



Te Kaunihera  
Rata o  
Aotearoa

**Medical  
Council of  
New Zealand**



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## **Submission on the draft terms of reference and standards for RA performance reviews**

### **Introduction**

1. We welcome the opportunity to make submissions on the draft terms of reference and standards for performance reviews. Please note this is a joint submission by the Medical, Nursing, Pharmacy and Dental Councils.

### **Structure of submission**

2. In Part 1 of this submission, we make some broader comments on the purpose of the review and the essential elements required to ensure that the reviews can achieve that purpose.
3. Part 2 and Part 3 follow the sequence of questions set out in the Ministry's online survey. That is, we comment first on the sections of the proposed Terms of Reference, then turn to address the specific questions asked.
4. No comments are provided on the proposed standards themselves, other than to recommend that they be reviewed considering the recommended approach to the drafting of standards outlined in this submission.

### **Executive Summary**

5. The Medical, Nursing, Dental and Pharmacy Councils jointly offer feedback to the terms of reference suggested by the Ministry of Health for performance reviews of Responsible Authorities. We offer several suggestions but most critically:
  - The importance of the review to reflect each Council's obligations to Te Tiriti o Waitangi.
  - The importance of reflecting risk-based and other modern regulatory strategies, including the principles of right touch regulation within the standards.

- The need for the review to add value to performance with an attention to costs. It is likely that there will be additional costs to the RA's borne from direct and indirect review preparation.
- Whilst we understand the possible value of the HealthCERT framework for reporting and coordinating the reviews, we support a quality assurance and improvement lens from a "team" of reviewers that understand the New Zealand health regulation context, as distinct from the delivery of health services.

### **Part 1 – A "fit for purpose" review**

6. We support the proposition that all responsible authorities (RAs) should be subject to ongoing and objective review, to support ongoing quality assurance and improvement, to improve public safety and ensure confidence in the regulatory system.
7. To support the purpose of the review we propose that a stronger focus should be placed on the international regulatory best practice. Examples include risk-based regulation (Professor Malcolm Sparrow, Professor of the Practice of Public Management, Harvard's Kennedy School of Government, Faculty Chair of Executive programme Strategic Management of Regulatory and Enforcement Agencies, teacher on ANZSOG programme), and response regulation (John Ayers, Professor at Yale Law School & Yale's School of Management and John Braithwaite, Emeritus Professor and Founder of the School of Regulation and Global Governance at the Australian National University) as well as the principles of right touch regulation, ensuring that regulation is proportionate, consistent, targeted, transparent, accountable and agile.
8. These reviews can be expensive, both in direct and indirect cost. We are conscious that the full costs of the reviews will be borne by the profession indirectly and so, it is necessary to ensure value for money and quality assurance and improvement from the review.
9. While we acknowledge the attraction of being able to tailor a review to the circumstances of a particular RA, the optimal benefit from a review framework will come from applying a consistent lens and set of criteria to all RAs. Establishing and publishing those criteria in advance, and applying them to each review, will not only allow RAs to have those criteria as a focus in their thinking as they explore policy options and approaches but to learn from the outcomes of the progressive body of reports and to apply them to their own regulatory strategy, policy and activity.
10. We are pleased to see that the terms of reference provide for reports that include recommendations to other agencies. However, to fully realise the potential for recommendations addressing systemic and regulatory improvement, we believe that this option should transparently and explicitly form part of the assessors' brief.

### **Part 2 – Comment on Terms of reference (by section)**

#### **Guiding Principles**

11. We note and support the overall purpose of the reviews, including improving public safety as well as confidence in the regulatory system.
12. We support the tenor of the Guiding principles, which we consider properly include reference to the "why and "how"; not just the "what" we do. The inclusion of the principles of right touch regulation is a fundamental, underpinning the risk based and

responsive approach to regulation we adopt. The “ability to be forward-looking, proactive and responsive” includes an ability to identify and pre-empt potential risks to health and safety. These ‘regulatory antennae’ are vital in a rapidly-changing health sector.

13. However, we note that the proposed standards focus on core functions and processes and we are concerned that this may result in RAs focusing more on a compliance based approach. This would be at the risk of a responsive approach, and the importance of taking into account the needs and expectations of the public, the community and key stakeholders.
14. International best practice would suggest for RAs a greater emphasis should be placed on taking a strategic approach (and therefore, the review) responding to current and emerging opportunities and challenges as they relate to public safety. Examples of emerging issues include the regulator role in cultural safety and health equity, telehealth and virtual care and interprofessional standards and scopes of practice. These all fall within the breadth of the Act.
15. The Productivity Commission’s 2014 report on Regulatory institutions and practices identified that *“Both traditional ‘responsive’ and newer ‘risk-based’ approaches are evident in the strategies of New Zealand regulators, although agencies differ on how far they prioritise reducing harm [risk-based] or maximising compliance [responsive] and to what extent the two objectives are integrated or treated separately... It is important to note that there is no single superior regulatory strategy. Different strategies and approaches have different strengths and weaknesses, with different levels of effectiveness, in different contexts. The key lies in understanding and adapting regulatory strategies to take account of the influences and dynamics of the many different contexts in which they are deployed”*.
16. We agree that the principles of modern regulatory strategy and practice including risk based, responsive and right touch regulation must be fully integrated into the standards. However, reviews should also consider whether RAs have adopted regulatory strategies that are effective and suit the context that they operate within. If not, there is a risk that the review will focus overwhelmingly on whether the RA has met each individual standard at the expense of the higher-level review. For the reviews to fully deliver the intended benefit to the RAs and to the public, it is essential that the standards do not drive a passive approach by the RAs at the expense of forward looking and proactive regulation.
17. In addition, we urge a stronger focus on engagement and partnership with key stakeholders. Our experience implementing a range of initiatives to strengthen our engagement with the public, the community and practitioner groups has emphasised the importance of true engagement in developing and maintaining trust and confidence in our regulatory roles and functions.

#### **Scope of review and methodology**

18. We note that the Ministry proposes further consultation on more detailed requirements with the RA being reviewed.
19. The option for tailored reviews departs from the ideal of having the same lens applied to all authorities and adds unnecessary complexity given the scope of the proposed standards. There is also a risk that the potential value of reviews to other authorities is reduced if terms of reference become too particularised to different authorities.

### **Roles and responsibilities**

20. We would like to know more about the stated intention of the reviews being undertaken within the “HealthCERT framework”. The scope of HealthCERT’s proposed role is unclear. If HealthCERT is merely providing a mechanism within the Ministry for coordinating the scheduling of reviews and depositing of reports, there seems little concern. However, any greater role has the potential to cut across the idea of “independent reviewers”, specifically provided for in the Act.
21. Performance reviews of RAs also require specific and relevant knowledge of health practitioner regulation and the functioning of regulatory authorities. We support the idea of a small permanent team of reviewers, if that is required to obtain the full knowledge and skills for the review. Consistency is the key, so there should be at least one or two reviewers who are involved in all reviews.
22. HealthCERT’s role to date has been primarily one of auditing providers for safe and reasonable levels of service for consumers, under the Health and Disability Services (Safety) Act 2001. HealthCERT might be one option to manage administrative aspects of reviews within the Ministry of Health (such as coordination and reporting) but we don’t consider that a case has been made for a more active role in the selection of reviewers or the reviews themselves. It will of course be important that some independent procurement process for such resourcing is undertaken to ensure value for money is assured.

### **Schedule for first round of reviews**

23. We note the suggestion that an amendment be made to the HPCAA in a Statutes Amendment Bill to push the review deadline back two years. This proposed solution, alone, does not provide the certainty required for RAs, who will be required to provide dedicated staff resource and budgeted finance for the reviews.
24. The regulatory impact statement considered by Cabinet recognised this crucial timing point; indicating that terms of reference should be set at least three years before the review takes place. At the very least, the Councils consider that scheduling need not be delayed by the current consultation and urges the Ministry to commence that consultation about scheduling as a matter of urgency.

### **Reporting**

25. We acknowledge that the terms of reference will necessarily focus on the guidelines and standards. However, we consider that the form of reporting needs to be further developed to ensure it balances current state reporting with higher level recommendations that can be applied at a strategic level. The reference to reporting, in relation to each standard, whether that standard has been met, partially met, or not met, runs the risk of defaulting to a tick box exercise and a focus on detail, at the expense of a more useful narrative approach. We would expect that this rating be accompanied by specific identified actions that describe what needs to be completed to meet the standard, as would be expected, for example, in an accreditation process.

## **Part 2 – Responses to specific questions**

26. **What negative impacts (if any) are foreseen to arise from the proposed approach to reviews?**

Treating the guiding principles and the standards separately, without integrating the right touch principles into the language and pitch of the standards, is an opportunity lost to

ensure quality improvement across the New Zealand health practitioner regulatory system, lifting our system to international best practice.

Pitching the standards at a functional level, might achieve a common lens on the variably-sized RAs, but will reduce the extent to which lessons from different regulatory strategies can be shared across RAs. Specifically, the opportunity for RAs to consider taking a strategic and evidence based modern approach to regulation will not be presented, nor will there be opportunity to assess the RA approach to important and emerging regulatory issues.

27. **Will review against the proposed standards provide confidence that an RA is carrying out its functions in the interest of public safety?**

‘Public safety’ is a narrow and limiting view of the role of an RA, which is to more broadly give effect to mechanisms to ensure practitioners are competent and fit to practice but also include mechanisms such as information on the register to ensure the public can make informed choices.

The review against the proposed standards will provide limited confidence in terms of public health and safety. The level of confidence will depend on the level of acceptance of the standards and this consultation process may provide greater assurance to stakeholders. Ultimately confidence will depend very much on how the reviews themselves are undertaken.

28. **Do the proposed standards adequately and appropriately reflect good regulatory practice (including the principles of Right Touch regulation)?**

No. The standards have been drafted at a functional level and do not reflect the principles of right-touch regulation (proportionate, consistent, targeted, transparent, accountable and agile). Nor do they reflect best practice health practitioner regulation around some of those other principles about proactive, forward looking regulation and the importance of engagement and partnership. These principles must be built into the standards.

29. **Are there gaps in the proposed standards?**

See above.

30. **Is it appropriate for the standards to include, in addition to picking up the s 118 functions, a broader focus; for example, on the principles of the Treaty of Waitangi and of Right Touch regulation?**

Yes, the principles of right touch regulation must be picked up as part of the review. See comments above. In addition, since the introduction of the Act there are several themes that have emerged more strongly for regulation - patient-centred care, harm reduction (Malcolm Sparrow, Harvard University) and equity are examples. There is an opportunity to consider whether the review should consider these aspects of regulation.

The proposed standards do not reflect the RA’s obligation to Te Tiriti o Waitangi and how each RA gives effect to these obligations.

While these obligations are not set out in the HPCAA each RA has an obligation to develop strong and enduring relationships with Māori in an authentic manner that gives effect to te Tiriti o Waitangi. This is important it address health outcome inequities through raised

awareness and clearly stated expectations of health practitioners, to promote Māori participation in decision-making and to encourage a growing Māori health workforce.

Both sets of principles are relevant and important. To ensure the focus and visibility as part of the review, it would be better to have the terms of reference “self-contained”, with all relevant aspects directly incorporated. Rather than referring to the New Zealand Public Health and Disability Act 2000, the terms of reference might better refer to the principles set out in that Act. That is “the need for mechanisms to enable Māori to contribute to decision-making on, and to participate in the delivery of, health and disability services.”

We would welcome an opportunity to meet to discuss our submission.



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**Chair, Pharmacy Council of New Zealand**



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