Regulatory Impact Statement: Regulation of the Physician Associate profession under the Health Practitioners Competence Assurance Act 2003

Coversheet

Purpose of Document	
Decision sought:	To regulate the Physician Associate profession under the Health Practitioners Competence Assurance Act 2003 (the HPCA Act) and for the profession to be added to the profession in respect of which the Medical Council of New Zealand is appointed.
Advising agencies:	Ministry of Health
Proposing Ministers:	Minister of Health
Date finalised:	18 November 2024

Problem Definition

Physician Associates (PAs) perform a range of activities that present serious risks of harm to patients if not performed competently. An effective and proportionate approach to regulation is required to mitigate those risks.

PAs' training equips them to competently perform a range of tasks that, as an unregulated profession, they are not currently authorised to perform in New Zealand. This detracts from their potential contribution to the health services and communities they work in.

Executive Summary

In 2017, the New Zealand Physician Associate Society (NZPAS) lodged a formal application with the Ministry of Health | Manatū Hauora (the Ministry) for regulation of the PA profession under the HPCA Act.

In accordance with government expectations, regulation should be proportionate to the risks being addressed. Statutory regulation under the HPCA Act is reserved for professions that pose a risk of harm to the public.

The evidence of risk of harm arising from PAs' practice is clear and comes from a range of (mostly international) sources, including healthcare journals and government reports. The risks were also assessed by an independent panel of New Zealand experts, who subsequently recommended regulation.

Four options have been considered: retain the *status quo*, enhance the *status quo*, regulate by adding to an existing responsible authority (RA), or regulate by adding to a new (amalgamated) RA.

The Ministry's preferred option (as reflected in the Cabinet paper) is for the PA profession to be regulated under the HPCA Act, and to be added to the profession already regulated by the Medical Council of New Zealand (the Medical Council).

Statutory regulation of the PA profession is a long-term intervention that will protect the public by ensuring that only practitioners who meet qualification, competency, and ethical

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standards requirements are able to hold themselves out to be registered members of the profession. The HPCA Act provides mechanisms to ensure ongoing competence and fitness to practise, as well as disciplinary and complaints (accountability) procedures. Adding the PA profession to the profession already regulated by the Medical Council will ensure effective and efficient regulation.

A targeted consultation found broad support for statutory regulation, based on the risk of harm. Some submissions, however, raised concerns about the impact a growing number of PAs might have on existing workforces and training pathways.

Members of the public who use the services of PAs will benefit by having confidence that registered members of that workforce are qualified, competent, and fit to practise their professions. PAs will benefit from enhanced credibility, increased status and professional identification, protected title(s), and opportunities and mechanisms to increase and maintain competence over the entirety of their career.

The initial and ongoing financial costs of regulation are significant. They are normally borne by the profession but, given that there are currently only about 50 PAs practising in New Zealand, it is proposed that – if Cabinet approves regulation of the profession – some public funds will also be contributed to help cover the initial (onboarding and first two years of running) costs and thereby ensure implementation. Thereafter, ongoing (running) costs will be met entirely by members of the profession but may be passed on to employers and funders (such as Health New Zealand).

Limitations and Constraints on Analysis

At present, New Zealand has a binary approach to the regulation of health professions. A profession is either regulated under the HPCA Act or there is no direct government involvement in its regulation. That is, there are no intermediate, more proportionate mechanisms mandated or otherwise endorsed by government. With any significant changes to our regulatory framework still some years away, our analysis has largely been restricted to considering whether the PA profession should be regulated under the HPCA Act (in its current form).

Given the small number of PAs practising in New Zealand, the Ministry has had to rely on overseas data regarding complaints and critical incidents with the assumption that, as the profession grows in New Zealand, we can expect a similar pattern of complaints to emerge here.

In 2023, the Ministry consulted with 67 organisations, including health agencies, employers, professional associations and colleges, responsible authorities, training organisations, unions, and others. We consider that opting for a targeted consultation did not have any deleterious impacts on our analysis.

No options other than adding the PA profession to the profession already regulated by an existing RA were costed. The *status quo* options do not meet policy objectives and the 'allied health' authority option (option 3B, described below) is beyond the scope of current consideration (but could be revisited in the future). Based on the cost of the recent establishment of the Chinese Medicine Council and the small number of PAs currently practising in New Zealand, we know that establishing a new responsible authority to regulate the (much smaller) PA profession would be prohibitively expensive and otherwise unsustainable.

The costs forecast prepared by the Medical Council was based on a range of current expectations, estimates, projections, and assumptions about future events that are

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inherently uncertain and subject to risks beyond the Council's control. The Council's approach and assumptions were subjected to an independent, expert review.

Responsible Manager(s) (completed by relevant manager)	
Simon Medcalf Deputy Director-General Regulation and Monitoring | Te Pou Whakamaru Ministry of Health  Date: 19/11/2024	
Quality Assurance (completed by QA panel)	
Reviewing Agency:	Ministry of Health (Papers and Regulatory Committee)
Panel Assessment & Comment:	The Ministry of Health QA panel has reviewed the Impact Statement titled "Regulation of the Physician Associate profession under the Health Practitioners Competence Assurance Act 2003", produced by the Ministry of Health and dated November 2024. The panel considers that the Impact Statement Partially Meets the quality assurance criteria. The Impact Statement is concise, complete, and consulted. The analysis is balanced in its presentation of the information but would benefit from clear and enhanced analysis how the proposal fits with wider workforce initiatives and challenges.

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Section 1: Diagnosing the policy problem

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

1. Physician Associates' (PA) practice poses a risk of harm to the public, and at present New Zealand relies on a mixture of professional supervision, employer oversight, self-regulation by the profession, and the Health and Disability Commissioner's (HDC) *Code of Health and Disability Services Consumers' Rights* (the HDC Code) to manage that risk.
2. There are currently about 50 PAs practising in New Zealand. They are working throughout the country, from Kaitaia to Invercargill, mostly in GP clinics and urgent care centres, but also in emergency departments and one in a dermatology service.
3. The PA profession has grown significantly in New Zealand in recent years, resulting in more interactions with patients and a corresponding increase in risk. Given the positive experience that employers and other health practitioners have reported about working with PAs, the profession is expected to continue to grow and – if the profession is regulated – growth is expected to accelerate.
4. PAs work only in employment settings (ie, not in sole practice) and under the supervision of a designated medical practitioner, so there is a degree of oversight of practice, although reportedly it is highly variable.
5. The New Zealand Physician Associate Society (NZPAS), which initiated the application for regulation, currently operates a voluntary self-regulation scheme for the profession. Although this approach has been functioning well, it has gaps and weaknesses (eg, lack of robust enforcement mechanisms such as suspension or competence review) that could be exposed by a serious incident.
6. All health service providers, including PAs, must comply with the HDC Code, which is a regulation under the Health and Disability Commissioner Act 1994. Complaints about practitioners (including PAs) can be taken to the HDC, who can investigate possible breaches of the Code.
7. The NZPAS has identified a number of reasons for wanting the profession to be regulated under the HPCA Act. They have stated that 'the only reason for supporting regulation is public health and safety'. They see regulation under the Act as imperative and view the current voluntary registration approach as inadequate. They note that, because some activities are restricted under section 9 of the Act to registered health practitioners, PAs are not currently able to perform some tasks that they are competent to perform, limiting their contribution to New Zealand's health system.

What is the policy problem or opportunity?

8. PAs perform activities that are physically invasive and carry serious potential for patient harm (including death) if not performed competently. These activities include (but are not limited to) assessment, ordering tests, reviewing results, diagnosis, treatment planning, and conducting invasive procedures such as suturing, punctures, and excisions. Although PAs must work under the supervision of a designated medical practitioner, the supervisor is not required to be in the same room or facility as the PA but rather must simply be readily available for consultation or advice as necessary.
9. The evidence of risk of harm arising from PAs' practice comes from a range of (mostly international) sources, including healthcare journals and government reports. Evidence of actual harm in New Zealand is scant, given the small number of PAs practising here since the profession was first introduced some 14 years ago.
10. An independent, expert panel convened by the Ministry met in January 2023 to assess the PA professions' application against the criteria for regulation under the HPCA Act.

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The panel was supported by the Ministry's subject-matter expert on the regulation of health professions and by an experienced PA. The panel comprised:

- A Medical Director who has employed PAs
- A Nurse Practitioner who has worked alongside PAs
- A Māori General Practitioner who has worked with PAs in a rural setting
- Two Chief Executives/Registrars of responsible authorities who have expertise in the regulation of health professions, including one who has experience in regulating a new profession.

11. A key part of the panel's assessment process was determining the degree of potential risk of harm to the public from PAs' practice. A rating scale guided that assessment, and the panel assessed the profession as presenting a high risk of harm to the public.
12. The current approach, voluntary self-regulation, does not (for example) allow for:
    - the accreditation of educational institutions and courses to ensure initial competency and subsequent safe practice
    - placing conditions on a practitioner's practice or requiring them to undertake further (or remedial) training
    - formal and effective assessment, investigation, suspension, and/or discipline or remediation of a practitioner if they are alleged to be practising unsafely.
13. While not a core focus of our (risk-focussed) analysis, there is evidence that suggests PAs could usefully and cost-effectively contribute to New Zealand's health workforce. A robust evaluation of the demonstration project conducted in New Zealand (2013 -2015) found that PAs made a cost-effective, valuable contribution to their clinical settings, and were of particular benefit in remote areas. Also, Gore Health estimates it has saved s 9(2)(b)(ii), s 9(2)(ba)(i) by employing two PAs over the past 12 years.
14. Although there is strong agreement amongst stakeholders that the PA profession's risk profile means that it should be regulated under the HPCA Act, a few organisations consider that the risks do not warrant statutory regulation at this time. They believe that other mechanisms (eg, guidelines for supervision) would be adequate, at least while there are so few PAs in New Zealand and there is no domestic training pathway. For others, the primary concern is not the need for regulation but rather the need to promote 'homegrown' solutions (eg, training more GPs and Nurse Practitioners).

What objectives are sought in relation to the policy problem?

15. Effective and proportionate regulation would help mitigate the risks posed to members of the public by PAs' practice.
16. Statutory regulation is a long-term intervention that will protect the public by ensuring that only practitioners who meet qualification, competency, and ethical standards requirements are able to hold themselves out to be registered members of the profession.
17. The HPCA Act provides mechanisms to ensure ongoing competence and fitness to practise, as well as disciplinary and complaints (accountability) procedures. Adding the PA profession to the profession already regulated by the Medical Council will ensure effective and efficient regulation.
18. Members of the public who use the services of PAs would benefit by having confidence that registered members of that workforce are qualified, competent, and fit to practise their professions. Employers and health practitioners who work with PAs would gain a better understanding of who PAs are, what their core competencies are, and what their scope of practice is. PAs will benefit from enhanced accountability and credibility, increased status and professional identification, protected title(s), and opportunities and mechanisms to increase and maintain competence. The wider health system may

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benefit as regulation would facilitate PAs working across the full breadth of their competence.

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

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

19. The Ministry's core criteria for regulation of a health profession, which underpin and complement the impact analysis criteria, are listed in full in Appendix 2. In brief, they include:
    - the primary criteria listed in section 116 of the HPCA Act, including that the profession delivers a health service, poses a risk of harm to the public, and has generally agreed on required qualifications, competencies, and standards that must be met
    - secondary criteria regarding alternatives to statutory regulation, the possibility and practicality of implementation of regulation, and a weighing of benefits versus potential negative impacts.
20. Additional criteria considered (see Table 1 below) were:
    - competence assurance: Does the option provide a robust system to prescribe qualifications and to set and enforce standards of clinical competence, cultural competence, and ethical conduct?
    - protection of the public. Will the risks of harm that have been identified be mitigated by the proposed option?
    - professional identity: Is the proposed option likely to bolster practitioners' connection with their profession and support their identification with the regulator (thereby facilitating effective and sustainable regulation)?
    - costs: What are the costs (financial and other) of implementing and sustaining the option?
    - implementation timeframe: How long is it likely to take to implement the option? (Noting identified risks would remain unaddressed in the interim.)

What scope will options be considered within?

21. The principal options for ensuring public safety in respect of the PA profession are:
    Option 1: *Status quo* – self-regulation by the NZPAS, alongside supervision and employer and HDC oversight.

    Option 2: Enhanced *status quo* – strengthen self-regulation.

    Option 3: Statutory regulation under the HPCA Act.

    Option 3A: Add the PA profession to the profession already regulated by an existing RA (ie, the Medical Council).

    Option 3B: Add the PA profession to a new 'Allied Health' RA, created by amalgamating two or more existing RAs.
22. It should be noted that, even if statutory regulation is instituted, the HDC Code will continue to apply as a form of regulatory oversight and, as the profession is not likely to ever practice independently, employer control/oversight will also remain a protective factor.
23. Two other options have been ruled out and not further analysed as they are not considered feasible at present:
    - Establish a new, dedicated RA for the PA profession. Because there are only about 50 PAs currently practising in New Zealand and forecast net growth is only 50 new

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practitioners per year, establishing a new, dedicated RA for the profession would be financially and operationally unsustainable. Further, Cabinet has previously expressed concern at the "proliferation of registration authorities" [CAB Min (07) 7/3 refers].

- Establish direct regulation (licensure) of the PA profession. The HPCA Act was drafted to optimise flexibility, and was therefore largely based on certification (ie, protection of title) rather than licensing of tasks performed by a profession. Licensing is a highly restrictive approach to regulation that would be prohibitively expensive to design and implement, and would introduce complications around the overlap in activities carried out by PAs and other health professions. (That is, licensing one profession to perform certain activities would become an obstacle to other professions performing those activities.) In the absence of a licensure regime, there is currently no mechanism to ban PAs from practising in New Zealand.

24. No other options have been identified.

Option 1 – *Status quo*

25. The Ministry considers that the *status quo* (self-regulation by the NZPAS, alongside supervision and employer and HDC oversight) is inadequate to protect the public from the risk of harm posed by the practise of this profession.
26. The ability of a voluntary registration body to prescribe and enforce minimum standards is limited. There are no disciplinary procedures available to such organisations (beyond a complaint to the HDC) and a practitioner who is removed from a voluntary register can continue to practise under the PA title.
27. With multiple employers involved, it is less likely that a uniform set of requirements (supervision, qualifications, codes of ethics, cultural competence standards etc) would be developed and consistently adopted. The HDC has no authority to set such standards.
28. A small number of stakeholders do, however, consider that this option would be adequate, noting that there are only 50 PAs practising in New Zealand and the fact they all practise in employment settings (rather than in independent practices).

Option 2 – Enhanced *status quo*

29. Steps could be taken to address the shortcomings noted above, such as accrediting the NZPAS's self-regulation scheme to enhance its credibility and utility.
30. A framework (such as the one operated by the Professional Standards Authority in the United Kingdom) for accrediting voluntary registers of health professionals would need to be established, with the Crown likely to shoulder significant costs. The establishment of such a framework is being considered as part of the Ministry's current review of health workforce regulation, and so could be considered at a later date (should a new framework be created).
31. We do not recommend this option, however, because the robust monitoring and accountability mechanisms and title protection provided under the HPCA Act would still not apply, and the risks posed by PAs would therefore not be adequately mitigated.
32. One stakeholder suggested that the *status quo* could be adequate if enhanced by instituting a credentialling or licensing system. The Ministry considers that credentialling would be difficult to implement consistently across a wide range of employers (including independent GP clinics). As noted above, licensure has also been ruled out.

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Option 3A – Add the profession to the profession(s) already regulated by an existing responsible authority

33. The Minister of Health has the authority under section 115(1)(b)(ii) of the HPCA Act to add a new profession to an existing RA. The Minister's preferred option (as reflected in the Cabinet paper) is for the PA profession to be regulated by the Medical Council. Although this can involve restructuring and renaming the RA, in this instance that would not be required as the Medical Council's name is broad enough to incorporate the PA profession.
34. This approach is most appropriate where the profession has similarities in practice or client groups and/or has strong working relationships with a profession already regulated under the HPCA Act.
35. By necessity, discussions with the NZPAS to determine an appropriate governance arrangement for regulating the PA profession focussed on adding the profession to an existing RA.
36. If the PA profession were to be added to an existing RA, one or more new governance board members would need to be appointed, and this would increase governance costs (unless the number of health practitioner members from the Medical Council's other professions was reduced). The RA would also need to establish new mechanisms and/or structures (eg, advisory groups) to garner advice on matters such as qualifications, scopes of practice, and competencies for the new profession.
37. The Ministry considers that regulation would have positive impacts on equity by ensuring that PAs, who practise mostly in the regions, provide clinically and culturally safe care to patients. Regulation would also make the establishment of a domestic training programme more likely, providing a more accessible career path for people who (for a range of possible reasons) are unable to commit to the lengthy training required for some other health professions.

Option 3B – Establish a new 'Allied Health' responsible authority

38. Amalgamation of two or more existing RAs is currently possible under section 116 of the HPCA Act.
39. Theoretically, a multi-profession RA could be established either by creating a new RA and subsequently adding other professions to it, or by renaming an existing RA and amalgamating other RAs with it.
40. Any future amalgamation of existing RAs into a multi-profession authority would depend on the outcome of consultation with the affected RAs, and a business case and regulatory impact analysis would need to be developed outlining the costs and benefits of such a proposal. This would further delay regulation of PAs and fail to address the risk of harm to the public in the meantime.

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How do the options compare to the *status quo*? (Table 1)

Criterion	Option 1 *Status quo*	Option 2 Enhanced *status quo*	Option 3A Statutory regulation - Add to existing RA	Option 3B Statutory regulation - Add to new (amalgamated) RA
Competence assurance	**0** Voluntary membership and no formal authority to effectively prescribe and enforce standards	**0** Voluntary membership and no formal authority to effectively prescribe and enforce standards **+** Accountability mechanisms bolstered, but still relatively weak	**++** Scopes of practice and registration qualifications are secondary legislation. **++** Accountability mechanisms provided for under Act	**++** Scopes of practice and registration qualifications are secondary legislation. **++** Accountability mechanisms provided for under Act
Protection of the public	**0** Inadequate to protect the public from the risk of harm No standardisation of codes of ethics, clinical standards, or qualifications Limited ability for voluntary registration body to investigate or discipline unsafe practitioners Does not prevent unqualified people from holding themselves out to be qualified members of the profession Difficult for public to check and appropriately weigh register	**0** The public may still perceive the organisation as profession-centric **0** Does not prevent unqualified people from holding themselves out to be qualified members of the profession **-** Can result in more than one accredited registration body, so can be inconsistency of standards etc and resultant confusion for the public	**++** Risk of harm reduced via full range of legislated (Act) mechanisms **0** Possibly complicated at times by need to tailor for each profession the RA regulates	**++** Risk of harm reduced via full range of legislated (Act) mechanisms **0** Possibly complicated at times by need to tailor for each profession the RA regulates
Professional identity	**0** No change to current status	**0** May be some (minor) boost to connection with regulator	**-** Practitioners' identification with regulator may be weakened	**-** Practitioners' identification with regulator may be weakened

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Cost	**0** No change to costs paid by practitioners for self-regulation	- Some establishment and ongoing costs to profession - There is currently no mechanism for accrediting a registration organisation or register, so one would have to be developed (financial and resource costs to government)	-- Significant costs involved to onboard new profession (cost to profession and government)	-- Significant costs involved to establish new (amalgamated) authority and to onboard new profession (cost to profession and government) -- Complex start-up process, larger governing board, likely resistance from existing RAs (cost to profession and financial and resource costs government, possible relationship costs)
Implementation timeframe	**0** No time required	-- Likely 2 to 3 years to establish accreditation scheme	- Likely 12 to 18 months to onboard new profession	-- Likely 4 to 5 years to amalgamate RAs and add new profession
Overall assessment	**0**	**0**	**++**	**+**

Key:

++	much better than doing nothing/the *status quo*
+	better than doing nothing/the *status quo*
0	about the same as doing nothing/the *status quo*
-	worse than doing nothing/the *status quo*
- -	much worse than doing nothing/the *status quo*

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

41. The preferred option is to designate PAs as a health profession under section 115 of the HPCA Act and to add it to the profession already regulated by the Medical Council.
42. The regulation of PAs will have benefits to consumers in terms of increased safety of practice and recourse to formal complaints and disciplinary procedures. The qualifications, standards, and scopes of practice set by the Medical Council will reduce the risk of harm to the public by ensuring practitioners are competent and fit to practise.
43. Regulation would not prohibit other regulated or unregulated practitioners from performing tasks that PAs perform* re a person who wishes to use the title associated with the profession (ie, Physician Associate) to register with. However, it would require the Medical Council and to meet the required qualification and competence standards. Registration would provide assurance to the public that anyone describing themselves as a PA is suitably qualified and competent and fit to practise.
44. The Ministry, an independent expert panel, the profession, and a clear majority of stakeholders share the common view that regulation under the HPCA Act is the only way to assure the public of the quality of the practice of PAs, and to minimise the risk of harm from unqualified or incompetent practice.

What are the marginal costs and benefits of the preferred option?

(Table 2)

Affected groups	Comment	Impact	Evidence Certainty.
Additional costs of the preferred option compared to taking no action			
Regulated practitioners	One-off onboarding fee, initial registration fee, ongoing Annual Practising Certificate (APC) fee (including Disciplinary Levy), and ongoing costs of maintaining competence year-to-year. Risks: Due to high costs of onboarding, a contribution of public funds is likely to be required to ensure implementation.	Onboarding costs estimated at s 9(2)(b)(ii), s 9(2)(ba)(i), s 9(2)(b)(ii), s 9(2)(ba)(i) Initial registration fee estimated at s 9(2)(b)(ii), s 9(2)(ba)(i) APC fee estimated at between s 9(2)(ba)(i), s 9(2)(b)(ii) Refer to Appendix 4 for detailed forecast of costs. Non-monetised: Medium impact.	High
Regulators	The regulator will have to invest time and staff resource into onboarding and ongoing regulation.	Non-monetised: Medium impact.	High
Wider government	As noted above, a contribution of public funds is likely to be required to ensure implementation. Risks: The Medical Council has requested upfront payment of all of its forecast	Costs: Between s 9(2)(b)(ii), s 9(2)(ba)(i) Non-monetised: Low impact.	Medium

* Paragraph 43 contains an error and should read ...performing tasks that PAs perform. However, it would require a person who wishes to use the title associated with the profession (ie, Physician Associate) to register with the Medical Council and to meet the required qualification and competence standards. Registration would provide assurance to the public that anyone describing themselves as a PA is suitably qualified and competent and fit to practise.

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	costs, but the exact amount of public funds actually required will not be clear for many months.		
Other parties	There will be an increase in annual fees paid by employers on behalf of employees. Risks: It is possible that there will be a larger increase in fees over time if practitioners' costs increase (eg, because of a high number or complexity of complaints) and/or if the number of practitioners decreases.	Costs will be modest, given the small number of practitioners (~50). Non-monetised: Low impact.	Medium
Total monetised costs		s 9(2)(b)(ii), s 9(2)(ba)(i)	Medium
Non-monetised costs	Non-monetised costs will be met by the profession, the regulator, and employers.	Low to medium impacts.	Medium
Additional benefits of the preferred option compared to taking no action			
Regulated groups	The profession's status may be enhanced once it is recognised as a regulated health profession. Regulation will improve practitioners' access to professional indemnity insurance and ACC will likely add them to its list of Registered Health Professionals.	Non-monetised: Medium impact.	Medium
Regulators	Nil		Medium
Wider government	Improved safety for the public.	Non-monetised: Medium to high impact.	Medium
Other parties	The safety and quality of services provided by PAs can be expected to improve overall. NZPAS expects that regulation will increase the number of PAs interested in working in NZ. Regulation would permit the profession to apply for prescribing authority. Gore Health estimates it has saved about s 9(2)(b)(ii), s 9(2)(ba)(i) over the past 12 years by employing two	Gore Health's savings equate to about s 9(2)(b)(ii), s 9(2)(ba)(i) per year per PA. Non-monetised: Medium to high impact.	Low to medium

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	PAs in its Emergency Department. Additional PAs may make health services more accessible in some areas.		
Total monetised benefits	Risk: Estimate is based on PAs employed in just one rural Southland ED.	s 9(2)(b)(ii), s 9(2)(ba)(i) per annum per PA.	Low
Non-monetised benefits	There is the potential for positive impacts on consumers, as accessibility to services improves. Enhanced public safety.	Medium impact.	Medium

Section 3: Delivering an option

How will the new arrangements be implemented?

Selection of an RA to regulate the PA profession

45. The Ministry conducted an analysis to identify which of the 18 RAs would be best suited to regulating the PA profession. RAs were shortlisted for further consideration based on:
    - measures of professional alignment (eg, areas of training, scopes of practice, practice standards, and work settings)
    - relevant regulatory expertise
    - organisational capacity (eg, staffing)
    - financial resources (ie, reserves)
    - level of interest/willingness to take the role on
    - any current performance concerns.
46. Based on the initial criteria and discussions with the RAs, the Ministry determined that two were acceptable candidates for the role and submitted a detailed briefing (H2024053104) to the Minister to facilitate his decision on which of them would be asked to regulate the PA profession.
47. The Minister subsequently chose the Medical Council for the role. The Council is highly capable and will also be able to draw on the experience of other RAs and the Ministry.
48. If Cabinet agrees to regulate the PA profession, the Medical Council will assume responsibility for that task and begin communicating with practitioners and other stakeholders about the transition to regulation. It would also initiate any necessary changes to its systems and policies. Following consultation with stakeholders, the Council would specify one or more scopes of practice, prescribe the qualifications required for registration, set practice standards, and prescribe fees – all before beginning to accept applications for regulation. This process is expected to take about 18 months.

Ensuring implementation

49. The main risk to implementation is the costs noted above. The Medical Council has forecast the costs of onboarding the PA profession at s 9(2)(b)(ii), s 9(2)(ba)(i), which far exceeds the s 9(2)(b)(ii), s 9(2)(ba)(the profession can guarantee to contribute, and also the s 9(2)(b)(ii), s 9(2)(ba)(i) the profession is 'reasonably confident' it can raise over the next 18 months. The projected shortfall is therefore between s 9(2)(b)(ii), s 9(2)(ba)(i) (plus GST if any).

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50. The Minister considered this issue when deciding on which RA would be asked to regulate PAs and, following discussions, Health New Zealand (HNZ) has confirmed that it will absorb up to $1,000,000 to subsidise the cost of onboarding for the first two years of registration. HNZ will negotiate with the Medical Council to minimise these costs.

Next steps

51. An Order in Council is required to designate PAs as a profession under the Act and add it to the profession(s) regulated by the Medical Council. The Council will be responsible for ongoing operation and enforcement. The Minister of Health has a number of statutory functions, such as tabling annual reports, which apply in respect of all responsible authorities.
52. Implementing regulation for the PA profession would involve the following steps:
    - Development of an Order in Council (subject to Cabinet agreement).
    - Minister of Health appoints a health practitioner (PA) member to the Medical Council.
    - The Medical Council assumes responsibility for regulating the profession, including making any necessary changes to its systems and policies, and communication with practitioners and other stakeholders about the transition to and impacts of regulation. Following consultation with all stakeholders, the Council prescribes fees and qualifications and sets standards of clinical and cultural competence and ethical conduct.
    - PAs can then begin registering with the Medical Council.

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

53. Under section 122A of the HPCA Act, RAs are subject to periodic performance reviews. This provides a mechanism for monitoring the impacts of any new arrangements on key functions of an RA.
54. RAs are also required to submit Annual Reports to the Minister of Health. This provides a mechanism for monitoring financial issues, registration growth, fitness, competence and conduct matters, and the development of the RA's operational and governance systems.
55. RAs are also required to gazette any new fees, levies, and scopes of practice (including prescribed qualifications). The Ministry and the Regulations Review Committee monitor such notices.
56. Concerns about an RA can be brought to the Minister's or to the Ministry's attention.

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Appendix 2: Criteria for regulation

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.

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.

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Appendix 3: Process of regulation

The process for a profession to become regulated under the Act is as follows:

1. The prospective applicant(s) meet with Manatū Hauora | Ministry of Health (Ministry) officials to discuss issues when considering applying.
2. The Ministry receives an application from the professional body or bodies.
3. The Ministry undertakes a preliminary assessment of the application and seeks further information if required.
4. If the Ministry 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 (eg, the Medical Council of New Zealand) 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, the Ministry undertakes a consultation process and analyses submissions.
7. The Ministry 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.

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Appendix 4 has been withheld in its entirety under section 9(2)(b)(ii) and section 9(2)(ba)(i) of the Official Information Act

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