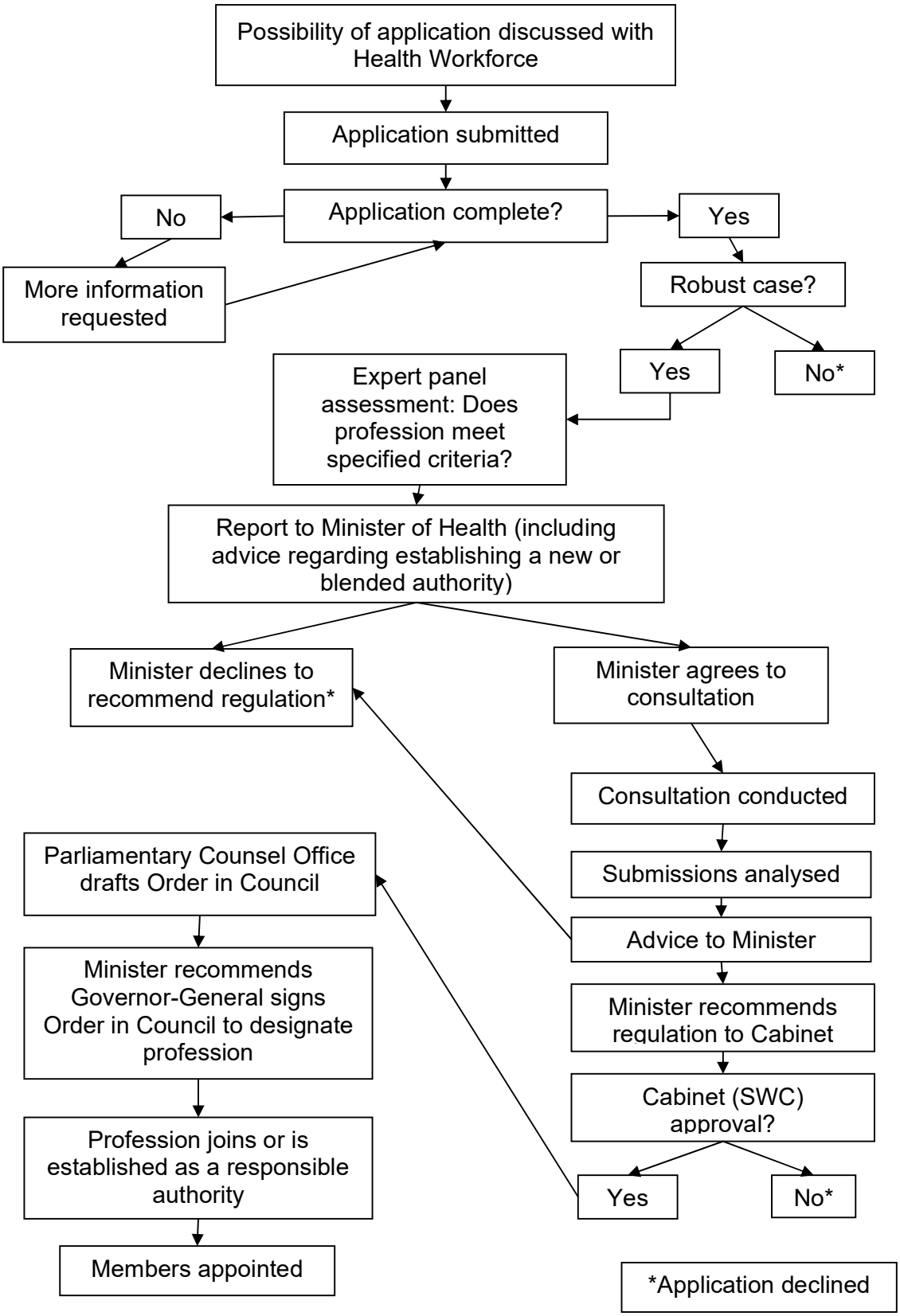
Section 116 of the Act also requires that the Minister consult with any organisation that, in the Minister's opinion, has an interest in the recommendations.

N.B.: The development of these steps is also guided by the policy framework for regulating occupations. The framework (Cabinet Office Circular No (99) 6) includes the following principles.

- Intervention by the government in occupations should generally be used only when there is a problem or potential problem that is either unlikely to be solved in any other way or inefficient or ineffective to solve any other way.
- The amount of intervention should be the minimum to solve the problem.
- The benefits of intervening must exceed the costs.

The following process and criteria help ensure compliance with this framework.

Section 3 – The application process



Section 4 – The criteria

To determine whether a health profession should be regulated under the Act, primary and secondary criteria were developed and consulted on in 2009. The criteria for applying are based on the consultation and the Minister's agreement. The primary criteria are specific requirements set out in the Act and must therefore be met in order to be regulated under the Act. Applications that meet the primary criteria will then be assessed on the extent to which they meet the secondary criteria. The secondary criteria focus more on the practicalities of a profession being regulated under the Act and whether this is, in fact, the most appropriate means to protect the health and safety of the public.

The primary and secondary criteria are set out below, followed, in Section 5, by guidelines to interpreting and demonstrating each of the criteria.

Primary Criteria

The following primary criteria apply to applications from new professions seeking regulation under the Act.

The primary criteria for regulation under the Act are that:

A. the profession delivers a health service as defined by the Act

B. i. the health services concerned pose a risk of harm to the health and safety of the public, **or**

ii. it is otherwise in the public interest that the health services be regulated as a health profession under the Act

C. that providers of the health services concerned are generally agreed on—

(i) the qualifications for any class or classes of providers of those health services; and

(ii) the standards that any class or classes of providers of those health services are expected to meet; and

(iii) the competencies for scopes of practice for those health services.

Secondary Criteria

If the primary criteria are met, the Ministry will apply the following second-level criteria to measure the appropriateness of regulation under the Act.

Criterion 1:	Existing regulatory or other mechanisms fail to address health and safety issues.
Criterion 2:	Regulation under the Act is possible to implement for the profession in question.
Criterion 3:	Regulation under the Act is practical to implement for the profession in question.

Criterion 4: The benefits to the public of regulation under the Act clearly outweigh the potential negative impacts of such regulation.

Section 5 – Guidelines for interpreting the criteria

In determining whether the primary and secondary criteria have been met, the Ministry will require detailed information from applicant professions. The following guidelines are intended to assist a profession to compile its application.

Primary Criteria

Criterion A: Does the profession deliver a health service as defined by the Act?

To be considered under this criterion the profession must provide a health service as defined by the Act. The Act defines a health service as "a service provided for the purpose of assessing, improving, protecting, or managing the physical or mental health of individuals or groups of individuals" (s 5).

The Act defines mental or physical condition as "any mental or physical condition or impairment; and includes, without limitation, a condition or impairment caused by alcohol or drug abuse" (s 5). This definition does not preclude emotional health.

Criterion B(i): Do the health services concerned pose a risk of harm to the health and safety of the public?

To be considered under this criterion the members of the profession must be involved in at least two of the following activities.

- Invasive procedures (including but not limited to cutting under the skin or inserting objects into the body).
- Clinical intervention with the potential for physical or mental harm.
- Making decisions or exercising judgement which can substantially impact on patient health or welfare, including situations where individuals work autonomously, that is unsupervised by other regulated health professionals.

Harm may include death, disablement or permanent negative change in a person's physical or mental health status. It may also include indirect harm (for example, failing to refer a consumer on when warranted).

To establish a 'risk of harm', the applicant must provide information that demonstrates:

- the nature and severity of the risk to consumers (including groups of vulnerable consumers who may lack the capacity to make decisions and understand the services they receive, refer Criterion B(ii))
- the nature and severity of the risk to the wider public.

The following questions should be explored when identifying a risk to public health and safety.

- To what extent does the practice of the profession involve the use of equipment, materials, or processes which could cause a risk of harm to the health and safety of the public?
- To what extent may the failure of a professional to practise in particular ways (that is, follow certain procedures, observe certain standards, or attend to certain matters), result in a risk of harm to the health and safety of the public?
- Are intrusive techniques used in the practice of the profession which can cause a risk of harm to the health and safety of the public?
- To what extent are dangerous substances used in the practice of the profession, with particular emphasis on, but not limited to, pharmacological compounds, chemicals, or radioactive substances?
- Is there significant potential for the professional to cause damage to the environment or some wider risk of harm to the health and safety of the public?
- Is there epidemiological or other data (for example, coroners' cases, trend analysis, complaints) which demonstrates the risks that have been identified?

Evidence should be provided on:

- the nature, frequency, and severity of the harm to, or the consequences for, the consumer
- the likelihood of the risk occurring
- the nature, frequency, and severity of the potential risk to the public which arises from the practice of the profession (for example, the number of cases reported to the Health and Disability Commissioner involving this profession)
- whether other sector stakeholders have public safety concerns about the practice of this health service
- whether members of the profession are regulated in similar overseas jurisdictions.

In addressing the risk of harm in this context, the applicant should identify the risks associated with the practice of the profession, as distinct from risks inherent in the area of health care within which the profession operates.

Criterion B(ii): Is it in the public interest that the provision of health services be regulated as a profession?

The Act acknowledges that, in some scenarios, criterion B(i) will not apply, but statutory regulation may still be in the public interest. Criterion B(ii) could include professional groups that:

- practise without the supervision or support of peers, managers, and other regulated health practitioners
- are highly mobile, locum, or work on short tenure
- are not guided by a strong professional (or employer) code of conduct
- provide services to vulnerable or isolated individuals
- are subject to such large numbers of complaints about the quality of services that oversight of competence from an independent body is required
- carry out roles where the training and educational requirements are short and there is no extended period through which the ethos and values which underpin safe practice can be absorbed.

In rare situations, statutory regulation may be in the public interest if the public and other health professionals need assistance to identify appropriately qualified professionals.

Criterion C: Are the providers of the health services concerned generally agreed on the qualifications, standards, and competencies required to practice?

Responsible authorities established under the Act are required to prescribe the qualifications required for scopes of practice within the profession and to set standards of clinical competence, cultural competence, and ethical conduct to be observed by health practitioners of the profession (refer s 118 of the Act). Applications for regulation should include evidence demonstrating that there is broad agreement across the profession on the qualifications and standards that should be prescribed. If there are significant differences of opinion on these matters within the profession, these should be outlined and any previous or current efforts to resolve the differences should be described.

Secondary Criteria

Criterion 1: Do existing regulatory or other mechanisms fail to address health and safety issues arising from the practice of the profession?

Can the potential health and safety issues that may cause harm to patients be addressed in any other way?

For example, can the identified risks of harm to the health and safety of the public be addressed through:

- any other New Zealand statute that restricts the activities of the profession, such as the Medicines Act 1981 or the Radiation Protection Act 1965
- other regulatory options which are available to limit the potential for harm, such as product regulation
- other groups of registered practitioners supervising the activities of the profession or working concurrently with other registered professions
- self-regulation by the profession?

Why do other forms of regulation not address health and safety issues arising from the practice of the profession?

Criterion 2: Is regulation under the Act possible to implement for the profession in question?

This criterion is not intended to provide a loophole for a profession that meets the primary criteria for regulation to avoid regulation under the Act but any barriers to such regulation need to be identified and addressed. Matters that should be addressed may include, but are not limited to, any of the following.

- Does the profession have a defined body of knowledge that can form the basis for standards of practice?
- Is the profession well defined?
- Does the profession cover a discrete area of activity displaying some homogeneity?
- Is this body of knowledge, with the skills and abilities necessary to apply the knowledge, teachable and testable?
- Where applicable, have functional competencies been defined?
- Do the members of the profession require accredited qualifications? (Please give details.)
- Is the practice based on evidence of efficacy?
- Are there defined routes of entry to the profession?
- Are there independently assessed entry qualifications? (Please give details.)
- Are there standards in relation to conduct, performance, and ethics?
- Are there procedures to enforce those standards?
- Are the professionals committed to continuous professional development?
- What professional titles are used?

To establish this criterion, please provide evidence of how the qualifications, standards, and competencies that will be expected of practitioners will reduce the risk of harm to the public or help achieve the public interest.

Criterion 3: Is regulation under the Act practical to implement for the profession in question?

This criterion is not intended to provide a loophole for a profession that meets the primary criteria for regulation to avoid regulation under the Act. It is intended to identify any barriers to such regulation that need to be addressed. The following are just some of the matters that should be considered.

- Is there an alternative to regulation under the Act that is practical to implement to limit any risk of harm posed by the profession, such as self-regulation or accreditation?
- Is there at least one established professional body or association which can represent a significant proportion of the profession?
- Is there currently a voluntary register of members of the profession?
- Does the professional leadership favour the public interest over occupational self-interest? (Please give details of policies or communications which demonstrate this.)
- Is it likely that individual professionals will welcome regulation and professional associations will encourage compliance amongst their members?
- Are there sufficient numbers in the profession to make regulation cost-efficient and are members of the profession willing to fund the costs of statutory regulation? (Please give numbers in the profession.)

Criterion 4: Do the benefits to the public of regulation under the Act clearly outweigh the potential negative impacts of such regulation?

The following information lists the types of things that may be considered when assessing the costs and benefits of regulation under the Act.

Benefits of regulation

The benefits of statutory regulation may include, but are not limited to, the following.

- Setting entry to the regulated professions.
- Setting standards of practice.
- Ensuring initial and ongoing competence.
- Ensuring high-quality education to assure those standards.
- Potential to remove from practice those who fall significantly short of those standards.
- Promoting and enforcing clinical and cultural competencies and standards of ethical conduct.
- Helping to foster, develop, and sustain an ethos of professionalism amongst their registrants.
- Consumer benefits, such as confidence in quality and safety of a profession.

Costs and risks of regulation

The costs of regulation may include, but are not limited to, the following.

- The cost of the professional's time taken to comply with the requirements of the regulator, such as meeting re-certification requirements, which may take professionals away from their primary purpose of providing quality care to patients.
- The costs to employers of ensuring they have additional systems in place necessary for the employment of regulated professionals.
- The costs of registration fees from registrants to their regulator as ultimately these costs are indirectly paid by the taxpayer (in publicly funded services) or the individual patient (in privately funded services).
- The costs of establishing and maintaining new regulatory regimes for newly regulated bodies (annual reports of a similar sized regulated profession may provide a guide to ongoing responsible authority costs).
- Statutory regulation of professionals in the health sector which implies a relatively high component of legal costs, with decisions being open to challenge in the courts, funded from legal indemnity insurance and the regulators' fees.
- The enshrining of professional roles in statute which can create 'closed shops'.
- The costs of any duplication of effort between local systems of management and clinical governance on one hand, and regulatory oversight on the other, which also may result in the risk of confusion over roles and responsibilities.
- The potential for gaps between different systems of oversight due to assuming wrongly that other parts of the system are taking responsibility for detecting and managing risks.
- The putting in place of national systems which may result in a weakened local focus, where there is a remaining need for employers to 'credential' professionals to ensure the practitioner is able to perform a particular role in a particular setting.
- The costs to trainees, employers, and taxpayers of the higher standards of education and of the training infrastructure which statutory regulation may require in order to assure the quality of new entrants to the register.
- The involvement of the regulator in some matters which are now dealt with internally by the employer, such as assessment of complaints.
- The potential for any costs or barriers to innovation.

Section 6 – Assessment and decision on regulation

As indicated in the flow diagram in Section 3 of this paper, if and when a robust case has been made that the profession meets the prescribed criteria for regulation, Health Workforce will advise the Minister of Health on decisions to be taken regarding an application. This will require the Ministry to convene an expert panel to assess whether the public is at risk of harm and/or whether it would be in the interest of the public to regulate the health service under the HPCA Act.

This assessment will also involve the following.

- Reviewing the evidence provided in the application (including undertaking separate investigation into overseas experience and evidence).
- Consulting internally, drawing on available Ministry clinical expertise and if necessary, engaging independent clinical advisors for advice.
- Consulting with any organisation that, in the Minister's opinion, has an interest in the recommendations. This may include consulting with district health boards, responsible authorities, and the practitioner group, including individuals or organisations.

If a decision is taken to recommend to the Minister that the profession applying should be designated as a health profession, a decision will then be made regarding which existing responsible authority will regulate it, or if it should be established as an independent authority. This may include the following steps.

- Consider the information provided by the applicant on the establishment of a new authority or joining with an existing authority.
- If a blended authority is considered appropriate, arrange a discussion between Health Workforce, the new profession, and the existing authority to talk through issues (including whether the proposed new profession should be represented on the authority).
- If agreement is reached, go ahead with the rest of the process.
- If agreement is not reached, look at why not and see if any of those issues can be resolved.
- If agreement between the relevant groups cannot be reached, the Minister has the authority under the Act to add the new profession to an existing authority (refer s 115(1)(b)(ii)).

Section 7 – Appointment of authority and requirement to register

The Minister will give effect to any decisions by recommending to the Governor-General an Order in Council. Any such Order in Council will prescribe the date that the decisions come into effect. It is likely that that date will take into account the time required to appoint authority members. The appointment process (which includes calling for nominations) can take some months.

Sections 11 and 12 of the Act (see Appendix 1) require a new authority (or any existing authority to which a profession has been added) to publish in the *New Zealand Gazette* the necessary scopes of practice and qualifications for that profession.

Appendix 1:

Health Practitioners Competence Assurance Act 2003 Sections 11, 12, 115, and 116

11 Authorities must specify scopes of practice

(1) Each authority appointed in respect of a profession must, by notice published in the *Gazette*, describe the contents of the profession in terms of 1 or more scopes of practice.

(2) A scope of practice may be described in any way the authority thinks fit, including, without limitation, in any 1 or more of the following ways:

- (a) by reference to a name or form of words that is commonly understood by persons who work in the health sector:
- (b) by reference to an area of science or learning:
- (c) by reference to tasks commonly performed:
- (d) by reference to illnesses or conditions to be diagnosed, treated, or managed.

12 Qualifications must be prescribed

(1) Each authority must, by notice published in the Gazette, prescribe the qualification or qualifications for every scope of practice that the authority describes under section 11.

(2) In prescribing qualifications under subsection (1), an authority may designate 1 or more of the following as qualifications for any scope of practice that the authority describes under section 11:

- (a) a degree or diploma of a stated kind from an educational institution accredited by the authority, whether in New Zealand or abroad, or an educational institution of a stated class, whether in New Zealand or abroad:
- (b) the successful completion of a degree, course of studies, or programme accredited by the authority:
- (c) a pass in a specified examination or any other assessment set by the authority or by another organisation approved by the authority:
- (d) registration with an overseas organisation that performs functions that correspond wholly or partly to those performed by the authority:
- (e) experience in the provision of health services of a particular kind, including, without limitation, the provision of such services at a nominated institution or class of institution, or under the supervision or oversight of a nominated health practitioner or class of health practitioner.

(3) A notice under subsection (1) may state that 1 or more qualifications or experience of 1 or more kinds, or both, is required for each scope of practice that the authority describes under section 11.

(4) An authority must monitor every New Zealand educational institution that it accredits for the purpose of subsection (2)(a), and may monitor any overseas educational institution that it accredits for that purpose.

(5) An authority may, at any time, give notice to an educational institution accredited under subsection (2)(a) that the institution's accreditation is revoked.

(6) The revocation of an educational institution's accreditation does not affect the registration of a health practitioner who qualified to practise within a scope of practice on the basis of having a degree or diploma from that institution.

115 Authorities may be appointed in respect of additional professions

(1) The Governor-General may from time to time, by Order in Council made on the recommendation of the Minister,—

(a) designate health services of a particular kind as a health profession; and

(b) either—

(i) establish a body corporate, to be known by a name stated in the order, as the authority appointed in respect of the profession designated under paragraph (a); or

(ii) provide that the profession designated under paragraph (a) is to be added to the profession or professions in respect of which an existing authority is appointed.

(2) If an Order in Council contains a provision of the kind authorised by subsection (1)(b)(ii), the order may also—

(a) change the name of the authority concerned to reflect the change made by the order; and

(b) amend any enactment (for example, this Act) to reflect the name change effected by the order.

(3) The Minister may recommend that an Order in Council be made under subsection (1) only if satisfied of the matters stated in section 116.

(4) An Order in Council under subsection (1) is a legislative instrument and a disallowable instrument for the purposes of the Legislation Act 2012 and must be presented to the House of Representatives under section 41 of that Act.

116 Conditions for designating health services as health profession

(1) Before making a recommendation under section 115(1), the Minister must, after consultation with any organisation that, in the Minister's opinion, has an interest in the recommendation, be satisfied of the following matters:

(a) either—

(i) that the provision of the health services concerned poses a risk of harm to the public; or

(ii) that it is otherwise in the public interest that the provision of health services be regulated as a profession under this Act:

(b) that providers of the health services concerned are generally agreed on—

(i) the qualifications for any class or classes of providers of those health services; and

(ii) the standards that any class or classes of providers of those health services are expected to meet; and

(iii) the competencies for scopes of practice for those health services.